BABU BANARASI DAS UNIVERSITY

BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES, LUCKNOW

COMPARATIVE EVALUATION OF AUTOLOGOUS FIBRIN GLUE WITH CONVENTIONAL SUTURING FOR PERIODONTAL FLAP CLOSURE: A CLINICAL STUDY

DISSERTATION

Submitted to

BABU BANARASI DAS UNIVERSITY,

LUCKNOW, UTTAR PRADESH

In the partial fulfilment of the requirements for the degree

of

MASTER OF DENTAL SURGERY

in

PERIODONTOLOGY

By

Dr. SHAIFALI

Under the guidance of

Dr. SUNIL C VERMA
READER

Dr. SURAJ PANDEY
READER

Batch 2020-2023

Year of submission 2023

Enrolment no: 1200328004

DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation entitled "**COMPARATIVE EVALUATION OF AUTOLOGOUS FIBRIN GLUE WITH CONVENTIONAL SUTURING FOR PERIODONTAL FLAP CLOSURE: A CLINICAL STUDY**" is a bonafide and genuine research work carried out by me under the guidance of **Dr. SUNIL CHANDRA VERMA**, Reader, Department of Periodontology, and Co-Guide **Dr. SURAJ PANDEY**, Reader, Babu Banarasi Das College of Dental Sciences, Babu Banarasi Das University, Lucknow, Uttar Pradesh.

Date: 31/01/2023

Place: Lucknow

Shaifali

Dr. SHAIFALI

CERTIFICATE BY THE GUIDE/CO-GUIDE

This is to certify that the dissertation entitled **"COMPARATIVE EVALUATION OF AUTOLOGOUS FIBRIN GLUE WITH CONVENTIONAL SUTURING FOR PERIODONTAL FLAP CLOSURE: A CLINICAL STUDY"** is a bonafide work done by **Dr. Shaifali**, under our direct supervision and guidance in partial fulfilment of the requirement for the degree of MDS in Periodontology.

Date: 31/01/2023

GUIDE

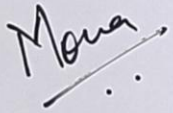
Dr. SUNIL CHANDRA VERMA
Reader,
Department of Periodontology
B.B.D.C.O.D.S
BBD University, Lucknow (U.P.)

CO- GUIDE

Dr. SURAJ PANDEY
Reader,
Department of periodontology
B.B.D.C.O.D.S
BBD University, Lucknow (UP)

ENDORSEMENT BY THE HOD

This is to certify that the dissertation entitled "**COMPARATIVE EVALUATION OF AUTOLOGOUS FIBRIN GLUE WITH CONVENTIONAL SUTURING FOR PERIODONTAL FLAP CLOSURE: A CLINICAL STUDY**", is a bonafide work done by **Dr. Shaifali**, under direct supervision and guidance of **Dr. SUNIL CHANDRA VERMA**, Reader, Department of Periodontology, Babu Banarasi Das College of Dental Sciences, Babu Banarasi Das University, Lucknow, Uttar Pradesh.



Dr. MONA SHARMA

Professor and Head
Department of Periodontology
B.B.D.C.O.D.S
BBD University, Lucknow (U.P.)

ENDORSEMENT BY THE HEAD OF THE INSTITUTION

This is to certify that the dissertation entitled "**COMPARATIVE EVALUATION OF AUTOLOGOUS FIBRIN GLUE WITH CONVENTIONAL SUTURING FOR PERIODONTAL FLAP CLOSURE: A CLINICAL STUDY**", is a bonafide work done by **Dr. Shaifali**, under direct supervision and guidance of **Dr. SUNIL CHANDRA VERMA**, Reader, Department of Periodontology, Babu Banarasi Das College of Dental Sciences, Babu Banarasi Das University, Lucknow, Uttar Pradesh.

Dr. PUNEET AHUJA
Principal
B.B.D.C.O.D.S
BBD University, Lucknow (U.P.)

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

COPYRIGHT

DECLARATION BY THE CANDIDATE

I hereby declare that the **Babu Banarasi Das University** shall have the right to preserve, use and disseminate this dissertation in print or electronic format for academic/research purpose.

Date: 31/01/2023

Place: Lucknow

Shaifali

Dr. SHAIFALI

“गरु ब्रह्मा ष्णुः देवो महेश्वरः।
ग ग

ग ुः सा ात् परं ब्रह्म तस्मै श्री ग वे नमुः।।“

Many people have bestowed their blessings and heartfelt support on me in the successful completion of this study, and I would want to take this opportunity to express my gratitude to each and every one of them. I believe that the capacity to ACKNOWLEDGE them is what makes life wonderful.

Any dissertation is like a dream, and much of its fulfilment depends on the support and advice of several other people. The guide in the dream is someone who believes in you and who pulls, pushes, and guides you to the next plateau while occasionally jabbing you with a sharp stick called "truth". I found one such great mentor in **Dr. Sunil Chandra Verma,** Reader, Department of Periodontology, Babu Banarasi Das College of Dental Sciences. I am so grateful for all of his support and assistance. I consider myself really blessed to have someone like him as a guide who both taught me to explore independently and provided the direction I needed to get back on track when my steps stumbled. His sheer presence inspired and encouraged me. He taught me how to challenge ideas and communicate them. I will always be grateful to him for the way his relentless pursuit of perfection has shaped and improved me. His persistence and encouragement enabled me to get through many challenging circumstances and conclude this dissertation.

My profound gratitude is also owed to my esteemed co-guide **Dr. Suraj Pandey**, Reader, Babu Banarasi Das College of Dental Sciences, for his insightful recommendations, consistent inspiration, and support throughout.

I take this opportunity to sincerely thank **Dr. Puneet Ahuja**, Principal, Babu Banarasi Das College of Dental Sciences for their timely advice, practical assistance during my post-graduation & providing the necessary facilities to carry out the dissertation work.

I want to express my gratitude to **Dr. Mona Sharma**, Professor and Head of the Periodontology Department at Babu Banarasi Das College of Dental Science, for her

understanding and encouragement, which helped me get through many stressful circumstances.

I also take this opportunity to express a deep sense of gratitude to **Dr. Vandana A Pant**, Professor and **Dr. Neelesh Singh, Dr. Akanksha Kashyap,** Reader, Department of Periodontology, Babu Banarasi Das College of Dental Science, for their astute observations and constructive criticism, which helped me focus my ideas. My motivation and assistance with my dissertation have come from their never-ending passion and energy.

I appreciate the generosity of **Dr. Meghna Nigam, Dr. Mohammad Aamir, Dr. Piyush Gowrav, Dr. Shalagha Parasher, Dr. Akanksha**, Senior Lecturer for their eternal and persistent advice.

I must of course extend my thanks to my seniors **Dr. Dilip Kr Maurya, Dr. Pallavi Goswami, and Dr. Chetan Chaudhary** for their timely help and moral support during my moments of despair. A very special mention to my co- pgs. **Dr. Ankit Bhadani, Dr. Sumati Patel, Dr. Jigme Palzor Drenzongpa, Dr. Rahul Anand and Dr. Snigdha Biswas** for their invaluable support and suggestions. Also, to my Juniors **Dr. Deepika Mishra, Dr. Akriti Jha, Dr. Dikishita Das, Dr. Hiya Datta, Dr. Arati Jaiswal, Dr. Bhibhuti Gupta, Dr. Shweta Raju Ghanvat, Dr. Surbhi Singh, Dr. Gyan Prakash Dubey, Dr. Alankrita, Dr. Rukmini Shah** and **Dr. Rainna Agarwal.**

It would be disrespectful if I do not remember my family at this venture. Words cannot explain how grateful I am to my parents, **Mr. Bal Govind Yadav and Mrs. Nirmala Yadav**, my in-laws and exceptional thanks to my husband, **Dr. Amit Yadav**, who has always supported me through my ups and downs and stood by me in my difficult times.

I express my sincere gratitude to The Almighty God for granting me this wonderful existence in which I may significantly change people's lives.

REGARDS,

Dr. SHAIFALI

TABLE OF CONTENTS

LIST OF TABLES

LIST OF GRAPHS

LIST OF FIGURES

LIST OF ANNEXURES

LIST OF ABBREVIATIONS

AFG	Autologous Fibrin Glue
OFD	Open Flap Debridement
FS	Fibrin Sealant
VAS	Visual Analogue Scale
EHI	Early Healing Index
PRP	Platelet Rich Plasma
PPP	Platelet Poor Plasma
RBC	Red Blood Cell
FAS	Fibrin Adhesive System
PGA	Polyglycolic Acid
NS	Nylon Suturing
FGG	Free Gingival Graft
CAL	Clinical Attachment Level
PPD	Probing Pocket Depth

ABSTRACT

Introduction: Periodontium is a specialized tissue that surrounds and supports the teeth. There is no specific age at which periodontitis would most likely start. The periodontal pocket provides ideal conditions for the proliferation of microorganisms and eliminating the local etiologic factors is of penultimate importance and can be achieved by periodontal therapy. But in certain cases, all the local factors cannot be eliminated via non-surgical therapy. Thus, many moderate to advanced cases are treated by surgically gaining access to the root surface. Debridement followed by scaling and root planing and then sutures are given to obtain adequate primary wound closure and stabilization of the tissues. But suturing takes time, risks infection, leaves scarring, necessitates technical expertise and understanding, and requires a second patient visit to have it removed. However, Autologous fibrin glue is a biological tissue adhesive that imitates the coagulation process's concluding phase. To close a wound without using sutures, autologous fibrin sealant can be employed. Its adhesive ability can seal the tissue well and can eliminate any potential gaps. Hence the aim of this study is to evaluate the potential use and efficiency of autologous fibrin glue in periodontal surgical procedures.

Materials and Method: A prospective, split-mouth randomized clinical trial was conducted, with two groups, a control and an experimental group. Twenty individuals in total were chosen, with twenty control and twenty experimental quadrants. The mucoperiosteal flaps were approximated with sutures in the control group and with AFG in the experimental group following the completion of the OFD.

Result: Autologous fibrin glue was superior to suture in terms of the stability following flap closure, post-operative healing, and post-operative pain of the patient.

Conclusion: AFG can offer stable flap closure and is well-liked by patients for causing less pain. While the clinical benefits of FS were evident, more research is required before society may choose fibrin glue over suture.

Periodontium is a specialized tissue that surrounds and supports the teeth. The periodontium supports the tooth, protects it against oral microflora, and makes the attachment of the tooth to the bone possible[1]. Periodontitis, an inflammatory condition of the teeth's supporting tissues brought on by particular microorganisms or groups of distinctive microorganisms, leads to the formation of periodontal pockets, gingival recession, or both, as well as the gradual destruction of the periodontal ligament and the alveolar bone.[2]. There is no specific age at which periodontitis would most likely start, and it is seen that the prevalence, severity, and extent of the disease increases steadily with age.[3] Each patient has a different rate at which their periodontitis develops. The periodontal pocket provides ideal conditions for the proliferation of microorganisms. However, there is a chance for a subsequent damaging phase if it persists and keeps harbouring the disease-causing microbes. The illness can then need a lengthy course of treatment. As a result, the elimination of the periodontal pocket and the clearing of the subgingival infection are prioritized in the treatment of periodontitis.[4] Elimination of local etiologic factors is of penultimate importance and can be achieved by periodontal therapy.

Scaling alone is sufficient to remove plaque and calculus completely from enamel, leaving a smooth, clean surface. However, in certain cases all the local factors cannot be eliminated via non-surgical therapy due to a lack of access, poor vision, etc. Many moderate to advanced cases cannot be resolved without surgically gaining access to the root surface for root planing and reducing or eliminating pocket depth to allow the patient to remove biofilm.[5] In such cases, open approach or surgical phase therapy is the method of choice as it provides adequate visibility and access to the underlying bone and root surface. The surgical stage of treatment is also known as phase II therapy. There are number of flaps that can be used and provide a better postoperative outcome in circumstances where surgical therapy may be required to increase accessibility for root planing or regenerative therapy.[5]

Surgical techniques[5] –

(1) the root surface can be accessed more easily, allowing the specialist to get rid of all irritants;

(2) minimize or eliminate the depth of the pocket, allowing the patient to keep the root surfaces clean of biofilm.; and
(3) to achieve a unified topography, remodels both soft and hard tissues.

Debridement followed by scaling and root planing and then sutures are given to obtain adequate primary wound closure and stabilization of the tissues.

Suturing is a frequent method used to achieve appropriate primary wound closure and tissue stabilization, but it takes time, risks infection, leaves scarring, necessitates technical expertise and understanding, and requires a second patient visit to have it removed.[2] The monofilament type of suture alleviates the "wicking effect" of braided sutures that may allow bacteria from the oral cavity to be drawn through the suture to the deeper areas of the wound.[5] For the optimal postsurgical wound healing, it is important to establish a non-tension initial wound closure of different soft-tissue flaps.[5]

The timing of suture removal is still more of an art than a science. Despite of one‟s best efforts, a degree of wound tension cannot always be avoided, and in some situations, it may be clinically appropriate to support the healing wound with suture material that remains in place for two weeks or even longer.[6] Rarely these sutures can carry significant tension, and when once removed there is the potential for leaving noticeable track marks[7] („Cross hatching‟, „railroad tracks‟ or „fishbone scars‟). Suture marks are an inherent risk in surgical procedures and may require specific mention in the context of written consent.

Adjuncts including tissue glues and adhesive strips can be used. Cosmetic surgery, general surgery, ophthalmic surgery, laryngology, neurological surgery, cardiovascular surgery, thoracic surgery, gynaecology, and urology are just a few medical specialties where FS is already used by doctors.[8] These techniques armour us with many ways to avoid or minimize suture marks.

Impaired blood vessel bleeding happens initially after tissue injury. A fibrin network fills the lesion space as a result of the ensuing coagulation process, serving as a natural adhesive that enables the wound's margins to be kept in unison. The network of fibrin may also function as a middle layer that promotes fibroblast adhesion and migration and proliferation. The fibrin degradation byproducts, activates

macrophages, which are the basic cell population for the course of regular repair, contributing with growth factors.[9]

Exogenous fibrin mimics and amplifies the final physiological steps of the coagulation stage when it is utilized as a tissue adhesive.[9]

Autologous fibrin glue is a biological tissue adhesive that imitates the coagulation process's concluding phase. It has been used to hold mucoperiosteal flaps and gingival grafts in place.[10,11] To close a wound without using sutures, autologous fibrin sealant can be employed. Its adhesive ability seals tissue well and eliminates any potential gaps.[12]

Hence the aim of this study is to evaluate the potential use and efficiency of autologous fibrin glue in periodontal surgical procedures.

AIM

To compare and assess the stability after flap closure, post-operative healing and post-operative pain of patient with autologous fibrin glue in one arch and with suture in another.

OBJECTIVES

To Evaluate the:

i. Adhesion -- with Roll Test[12]

ii. Pain assessment -- with the Visual analogue scale (VAS) McCaffery, Beebe et al. 1989[13]

iii. Healing -- using Early Healing Index (EHI) by Wachtel et al[14]

Young et al (1940)[15] used fibrin as an adhesive for the first time. He devised a method by which stumps can be held together with concentrated coagulated blood plasma. The method consisted simply in holding the cut stumps together and pouring round them plasma which has just been mixed with a little strong tissue-extract. In about 2 min., according to the age of the plasma and the strength of the extract, the plasma clotted to a firm jelly, which sticked to the nerves and held the stumps together. The plasma was freely permeable and during the subsequent days was dissolved away.

Bartolucci et al (1982)[9] investigated clinically the bioadhesive qualities of Tissucol® in periodontal surgery. In a pilot study they attempted to investigate clinically the bioadhesive qualities of Tissucol® in periodontal surgery. The biologic sealant, after its application, sets into a white, rubberlike mass in 20 to 30 seconds and is known to gain in strength in the course of the next 2 hours. The tissues sealed showed a negligible local inflammation at the 1-week, 2-week and 1-month postoperative observations. The biomechanical requirements were excellently met with the flap and the graft maintained in the desired positions. The healing process appeared faster than when sutures were used.

Prato et al (1987)[10] A fibrin-sealing system consisting of symmetrical flap and graft procedures versus silk sutures in a split-mouth clinical trial was tested in 51 patients. Clinical parameters and operative times were recorded and compared. In clinical use, the fibrin glue provided quick hemostasis and adequate tissue adhesion on the whole inner surface of grafts or flaps. Its use saved remarkable amounts of time and made it easier to fix tissues in difficult areas. The convenience of the fibrin glue was especially appreciated in pedicle flap procedures.

Brennan et al (1991)[16] Fibrin glue has been shown to be an effective topical haemostatic agent in numerous surgical procedures. The use of fibrin glue can be effective when conventional techniques have failed 6 or access is difficult. Its use may

reduce tissue ischaemia caused by sutures placed too close together and may avoid sutures cutting into parenchymatous organs.

Kjaergard et al (1992)[17] Autologous fibrin glue was used in 20 patients undergoing lung resection to reduce pulmonary air leaks and improve hemostasis. The fibrinogen in the glue was prepared by ethanol precipitation of plasma separated from 88 ml of the patient‟s blood. One part of fibrinogen concentrate was converted to solid fibrin by means of 0.3 parts of thrombin solution. The outcome was 6.4 ml of two-component fibrin glue. The preparation was performed in a closed system to ensure sterility, and was completed within 90 min. Pulmonary air leak decreased following sealing of the resection lines with autologous fibrin glue and the hemostasis was effective. No adverse effects were observed, and all cultures from the glue were negative. Autologous fibrin glue has the obvious advantages of safety from transmission of viral diseases and from immunological reactions. Therefore, they reported a new technique for preparing autologous fibrin glue with a high concentration of fibrinogen making it a safe and effective sealant of pulmonary air leak and hemostatic agent in thoracic surgery**.**

Park et al (1993)[18] studied the biochemical aspects of Autologous Fibrin Glue derived from Ammonium sulfate precipitation. The autologous fibrin glue (AFG) was produced from 30 human donors using the ammonium sulfate precipitation method, and a study of its biochemical composition was performed. The fibrinogen concentration ranged 13 to 57 mg/mL, the yield averaged 54.6%, and there was a direct relationship between the level of fibrinogen in plasma and AFG which had been made from the same donor's plasma. The results suggested that the quality of this category of AFG depends partially on the fibrinogen level of donor's plasma.

Tawes et al (1994)[19] conducted study with 36 patients undergoing aortic, thoracoabdominal, and thoracic surgery, as well as patch graft angioplasty cases. The object of the study was to evaluate the ease and efficacy of two methods of AFG production: preoperative donation and perioperative plasmapheresis. One of two methods was used with 36 patients over a l-year period: preoperative plasma donation

by the patient to produce autologous fibrin glue (26 patients), and intraoperative production of AFG from platelet-rich plasma (PRP) derived from pcrioperative plasmapheresis (10 patients) using the Plasma-Saver (Haemonetics Corporation, Braintree, Massachusetts). They concluded with AFG as a hemostasis agent that supports the safety, ease, and efficacy of both preoperative donation and perioperative production. Preoperatively donated AFG has a higher concentration of fibrinogen and acts more like an epoxy glue, whereas perioperatively produced AFG is less viscous but equally effective as an adjunct agent for controlling nonsuturable bleeding or oozing.

