Dissertation

COMPARATIVE EVALUATION OF THE EFFECTIVENESS OF ACELLULAR DERMAL MATRIX WITH LEUKOCTYE- AND PLATELET-RICH FIBRIN IN THE TREATMENT OF LOCALIZED GINGIVAL RECESSION: A CLINICAL STUDY

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By

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Under the guidance of

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I hereby declare that this dissertation entitled **"COMPARATIVE EVALUATION OF THE EFFECTIVENESS OF ACELLULAR DERMAL MATRIX WITH LEUKOCTYE- AND PLATELET-RICH FIBRIN IN THE TREATMENT OF LOCALIZED GINGIVAL RECESSION: A CLINICAL STUDY"** is a bonafied and genuine research work carried out by me under the guidance of ***Dr.*** **Vandana A. Pant**, Professor & Head, Department of Periodontics, Babu Banarasi Das College Of Dental Sciences, Babu Banarasi Das University, Lucknow, Uttar Pradesh.

Date: 15/11/2017

Place: Lucknow

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MY PARENTS

ACKNOWLEDGEMENT

"Wisdom is not a product of schooling but of the lifelong attempt to acquire it."

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ABBREVIATIONS

L-PRF/PRF	LEUKOCYTE- AND PLATELET-RICH-FIBRIN
TGF-β1	TRANSFORMING GROWTH FACTOR-BETA ONE
PDGF-αβ	PLATELET DERIVED GROWTH FACTOR- ALPHA BETA
VEGF	VASCULAR ENDOTHELIAL GROWTH FACTOR
ADMA	ACELLULAR DERMAL MATRIX ALLOGRAFT
CAF	CORONALLY ADVANCED FLAP
PRP	PLATELET RICH PLASMA
KT	KERATINIZED TISSUE
LPF	LATERALLY POSITIONED FLAP
GR	GINGIVAL RECESSION
SLCRF	SEMILUNAR CORONALLY RE-POSITIONED FLAP
CTG	CONNECTIVE TISSUE GRAFT
PRGF	PLASMA RICH IN GROWTH FACTORS
VISTA	VESTIBULAR INCISION SUB-PERIOSTEAL TUNNEL ACCESS
FGG	FREE GINGIVAL GRAFT
SCTG	SUB-EPITHELIAL CONNECTIVE TISSUE GRAFT
PDM	PUROS DERMIS
VAS	VISUAL ANALOGUE SCALE
IGF-1	INSULIN-LIKE GROWTH FACTOR-1
PPP	PLATELET POOR PLASMA

MCAF	MODIFIED CORONALLY ADVANCED FLAP
GTH	GINGIVAL THICKNESS
PRP	PLATELET RICH PLASMA
PI	PLAQUE INDEX
RD	RECESSION DEPTH
RW	RECESSION WIDTH
PPD	POCKET PROBING DEPTH
CAL	CLINICAL ATTACHMENT LEVEL
KG	WIDTH OF KERATINIZED GINGIVA
CEJ	CEMENTO-ENAMEL JUNCTION
PPS	PERIODONTAL PLASTIC SURGERY
CRC	COMPLETE ROOT COVERAGE
FDA	FOOD AND DRUG ADMINISTRATION
AATB	AMERICAN ASSOCIATION OF TISSUE BANKS

Abstract

ABSTRACT

Gingival recession is exposure of the root surface by an apical shift in the position of the marginal gingiva. Regeneration of lost structure has become the primary therapeutic goal in periodontics and there are numerous therapeutic modalities for recession coverage that have been investigated. The main indication for root coverage procedures are esthetics and/or cosmetic demands followed by the management of root hypersensitivity, root caries or when it hampers proper plaque removal. Recently, the use of an ADMA (PUROS DERMIS) has become an increasingly popular technique as a substitute for connective tissue graft. Because of their strong fibrin matrix, the L-PRF family fits the needs of the applications in oral and maxillofacial surgery, as L-PRF clots and membranes present a volume and shape easy to combine with most surgical techniques, as filling and interposition healing biomaterial or as protection healing membrane. Hence, this study has been undertaken to enable us to compare the clinical and cosmetic improvement in the treatment of localized marginal tissue recession with ADMA (Puros Dermis) and with L- PRF. 30 sites of localized gingival recession were divided into two groups to receive root coverage treatment with Puros Dermis or L-PRF. The patients underwent Phase I therapy, and were recalled after one month for the surgical procedure. Clinical parameters were recorded at baseline, 3 months, and 6 months post-operatively. Statistical analysis of results showed significant reduction in plaque index, recession depth, recession width, probing pocket depth, clinical attachment level and increase in width of keratinized gingiva from baseline to 3 months and 6 months in both groups; however, Puros Dermis showed far more stable and significant reduction when compared to L-PRF. Our study thus demonstrated that Puros Dermis was the superior material for root coverage when compared to L-PRF.

Introduction

Periodontitis is "an inflammatory disease of the Periodontium, caused by specific microorganisms or groups of specific microorganisms, resulting in progressive destruction of the hard and soft periodontal tissues[1]".

The progress of inflammatory periodontal disease, if unhampered, ultimately results in attachment loss sufficient enough to cause gingival recession. Recession is exposure of the root surface by an apical shift in the position of the marginal gingiva[1]. Etiologic factors that have been implicated in gingival recession include: faulty tooth-brushing technique (gingival abrasion), tooth malposition, and friction from soft tissues (gingival ablation)[2]. Regeneration of lost structure has become the primary therapeutic goal in periodontics; well documented in periodontal literature and there are numerous therapeutic modalities for recession coverage that have been investigated. The periodontal literature has well documented therapeutic efforts designed to induce new attachment and/or regeneration on exposed root surfaces. The main indication for root coverage procedures are esthetics and/or cosmetic demands followed by the management of root hypersensitivity, root caries or when it hampers proper plaque removal.