Kjaergard et al (1994)[20] did the study for factors influencing the strength of Autologous fibrin glue; fibrin concentration and reaction time with the commercial fibrin glue. Fibrin glue was prepared from citrated plasma of human donors by means of ethanol. The outcome was a fibrinogen concentrate with a mean concentration of 43 mg/ml. The fibrinogen was converted to fibrin by the addition of 0.3 part of thrombin solution, 150 NIH U/ml, containing 100 m*M* calcium chloride. In a rat model full-thickness skin grafts were sealed with the glue, and the adhesive strength was measured at different fibrin concentrations, and after a variable reaction time, and compared to commercial fibrin glue (Tisseel®). The strength of ethanol-prepared glue was directly proportional to the fibrin concentration, and increased rapidly within the first minutes of the reaction time. The strength of the commercial glue could be obtained with autologous fibrin glue at the same fibrin concentration

Siedentop et al (1995)[21] described and evaluated an autologous fibrin tissue adhesive (AFTA) that uses a combination of ethanol and freezing to precipitate fibrinogen (AFTA-E)**.** The bonding power of AFTA-E was compared with that of a conventional AFTA based on ammonium sulfate precipitation of fibrinogen (AFTA-A). In this study, Silastic, porcine dermis, and human dura mater blocks were bonded together for 10 and 30 minutes with AFTA-E or AFTA-A. The blocks were then separated and the bonding power was measured. The efficacy of AFTA-E was also evaluated after a 24-hour refrigeration. The AFTA-E was shown statistically to bond stronger than the AFTA-A. In addition, it was found that the efficacy of AFTA-E was unchanged after

a 24-hour refrigeration. The improved AFTA, AFTA-E, is a superior alternative to the conventional AFTA-A. Furthermore, AFTA-E can be manufactured before surgery and stored, thus minimizing preparation time during surgery.

Mintz et al (2001)[22] Stated thrombin concentration directly influences the clotting time and is used to affect the working time of fibrin sealant.

Thorn et al (2004)[23] described a method for the preparation of autologous fibrin glue with platelet growth factors and reported its use with particulate cancellous bone in reconstructive maxillofacial surgery. The glue was prepared from platelet rich plasma which was separated from 200 ml of the patient‟s blood prior to the operation. Glue was used successfully with particulate bone grafts for reconstructive purposes within the oral and maxillofacial field.

Alston et al (2008)[24] conducted a study where they used fibrin sealant containing various fibrinogen concentrations (ranging from 15 to 60 mg/mL). It was applied to controlled renal incisions, and bleeding time and blood loss was measured. Bleeding from the wounds was also predicted using a mathematical model based on tensile strength and adhesion strength of the sealants. The sealants, when applied under controlled conditions, reduced the blood loss and bleeding time more effectively than controls (where no sealant, plasma, or the commercial product Tisseel (Baxter Healthcare Corp., Westlake Village, CA) was applied).

Jathal et al (2008)[25] reported two patients in whom flaps were closed using fibrin in the first patient and sutures in the second. The aim was to check the consequence of fibrin sealant as an alternative to sutures. There was a definite ease of usage on the part of clinician of the fibrin glue, while there was painless and early recovery of the glued area in the first patient as compared to the sutured area in the second patient.

Panda et al (2009)[26] stated autologous samples contain low concentration of fibrinogen than commercially prepared sealants.

Manimegalai et al (2010)[27] evaluated the efficacy of fibrin adhesive sealant (Tisseel®), a human biological tissue adhesive, as compared to conventional suture placement in pocket elimination and mucogingival surgical procedures. The study sample consisted of 25 patients (10 male and 15 female patients), in the age group of 25-40 years, with localized periodontitis in relation to the anterior region of the maxilla and mandible. They were divided into three surgical groups: Group I, Group II and Group III. Each of these groups was further divided into control and experimental groups. In all the control groups, the flaps/grafts were approximated with 4-0 black braided silk. In the experimental groups, the flaps/grafts were approximated with fibrin adhesive sealant (Tisseel®). The Fibrin Adhesive System showed superior results in all the parameters measured, i.e., hemostasis, fixation of tissues, reduction in plaque and gingival index and probing depth postoperatively. The results of this study indicated that periodontal surgery using FAS enhances various periodontal regenerative surgical procedures.

Joshi et al (2011)[28] Conducted a study to compare the efficacy of tissue glue placement after surgical removal of impacted mandibular third molars. Thirty patients with bilaterally impacted mandibular third molars were studied in this controlled clinical trial. One side closure after surgical removal of third molar was done with conventional sutures and other side with the glue. The data was analyzed and showed that postoperative bleeding with glue method was less significant than with suturing on the first and second day after surgery. There was no significant difference in the severity of pain between the two methods. So the study suggested that the efficacy of both, glue and suturing in wound closure were similar in the severity of pain, but use of glue showed better hemostasis.

Pulikkotil et al (2013)[29] The trial conducted which compared wound healing clinically, histologically and morphometrically after the use of fibrin sealant and sutures for periodontal flap closure. Ten patients were selected for this split-mouth randomized controlled clinical trial. On the test site fibrin sealant was applied for flap closure after periodontal flap surgery and on the control site sutures were used. Clinically wound healing was observed at 7, 14 and 21 days and biopsy was taken on the 8th day. At seventh day better healing was observed in fibrin sealant site.

Histologically mature epithelium and connective tissue formation was seen in fibrin sealant site with increased density of fibroblasts and mature collagen fibers. The suture site had a greater number of inflammatory cells and more number of blood vessels. Fibrin sealant can form a better alternative to sutures for periodontal flap surgery.

Kouketsu et al (2016)[30] evaluated autologous fibrin glue and polyglycolic acid sheets as oral surgical wound coverings after partial glossectomy. Polyglycolic acid (PGA) sheets and commercial fibrin glue are commonly used to cover open wound surfaces in oral surgery. They evaluated postoperative pain, scar contracture, ingestion, tongue dyskinesia, and postoperative bleeding in 24 patients who underwent partial glossectomy plus the application of a PGA sheet and an autologous fibrin glue covering (autologous group) versus 11 patients in whom a PGA sheet and commercial fibrin glue were used (allogeneic group). The evaluated clinical measures were nearly identical in both groups. Remarkable wound surface granulation was recognized in two cases in the autologous group. Coagulation and adhesion of the autologous fibrin glue were equivalent to those of conventional therapy with a PGA sheet and commercial fibrin glue. Thus, results showed that covering wounds with autologous fibrin glue and PGA sheets may help avoid the risks of viral infection and allergic reaction in partial glossectomy cases.

Alamdari et al (2017)[31] compared the safety, operating time, postoperative ocular signs, symptoms, overall patient satisfaction, complications rate and recurrence rate of autologous fibrin glue (AFG) and nylon suturing (NS) for attaching conjunctival autografts in pterygium surgery. Study was performed among 120 patients (120 eyes) with primary pterygium. Superior conjunctival autograft was harvested and transferred on to bare sclera after pterygium excision. For attaching the autograft, AFG and NS were used. All conjunctival autografts in both groups were successfully attached. The average operating time for the AFG group was significantly shorter. Postoperative symptoms were fewer for the AFG group than the suture group. After 12 months of follow-up, no recurrence was reported for the AFG group, but 8.3% of patients experienced recurrence in the NS group.

Uslu et al (2019)[32] conducted the study aiming to minimize the complications that can be seen in the donor area after free gingival graft operation with „autologous fibrin glue"(AFG) application. In FGG patient, AFG application to the palatal region was planned in order to minimize the complications that may be seen in the donor area after the operation. Wound healing was assessed with clinical parameters at 3, 7, 14 days and 1 month postoperatively. Wound healing was achieved without any complications. It was seen that the use of AFG in palatal wound healing, reduced post-operative complications and accelerated the healing process.

Dave et al (2020)[12] reported the use of an autologous fibrin glue in two cases. At the end of periodontal flap surgery, the flaps were closed with sutures in two papillae and fibrin glue in other two papillae in both cases. The papillae closed with fibrin glue showed better healing and good stability after flap closure.

Kızıltoprak et al (2020)[33] compared the effects of AFG and i-PRF on palatal wound healing and postoperative discomfort. Thirty-six patients in need of FGG were divided into three groups. AFG (n = 12) or i-PRF (n = 12) was applied and compared with control group (n = 12). Wound healing with H2O2 test, VAS, MSS, and LTH index were evaluated. Epithelialization was higher in the test groups on the 14th day than the control group. MSS scores at the 14th day and 1st month were lower in the AFG group than the control and the i-PRF group ($p < 0.05$). In the AFG group, LTH levels at the 3rd,7th, and 14th days and 1 month were higher than control and i-PRF groups. VAS scores of the AFG group were lower than the control and i-PRF groups at the 7th day. Bleeding was lower in the test groups than in the control group. AFG and i-PRF have positive effects on the healing process by accelerating wound healing and reducing postoperative morbidity. AFG had superior properties in wound healing compared with i-PRF.

Soundarajan et al (2021)[34] assessed the post operative healing and stability of flap closure using autologous fibrin glue when compared to silk suture. Thirty subjects with moderate to severe periodontitis who requires periodontal flap surgery involving

at least four adjacent teeth, as determined by clinical criteria (i.e., probing depth of 5 mm and bone loss on radiograph of 50%), between 20 and 50 years of age of both sexes, and showing adequate oral hygiene before surgical therapy were included in the study. Autologous fibrin glue was prepared. The surgical area to be treated was randomly selected into two areas, Group A: Two papilla were secured with sutures (3-0 silk) after surgery; Group B: Two papilla were secured with autologous fibrin glue after surgery. Parameters assessed & tests performed - The roll test for flap closure stability was used to verify the flap's adhesion. The postoperative healing was evaluated using the simplified healing index.

Narendran et al (2021)[35] evaluated the effectiveness of autologous platelet- rich fibrin as an adjunct to scaling and root planning in moderate periodontal pockets. The split mouth study involved 32 sites from 16 patients. Baseline parameters were recorded followed by complete full- mouth SRP. The test and control sites were randomly selected and autologous PRF was placed in the test site and other site served as control. Clinical parameters were recorded at baseline, 60 days, and 90 days. No statistical significance was found at baseline in probing depth (PD) and clinical attachment level (CAL). A statistically significant difference in test sites was found in terms of reduction in probing depth (PD) and clinical attachment gain (CAG) compared to the control sites at the end of the study period. This study emphasized a statistically significant improvement in pocket depth reduction and CAL gain when PRF was used as an adjunct to SRP in moderate periodontal pockets.

Mounsif et al (2022)[36] assessed the effectiveness of fibrin sealant compared to sutures in periodontal surgery. They screened five electronic databases (PubMed, Scopus, EBSCO, Cochrane and Web of Science) from initiation to January 2021 for randomized controlled trials (RCTs) comparing fibrin sealant to sutures in periodontal surgery using the search equation: (Periodont* OR Periodontitis) AND (“fibrin tissue adhesive” OR “fibrin glue” OR “fibrin sealant” OR “fibrin sealant system” OR “fibrin adhesive system” OR “fibrin fibronectin sealant system”). Quality assessment of the included studies was performed using the revised tool to assess risk of bias in randomized trials. The level of evidence was evaluated using the GRADE tool. A

total of 240 publications were found as search results in the screened databases. Four RCTs were included in this systematic review based on predetermined inclusion criteria. All the RCTs, compared fibrin sealant to sutures in periodontal surgery. The sample size included 101 patients. The overall risk of bias in this systematic review was at high risk in 75% of the studies, while 25% of the studies raised some concerns. The level of evidence evaluated using GRADE tool was very low. The systematic review indicated a low level of evidence of the use of fibrin sealant as an alternative to sutures in periodontal practice.

Bozkurt et al (2022)[37] evaluated the effect of platelet-rich fibrin (PRF), concentrated growth factors (CGF), and autologous fibrin glue (AFG) application on early wound healing after gingivectomy and gingivoplasty operations. In this split-mouth study, gingivectomy and gingivoplasty surgery were performed on 19 patients. The postoperative PRF, CGF, and AFG applied areas were compared with the control regions. On days 0, 7, 14, and 28, the surgical area was stained with a plaque-disclosing agent and evaluated in the ImageJ program. Wound healing was evaluated. The amount of staining at days 7 and 14 was found to be significantly higher in the control group than in the test groups, but there was no difference between the test groups. LTH index values of the control group at days 7, 14, and 28 were found to be significantly lower than the test groups. It was observed that the use of platelet concentrates at day 7 reduced postoperative early pain. After gingivectomy and gingivoplasty operations, PRF, CGF, and AFG application were found to have positive effects on wound healing.

Place of the study where it is conducted

Clinical study was carried out in the Department of Periodontology, Babu Banarasi Das Collage 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 DESIGN

A **prospective, split-mouth randomized clinical trial** was conducted, with two groups:

- A control group/OFD group with conventional suturing,
- Experimental group /OFD group with Fibrin glue

1. **Control group/OFD group with conventional suturing:** Open flap debridement procedure with flap approximation using sutures.
2. **Experimental group /OFD group with Fibrin glue:** Open flap debridement procedure with flap approximation using fibrin glue.

Study subjects

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

Study sample size

Number of patients = 20 (Split- mouth method)

A total of 40 quadrants.

SUBJECT SELECTION

Eligibility criteria:

Patients will be selected based upon the following inclusion and exclusion criteria.

- **Inclusion criteria:**

1. Age 25-60 years
2. Bleeding on probing present
3. Probing depth >5 mm
4. Radiographic crestal bone loss present
5. CAL of >2 mm
6. Patients fulfilling ASA physical status classification system criteria

- **Exclusion criteria:**

1. Immunodeficiency disease
2. Uncontrolled systemic diseases
3. Pregnant and lactating females

Materials

Material and equipment used in this study are –

Armamentarium for Diagnosis and Pre-clinical Assessment

- Mouth mirror
- Tweezers
- Explorer
- Hu-Friedy's UNC 15 Graduated periodontal probe

Armamentarium for procedure

- BP Handle
- Blade- 12 no., 15 no.
- Periosteal elevator
- Crane Kaplan
- Curettes
- Castro Viejo Scissors
- Castro Viejo Needle Holder
- Scissor
- Mixing Spatula
- Kidney Tray
- Betadine
- Saline
- Photographic Mirror (Occlusal, Buccal)
- Centrifuge Machine (SSU Model Name/Number: SSU-173)
- Sterile sodium citrate containing vacutainers
- Sterile test tubes
- Protamine sulfate 10 mg/ml
- Calcium chloride- 0.025 mmol/l
- Suture
- Coe Pak

SURGICAL ARMAMENTARIUM

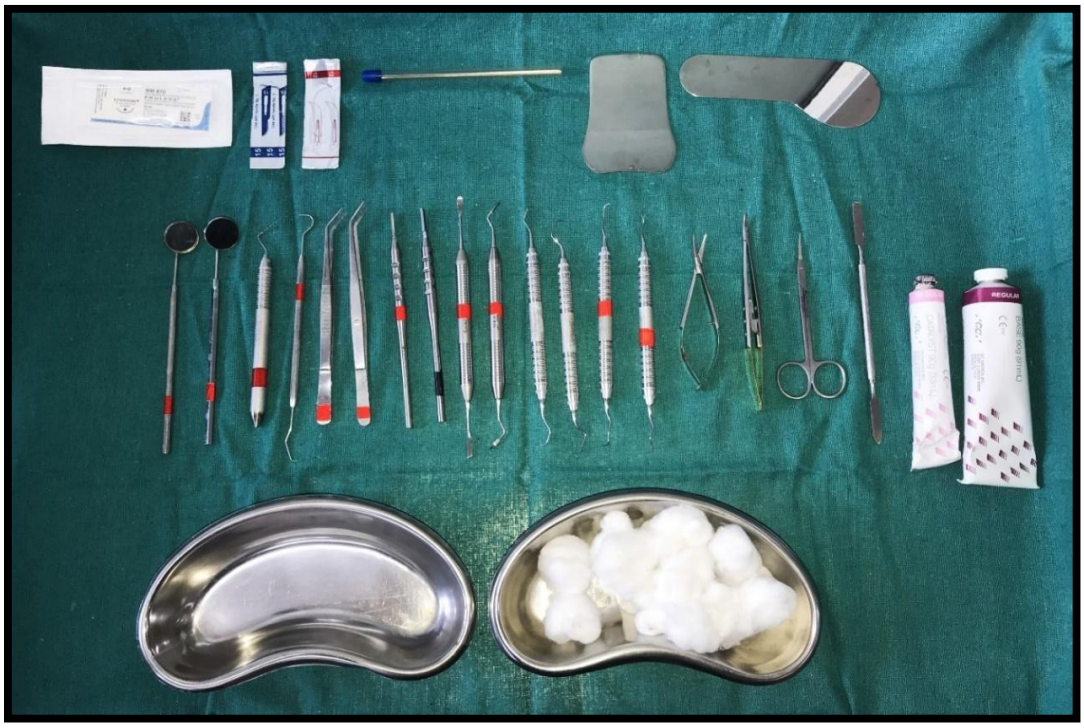


Figure 1: Armamentarium for Open Flap Debridement

PLATE NO. 1

AFG PREPARATION ARMAMENTARIUM

Figure 2: Armamentarium for Fibrin Glue Preparation

Figure 3: Protamine Sulphate and Calcium Chloride

PLATE NO. 2

INITIAL THERAPY

All 20 patients (11 males and 9 females), 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 OFD were randomly assigned to one of the two different study groups (OFD with conventional suturing or OFD with fibrin glue). After randomization PPD and CAL were evaluated at baseline using *Hu-friedy's* UNC-15 graduated periodontal probe and were recorded to the nearest millimeters. All the 6 sites (mesio-buccal, mid-buccal, disto-buccal, mesio-lingual, mid-lingual, disto-lingual) per tooth were examined for PPD and CAL.

METHODOLOGY

A split-mouth, randomized, prospective study was conducted in the Department of Periodontology of Babu Banarasi Das College of Dental Sciences (BBDCODS). 20 Patients were included in the study based upon the inclusion and exclusion criteria. Informed consent was taken prior to the treatment. Patients were randomly divided into:

The control group - 20 sites, and

The experimental group – 20 sites.

Pre-operative evaluation of bleeding on probing, probing depth, radiographic crestal bone loss, CAL was recorded.

SURGICAL PROCEDURE

Pre-operative mouth rinsing with 5 ml of betadine 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.

In **Control Group,** after thorough debridement using hand instruments the flaps were repositioned and sutured to achieve a primary soft tissue closure with non-resorbable 3-0 silk sutures *(Ethicon, Johnson and Johnson, Somerville, NJ, USA)* utilizing figure of eight suture technique.

In **Experimental Group,** immediately after the complete debridement AFG was prepared.
Method of preparation of Autologous Fibrin Glue:[36]

10 ml of patient's blood was withdrawn and collected in sterile sodium citrate containing vacutainers (Becton, Dickinson and Company) for autologous fibrin glue preparation and was immediately centrifuged at 3000 rpm for 10 minutes (FIGURE 4). The vacutainer comprised Red Blood Cells at the bottom fraction, Platelet-Rich Plasma in the middle, and Platelet-Poor Plasma at the top (FIGURE 5). A sterile syringe was used to aspirate the platelet-poor and platelet-rich plasma, which was then transferred in a separate tube without an anticoagulant. RBC portion at the bottom was discarded (FIGURE 6). Protamine sulphate 10 mg/ml was added to platelet-rich and platelet-poor plasma in order to precipitate the most fibrinogen possible. The test tube was then centrifuged for five minutes at 1000 rpm. The centrifuged tube constituted bottom layer of fibrinogen precipitate and a top layer of serum with autologous thrombin (FIGURE 7). The top serum was discarded, but 0.5 ml of it was kept in the test tube to dilute out the fibrinogen precipitate (FIGURE 8). This preparation was then aspirated into a different syringe along with the Calcium chloride-0.025 mmol/l in another syringe (FIGURE 9). Both the solutions were then administered equally under the flaps and were subjected to digital pressure for two to three minutes (FIGURE 10).

METHOD OF PREPARATION OF AUTOLOGOUS FIBRIN GLUE

FIGURE 4: Blood withdrawal from the median antecubital vein

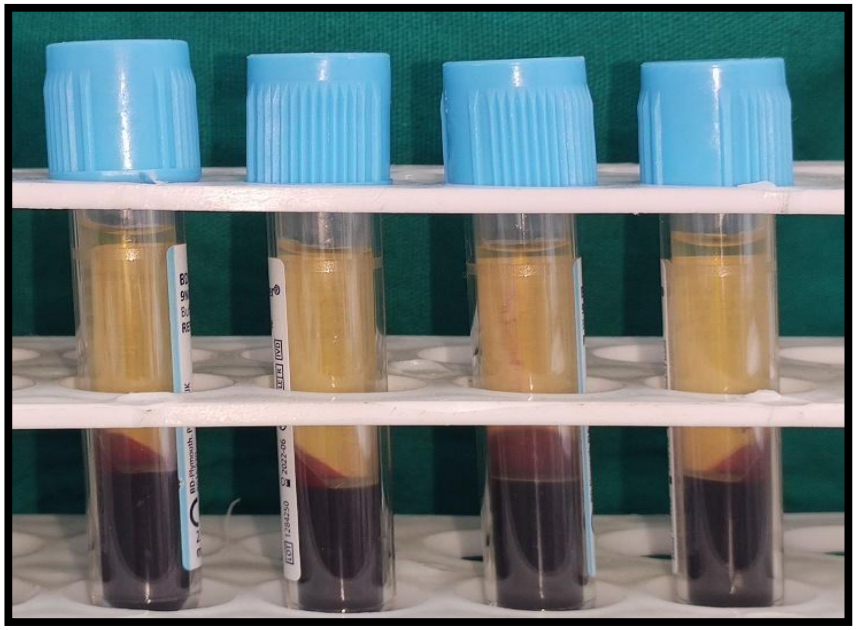


FIGURE 5: Vacutainers comprising of RBC at bottom, Platelet Rich Plasma in middle and Platelet Poor Plasma at top

PLATE NO. 3

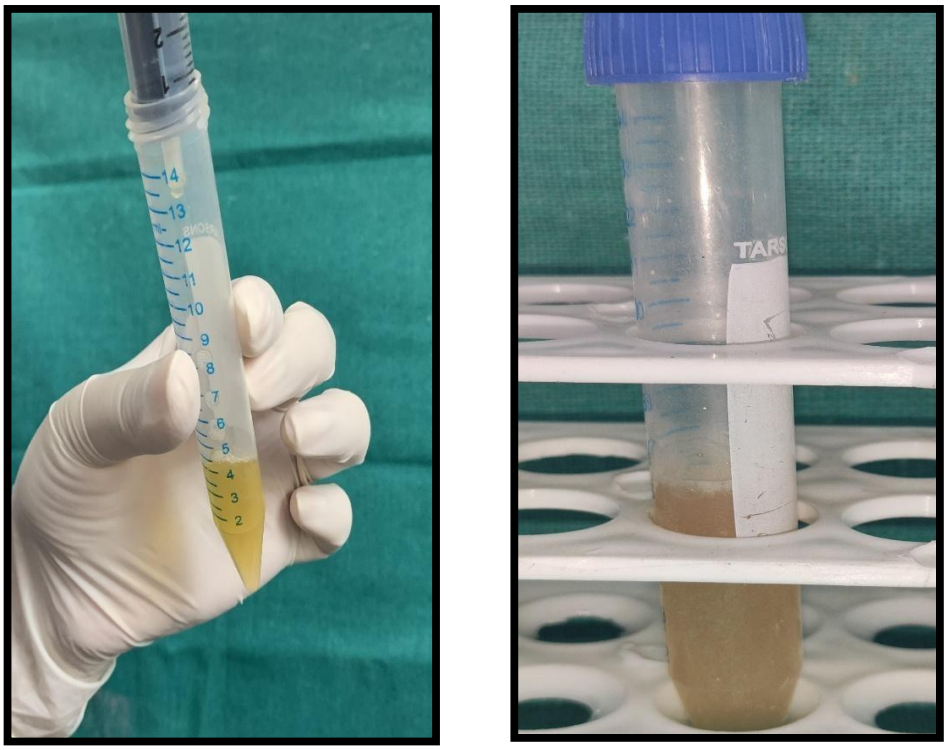


FIGURE 6: Platelet Poor and Platelet Rich Plasma in a tube without anticoagulant

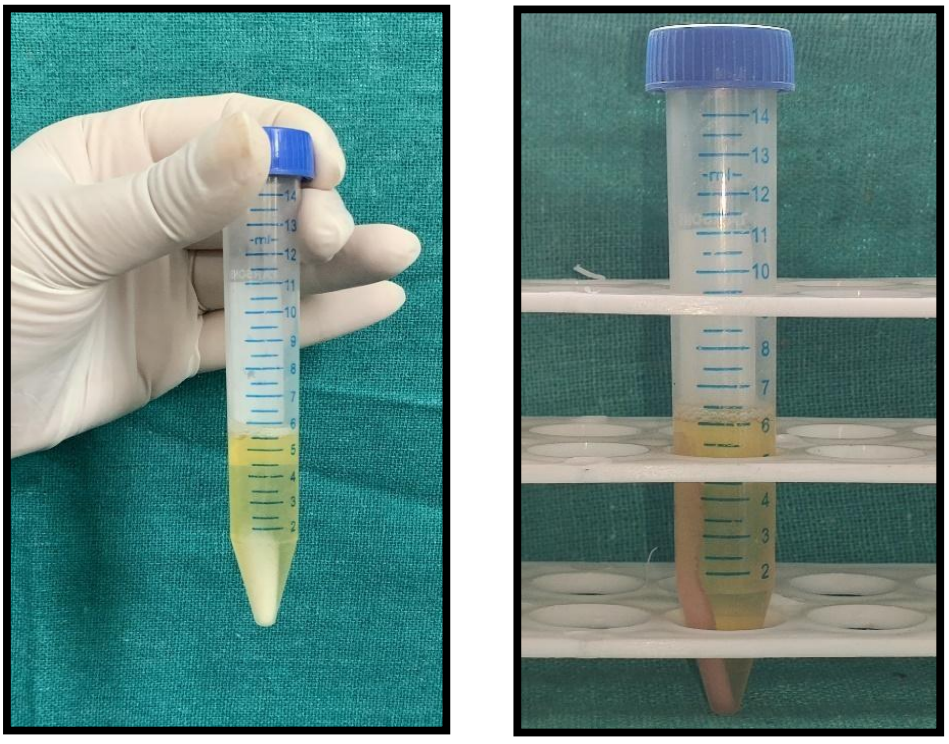


FIGURE 7: Fibrinogen precipitate in serum

PLATE NO. 4

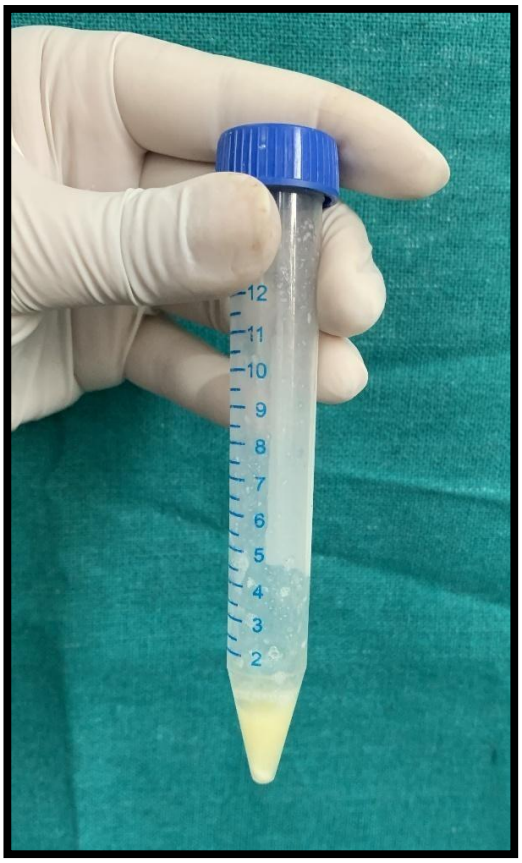


FIGURE 8: Fibrinogen precipitate diluted with serum

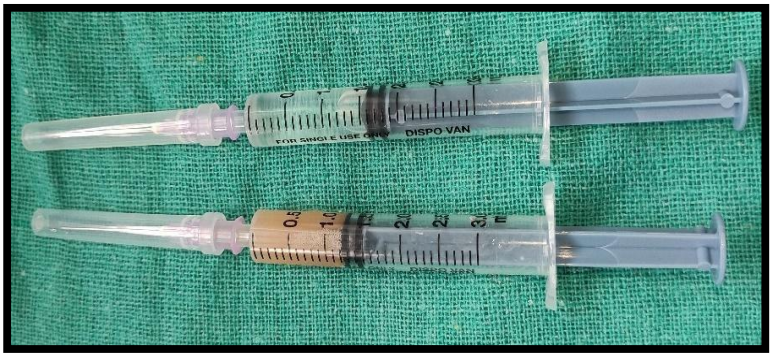


FIGURE 9: Two syringes containing diluted fibrinogen and calcium chloride, respectively

PLATE NO. 5

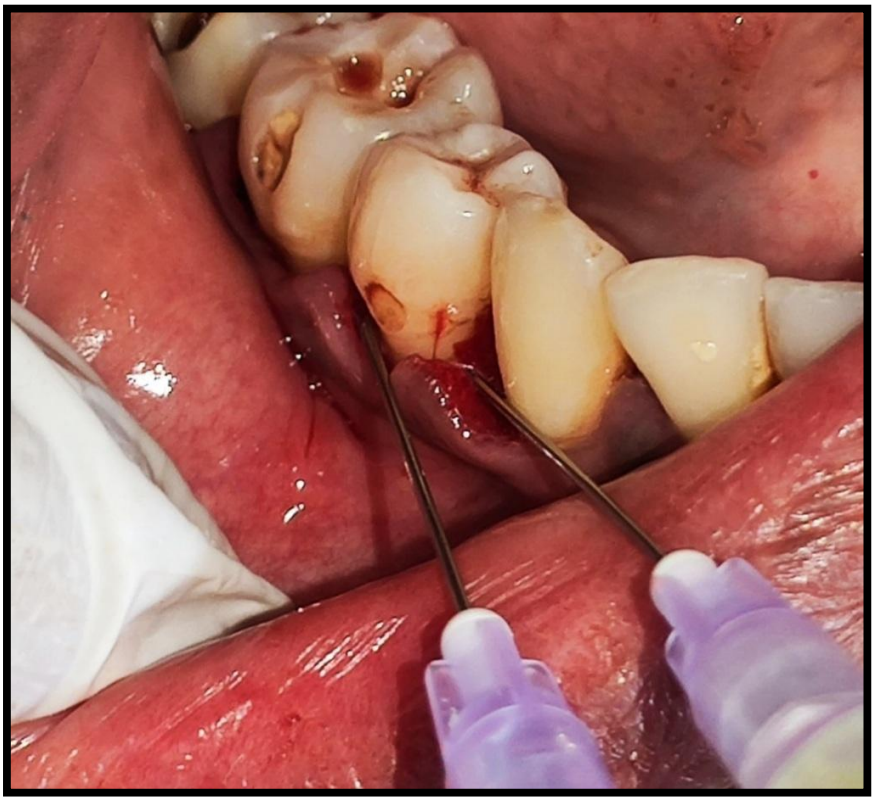


FIGURE 10: Diluted fibrinogen and calcium chloride being administered under flaps

PLATE NO. 6

After fifteen minutes, a **Roll Test** was conducted to assess the stability of the flap closure.

Roll test was checked by placing the side of the periodontal probe at the base of each papilla, probe was rolled in an apical direction, and the movement of the papilla was evaluated.

SCORE	CRITERIA
Score 1	Barely visible movement of the papilla
Score 2	Clearly visible movement but no retraction of the papilla
Score 3	Clearly visible movement with retraction of the papilla

Post-surgery, the surgical area was protected and covered with the periodontal dressing (COE $PACK_{TM}$ GC America Inc. Illinois, USA). Each patient was kept under an antibiotic, analgesic coverage for 5-days.

Periodontal dressing and sutures (in control group) 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.

One-week post-operatively the **Early Healing Index** by Wachtel et al was recorded.

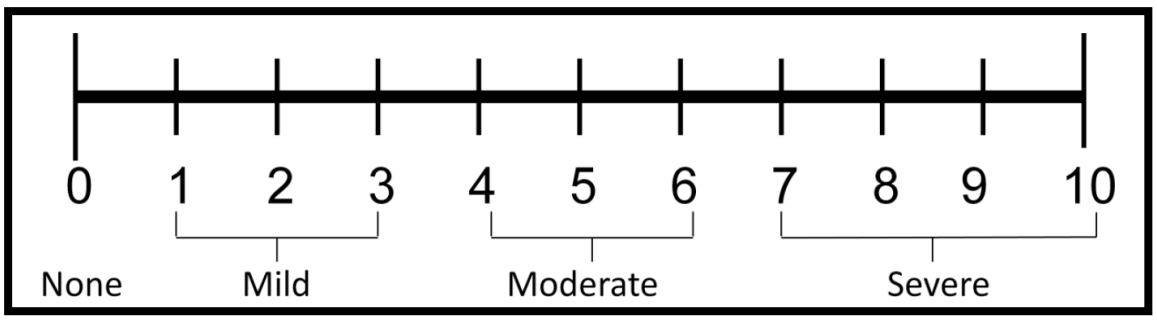
Early Healing Index (EHI) by Wachtel et al: -

Postoperative healing was assessed by the EHI differentiating between 5 different degrees:

SCORE	CRITERIA
Score 1	Complete flap closure – no fibrin line in the interproximal area
Score 2	Complete flap closure – fine fibrin line in the interproximal area
Score 3	Complete flap closure – fibrin clot in the interproximal area
Score 4	Incomplete flap closure – partial necrosis of the interproximal tissue
Score 5	Incomplete flap closure – complete necrosis of the interproximal tissue

Pain assessment was done with Visual Analogue Scale (VAS)
McCaffery, Beebe et al. 1989: -

Patient was asked to indicate the intensity of pain over the past 24 hours on a scale of 0 (no pain) to 10 (worst pain imaginable)



Recall appointments were scheduled for re-evaluation at 14 days, 21 days and 6 weeks interval from the day of surgery to assess the healing and flap stability. Postoperative care also included the reinforcement of oral hygiene instructions at each appointment.