Platelet concentrates for topical and infiltrative use are first of all blood extracts obtained after various processing of a whole blood sample, mostly through centrifugation[3]. In short, all these products, are tissues extracted from the circulating blood.

Leukocyte- and Platelet-Rich Fibrin (L-PRF) products are autologous biomaterials containing leukocytes, platelets, wide range of key healing proteins with a high-density fibrin network[4]. PRF holds promise as a regenerative material as it releases high amounts of growth factors (TGFb1, PDGF-AB, and VEGF) and matrix glycoproteins. Thus it may enhance proliferation of different cell types, including fibroblasts, osteoblasts, adipocytes, and keratinocytes[5]. Because of their strong fibrin matrix, the L-PRF family fits the needs of the applications in oral and

maxillofacial surgery[6,7], as L-PRF clots and membranes present a volume and shape easy to combine with most surgical techniques, as filling and interposition healing biomaterial or as protection healing membrane.

Free gingival grafting (FGG), connective tissue grafts (CTGs), coronally advanced flaps (CAFs), and a combination of CTG, CAF, and guided tissue regeneration have been introduced to treat gingival recession. Overall comparative studies suggest that CTGs are considered the "gold standard" procedure; but they are associated with patient morbidity, need for a second surgical site and limited supply of donor tissue.

Recently, the use of an Acellular Dermal Matrix Allograft (ADMA) has become an increasingly popular technique as a substitute for connective tissue graft. Acellular dermal matrix is obtained from a human donor skin tissue, processed in a way that removes its cell component while preserving the remaining bioactive components, which is subsequently freeze dried[8]. Multiple clinical studies[9] have also documented predictable and esthetic results with an acellular dermal graft in the form of Alloderm.

Puros Dermis offers several advantages over Alloderm in that it needs less time for rehydration; it is not site-specific i.e., can be placed from either side and is manufactured by the company's proprietary Tutoplast process.

To the best of the authors' knowledge, no study has been conducted so far comparing the treatment outcomes of Puros Dermis vs L-PRF in treating localized gingival recession.

Hence, this study has been undertaken to enable us to compare the clinical and cosmetic improvement in the treatment of localized marginal tissue recession with ADMA (Puros Dermis) and with L- PRF.

AIM:

The aim of the study is to compare the effectiveness of acellular dermal matrix allograft (Puros Dermis) with leukocyte- and platelet rich fibrin (L-PRF) in the treatment of localized gingival recession.

OBJECTIVES:

- To evaluate the efficacy of Puros Dermis in the treatment of localized gingival recession after six months
- To evaluate the efficacy of L-PRF in the treatment of gingival recession after six months
- To compare the difference in root coverage achieved between the two procedures after six months

Review of Literature

Review of Literature

GINGIVAL RECESSION

Gorman WJ (1967)[10] conducted a study on 164 individuals to determine the prevalence and incidence of gingival recession and to correlate gingival recession with apparent clinical etiologic factors. The results showed that the occurrence of recession was found to vary from 54.5 percent of all the subjects in the 16-26 age group to 100 percent of the subjects in the 46-86 age group, with males showing greater recession than females in the same age group. Individuals with good oral hygiene, particularly males, showed more gingival recession than individuals with poor oral hygiene. Malpositioned teeth and toothbrush trauma were found to be the most frequent etiologic factors associated with gingival recession.

Baker D, Seymour G (1976)[11] observed the possible stages in the pathogenesis of gingival recession were in rats in which pocketing had been induced by replacement of natural incisors with dental implants. The recession process was examined at intervals by taking transverse serial sections. The study suggested that gingival recession involves a localized inflammatory process which causes breakdown of connective tissue and leads to proliferation of the epithelium into the site of connective tissue destruction. Proliferation of the epithelial cells into the connective tissue brings about a subsidence of the epithelial surface, which is manifest clinically as recession.

Bernimoulin J-P, Curilovic Z (1977)[12] carried out tooth mobility measurements on 107 teeth with gingival recession in 20 subjects and found no significant correlation between gingival recession and tooth mobility, and between tooth mobility and alveolar bone dehiscence.

Björn A-L, Anderson V, OIsson A (1981)[13] conducted a clinical examination on 174 15-year old pupils out of which approximately 62 per cent showed some degree of gingival recession on the labial surfaces of maxillary teeth. The number of affected teeth per individual was low, one

tooth in about 35 per cent and teeth in 25 per cent of the individuals. First molars and first premolars were the teeth most often affected. The number of cases affected by recession was lower in individuals using an "unspecific" toothbrushing technique compared with those using roll or vibratory technique.

Vehkalahti M (1989)[14] investigated the occurrence of gingival recession in adults by age and gender and in relation to their dental status and frequency of toothbrushing. A total of 258 dentate subjects were clinically examined and found frequent toothbrushers had, both in the maxilla and mandible, more surfaces with recession than had those brushing their teeth infrequently. Frequent toothbrushing also had a greater association with recession among women and in the youngest age group.

Kassab MM Cohen RE (2003)[15] reviewed cross-sectional epidemiological studies to describe the prevalence, etiology and factors associated with gingival recession and found that they correlated the prevalence of recession to trauma, sex, malpositioned teeth, inflammation and tobacco consumption. The recent surveys in this review revealed that 88 percent of people 65 years of age and older and 50 percent of people 18 to 64 years of age have one or more sites with recession. The presence and extent of gingival recession also increased with age.