CONTROL GROUP

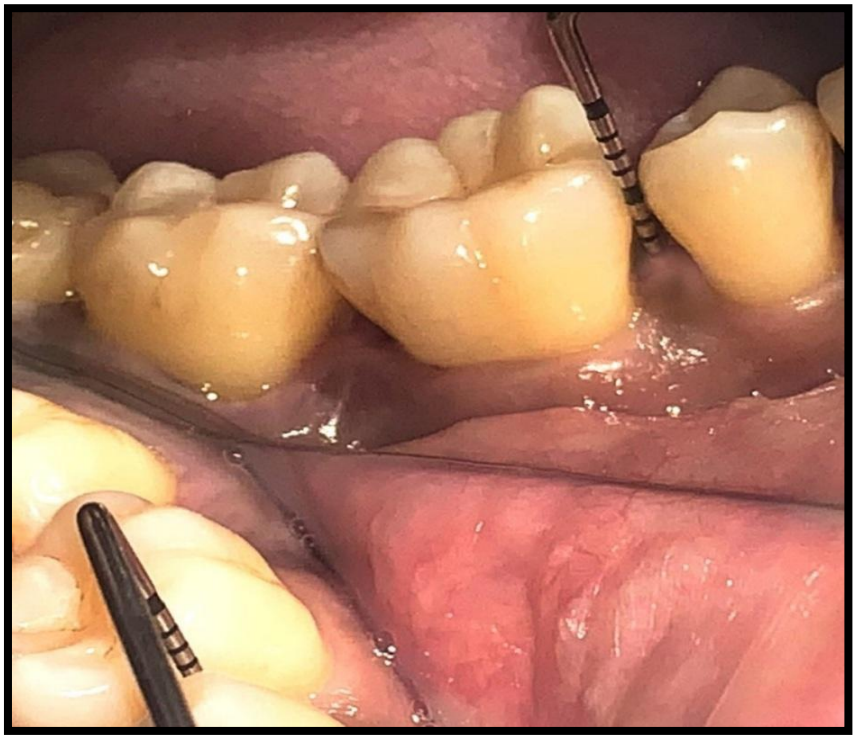


Figure 11(i): Pre-Operative Probing Pocket Depth

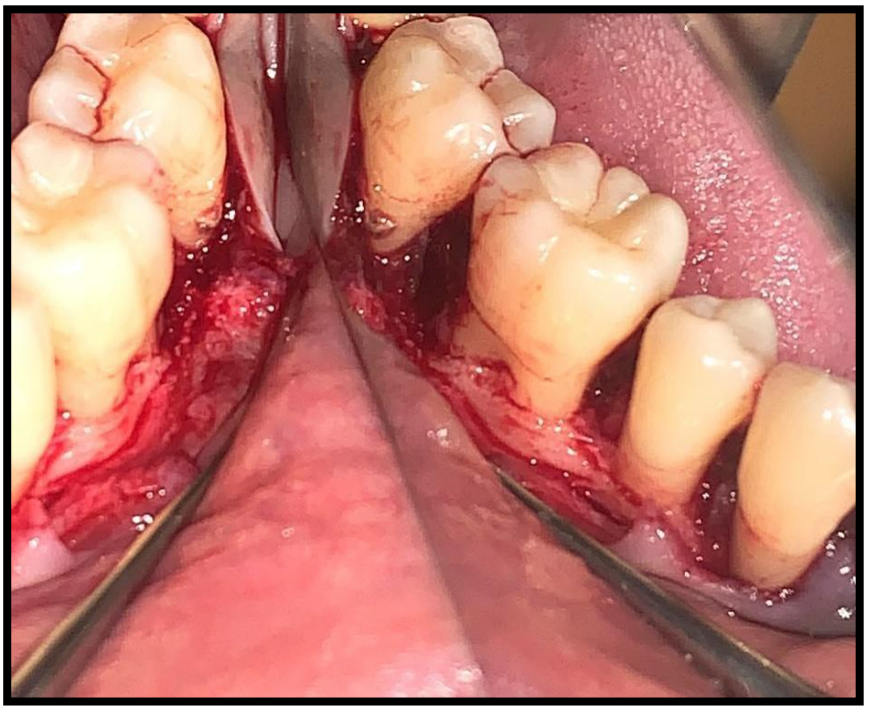


Figure 11(ii): Reflection of the Mucoperiosteal flap

PLATE NO. 7

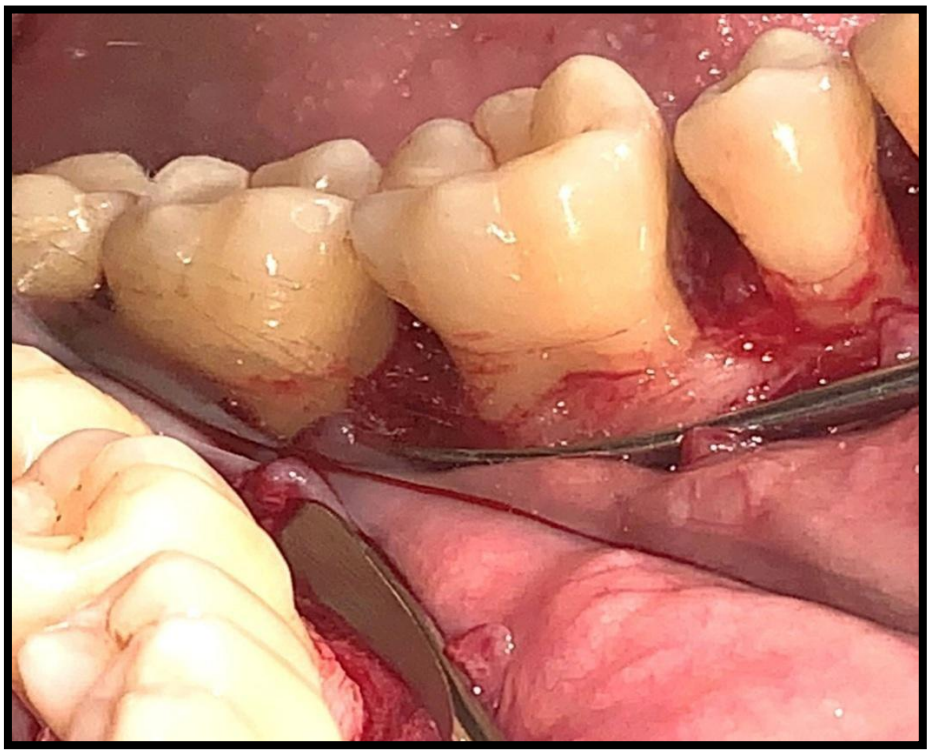


Figure 11(iii): Intraoperative View

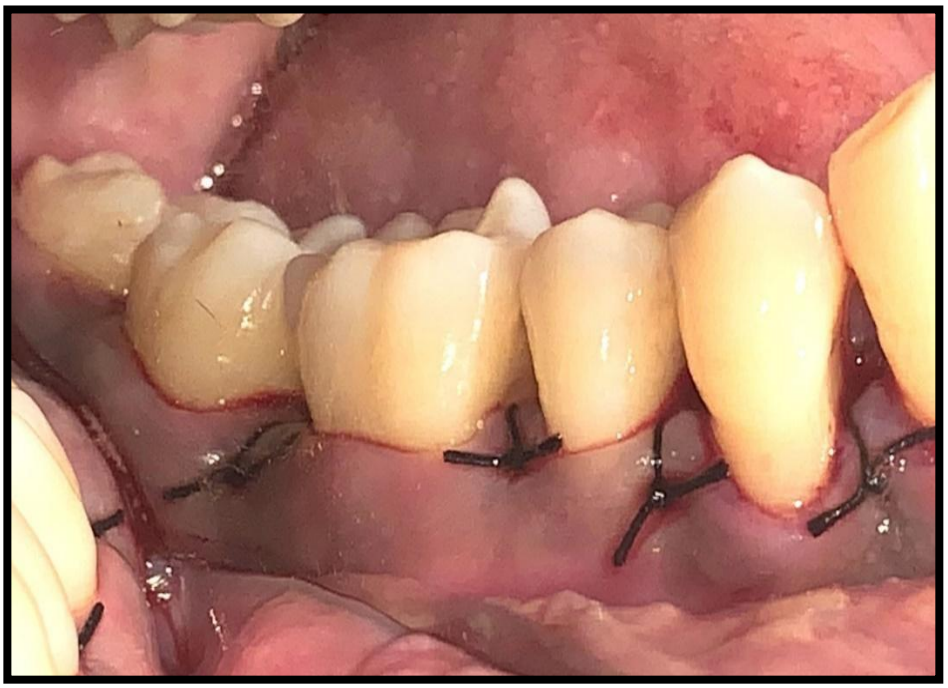


Figure 11(iv): Flap approximated with Sutures

PLATE NO. 8

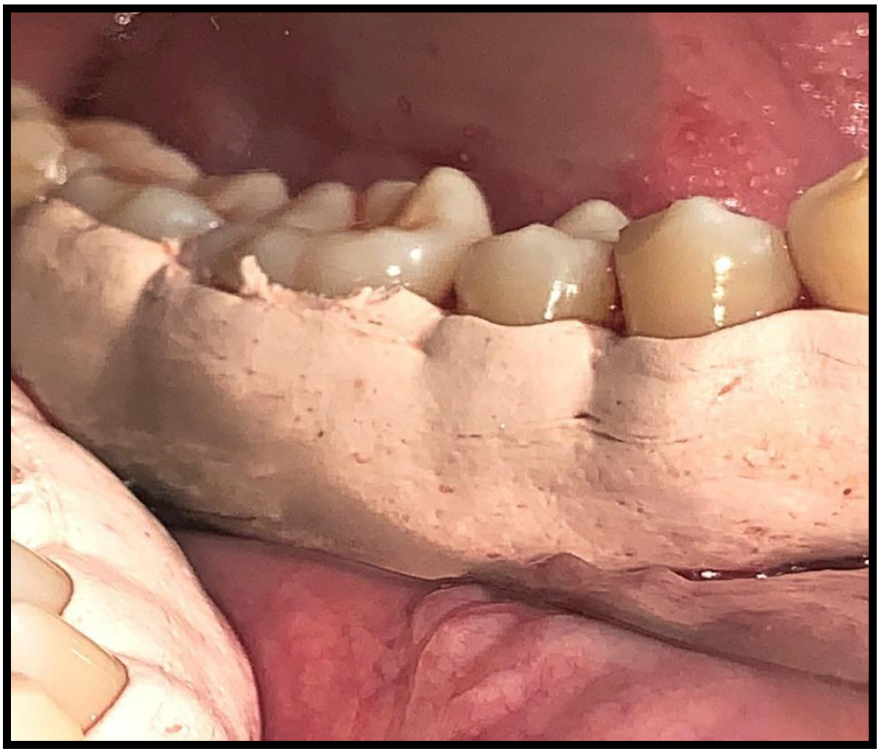


Figure 11(v): Periodontal Dressing

PLATE NO. 9

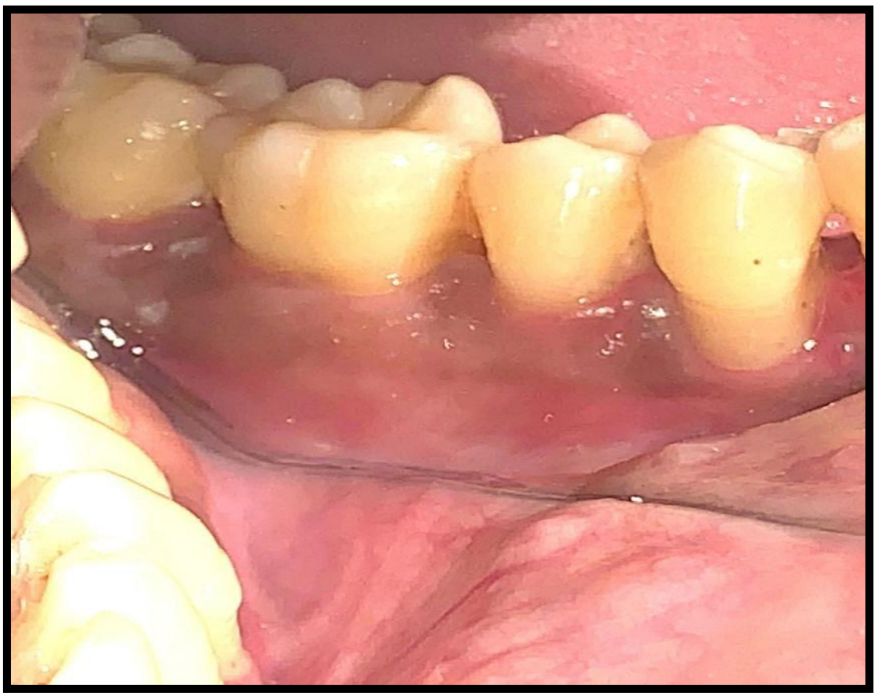


Figure 11(vi): 1 Week Follow Up

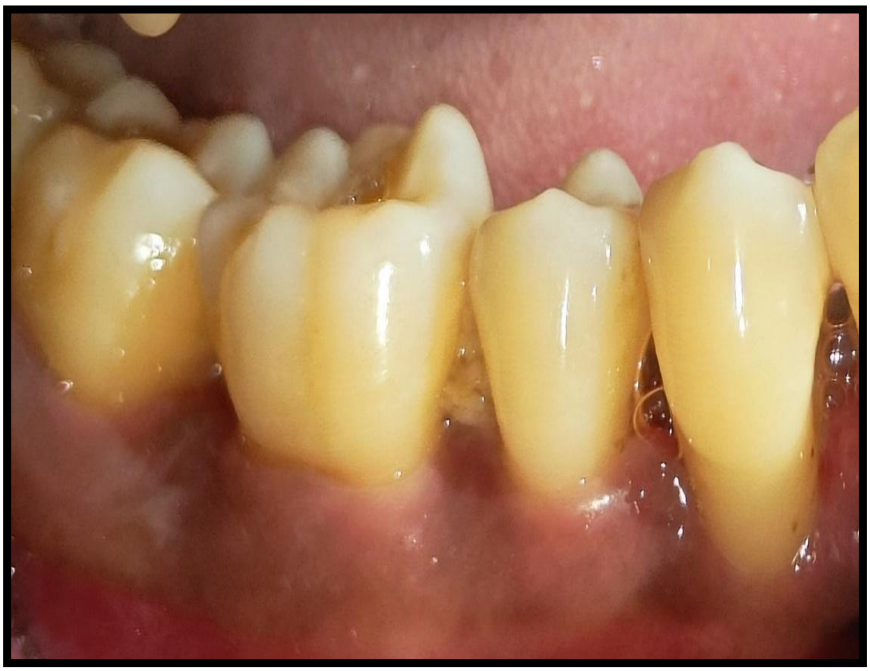


Figure 11(vii): 2 Week Follow Up

PLATE NO. 10

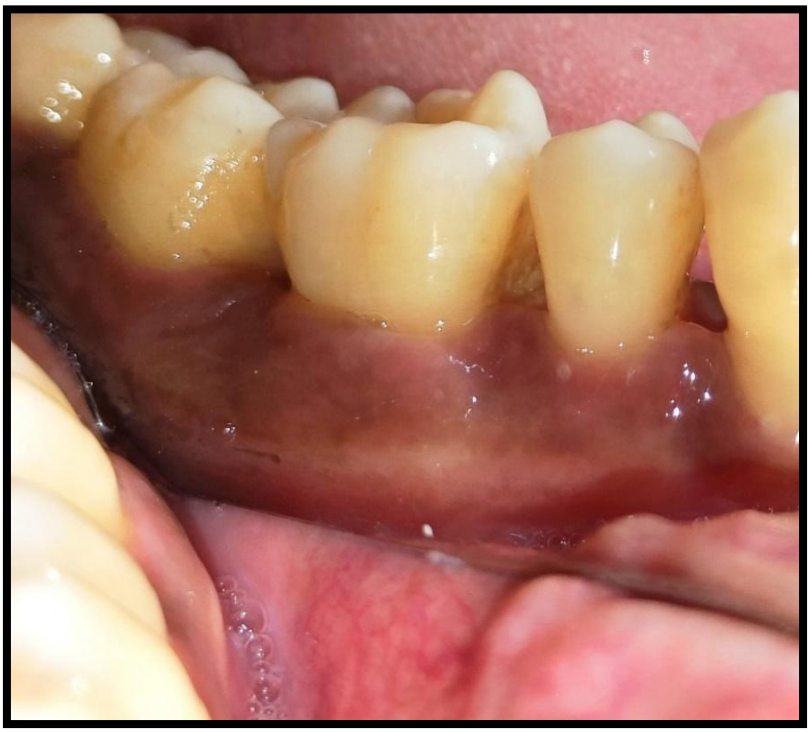


Figure 11(viii): 3 Week Follow Up

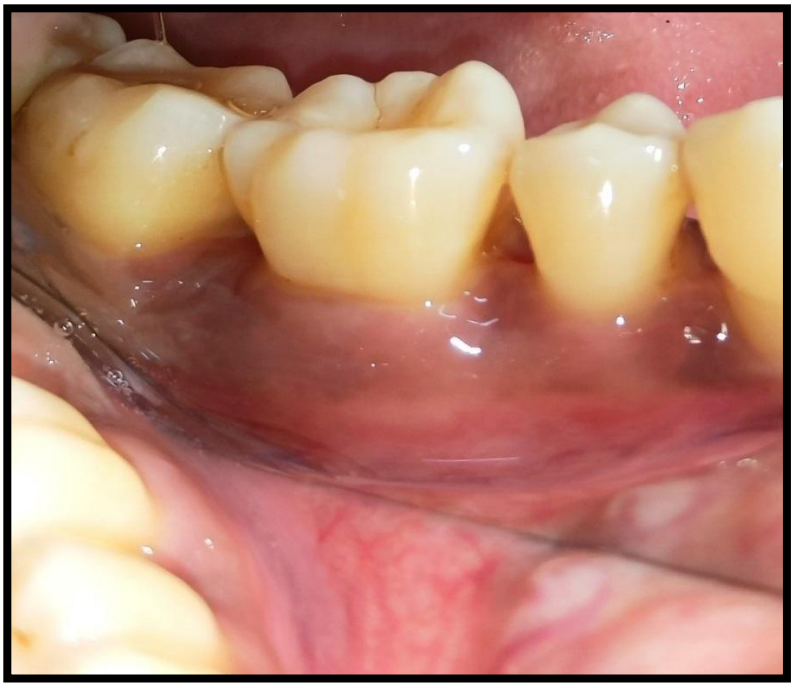
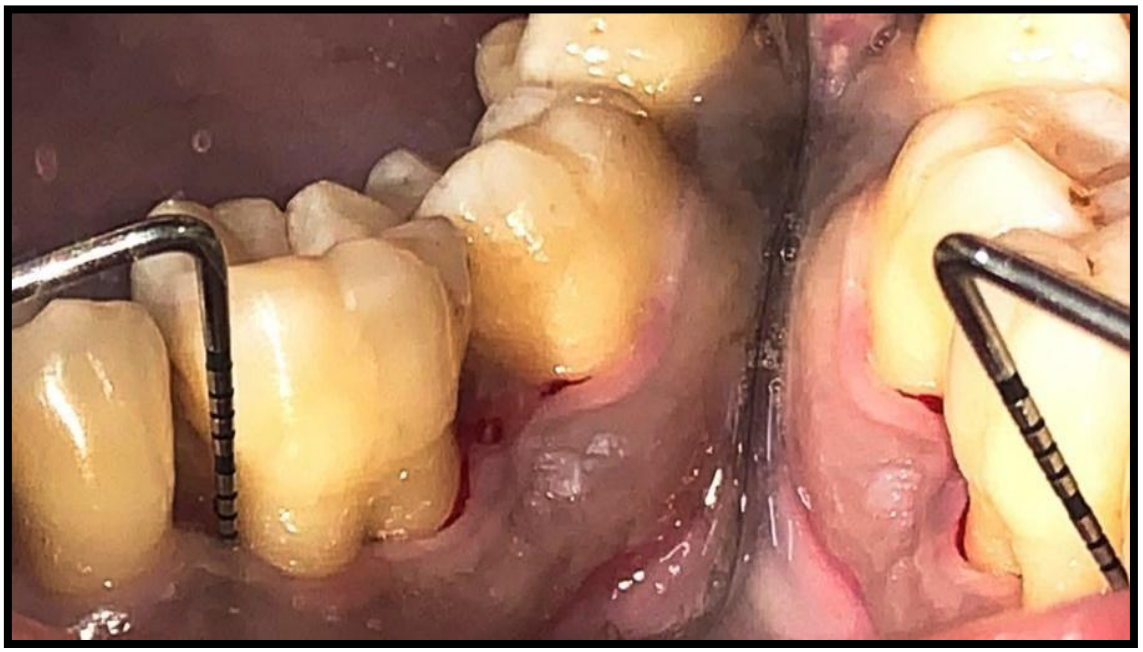