Sarpangala M (2015)[16] conducted a study to determine the occurrence of gingival recession and to identify the most common factor associated with the cause of gingival recession. A total of 710 subjects aged between 15 years to 60 years were selected. The most common cause for gingival recession was dental plaque accumulation (44.1%) followed by faulty toothbrushing (42.7%). Approximately half of the subjects examined exhibited gingival recession. The etiology

of gingival recession was found to be multifactorial, with its appearance always the result of more than one factor acting together.

SURGICAL TECHNIQUES

Langer B, Langer L (1985)[17] described the use of the subepithelial connective tissue graft as a donor source for root coverage. An increase of 2 to 6 mm of root coverage was achieved in 56 cases over 4 years with minimal sulcus depth and no recurrence of recession.

Tarnow DP. (1986)[18] described a semilunar coronally positioned flap. The technique involves a semilunar incision made parallel to the free gingival margin of the facial tissue, and coronally positioning this tissue over the denuded root. This technique has the advantage over other coronally positioned flaps, in that no sutures are required, there is no tension on the flap, there is no shortening of the vestibule, and the existing papillae are not interfered with.

de Waal H, Kon S, Ruben MP. (1988)[19] stated that laterally positioned flap has shown itself to be the most predictable and aesthetically successful procedure in the treatment of mucogingival defects such as gingival/periodontal recessions and root exposures. They also stated that it is of utmost importance that the biologic principles of wound healing should be adhered to prior, during and after the surgical procedure.

Allen EP, Miller PD Jr. (1989)[20] described the fairly known coronal positioning of existing gingiva in CAF(Coronally advanced flap) may be used to enhance aesthetics and reduce sensitivity. Unfortunately when recession is minimal and the marginal tissue is healthy, many periodontists do not suggest treatment. They described a simple surgical technique of CAF with the criteria for its use which results in a high degree of predictability and patient satisfaction.

Allen EP (1993)[21] conducted a study to review the current modalities of treatment including pedicle flaps, gingival grafts and connective tissue grafts for the aesthetic treatment of gingival recession to review these surgical procedures for an increased predictability in implementation.

Allen A L (1994)[22] advocated the use of the supraperiosteal envelope in soft tissue grafting for root coverage, with recent advances in graft procurement and suturing encouraging a reassessment of the "envelope" technique in soft tissue grafting for root coverage. Use of the supraperiosteal envelope permits conservation of existing gingiva, minimal surgical trauma to the recipient area, and firm fixation of the connective tissue graft over single and multiple adjacent areas of recession. The intimate coadaptation of the bilaminar soft tissue complex thus achieved may facilitate graft survival and postoperative blending of soft tissues.

Trombelli L, Scabbia A, Wikesjö UM, Calura G (1996)[23] treated Class I and II Miller maxillary buccal recession defects in a split-mouth therapy to determine the effect of fibrin glue in addition to tetracycline HCI root conditioning and the coronally positioned flap procedure. 6 months post surgery, significant recession depth reduction and attachment gain were observed for both treatments resulting in no clinical and statistical significant differences. This suggests that fibrin glue may not meaningfully enhance the outcome of these procedures.

Paolantonio M, di Murro C, Cattabriga A, Cattabriga M (1997)[24] compared Class I and II Miller gingival recessions, when treated with free gingival and bilaminar connective sub-pedicle grafts over a 5 year post operative period. They concluded that the sub-pedicle graft promises better results in the coverage of exposed root surfaces when compared with the free gingival graft.

Pini-Prato G, Baldi C, Pagliaro U, Nieri M, Saletta D, Rotundo R, et al (1999)[25] conducted a clinical study which was designed to determine if mechanical instrumentation (root planing) of the exposed root is useful in treating gingival recession caused by traumatic tooth brushing following a coronally advanced flap (CAF). Their prospective clinical, controlled, randomized study showed that mechanical instrumentation (root planing) of the exposed root surfaces is not necessary when shallow recessions caused by traumatic tooth brushing are treated using a CAF in patients with high levels of oral hygiene.

Pini-Prato G (2000)[26] conducted a clinical controlled study designed to measure the tension of coronally advanced flaps (CAF) performed to treat shallow gingival recessions and to compare the recession reduction (Rec Red) achieved in a test group (flaps with tension) and in a control group (flaps without tension) 3 months after surgery. The results showed that minimal flap tension does not influence recession reduction after 3 months when shallow recessions are treated by means of CAF. In the test group (with tension), the statistical analysis suggested that the higher the flap tension, the lower the recession reduction.

Tözüm TF (2003)[27] focused on the importance of connective tissue grafting, combined with a recent approach known as the tunnel procedure, in managing gingival recession defects with a single operation. Clinical trials yielded good results, including early tissue healing because of increased blood supply, good aesthetic results, excellent patient cooperation and avoidance of secondary periodontal plastic surgery. These were the benefits of this technique, which improved the success rate of connective tissue grafting and increased the amount of root coverage.

Zucchelli G, Cesari C, Amore C, Montebugnoli L, De Sanctis M (2004)[28] evaluated the effectiveness with respect to root coverage of a modified surgical approach of the laterally

moved flap procedure for the treatment of an isolated type of recession defect. They concluded that the laterally moved, coronally advanced surgical technique was very effective in treating isolated gingival recessions.

Huang LH, Neiva RE, Soehren SE, Giannobile WV, Wang HL. (2005)[29] evaluated the effects of Plater-rich Plasma (PRP) in combination with CAF. Based on the results of their study, the application of PRP in CAF root coverage procedure provided no clinically measurable enhancements on the final therapeutic outcomes of CAF in Miller's Class I recession defects.

Baghdadi K, (2006)[30] described a modified semilunar coronally advanced flap for the treatment of recession defects on multiple adjacent teeth. The flap design gave better mobility and stability to the repositioned pedicle than previously described semilunar coronally advanced flap procedures.

Agudio G, Nieri M, Rotundo R, Cortellini P, Pini Prato G (2008)[31] conducted a retrospective long-term study to evaluate changes in the amount of keratinized tissue (KT) and in the position of the gingival margin after free gingival graft procedures over a period of 10 to 25 years. One hundred three subjects presenting with 224 sites completely lacking attached gingiva associated with gingival recessions were treated with free gingival grafts. Results of this study showed gingival augmentation procedures performed in sites with an absence of attached gingiva associated with recessions provide an increased amount of KT associated with recession reduction over a long period of time.

Chambrone LA, Chambrone L (2009)[32] conducted a study to assess the clinical results obtained with laterally positioned flap (LPF) for the treatment of localized maxillary and mandibular gingival recessions (GR). Patients with maxillary recessions recorded statistically

superior gains in the width of keratinized tissue than patients with mandibular recessions. The results of their study demonstrated that the LPF is an effective procedure to cover localized gingival recession. Moreover, width of keratinized tissue was statistically higher for maxillary recessions.

Santana RB, Mattos CML, Dibart S (2010)[33] compared the clinical outcomes of the semilunar coronally re-positioned flap (SLCRF) and CAF procedure in the treatment of maxillary Miller class I GR defects. Both flap designs were effective in obtaining and maintaining a coronal displacement of the gingival margin. Root coverage is significantly better with CAF compared with the original SLCRF technique in the treatment of shallow maxillary Miller class I GR defects.

Pini-Prato GP, Cairo F, Nieri M, Franceschi D, Rotundo R, Cortellini P(2010)[34] conducted a long-term study to compare the clinical outcomes of CAF alone versus coronally advanced flap plus connective tissue graft (CAF+CTG) in the treatment of multiple gingival recessions using a split-mouth design over 5 years of follow-up. CAF+CTG provided better root coverage than CAF alone in the treatment of multiple gingival recessions at the 5-year follow-up.

Pini Prato G, Rotundo R, Franceschi D, Cairo F, Cortellini P, Nieri M (2011)[35] conducted a long-term 14-year-randomized split-mouth study aimed at evaluating (1) the outcomes of two different methods of root surface modifications (root surface polishing versus root planing) used in combination with a coronally advanced flap (CAF) and (2) the long-term results of CAF performed for the treatment of single gingival recession. Their study showed that during a long-term follow-up, gingival recession recurred in 39% of the treated sites following the CAF procedure.

Lafzi A, Chitsazi MT, Farahani RM, Faramarzi M (2011)[36] conducted a study to evaluate the clinical efficiency of the CAF with and without plasma rich in growth factors (PRGF) in the management of gingival recession defects. Both treatment protocols led to a significant improvement in all measured variables compared to the baseline values, except the width of keratinized tissue. While PRGF enhanced the outcomes of CAF especially throughout the first month post-operatively, it offered no clinical advantage over CAF alone during the subsequent 2 months.

Fischer KR, Alaa K, Schlagenhauf U, Fickl S (2012)[37] presented a double sliding flap technique designed to meet the special requirements encountered in the often-fragile incisal mandibular area. Their surgical approach combined two laterally repositioned flaps with the dissection of the frenulum, to cover two deep neighboring recessions in the area of the central incisors. Providing that correct indication and adequate surgical tissue handling are used, this complex and advanced technique would have the potential to achieve complete long term root coverage and an aesthetically satisfying treatment outcome.

Chatterjee A, Sharma E, Gundanavar G, & Subbaiah S K (2015)[38] presented two current case reports that introduce a novel, minimally invasive approach applicable for both isolated recession defects as well as multiple contiguous defects in the maxillary anterior region. Access to the surgical site is obtained by means of an approach referred to as vestibular incision subperiosteal tunnel access. The minimally invasive Vestibular incision sub-periosteal tunnel access (VISTA) approach presented in these case reports, combined with a broad wound-healing growth factor, affords a number of unique advantages to the successful treatment of multiple recession defects

ACELLULAR DERMAL MATRIX ALLOGRAFT (ADMA)

Wei PC, Laurel L, Geivelis M, Lingen MW, Maddalozzo D (2000)[39] investigated the clinical efficacy of acellular dermal matrix allograft to achieve increased attached gingiva. Autogenous Free gingival graft (FGG) harvested from the palate was compared with the ADM graft in 12 patients with attached gingiva < or =1 mm on the facial aspect of mandibular anterior teeth. The results of this study suggested that the esthetic results using the ADM allograft might be better than those using the autogenous FGG.

Aichelmann-Reidy ME, Yukna RA, Evans GH, Nasr HF, Mayer ET (2001)[40] evaluated the effectiveness of an alternate material that would reduce morbidity while providing sufficient available donor tissue by using acellular dermis allograft for treatment of human gingival recession. An acellular allogeneic dermal connective tissue matrix (AD) and autogenous palatal connective tissue (CT) were compared in twenty patients with similar isolated gingival recession of > or = 2 mm on 2 separate teeth. The study concluded that acellular allogeneic dermal matrix may be a useful substitute for autogenous connective tissue grafts in root coverage procedures.

Tal H, Moses O, Zohar R, Meir H, Nemcovsky C (2002)[41] clinically compared the efficiency of ADMA and CTG in the treatment of gingival recession > or =4 mm in seven patients with bilateral recession lesions. Fourteen teeth were randomly treated with ADMA or CTG covered by coronally advanced flaps. The results of this study concluded that recession defects may be covered using ADMA or CTG with no practical difference.

Cortes Ade Q (2004)[42] clinically evaluated the treatment of Class I gingival recessions by coronally positioned flap with or without ADM on thirteen patients with comparable bilateral

Millers Class I gingival recession (> or = 3.0 mm) where the defects were randomly assigned to one of the treatments. The conclusion of this study was that both techniques could provide significant root coverage in Class I gingival recessions; however, a greater keratinized tissue thickness can be expected with ADM.