Figure 11(ix): 6 Week Follow Up

PLATE NO. 11

EXPERIMENTAL GROUP



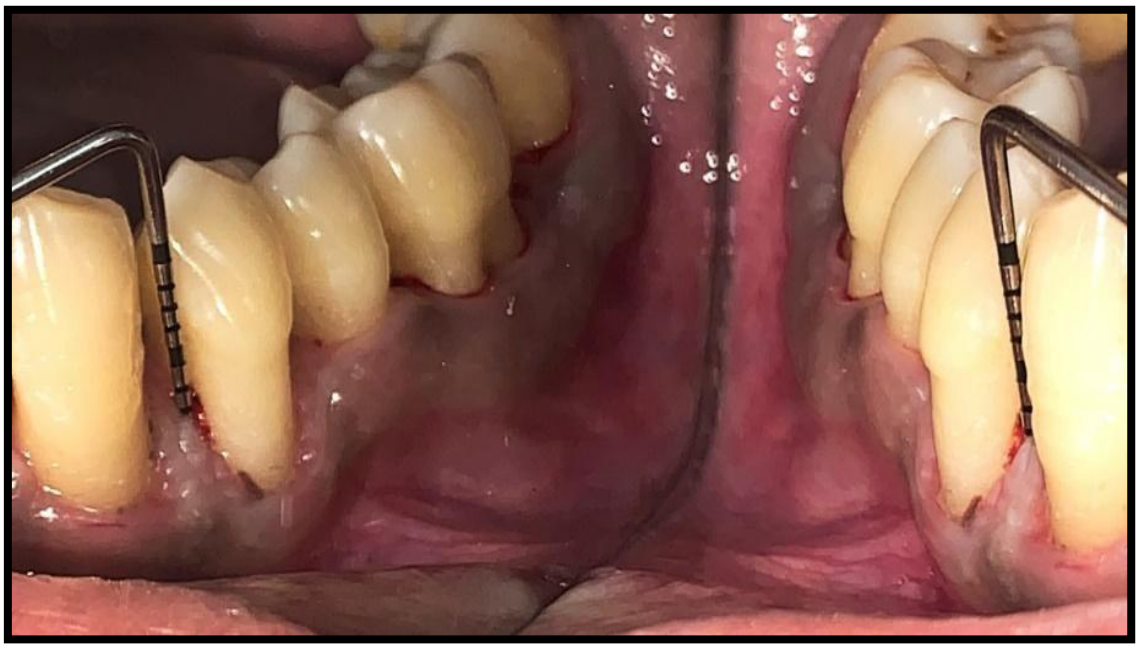


Figure 12(i): Pre-Operative Probing Pocket Depth Measurement

PLATE NO. 12

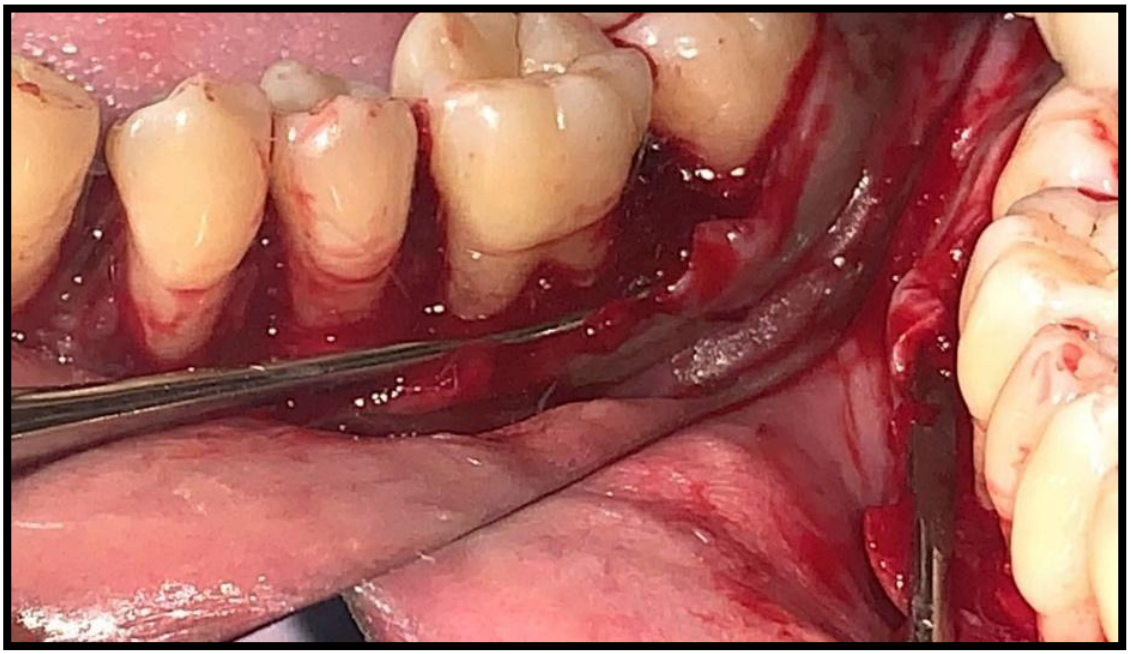


Figure 12(ii): Reflection of the Mucoperiosteal flap

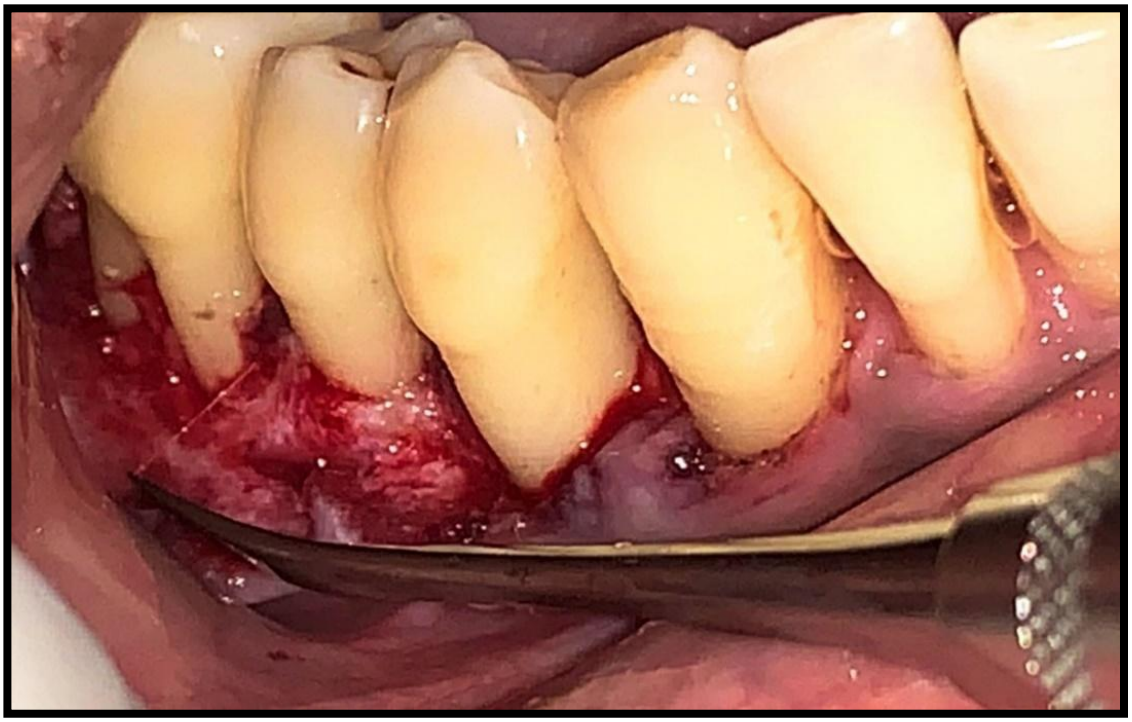


Figure 12(iii): Intraoperative View

PLATE NO. 13

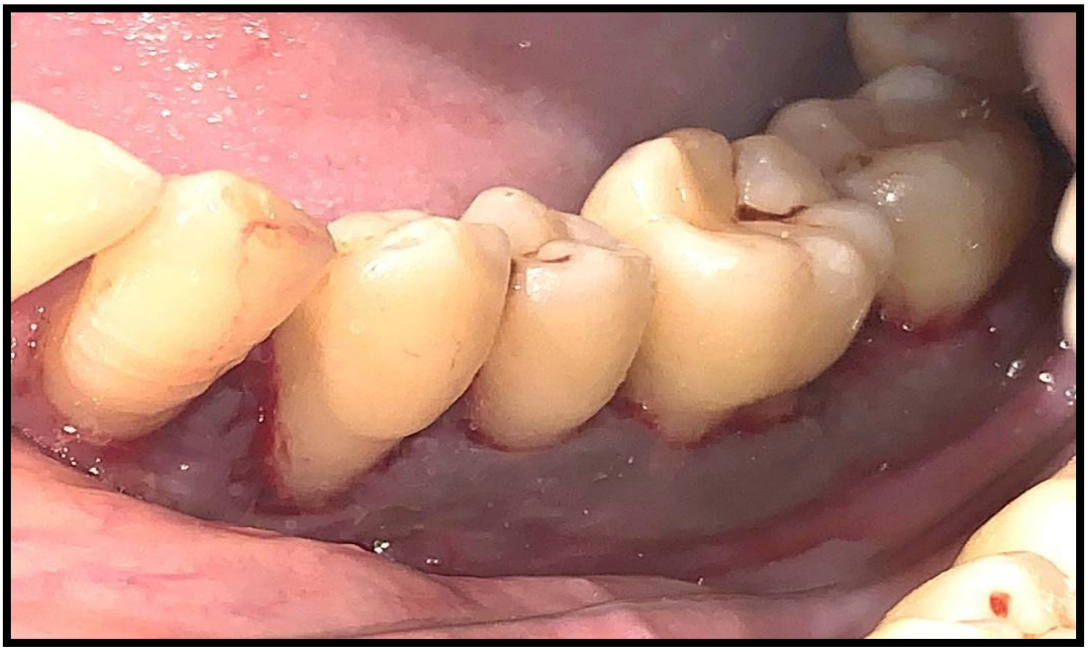


Figure 12(iv): Flap approximated with Autologous Fibrin glue

Figure 12(v): Periodontal Dressing

PLATE NO. 14

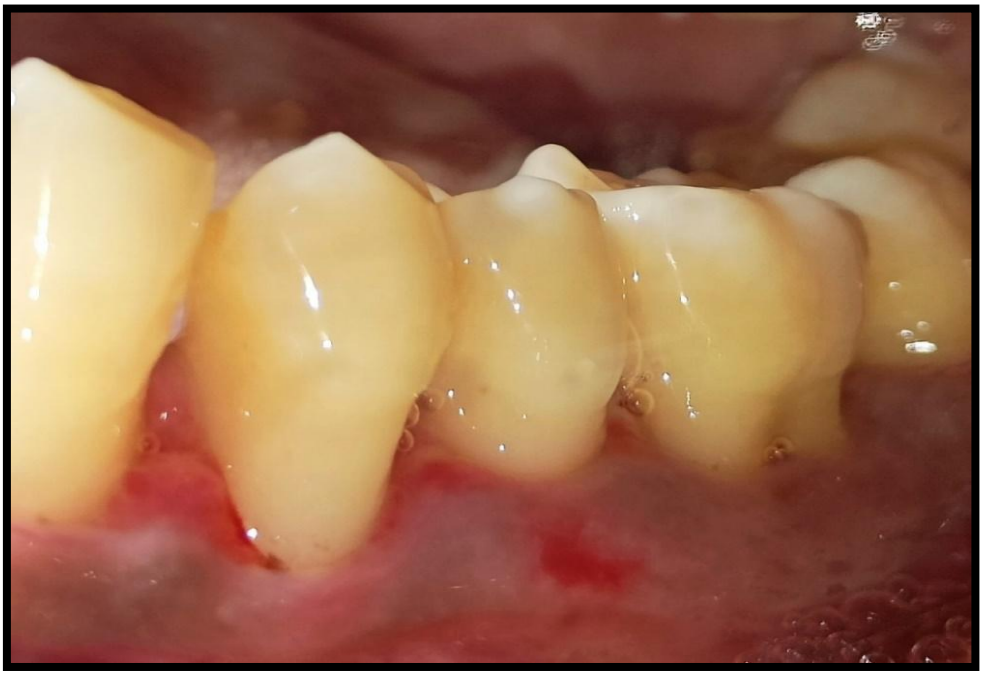


Figure 12(vi): 1 week Follow Up

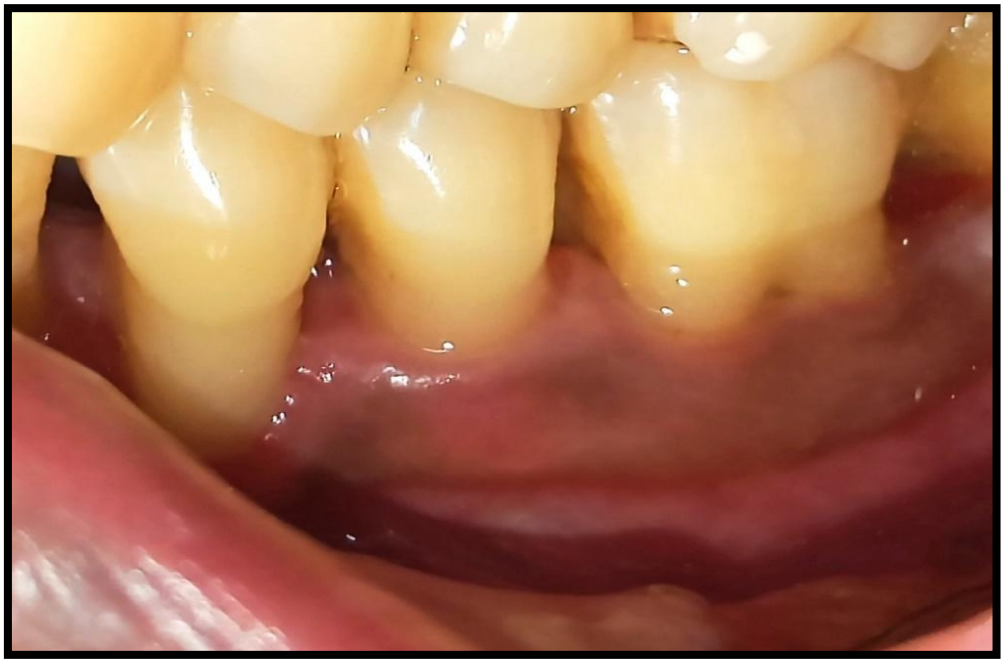


Figure 12(vii): 2 Week Follow Up

PLATE NO. 15

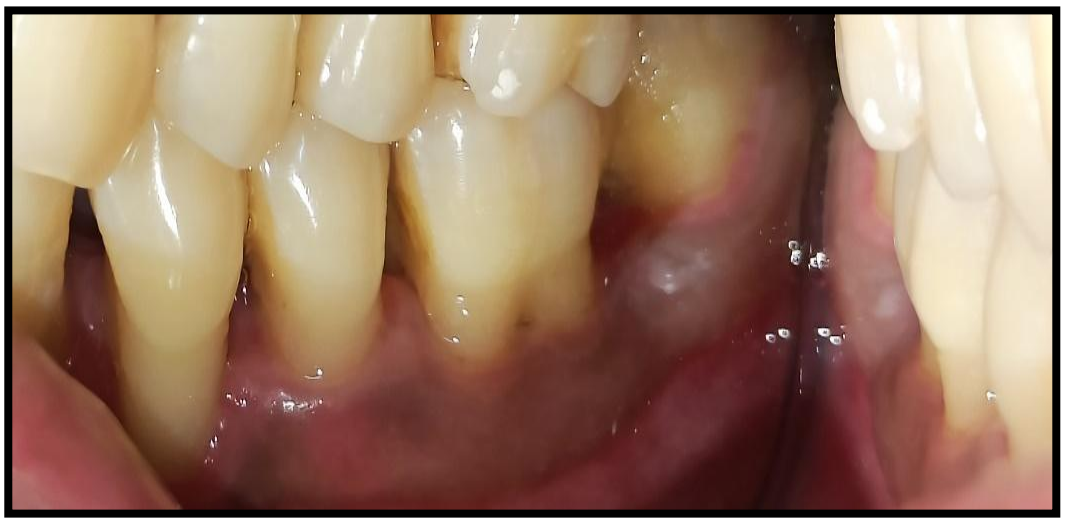


Figure 12(viii): 3 Week Follow up

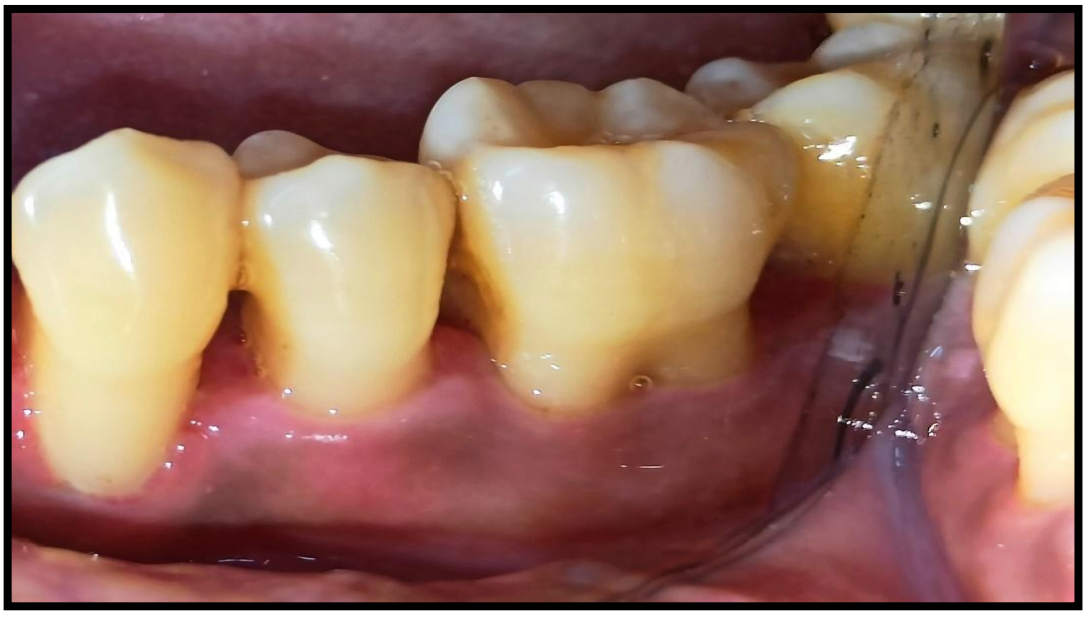


Figure 12(ix): 6 Week Follow Up

PLATE NO. 16

The present concurrent parallel study design, was conducted to evaluate and also to compare and assess the stability after periodontal flap closure, post-operative healing and post-operative pain of patient with one quadrant gingiva approximated with suture and other with the Autologous Fibrin Glue. Subjects were broadly divided into two groups, Control group and the experimental group. Control group comprised of 10 subjects i.e., 20 quadrants where sutures were placed. Experimental group comprised of 10 subjects i.e., 20 quadrants where gingiva was approximated with the Autologous Fibrin Glue.

Adhesion with the Roll Test, Pain with the Visual analogue scale (VAS), and healing with the Early Healing Index (EHI) by Wachtel et al was evaluated.

Table 1: Comparative evaluation of Roll test between groups

	Control Group	Experimental Group	Total	Chi square statistic	df	P value
Score 1	3 (15.0%)	7 (35.0%)	10 (25.0%)	2.133	1	0.144
Score 2	17 (85.0%)	13 (65.0%)	30 (75.0%)			
Score 3	0 (0.0%)	0 (0.0%)	0 (0.0%)			
Total	20 (50.0)	20 (50.0)	40 (100.0)			

P value < 0.05

On assessing between the groups for Roll test, Control group demonstrated 17 (85%) of its cases to have Score 2 and the remaining 3 (15%) categorized as Score 1. On the other hand, Experimental group also showed majority of its participants 13 (65%)

categorizing into Score 2 and the remaining 7 (35%) in Score 1. The difference between the two groups was not statistically significant at p=0.144 as seen in Table 1 and Graph 1. None of the cases displayed Score 3 for Roll test in both groups. Since score 1 stands better than score 2 in terms of the movement and retraction of the papilla. It is seen that the stability of flap after periodontal flap closure in experimental group is better than the control group as depicted by the statistical data regarding Roll Test.