Harris RJ (2004)[43] evaluated the short-term and long-term root coverage results obtained with an acellular dermal matrix and a subepithelial graft. Twenty five patients that were treated with either an acellular dermal matrix or a sub-epithelial graft for root coverage were included in the study and the short term (mean 12.3 to 13.2 weeks) and long term (mean 48.1 to 49.2 weeks) were compared. The results showed that the cases treated with an acellular dermal matrix improved or remained stable with time.

Woodyard JG, Greenwell H, Hill M, Drisko C, Iasella JM, Scheetz J (2004)[44] compared the coronally positioned flap plus an acellular dermal matrix allograft to CPF alone to determine their effect on gingival thickness and percent root coverage. Twenty four subjects with one Miller Clas I or II buccal recession defects were treated with the same flap procedure and studied for six months. The results concluded that treatment with a CPF plus an ADM allograft significantly increased gingival thickness when compared with a CPF alone.

Gapski R, Parks CA, Wang HL (2005)[9] conducted a meta-analysis to compare the efficacy of ADM-based root coverage and ADM-based increase in keratinized tissue to other commonly used mucogingival surgeries. Randomized controlled clinical trial articles from January 1, 1990 to October 2004 related to ADM were searched using the MEDLINE database from the National Library of Medicine, the Cochrane Oral Health Group Specialized Trials Registry and through hand searches of recent journals and reviews. Most of the analyses showed moderate to high

levels of hererogeneity, three out of four studies favored ADM-based coverage, and there were trends of increased clinical attachment gains comparing ADM to CAF procedures

Cummings LC, Kaldahl WB, Allen EP (2005)[45] documented the histological results of CT grafts, ADM grafts, and coronally advanced flaps to cover denuded roots in humans. The study was conducted on four patients previously treatment planned for extractions of three or more anterior teeth. Three teeth were selected in each patient and randomly designated to receive CT grafts or ADM graft beneath a coronally advanced flap or a coronally advanced flap alone. Block section extractions were performed six months postoperatively and histologic examination concluded that although CT and ADM grafts have slightly different histologic appearance, both can be successfully used to cover denuded roots with similar attachment and no adverse healing.

Rahmani ME, Lades MA (2006)[46] compared the ADMA with the conventional subepithelial connective tissue graft (SCTG) in the treatment of gingival recession. Fourteen patients with 20 gingival recessions of Miller's grade I and II were selected and randomly assigned to the test and control groups and in each group ten recession defects were treated. The findings implied that both ADMA and SCTG techniques could produce the same results when used for the successful treatment of gingival recessions. In addition the ADMA could be used as an adequate alternative treatment modality for conventional techniques.

Barker TS et al (2010)[47] compared the healing associated with a coronally advanced flap for root coverage in areas of localized tissue recession when using Alloderm (ADM) and Puros Dermis (PDM). A split-mouth design was used for this study, with 52 contralateral sites in 14 patients with Miller Class I or III facial tissue recession. Twenty-six sites were treated with coronally advanced flap using PDM, and 26 sites were treated with coronally advanced flap

using ADM, all followed for 6 months. Both materials were successful in achieving root coverage.

Shanmugam M, Sivakumar V, Anitha V, Sivakumar B (2012)[48] evaluated the effectiveness of an Acellular dermal matrix graft for root coverage procedures and to objectively analyze the post-operative esthetics using a Visual Analog Scale (VAS). Both male and female patients aged 20-50 years with aesthetic problems due to exposure of recession defects when smiling with each site falling into Miller's Class I and II gingival recession were selected. The study showed that acellular dermal matrix graft (alloderm) may be successfully used to treat gingival recession, as adequate root coverage may be predictably obtained.

Koudale SB, Charde PA, Bhongade ML (2012)[49] compared and evaluated the effectiveness of ADMA and SCTG in combination with coronally positioned flap in the treatment of multiple gingival recessions in aesthetic areas. Ten patients aged between 18 to 40 years were selected and randomly assigned to one of the groups and treated. The clinical parameters were measured at baseline and then at 6 months after surgery and the data was statistically analyzed. Their results suggested that ADMA may be a useful substitute instead of subepithelial connective tissue graft for root coverage.

Shori T, Kolte A, Kher V, Dharamthok S, Shrirao T (2013)[50] compared the effectiveness of subpedicle ADMA with SCTG in the treatment of isolated marginal tissue recession. Twenty systemically healthy patients aged between 18 to 50 years with a recession defect on the labial and the buccal surfaces of any teeth were selected for the study. Results showed that both treatments produced a significant reduction in gingical recession and significant gain in width of keratinized gingiva.

Goyal N, Gupta R, Pandit N, Dahiya P (2014)[51] evaluated the degree of patient acceptance with ADM allograft in the treatment of buccal gingival recession and to compare it with subepithelial connective tissue graft. Thirty patients with Miller's class II recessions were treated by randomly assigning them to the test and control groups. The subepithelial connective tissue graft and ADM graft were able to successfully treat gingival recession defects; however, the ADM showed better patient acceptance than the connective tissue graft.

Thakare P, Baliga V, Bhongade ML (2015)[52] appraised the effectiveness of ADMA and SCTG compared to CAF in the treatment of multiple gingival recessions. Thirty patients aged between 18 to 50 years with multiple Miller's Class I and II recessions on labial or buccal surfaces of teeth were selected and randomly assigned to three groups. It was concluded that all three techniques could provide root coverage in Miller's class I and II gingival recessions; but greater % root coverage and predictability for coverage of >90% could be expected with CAF + ADMA and CAF + SCTG groups when compared with CAF alone

A-PRF

Choukroun J et al (2006)[53] conducted a study where investigations were made into the previously evaluated biology of PRF with the first established clinical results, to determine the potential fields of application for this biomaterial. The reasoning is structured around 4 fundamental events of cicatrization, namely, angiogenesis, immune control, circulating stem cells trapping, and wound-covering epithelialization. All of the known clinical applications of PRF highlight an accelerated tissue cicatrization due to the development of effective neovascularization, accelerated wound closing with fast cicatricial tissue remodelling, and nearly

total absence of infectious events. Their initial research therefore makes it possible to plan several future PRF applications, including plastic and bone surgery, provided that the real effects are evaluated both impartially and rigorously.

Dohan DM, et al (2006)[54] conducted a study to investigate the platelet-associated features of PRF as a biomaterial. During PRF processing by centrifugation, platelets are activated and their massive degranulation implies a very significant cytokine release. They undertook to quantify PDGF-β, TGFβ-1, and IGF-1 within PPP (platelet-poor plasma) supernatant and PRF clot exudate serum. Their initial analyses revealed that slow fibrin polymerization during PRF processing leads to the intrinsic incorporation of platelet cytokines and glycanic chains in the fibrin meshes. This result would imply that PRF, unlike the other platelet concentrates, would be able to progressively release cytokines during fibrin matrix remodeling; such a mechanism might explain the clinically observed healing properties of PRF.

Aroca S et al (2009)[55] evaluated the additional effect of PRF in coronally advanced flap for the treatment of gingival recession. Twenty subjects, presenting three adjacent Miller Class I or II multiple gingival recessions of similar extent on both sides of the mouth, were enrolled in the study. Each patient was treated on both sides by an MCAF technique; the combination treatment (with a PRF membrane) was applied on the test side. Probing depth (PD), recession width, clinical attachment level (CAL), keratinized gingival width, and gingival/ mucosal thickness (GTH) were measured at baseline and at 6 months post-surgery. Gingival recession was measured at baseline and at 1, 3, and 6 months post-surgery. They concluded that the addition of a PRF membrane positioned under the MCAF provided inferior root coverage but an additional gain in GTH at 6 months compared to conventional therapy

Anilkumar K, Geetha A, Umasudhakar, Ramakrishna T, Vijayalakshmi R and Pameela E. (2009)[56] described a recent innovation in dentistry is the preparation and use of platelet-rich plasma (PRP), a concentrated suspension of the growth factors, found in platelets. These growth factors are involved in wound healing and postulated as promoters of tissue regeneration. Their study reported the use of PRF membrane for root coverage on the labial surfaces of the mandibular anterior teeth using laterally displaced flap technique with PRF membrane at the recipient site.

Aleksic Z, Jankovic S, Dimitrijevic B, Diynic-Resnik T, Milinkovic I, Lekovic V (2010)[57] evaluated the clinical effectiveness of activated platelet-rich fibrin (PRF) membrane in treatment of gingival recession. 19 gingival recessions Miller class I or II were treated with a coronally advanced flap and the PRF membrane (PRF group). In the same patients, 19 other gingival recessions were treated with CTG in combination with the coronally advanced flap (the CTG group). Both procedures were effective with equivalence of clinical results in solving gingival recession problems. The utilization of the PRF resulted in a decreased postoperative discomfort and advanced tissue healing.

Femminella et al (2014)[58] compared the effects of PRF and gelatin sponge on the healing of palatal donor sites and the patient's morbidity. Forty patients with at least one site of Miller's Class I or II gingival recession were treated by a coronally advanced flap with connective tissue graft resulting from the de-epithelialization of free gingival graft. The PRF-enriched palatal bandage significantly accelerates palatal wound healing and reduces the patient's morbidity.

Kumar A P, Fernandes B, Surya C (2011)[59] stated that PRF is a novel treatment option available for various mucogingival defects with varied outcome. Although it is as its infancy, the best part of platelet-rich fibrin is acquirement of optimal aesthetic results with excellent soft

tissue contour and texture. Their case report highlighted the usage of platelet rich fibrin membrane for the treatment of mucogingival defects such as gingival recession.

Naik B, Karunakar P, Jayadev M, Marshal VR. (2013)[60] described platelet rich fibrin (PRF) as a fibrin matrix in which platelet cytokines, growth factors, and cells are trapped and may be released after a certain time and that can serve as a resorbable membrane. Autologous PRF is considered to be a healing biomaterial and studies have shown its application in various disciplines of dentistry.

Chandran P, Sivdas A (2014)[61] reviewed the role of PRF in periodontal regeneration and concluded that PRF is a powerful healing biomaterial with inherent regenerative capacity and can be used in various procedures such as for the treatment of periodontal intra-bony defects, treatment of furcation, sinus lift procedures and as a scaffold for human periosteal cells in vitro, which finds application in tissue engineering.

Suchetha A et al (2015)[62] evaluated and compared, clinically and radiographically, the efficacy of PRF and PRP in the treatment of periodontal endosseous defects and to assess the effect of platelet concentration on periodontal regeneration. Twenty intrabony defects were selected and divided into two groups randomly and treated by either PRP or PRF, and clnical parameters measured at baseline, 3 months, 6 months and 9 months post-operatively; concluding favourably that both PRF and PRP have comparable effects on periodontal regeneration.

Keceli HG et al (2015)[63] conducted a randomized controlled trial to evaluate the adjunctive effect of PRF to CTG in the treatment of buccal recession defects. According to the results, PRF did not develop the outcomes of CAF+CTG treatment except increasing the tissue thickness.

Hehn J et al (2016)[64] conducted a randomized controlled clinical trial to evaluate the effect of PRF on soft tissue thickening and bone loss around implants. Their study concludes that soft tissue augmentation with PRF performed with a split-flap technique cannot be recommended for thickening thin mucosa.