Graph 1: Comparative evaluation of Roll test between groups

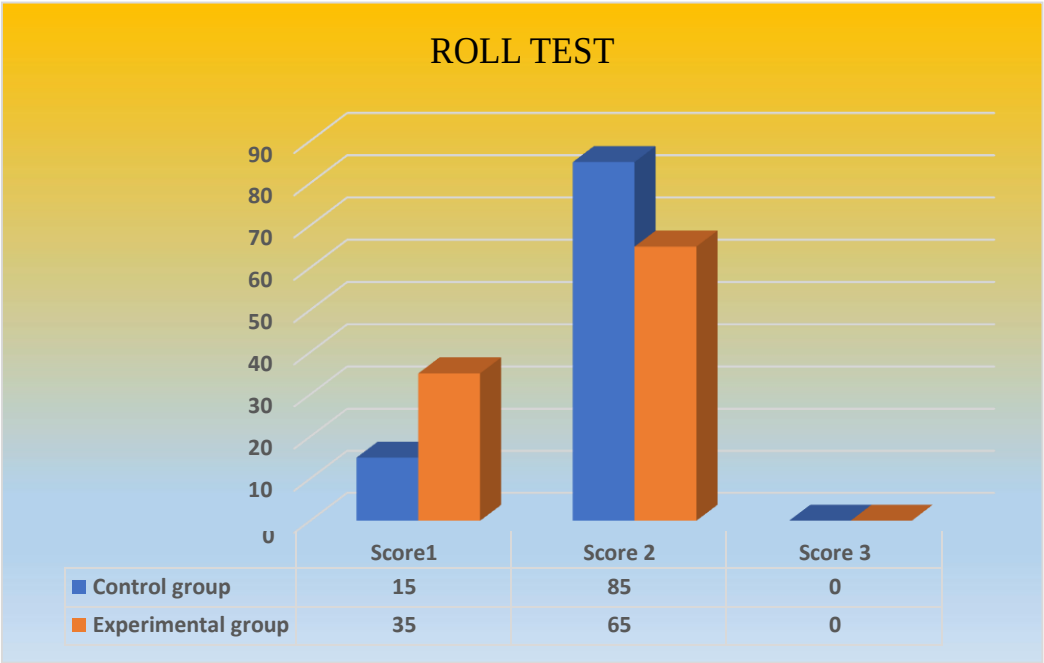


Table 2: Comparative evaluation of Healing Index between groups

	Control Group	Experimental Group	Total	Chi square test	df	P value
Score 1	0 (0.0%)	5 (25.0%)	5 (12.5%)	6.982	3	0.072
Score 2	12 (60.0%)	10 (50.0%)	22 (55.0%)			
Score 3	4 (20.0%)	4 (20.0%)	8 (20.0%)			
Score 4	4 (20.0%)	1 (5.0%)	5 (12.5%)			
Score 5	0 (0.0%)	0 (0.0%)	0 (0.0%)			
Total						

P value < 0.05

Post operative healing as assessed by EHI, showed Complete flap closure with no fibrin line in the interproximal area (Score 1) in 5(25%) cases of Experimental group while none in the control group. Hence, as depicted by the statistical data regarding healing, better healing was noted in the experimental group as compared to the control group. Comparing the score 4 in both the groups, experimental group proved to show better results. But this was not statistically significant as seen in Table 2 and Graph 2.

Graph 2: Comparative evaluation of Healing Index between groups

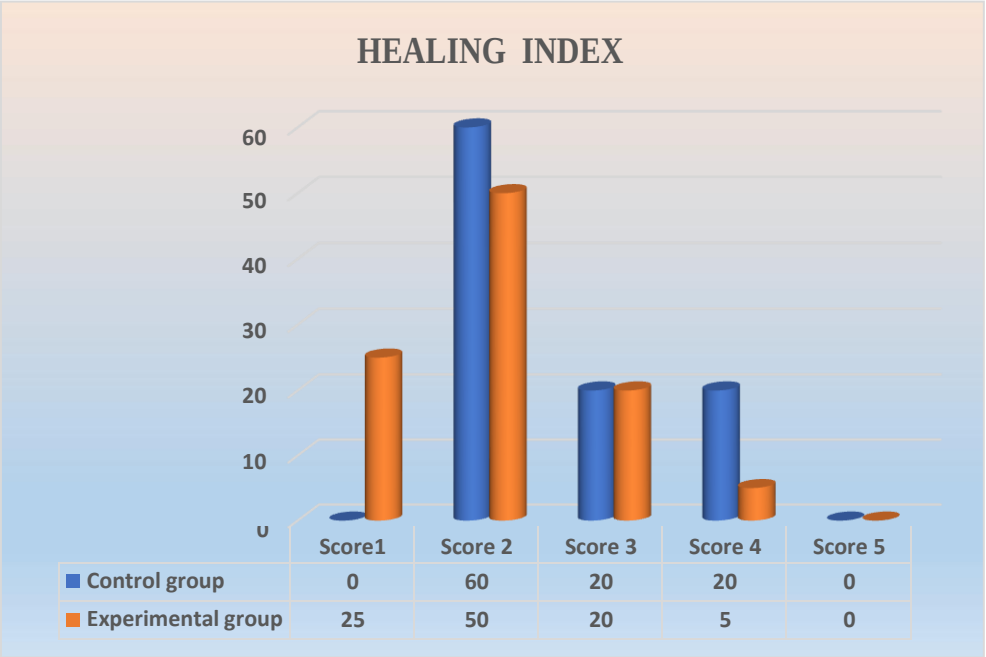


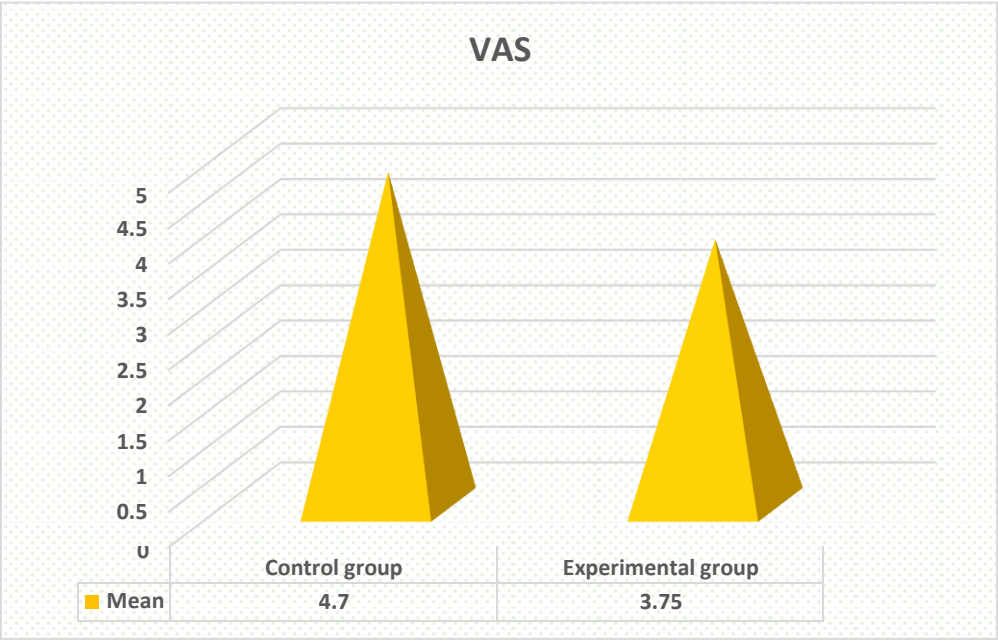
Table 3: Comparative assessment of VAS between groups

	Control Group	Experimental Group	Student 't' statistic	df	P value
N	20	20	3.953	38	0.000
Mean	4.7000	3.7500			
St. Deviation	.65695	.85070			
Std. Error Mean	.14690	.19022			

P value < 0.05

Pain as evaluated by VAS showed significant differences between the groups. Experimental group had a lesser mean for pain, 3.7500 ± .85070 as compared to 4.7000 s .65695 of the control group as seen in Table 3 and Graph 3. The difference is statistically significant.

Graph 3: Comparative assessment of VAS between groups



This clinical study was designed to do a comparative evaluation of autologous fibrin glue with conventional suturing for periodontal flap closure.

After debridement of the pathological pocket the flaps are approximated with the sutures to obtain adequate primary wound closure and stabilization of the tissues. But it can be time consuming and may get infected, with the scarring and also demands technical expertise, knowledge, and a further patient visit for its removal. Wicking effect of braided sutures, can cause bacteria from the oral cavity to be carried through the suture and into the deeper parts of the lesion.

Sometimes wound tension cannot be avoided, and sutures if removed, there is a high possibility of leaving noticeable track traces, so to support the healing, wound with the suture material has left in place for two weeks or even longer. This in turn makes the patient anxious at times.

Other disadvantages of suture are it can be time consuming and also need to re-grasp and position the needle after each throw.[38] Suture hypersensitivity resulting from an exaggerated immunologic response to the suture material serving as an external antigen has also been reported.[39]

Whereas advantages of Fibrin Glue over suture are it is easy to apply, has decreased tissue reactivity compared to sutures and is also an excellent hemostatic and sealant.

So, in order to overcome the limitations of sutures, flap approximation via Autologous Fibrin Glue came into light. Conventional suturing provides only a marginal fixation, while the fibrin-sealing system makes the tissue adhere on its whole surface[10].

Several studies have demonstrated the usefulness of a fibrin adhesive system (FAS) in many surgical fields[40-43]

The fibrinogen precipitate solution and calcium chloride are two solutions that, when combined in an equal volume, replicate the last stage of the coagulation cascade and are used in the flap approximation. First solution contains Calcium chloride whilst the second solution consisted of fibrinogen with some plasma proteins and possibly the factor XIII i.e., the Fibrin-Stabilizing Factor.

Calcium chloride is used to reconstitute thrombin, and Ca^{2+} ions are necessary for turning fibrinogen into fibrin[44]. Platelets are activated by thrombin and get caught in

the fibrin mesh. Collagen and fibrin in the area bind to platelet receptors and help the clot become more stable[45]. It not only breaks down fibrinogen to produce fibrin, but also activates factor XIII to factor XIIIa, which in turn catalyses the cross-linking of fibrin polymers to a covalently bound fibrin clot, improving the clot's stability and elasticity[46]. Factor XIII plays an important role in the regulation of coagulation and fibrinolysis by cross-linking the developing fibrin clot[44,47.] Factor XIII has been found to significantly contribute to clot stability, as evidenced by the fact that clots made with factor XIII-deficient plasma only have 20% of normal stability[48]. AFG's tensile strength and adhesive properties are proportional to its concentration of fibrinogen[20].

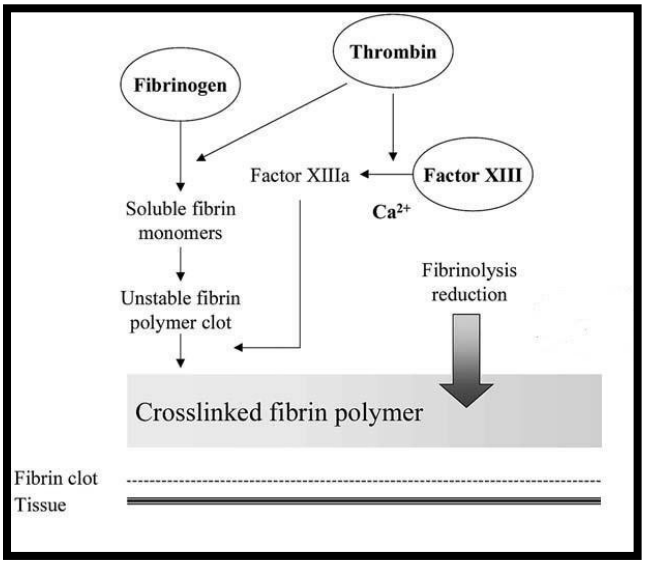


Figure 13[46]: Mode of action of Fibrin Sealant

Therefore, mixing the two components results in the conversion of fibrinogen to fibrin by thrombin with calcium present, thereby initiating clotting and rapid solidification of the mixture. The clot material is eventually lysed and absorbed as the wound heals[49].

This study was then done to compare and assess the stability after flap closure, post-operative healing and post-operative pain of patient with flaps being approximated by autologous fibrin glue and with the suture.

Manimegalai[24] compared the efficacy of fibrin adhesive sealant (Tisseel), with the conventional suture placed in pocket elimination and mucogingival surgical

procedures. Clinical parameters were taken pre-operatively, operatively and post-operatively on the 1st, 2nd, 3rd, 7th, and 10th, day. The Fibrin Adhesive System (FAS) showed superior results as compared to conventional suturing in all the parameters measured, i.e., hemostasis, fixation of tissues, reduction in plaque and gingival index and probing depth postoperatively. Their results revealed that the Tisseel mixture adhered the tissues. The remaining Tisseel mixture was stable for the next 4 hours, which allowed its use for the same or on different patients. In our study, autologous glue was employed to approximate the flap instead of commercial adhesive, increasing patient body acceptability. In contrast to the studies mentioned above, AFG has the drawback that any remaining concoction cannot be utilised on another patient.

Joshi[25] et al compared the efficacy of cyanoacrylate (tissue glue) placement after surgical removal of impacted mandibular third molars. One side closure was done with conventional sutures and other side with the cyanoacrylate. Postoperative bleeding with cyanoacrylate method was less significant than with suturing on the first and second day after surgery. There was no significant difference in the severity of pain between the two methods. The study suggested that the efficacy of both, cyanoacrylate and suturing in wound closure were similar in the severity of pain, but use of cyanoacrylate as a tissue glue showed better hemostasis. In contrast, the AFG Group's patients reported less pain during our study. However, cyanoacrylates have a number of drawbacks when compared to fibrin, including their toxicity and rigidity.[1]

Pulikkotil[26] et al conducted a trial comparing wound healing clinically, histologically and morphometrically after the use of fibrin sealant and sutures for periodontal flap closure. Clinically wound healing was observed at 7, 14 and 21 days and biopsy was taken on the 8th day. At seventh day better healing was observed in fibrin sealant site. Histologically mature epithelium and connective tissue formation was seen in fibrin sealant site with increased density of fibroblasts and mature collagen fibers. The suture site had a greater number of inflammatory cells and a greater number of blood vessels. Fibrin sealant can therefore be a more advantageous option and an efficient way to restore tissues following periodontal surgery.

Prato[10] et al conducted a study on fifty-one patients, aged 9 to 63 years, 22 males and 29 females, symmetrical flap or graft procedures, were selected for the study over a period of 3 years. On one side (control side), chosen on a random basis, Ethicon 4-0

silk sutures were used; on the other side (test side) the fibrin glue (Tissucol kit) was employed. In each case it was observed that bleeding subsided definitely more quickly after the application of Tissucol than after suturing. In only one case, bleeding persisted a minute more after suturing. Slight discomfort on removal of the sutures was noticed by the patients. AFG is more biocompatible than the commercially available fibrin sealant, and it was found in our study as well that bleeding stopped more quickly following AFG application than after suturing.

Jathal[22] et al reported two patients in whom flaps were closed using fibrin in the first patient and sutures in the second. They aimed to check the consequence of fibrin sealant as an alternative to sutures. There was a definite ease of usage on the part of clinician of the fibrin glue, while there was painless and early recovery of the glued area in the first patient as compared to the sutured area in the second patient. From the perspective of our study, using AFG was undoubtedly simpler than approximation using several sutures.

Soundarajan[32] et al assessed the post operative healing and stability of flap closure using autologous fibrin glue when compared to silk suture. He chose thirty subjects with moderate to severe periodontitis who required periodontal flap surgery involving at least four adjacent teeth. Autologous fibrin glue was prepared. The surgical area to be treated was randomly selected into two areas, Group A: Two papilla were secured with sutures (3-0 silk) after surgery; Group B: Two papilla were secured with autologous fibrin glue after surgery. Parameters were assessed & tests were performed. At 1 week follow up, better healing in autologous fibrin glue group was seen. Whereas, the inter group comparisons of Roll test score at 1 week follow up, there was no significant difference between two study groups. Both autologous fibrin glue and silk suture showed similar flap adaptation 1 week after the flap surgery. In the intra group comparisons, significant difference was seen in Roll test score between baseline and 1 week follow up in both the groups. The goal of the current study, which used a split mouth design, was to assess the stability, healing, and discomfort in two groups: Group 1 (the suture group), and Group 2 (AFG). Results showed that Group 2 had improved healing and flap stability at a one-week interval. Additionally, Group 2 experienced less discomfort than Group 1.

Bartolucci[9] et al in their study on lateral pedicle flap and free gingival graft used Tissucol- Aprotinin solution and a calcium chloride-thrombin solution to the wounded areas with a special applicator (Duploject). Kodachrome slides were taken before and immediately after procedures, then after 1 week, 2 weeks and 1 month. Tissues sealed showed a negligible local inflammation at the 1-week, 2-week and 1-month postoperative observations. The biomechanical requirements were excellently met with the flap and the graft maintained in the desired positions. The healing process appeared faster than when sutures were used. At one week in our trial, there was less inflammation on the AFG side than on the suture side. Following the apposition, whether with glue or a suture, the flap kept its desired position.

Uslu[29] et al used Autologous Fibrin Glue as a Novel Platelet Concentration in Palatal Wound Healing. They aimed to minimize the complications that can be seen in the donor area after free gingival graft operation with AFG application. Wound healing was assessed with clinical parameters at 3, 7, 14 days and 1 month postoperatively. Wound healing was achieved without any complications. It was seen here the healing process was rapid. In our study, the AFG group healed more well than the suture group because the inflammation was lower.

Alamdari[28] et al compared autologous fibrin glue versus nylon sutures for securing conjunctival autografting in pterygium surgery. Study was performed on 120 patients (120 eyes) with primary pterygium. Superior conjunctival autograft was harvested and transferred on to bare sclera after pterygium excision. For attaching the autograft, AFG (n = 60 eyes) and NS (n = 60 eyes) were used. The patients were followed up for 12 months. The groups were compared for the safety, operative time, postoperative ocular signs, symptoms, overall patient satisfaction, recurrence and complications rate. All conjunctival autografts in both groups were successfully attached. The average operating time for the AFG group was significantly shorter. Postoperative symptoms were fewer for the AFG group than the suture group. The study demonstrated the superiority of AFG to NS in saving operating time and elimination of recurrence without any complications in pterygium surgery. AFG can minimize the need for suturing and improve tissue flap viability. Our study demonstrated that AFG outperformed sutures in terms of improved healing, decreased pain, and flap stability upon approximation. When the roll test was performed, tissues approximated with

AFG were adhered to the underlying layer and were stable; in contrast, tissues approximated with sutures were moveable and unstable. Gluing saved an average of 5–10 minutes.

Warrer[44] et al evaluated the effect on healing of fast and slow absorbable Tisseel in combination with periodontal flap surgery, Mucoperiosteal flaps were raised on the buccal aspect of maxillary premolars and mandibular premolars and first molars in 4 beagle dogs. On the control teeth, the flaps were sutured immediately after creation of the defects, while on the test teeth, a layer of fast (group I) or slow {group II) absorbable Tisseel was applied between the curetted roots and the subsurface of the flaps prior to suturing, Histological analysis revealed that the amounts of new attachment and bone regrowth were similar in the test and control groups, although the results tended to be most favorable for the group of teeth treated with fast absorbable Tisseel (Group I). In our investigation, humans were employed in place of the dogs, and autologous glue was utilized in place of commercial glue. This glue exhibited better results in terms of healing and pain reduction than the suture, but no histological examination was carried out.

Periodontal flap surgery has been carried out for a long time with the traditional technique of utilizing sutures for its closure. This is done to eradicate the illness and restore the health of the tissues.

Different innovative approaches have been developed in addition to employing traditional sutures to approximate the flaps in order to maximize primary closure and reduce surgical trauma. Staples, adhesive tapes, and skin glues are among the various items utilized in wound closure.

Fibrin sealants (FS) are natural adhesives that resemble the concluding phases of blood coagulation and are generated from plasma coagulation proteins. Medical practitioners already employ FS in regenerative medicine, cosmetic surgery, general surgery, ophthalmic surgery, laryngology, neurological surgery, cardiovascular surgery, thoracic surgery, gynecology, and urology.

Due to its simplicity of application, low tissue reactivity, and abilities as a great hemostatic agent and sealer, it is now also employed by dental experts.

From the current study, the following conclusions have been made:

The AFG is quicker and easier to perform than sutures, provides superior early hemostasis, and improves early wound healing. AFG revealed stronger flap stability than the suture. Papillary movement was little, and if it did occur, there was no evidence of retraction in the flap that the AFG approximated. AFG is proven to offer better recovery. When asked about their pain experiences, the majority of the patients showed a higher acceptance of the AFG.

AFG preparation is not only quick and uncomplicated to make, but it also gives the flap good stability and postoperative healing, on par with or better than sutures.

Our study assessed the clinical aspects of wound healing between the two groups, and while the clinical advantages of FS were evident, enhanced healing may have been best evaluated by a histological investigation, which could not be carried out due to aesthetic and patient compliance concerns.

In order for society to adopt fibrin glue over suture, more research is thus needed.

1. Melcher AH. On the repair potential of periodontal tissues. *J Periodontol*. 1976 May;47(5):256-60.
2. Newman MG, Carranza FA, Takei H, Klokkevold PR. Carranzas clinical Periodontology. 10th ed. Elsevier health sciences; 2006
3. Flemmig TF. Periodontitis. *Ann Periodontol.* 1999 Dec;4(1):32-8.
4. Jain N, Jain GK, Javed S, Iqbal Z, Talegaonkar S, Ahmad FJ, Khar RK. Recent approaches for the treatment of periodontitis. *Drug Discov Today*. 2008 Nov;13(21-22):932-43.
5. Newman MG, Carranza FA, Takei H, Klokkevold PR. Carranzas clinical Periodontology. 13th ed. Elsevier health sciences; 2018
6. Prowse P, Shokrollahi K. Leaving our mark–are suture marks acceptable?. The Bulletin of the Royal College of Surgeons of England. 2014 Sep;96(8):264-6.
7. Jonathan Kantor. Atlas of Suturing Techniques: Approaches to Surgical Wound, Laceration, and Cosmetic Repair. McGraw Hill; 2016
8. Goczyńska P, Lasocka J, Lachert E. Fibrin glues—the current state of knowledge. Journal of Transfusion Medicine. 2021;14(4):215-25.
9. Barbosa MD, Stipp AC, Passanezi E, Greghi SL. Fibrin adhesive derived from snake venom in periodontal surgery: histological analysis. *J Appl Oral Sci.* 2008 Sep-Oct;16(5):310-5.
10. Bartolucci EG, Prato GP. Preliminary observations on the use of a biologic sealing system (Tissucol) in periodontal surgery. J Periodontol. 1982 Dec;53(12):731-5
11. Pini Prato GP, Cortellini P, Agudio G, Clauser C. Human fibrin glue versus sutures in periodontal surgery. J Periodontol. 1987 Jun;58(6):426-31.
12. Spotnitz WD, Falstrom JK, Rodeheaver GT. The role of sutures and fibrin sealant in wound healing. Surg Clin North Am. 1997 Jun;77(3):651-69.
13. Dave BP, Sathyanarayana S. Periodontal flap closure using a simplified autologous fibrin glue preparation: A report of two successful cases. J Indian Soc Periodontol. 2020 Nov-Dec;24(6):579-582.
14. McCaffery M, Beebe A. Pain: Clinical manual for nursing practice. Mosby Incorporated; 1989.

15. Wachtel H, Schenk G, Böhm S, Weng D, Zuhr O, Hürzeler MB. Microsurgical access flap and enamel matrix derivative for the treatment of periodontal intrabony defects: a controlled clinical study. J Clin Periodontol. 2003 Jun;30(6):496-504.

16. J. Z. Young and P. B. Medawar, ―Fibrin suture of peripheral nerves. Measurement of the rate of regeneration,‖ The Lancet 1940;236,6101,126–128

17. Brennan M. Fibrin glue. Blood Rev. 1991 Dec;5(4):240-4.

18. Kjaergard HK, Weis-Fogh US, Sørensen H, Thiis J, Rygg I. Autologous fibrin glue--preparation and clinical use in thoracic surgery. Eur J Cardiothorac Surg. 1992;6(1):52-4.

19. Park MS, Cha CI. Biochemical aspects of autologous fibrin glue derived from ammonium sulfate precipitation. Laryngoscope. 1993 Feb;103(2):193-6.

20. Tawes RL Jr, Sydorak GR, DuVall TB. Autologous fibrin glue: the last step in operative hemostasis. Am J Surg. 1994 Aug;168(2):120-2.

21. Kjaergard HK, Weis-Fogh US. Important factors influencing the strength of autologous fibrin glue; the fibrin concentration and reaction time--comparison of strength with commercial fibrin glue. Eur Surg Res. 1994;26(5):273-6.

22. Siedentop KH, Park JJ, Sanchez B. An autologous fibrin tissue adhesive with greater bonding power. Arch Otolaryngol Head Neck Surg. 1995 Jul;121(7):769-72.

23. Mintz PD, Mayers L, Avery N, Flanagan HL, Burks SG, Spotnitz WD. Fibrin sealant: clinical use and the development of the University of Virginia Tissue Adhesive Center. Ann Clin Lab Sci. 2001 Jan;31(1):108-18.

24. Thorn JJ, Sørensen H, Weis-Fogh U, Andersen M. Autologous fibrin glue with growth factors in reconstructive maxillofacial surgery. Int J Oral Maxillofac Surg. 2004 Jan;33(1):95-100.

25. Alston SM, Solen KA, Sukavaneshvar S, Mohammad SF. In vivo efficacy of a new autologous fibrin sealant. J Surg Res. 2008 May 1;146(1):143-8.

26. Jathal B, Trivedi A, Bhavsar N. Use of fibrin glue in periodontal flap surgery. J Indian Soc Periodontol. 2008 Jan;12(1):21-5.

27. Panda A, Kumar S, Kumar A, Bansal R, Bhartiya S. Fibrin glue in ophthalmology. Indian J Ophthalmol. 2009 Sep-Oct;57(5):371-9.

28. Manimegalai AG. A comparative study on the efficacy of a commercial fibrin adhesive (Tisseel) vis-à-vis silk suture on wound closure following

periodontal surgical procedures. J Indian Soc Periodontol. 2010 Oct;14(4):231-5.

29. Joshi AD, Saluja H, Mahindra U, Halli R. A comparative study: efficacy of tissue glue and sutures after impacted mandibular third molar removal. J Maxillofac Oral Surg. 2011 Dec;10(4):310-5.

30. Pulikkotil SJ, Nath S. Fibrin sealant as an alternative for sutures in periodontal surgery. J Coll Physicians Surg Pak. 2013 Feb;23(2):164-5.

31. Kouketsu A, Nogami S, Fujiwara M, Mori S, Yamauchi K, Hashimoto W et al. Clinical evaluations of autologous fibrin glue and polyglycolic acid sheets as oral surgical wound coverings after partial glossectomy. J Craniomaxillofac Surg. 2016 Aug;44(8):964-8.

32. Alamdari DH, Sedaghat MR, Alizadeh R, Zarei-Ghanavati S, Naseri H, Sharifi F. Comparison of autologous fibrin glue versus nylon sutures for securing conjunctival autografting in pterygium surgery. Int Ophthalmol. 2018 Jun;38(3):1219-1224.

33. Uslu MO, Kiziltoprak M, Kirmizigul OA. Autologous Fibrin Glue as a Novel Platelet Concentration in Palatal Wound Healing. Dental Research and Oral Health. 2019;2(3):40-6.

34. Kızıltoprak M, Uslu MÖ. Comparison of the effects of injectable platelet-rich fibrin and autologous fibrin glue applications on palatal wound healing: a randomized controlled clinical trial. Clin Oral Investig. 2020 Dec;24(12):4549-4561.

35. Soundarajan S, Rajasekar A. Comparison Of Simplified Autologous Fibrin Glue Versus Suturing For Periodontal Flap Closure - A Randomised Controlled Trial. *Int J Dentistry Oral Sci.* 2021;8(8):3810-3815

36. Narendran N, Anegundi RV, Shenoy SB, Chandran T. Autologous platelet-rich fibrin as an adjunct to non-surgical periodontal therapy-A follow up clinical pilot study. Wound Repair Regen. 2022 Jan;30(1):140-145.

37. Mounsif M, Smouni FE, Bouziane A. Fibrin sealant versus sutures in periodontal surgery: A systematic review. Ann Med Surg (Lond). 2022 Mar 29;76:103539.

38. Bozkurt E, Uslu MÖ. Evaluation of the effects of platelet-rich fibrin, concentrated growth factors, and autologous fibrin glue application on wound

healing following gingivectomy and gingivoplasty operations: a randomized controlled clinical trial. Quintessence Int. 2022 Mar 14;53(4):328-341.

39. Wolf JS Jr. Laparoscopic tissue approximation. World J Urol. 2000 Sep;18(4):257-66.

40. Titley-Diaz WH, De Cicco FL. Suture Hypersensitivity. 2022 Sep 18. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan–.

41. Baudo F, de Cataldo F, Gatti R, Landonio G, Muti G, Scolari G. Local hemostasis after tooth extraction in patients with abnormal hemostatic function. Use of human fibrinogen concentrate. Haemostasis. 1985;15(6):402-4.

42. Immuno AG. Vienna: Immuno AG; 1991. Art of Tisseeling.Historical background application techniques and indication of fibrin sealing in modern surgery.

43. Wittkampf AR. Fibrin glue as cement for HA-granules. J Craniomaxillofac Surg. 1989 May;17(4):179-81.

44. Sierra DH. Fibrin sealant adhesive systems: a review of their chemistry, material properties and clinical applications. J Biomater Appl. 1993 Apr;7(4):309-52.

45. Bale MD, Westrick LG, Mosher DF. Incorporation of thrombospondin into fibrin clots. J Biol Chem. 1985 Jun 25;260(12):7502-8

46. Wozniak G. Fibrin sealants in supporting surgical techniques: The importance of individual components. Cardiovasc Surg. 2003 Aug;11 Suppl 1:17-21.

47. McDonagh J, Fukue H. Determinants of substrate specificity for factor XIII. Semin Thromb Hemost. 1996;22(5):369-76

48. Shen L, Lorand L. Contribution of fibrin stabilization to clot strength. Supplementation of factor XIII-deficient plasma with the purified zymogen. J Clin Invest. 1983 May;71(5):1336-41.

49. Matras H. Fibrin seal: the state of the art. J Oral Maxillofac Surg. 1985 Aug;43(8):605-11.

50. Baum BJ, Wright WE. Demonstration of fibronectin as a major extracellular protein of human gingival fibroblasts. J Dent Res. 1980 Mar;59(3):631-7.

51. Warrer K, Karring T. Effect of Tisseel on healing after periodontal flap surgery. J Clin Periodontol. 1992 Aug;19(7):449-54.

ANNEXURES

ANNEXURE - 1

Institutional Ethical Committee

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

Dr. Lakshmi Bala
Professor and Head Biochemistry and
Member-Secretary, Institutional Ethics Committee

Communication of the Decision of the IXth Institutional Ethics Sub-Committee

IEC Code: 10 **BBDCODS/04/2022**

Title of the Project: Comparative Evaluation of Autologous Fibrin Glue with Conventional Suturing for Periodontal Flap Closure: A Clinical Study.

Principal Investigator: Dr Shaifali **Department:** Periodontology

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

Type of Submission: New, MDS Project Protocol

Dear Dr Shaifali,

The Institutional Ethics Sub-Committee meeting comprising following four members was held on 07th April, 2022.

1.	Dr. Lakshmi Bala Member Secretary	Prof. and Head, Department of Biochemistry, BBDCODS, Lucknow
2.	Dr. Amrit Tandan Member	Prof. & Head, Department of Prosthodontics and Crown & Bridge, BBDCODS, Lucknow
3.	Dr. Rana Pratap Maurya Member	Reader, Department of Orthodontics, BBDCODS, Lucknow
4.	Dr. Akanksha Bhatt Member	Reader, Department of Conservative Dentistry & Endodontics, BBDCODS, Lucknow

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:

Lakshmi Bala

(Dr. Lakshmi Bala)
Member-Secretary
IEC

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

(Dr. Puneet Ahuja)
Principal
BBDCODS

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

ANNEXURE – 2

Institutional research committee approval certificate

BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES (FACULTY OF BBD UNIVERSITY), LUCKNOW

INSTITUTIONAL RESEARCH COMMITTEE APPROVAL

The project titled **"Comparative Evaluation of Autologous Fibrin Glue with Conventional Suturing for Periodontal Flap Closure: A Clinical Study"** submitted by **Dr Shaifali** Post graduate student from the **Department of Periodontology** as part of MDS Curriculum for the academic year 2020-2023 with the accompanying proforma was reviewed by the Institutional Research Committee present on **11th October 2021** 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. Vandana A Pant
Co-Chairperson

Prof. B. Rajkumar
Chairperson

ANNEXURE -3

Consent Form

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…….

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 the purpose 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 my medical 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 be conducted 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 [] Not Applicable

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's Information document given to me.

Signature (or Thumb 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 Acceptable representative Date…….

ANNEXURE - 4

PID Form

Babu Banarasi Das College of Dental Sciences

(A constituent institution of Babu Banarasi Das University)

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

Participant Information Document (PID)

1. **Study Title**

   Comparative evaluation of autologous fibrin glue with conventional suturing for periodontal flap closure: a clinical study

2. **Invitation Paragraph**

   You are being invited to take part in a research study, it is therefore important for you to understand why the study is being done and what it will involve. Please take time to read the following information carefully. Ask us for any clarifications or further information. Whether or not you wish to take part is your decision.

3. **What is the purpose of the study?**

   The purpose of this study is to compare the autologous fibrin glue with conventional suturing for periodontal flap closure.

4. **Why have I been chosen?**

   You have been chosen for this study as you are fulfilling the required criteria for this 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 still are free to withdraw at any time and without giving a reason.

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

   You will be one of the 20 patients enrolled in the study. After the completion of the surgical procedure flap will be closed using Fibrin glue.

7. What do I have to do?

You do not have to change your regular lifestyles for the investigation of the study other than the normal regular precautions one has to take post periodontal surgical procedures.

8. What is the procedure that is being tested?

The procedure will involve evaluating and comparing the effectiveness of wound closure by suture and fibrin glue.

9. What are the interventions for the study?

It is a split - mouth randomized control trial involving two groups.

- Total number of patients = 20
- A total of 40 quadrants (Split mouth method)

  Sample size will be of 40 quadrants, CONTROL GROUP (Suture group - 20 quadrants), EXPERIMENTAL GROUP (Autologous fibrin glue - 20 quadrants)

10. What are the side effects of taking part?

There are no reported side effects on patients of this study.

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

There is no risk or disadvantage of taking part in this study.

Exclusion Criteria:

- Immunodeficiency disease
- Uncontrolled systemic diseases
- Severe bone loss
- Pregnant and lactating women

12. What are the possible benefits of taking part?

This study will help us to evaluate the efficacy of autologous fibrin glue, thereby eliminating the need for sutures.

13. What if new information becomes available?

If additional information becomes available during the course of the research you will be told about these and you are free to discuss it with your researcher, your researcher will tell you whether you want to continue in the study. If you decide to withdraw, your researcher 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 stops/finishes before the stipulated time, this will 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 reporting to the institution (s), and Institutional ethical community.

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

Yes, it will be kept confidential.

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

The results of the study will be used to compare Autologous fibrin glue with conventional suture. Your identity will be kept confidential in case of any report/publications.

18. Who is organizing the research?

This research study is organized by the academic institution (BBDCODS).

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

Yes

20. Who has reviewed the study?

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

21. Contact for further information

Dr. Shaifali
Department of Periodontology and Implantology
Babu Banarasi College of Dental Sciences.
Lucknow-227105
Mob- 7007950684

Dr. Sunil Chandra Verma (Reader)
Department of Periodontology and Implantology
Babu Banarasi College of Dental Sciences.
Lucknow-227105
Mob- 9335928773

Dr. Suraj Pandey (Reader)
Department of Periodontology and Implantology
Babu Banarasi College of Dental Sciences.
Lucknow-227105
Mob- 9628931689

Dr. Mona Sharma (HOD)
Department of Periodontology and Implantology
Babu Banarasi College of Dental Sciences.
Lucknow-227105
Mob-9984110444

ANNEXURE - 5

बाबूबनारसीदासकॉलेजऑफडेंटलसाइंसेज

(बाबूबनारसीदासविश्वविद्यालयकाएकघटकसंस्थान)

बीबीडीसिटी, फैजाबादरोड, लखनऊ - 227105 (भारत)

प्रततभागी स ना दस्तावेज (पीआईडी)

1.अध्ममन शीषक

नीरयमोडॉन्टर फ्रैन क्रोजय के लरए नायंनरयक लसराई के साथ ऑटोरॉगस पाइब्रिन गोंद का तुरनात्भक भूलमांकन: एक नैदाननक अध्ममन

2. ननभंत्रण अनुच्छेद

आनको एक शोध अध्ममन भेंं बाग रेने को लरए आभंब्रत्रत ककमा जा रेने से नहरे यहा है। ननणम

आनके लरए मह सभझना भहत्वनूणष है कक शोध/अध्ममन क्मों ककमा जा यहा है औय इसभें क्मा शालभर होगा। कृ नमा ननम्नलरखित जानकायी को ध्मान से नढ़ने को लरए सभम ननकारेंं औय मदद आन चाहेंं तो दोस्तोंं, रयश्तेदायों औय अनने इराज कयने वारे चचकत्सक/नारयवारयक चचकत्सक को साथ इस नय चचा कयेंं। हभसे नूछेंं कक क्मा कु छ ऐसा है जो स्नष्ट नहींं है मा मदद आन अचधक जानकायी चाहते हैं। मह तम कयने के लरए सभम ननकारें कक आन बाग रेना चाहते हैं मा नहीं।

3. अध्ममन का उद्देश्म क्मा है ?

इस अध्ममन का उद्देश्म ऩीरयमडोंटर फ्रैऩ क्रोजय के लरए ऩायंऩरयक टांके के साथ ऑटोरॉगस पाइब्रिन गोंद की तुरना कयना है।

4. भुझे इस अध्ममन के लरए क्मों चना गमा है?

आऩको इस अध्ममन के लरए चना गमा है क्मोंकक आऩ इस अध्ममन के लरए आवश्मक भानदंडों को ऩ ा कय यहे हैं।

5. क्मा इसभें भुझे बाग रेना चादहए ?

शोध भें आऩकी बागीदायी नूयी तयह से स्वैच्च्छक है। मदद आऩ ऐसा कयते हैं, तो आऩको मह सूचना ऩत्रक यिने के लरए ददमा जाएगा औय सहभनत प्रऩत्र ऩय हस्ता□य कयने के लरए कहा जाएगा। अध्ममन के दौयान आऩ ककसी बी सभम औय ब्रफना कोई कायण फताए वाऩस रेने के लरए स्वतंत्र हैं।

6. भुझे क्मा होगा मदद भैं इस अध्ममन भें बाग रेता हूं।

आऩ अध्ममन भेंं नाभांककत 20 मोग्गमों भेंं से र प्रक्रिमा ा होने क एक होंगे। सज्जक को ऩ

फाद पाइब्रिन गोंद का उऩमोग कयके फ़ैरेऩ को फंद कय ददमा जाएगा।

7. भुझे क्मा कयना है?

अध्ममन की जांच के लरए आऩको अऩनी ननमलभत जीवन शैरी को फदरने की आवश्मकता नहीं है।

8. ककस प्रकिमा का अध्ममन ककमा जा यहा है?

प्रकिमा भें लसवनी औय पाइब्रिन गोंद द्वाया घाव को फंद कयने की प्रबावशीरता का भ मांकन औय तुरना कयना शालभर होगा।

9. इस शोध भंे कौन सं हस्त□ेन ददए जाएंगे?

महएक च्स्टरट-भाउथ यौंडभाइज्ड कं ट्रोर ट्रामर शालभर हैं। हैं च्जसभंे दो सभ

· योचगमों की कु र संख्मा = 20

· कु र 40 चतुथाश (च्स्लरट भाउथ भेथड)

नभम्नू ा आकाय स, कं ट्रोर ग्रुऩ (लसवनी ग्रुऩ), एक्सनेरयभेंटर ग्रुऩ 40 क्वाड्रट् – 20 क्वाड्रट

(ऑटोरॉगस पाइब्रिन ग्रू – 20 क्वाड्रट) का होगा।

10. इस अध्ममन भेंं बाग रेने को क्मा दष्ु प्रबाव हैं ?

इस अध्ममन को योचगमोंं नय कोई दष्ु प्रबाव नहीं है।

11. इस अध्ममन भें बाग रेने के संबाववत जोखिभ औय नुकसान

क्मा है?इस अध्ममन भें बाग रेने का कोई जोखिभ मा नुकसान

नहीं है। फदहष्कयण की शतष

· इम्मूनोडफ<:: T<::लशएंसी योग

· अननमंत्रत प्रणारीगत योग

· हड्डी का गंबीय नुकसान

· गबवती औय स्तननान कयाने वारी भदहरा

12. अध्ममन भें बाग रेने के संबाववत राब क्मा है?

मह अध्ममन हभें ऑटोरॉगस पाइब्रिन गोंद की प्रबावकारयता का भ मांकन कयने भें भदद कयेगा।

13. क्मा होगा मदद कोई नई जानकायी उऩरब्ध हो जाती है ?

मदद शोध के दौयान अनतरयक्त जानकायी उऩरब्ध हो जाती है तो आऩको इनके फाये भें फतामा जाएगा औय आऩ अऩननेे शोधकताा कके साथ इस ऩय चचाा कयनेे कके लरए स्वतंत्र हैं,

आऩका शोधकताा आऩको फताएगा कक क्मा आऩ अध्ममन जायी यखिना चाहते हैं। मदद

आऩ वाऩस रेने का ननणम रेने े हैं, तो आऩका शोधकताा आऩकी वाऩसी की व्मवस्थ

कयेगा। मदद आऩ अध्ममन जायी यखिने का ननणम रेने े हैं, तो आऩसे एक अद्मतन

सहभनत पॉभष ऩय हस्ता□य कयने के लरए कहा जा सकता है।

14. क्मा होता है जफ अध्ममन / शोध ऩयी□ण पंद हो जाता है।

मदद अध्ममन ननधाायत सभम से ऩहरे रुक जाता

है/सभालत हो जाता है, तो योगी/स्वमंसेवक को मह सभझामा जाएगा।

15. क्मा होगा अगय कु छ गरत हो जाता है?

मदद कोई गंबीय प्रनतकू र घटना होती है, मा अध्ममन के

दौयान कु छ गरत हो जाता है, तो संस्थान (संस्थाओं), औय

संस्थागत नैनतक सभुदाम को रयऩोटष कयके ग्राशकामतों का

ननमंब्रत्रत ककमा जाएगा।

16. क्मा इस अध्ममन भें भेया दहस्सा गोऩनीम यिा

जाएगा?हां, इसे गोऩनीम यिा जाएगा।

17. अध्ममन / शोध ऩयी□ण के ऩरयणाभ का क्मा होगा?

अध्ममन के ऩरयणाभों का उऩमोग ऩायंऩरयक लसवनी के साथ ऑटोरॉगस पाइब्रिन गोंद की तुरना कयने के लरए ककमा जाएगा। ककसी रयऩोटष/प्रकाशन के भाभरे भें आऩकी ऩहचान गोऩनीम यिी जाएगी।

18. इस अध्ममन को कौन आमोच्जत कय यहा है औय इस ऩयी□ण के लरए धन कहां से आएगा। मह शोध अध्ममन शै□खणक संस्थान (फीफीडीसीओडीएस) द्वाया आमोच्जत ककमा जाता है।

19.क्मा सेवाएं शोध ि◌ित्भ हो जाने के फाद उऩरब्ध

यहेगी मा नहीं? हां।

20.अध्ममन की सभी□ा ककसने की है?

अध्ममन की सभी□ा की गई है औय संस्थान के ववबागाध्म□ औय

आईईसी/आईआयसी द्वाया अनुभोददत ककमा गमा है।

21.अचधक जानकायी के लरए संऩकष

कयें ।डॉ. शैपारी

ऩीरयमोडोंटोरॉजी औय इम्लरांटोरॉजी

ववबाग फाफू फनायसी कॉरेज ऑप डेंटर

साइंसेज। ि◌िनऊ-227105

भोफ- 7007950684

डॉ. सुनीर चन्र वभाष (ऩाठक)

ऩीरयमोडोंटोरॉजी औय इम्लरांटोरॉजी

ववबाग फाफू फनायसी कॉरेज ऑप डेंटर

साइंसेज। ि◌िनऊ-227105

भोफ- 9335928773

डॉ स ज ऩांडे (ऩाठक)

ऩीरयमोडोंटोरॉजी औय इम्लरांटोरॉजी

ववबाग फाफू फनायसी कॉरेज ऑप डेंटर

साइंसेज।

रिनऊ-

227105 भोफ-

9628931689

डॉ भोना शभाष (एचओडी)

नीरयमोडोंटोरॉजी औय इम्लरांटोरॉजी

ववबाग फाफू फनायसी कॉरेज ऑप डेंटर

साइंसेज। रिनऊ-227105

भोफ-9984110444

bbdcods.iec@gmail.com

ANNEXURE – 6
Case History

DEPARTMENT OF PERIODONTICS

PATIENT'S CASE SHEET

Date: O.P.D. No.

Name: Age: Sex: Occupation

Address: Mobile No. :

CHIEF COMPLAINT(S):

HISTORY OF PRESENT ILLNESS

HISTORY OF PAST ILLNESS

A. Past Medical History

B. Past Dental History

(a) Periodontal Treatment Region

(b) **Other dental therapy**

Conservative

Prosthetics

Orthodontics

Oral Surgery

Any Other

C. Present Medical History

(a) General health

1. Bleeding Tendencies
2. Allergy
3. Cardiovascular Diseases
4. Endocrinal Diseases
5. Gastro Intestinal Diseases
6. Neurological Disorder
7. Respiratory Diseases
8. Genito Urinary Diseases
9. Hereditary/Genetic Disorder
10. Puberty/ Pregnancy/ Menopause
11. Any Infectious Disease(s)
12. Medication
13. Any other abnormality

(b) Nutritional Status: i) Well Built /Average /Poor
ii) Non Vegetarian / Vegetarian

D. PRESENT DENTAL HISTORY

(a) **Oral Hygiene Maintenance:** Brush/ Finger/ Stick / Paste/ Powder
Frequency: Once/ Twice/ Thrice
Direction

(b) **HABITS**

1.	Awareness of any Traumatising habits	Yes	No
2.	Grinding of Teeth	Yes	No
3.	Masticatory Muscle Tiredness	Morning	Evening
4.	Biting Habits	Lip/ Tongue/ Cheek/ Misc	
5.	Chewing	Betel/ Tobacco/ Mis.	
6.	Smoking	Beedi/ Cigarette/ Misc.	
7.	Mouth Breathing/ Tongue Thrusting		

CLINICAL EXAMINATION

EXTRA ORAL EXAMINATION

Face

Lips:	Competency
Skin:	Color: Normal or Palor
Neck	Swellings- Unilateral or Bilateral
Jaws:	Symmetry- Antero- Posterior relationship & movements Temporo-Mandibular Joint

INTRA ORAL EXAMINATION:

A. Soft Tissue

Labial & Buccal Mucosa:		Colour, texture
Cheek:		Colour, Stretchability, Consistency
Tongue:		Colour, Size, Mobility, Texture
Floor of the Mouth:		
Palate:	Hard:	Colour, Defect, Depth, Rougae, Tori.
	Soft:	Color, Defect
Vestibule:		
Saliva:		Flow: heavy/ diminished/ Normal Viscosity: thin/thick
Frenum/ Frenii		Number, Size, Attachment

Perio- Endo Problem

B. Gingival Status

1. Colour
2. Contour
3. Consistency
4. Surface Texture
5. Position
6. Size
7. Exudate

C. Hard Tissue

1. No. of teeth present
2. Hypersensitivity
3. Missing teeth (why, when)
4. Caries / Non-vital
5. Supernumerary
6. Proximal contact relationship
7. Plunger cusp
8. Crown size and Colour
9. Pathologic Tooth Migration
10. Mobility — Grade I / II / III
11. Hypoplasia
12. Occlusion — Angle's Classification : Class I / II / III
    Bite: Normal /Open/ Deep/Cross/Crowding
13. Retained / Impacted
14. Attrition/ Erosion/ Abrasion
15. Furcation Involvement
16. Trauma from Occlusion
17. Halitosis
18. Any dental anatomic factors
19. Calculus - Mild / Moderate / Severe
20. Stains - Mild / Moderate / Severe

19. Probing depth

8	7	6	5	4	3	2	1	1	2	3	4	5	6	7	8

INDICES

1. Plaque Index (Silness & Loe / Turesky-Gilmore-Glickman Modication of Quigley-Hein

8	7	6	5	4	3	2	1	1	2	3	4	5	6	7	8

2. Gingival index (Loe & Silness / Modified Gingival Index)

8	7	6	5	4	3	2	1	1	2	3	4	5	6	7	8

3. Calculus index

8	7	6	5	4	3	2	1	1	2	3	4	5	6	7	8

4. Clinical attachment Level

8	7	6	5	4	3	2	1	1	2	3	4	5	6	7	8

DIFFERENTIAL DIAGNOSIS :

INVESTIGATION

1. ROENTENOGRAPHIC EXAMINATION :

OPG/IOPA/BITE WING/OCCLUSAL

	DESCRIPTION	**REGION**
1. Lamina dura		
2. Periodontal ligament space		
3. Root form		
4. Bone loss	Vertical	
	Horizontal	
	Infra bony crater	
	Miscellaneous	
5. Periapical pathology		
6. Any other finding		

2. LAB INVESTIGATIONS

Date	Investigation	Result
	BLOOD	
	Hb%	
	RBC	
	TLC	
	DLC	
	ESR	
	Random Sugar	
	Bleeding time	
	Clotting time	
	HbS Ag Status : Positive / Negative	
	HIV Status : Positive / Negative	

DIAGNOSIS

PROGNOSIS

TREATMENT PLAN

EMERGENCY -

PHASE I -

PHASE II -

PHASE III -

PHASE IV -

S.No.	Date	Procedure Done	Next Appointment	Staff Signature

DEPARTMENT OF PERIODONTICS
BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES
LUCKNOW

PROFORMA OF PATIENT'S INFORMED CONSENT

I..... son/daughter/wife of..... aged..... years, resident of..... being under the treatment of Dr..... do hereby willfully consent to the performance of a surgical procedure under local anaesthesia for the treatment of ..... (Diagnosis) upon myself / upon..... aged..... years, who is related to me as..... (for e.g. son, daughter, wife etc).

I have been informed regarding the inherent risk involved during and after the surgical procedure and that the success of the treatment cannot be guaranteed. I have signed this consent from voluntarily out of my free will without any compulsion or influence.

Date : Place :

Signature : Time :

(To be signed by parent / guardian in case of minor)

सहमति पत्र

मैं.....पुत्र/पुत्री/पत्नी.....आयु.....वर्ष

निवासी.....

मेरे दंत एवं मुख रोग का उपचार डा. ..... कर रहे हैं।

दंत एवं मसूड़े की शल्य क्रिया के लिए मुख निश्चेतना (Local anesthesia) आवश्यक है।

मुझे पूरी शल्य प्रक्रिया के दौरान होने वाले संभावित खतरों के बारे में ठीक से बता दिया गया है एवं उचार की सफलता के बारे में कोई निश्चितत नहीं है से भी अवगत करा दिया गया है मैं इस सहमति पत्र पर भलीभांति, बिना किसी दवाब के अपनी इच्छानुसार हस्ताक्षर कर रहा हूँ।

दिनांक हस्ताक्षर

स्थान समय

नोट : अवस्यक / नाबालिग होने की अवस्था में अभिभावक के हस्ताक्षर आवश्यक है।

ANNEXURE – 7

Statical Analysis

DATA ANALYSIS:

The data obtained were subjected to statistical analysis using Statistical Package for the Social Sciences (SPSS Version 23; Chicago Inc., IL, USA). Data comparison was done by applying specific statistical tests to find out the statistical significance of the comparisons.

Kolmogorov –Smirnov and Shapiro Wilk tests were performed to determine the normality of the data for the two groups to check for efficiency of periodontal flap closure between conventional suture (control group) and autologous fibrin glue (experimental group). Both the tests showed no significant differences and hence confirmed that the data obtained were normally distributed.

Variables were compared using number, percentages. mean values and standard deviation. The mean for different readings for pain between Control group and Experimental group was tested using independent / student 't' test. Comparison between groups for Roll test and Healing index were done by applying Chi square test. P value lesser than 0.05 was considered to be statistically significant.

The following formulas were employed for calculation for various parameters:

1. **Mean/ Average**

Mean or Average is defined as the sum of all the given elements divided by the total number of elements

Mean = sum of elements / number of elements It is denoted by the letter X.

$$X = \frac{\Sigma X}{No.\ of\ observations(n)}$$

2. **Standard Deviation**

The **standard deviation** of a statistical population, a data set, or a probability

distribution is the square root of its variance. Standard deviation is a widely used measure of the variability or dispersion.

It shows how much variation there is from the **"Average" or Mean**. It is denoted by the **letter σ**.

For Small samples, n<30

$$SD = \frac{\sum(X - \bar{X})^2}{n - 1}$$

For Large samples, n>30

$$SD = \frac{\sum(X - X)^2}{n}$$

3. Shapiro-Wilk Test

The **Shapiro-Wilk test** was used for testing the normality (uniformity of the distribution of the data) of the data. This approach is limited to samples between 3 and 50 elements.

The basic approach used in the Shapiro-Wilk (SW) test for normality is as follows:

A non-significant test means the sample distribution is shaped like a normal curve (uniform distribution of the values around an average value or a measure of central tendency) and Parametric test are to be used.

4. Independent / student 't' test

The independent-samples t-test (or independent t-test, for short) compares the means between two unrelated groups on the same continuous, dependent variable

5. Chi square test for association:

The chi-square test for independence, also called Pearson's chi-square test or the chi-square test of association, is used to discover if there is a relationship between two or more categorical variables.

6. Level of Significance (p-value)

The maximum probability of rejecting a correct null hypothesis.

In testing a given hypothesis, the maximum probability with which we would be willing to take risk is called Level of Significance of the Test.

P-value ≥ 0.05 – non-significant

P-value < 0.05 - Significant

P-value < 0.01 - Highly Significant

P-value < 0.001 - Very Highly Significant

7. Degree of Freedom

Degree of freedom refers to the maximum number of logically independent values, which are values that have the freedom to vary, in the data sample. Degree of freedom are commonly discussed in relation to various forms of hypothesis testing in statistics

The statistical formula to determine degrees of freedom is quite simple. It states that degrees of freedom equal number of values in data set minus 1, and it looks like this:

$D f = N-1$

Where N is the number of values in the data set (sample size)

8. Bar charts:

A bar graph is a chart that plots data using rectangular bars or columns (called bins, can even be presented as a cylinder or a cone) that represent the total amount of observations in the data for that category. Bar charts can be displayed with vertical columns, horizontal bars, comparative bars (multiple bars to show a comparison between values), or stacked bars (bars containing multiple types of information)

Bar graphs have an x- and y-axis and can be used to showcase one, two, or many categories of data. The vertical axis of the bar graph is called the y-axis, while the bottom of a bar graph is called the x-axis. When interpreting a bar graph, the length of the bars/columns determines the value as described on the y-axis. Bar graphs are ideal for comparing two or more values, or values over time.

PLAGIARISM REPORT

Ouriginal by Turnitin

Document Information

Analyzed document	THESIS Dr. SHAIFALI.pdf (D156112933)
Submitted	2023-01-17 09:01:00
Submitted by	Dr Mona Sharma
Submitter email	maniona2@bbdu.ac.in
Similarity	4%
Analysis address	maniona2.bbduni@analysis.urkund.com

[DR. SUNIL CHANDRA VERMA]