Arunachalam M et al (2016)[65] stated that in patients with periodontitis, regeneration of the lost tissues has faced difficulties primarily due to the lack of support during the intricate healing processes. PRF has been considered to be an important, easy to obtain, predictable surgical additive for periodontal regeneration. This autologous scaffold provides the much needed bio-chemical mediators which has the potential for enhancing reconstruction of the periodontium. Their review tries to understand as to why PRF would be an important link to reach predictable periodontal regeneration.

Al Jasser R, AlKudmani H and Andreana S. (2017)[66] conducted a review which indicated no statistical or clinical difference in the use of PRF when compared to CAF. This lack of statistical difference makes PRF a comparative alternative to CAF for soft tissue regeneration in the treatment of Miller class I and II gingival recession. They found that the reduced post-operative pain and accelerated healing by the PRF offers an advantage of using it compared to CTG or EMD which also need to be confirmed by future clinical and histological evaluation.

Materials & Methods

The following clinical, experimental prospective study was carried out in the Department of Periodontology, Babu Banarasi Das College of Dental Sciences (BBDCODS), Lucknow. After obtaining ethical clearance from the Institutional Ethical Committee, patients were selected based upon the following inclusion and exclusion criteria.

Inclusion criteria -

- Patients aged between 18-50 years
- Presence of recession defect affecting labial/buccal surfaces of the teeth falling under 'Millers' Class I or II,
- Presence of ≥ 3 mm recession depth with the loss of clinical attachment level (CAL) ≥ 4 mm.
- Radiographic evidence of sufficient interdental bone (the distance between the crestal bone and cementoenamel junction as < 2mm).

Exclusion criteria –

- Molars, cervical abrasion, root caries, abnormal frenal attachments, tooth modifications.
- Pregnant and lactating women.
- Smokers, tobacco and/or pan masala chewers.
- Patients with any systemic diseases that will affect the periodontal treatment outcome.
- Subjects with a known allergy to the material being used.
- Patients who have been taking antibiotics for the previous 3 months.
- Non co-operative patients.

Materials:-

1. Local anaesthetic agent 2% Lignocaine (Xicaine).
2. Acellular dermal matrix allograft (Puros Dermis – Zimmer Dental; Zimmer Holdings Inc.)
3. Syringe 3ml and 5ml.
4. Diagnostic PMT set [Mouth mirrors, UNC-15 probe (Hu-Friedy) and tweezers]
5. Head cap
6. Surgical gloves
7. Patient drape
8. BP blade handle and blades no. 12, 15
9. Periosteal elevator (GDC)
10. Adams tissue holding forceeps (GDC)
11. A set of surgical curettes (Hu-Friedy)
12. Sutures (4-0) non-resorabable braided prolene.
13. Table top L-PRF centrifuge (Remi centrifuge R303).
14. Coe-pack dressing (GC AMERICA INC.)
15. Castroviejo scissors, needle holder (GDC)

Study design:

12 patients fulfilling the above mentioned inclusion and exclusion criteria were selected from the O.P.D of the department. The treatment procedure was fully explained to the patients and a duly signed consent form was taken from each patient before initiating the procedure. 30

sites fulfilling the criteria were evaluated and then randomly distributed into two groups viz. Group A and Group B.

- Group A – localized marginal tissue recession treated with PUROS DERMIS with Coronally Advanced Flap (CAF)
- Group B – localized marginal tissue recession treated with L-PRF with Coronally Advanced Flap (CAF)

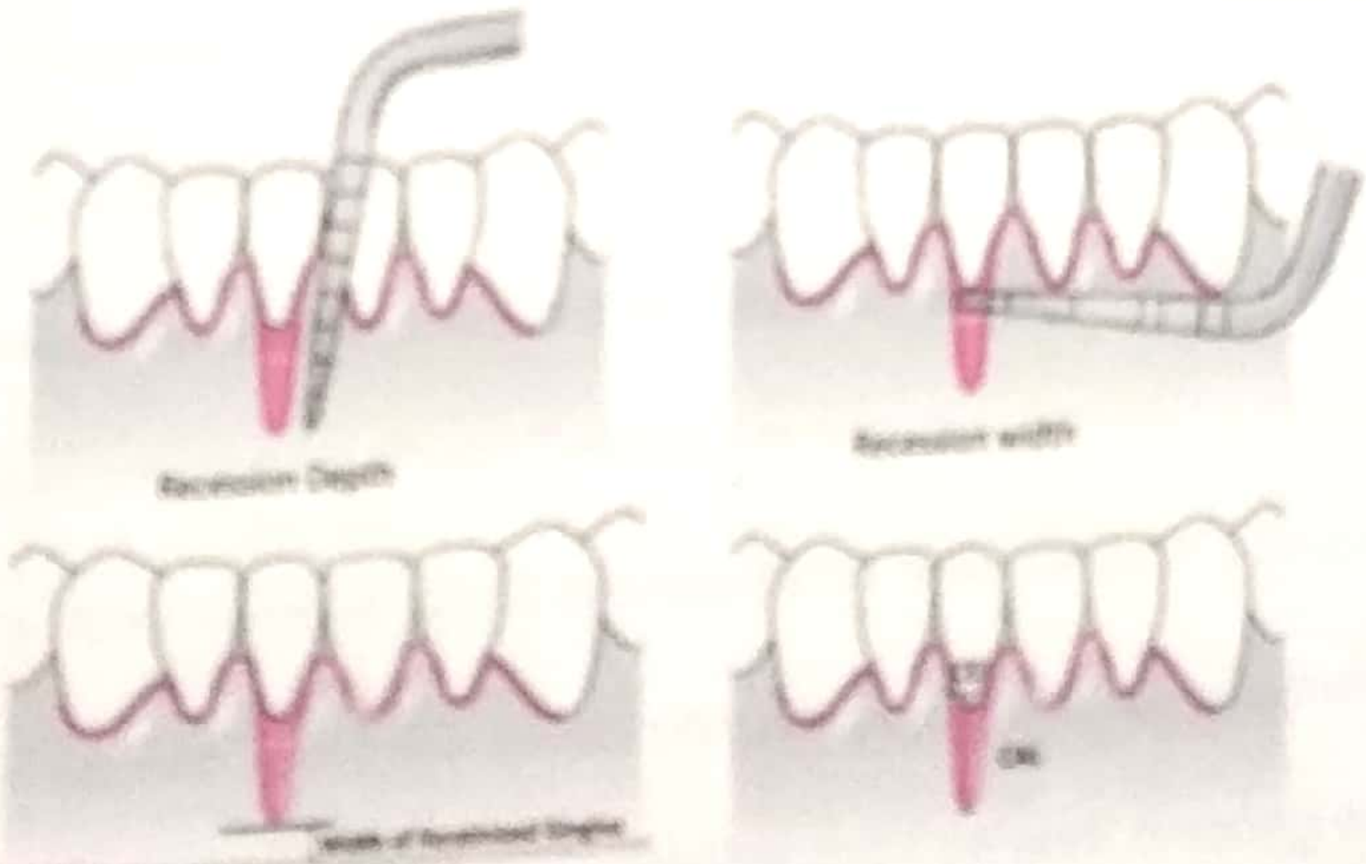
At Baseline following parameters were recorded:

Clinical parameter:

- Plaque Index[87]

Gingival Recession:-

- Recession depth: from CEJ to free gingival margin
- Recession width: from horizontal dimension of gingival defect.
- Probing pocket depth.
- Clinical Attachment Level
- Width of Keratinized Gingiva



Surgical procedure

All the subjects underwent Phase I therapy. They were recalled after one month, those who fulfilled all inclusion and exclusion criteria were included in the study.

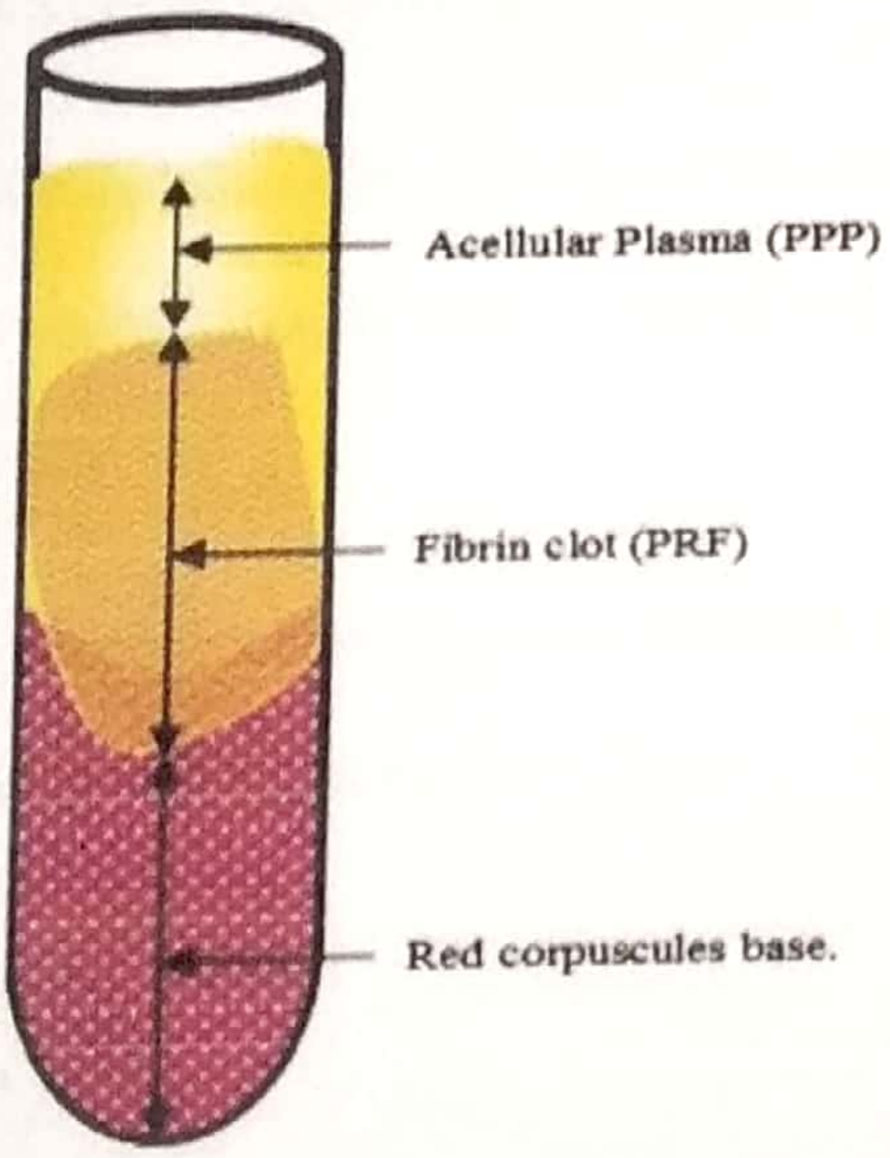
12 patients were selected from the OPD of the department fulfilling all inclusion and exclusion criteria. 30 gingival recession sites were selected and divided into two groups randomly and treated by either Puros Dermis or L-PRF. All patients were informed about the procedure and a duly signed consent form was taken from before initiating the surgical treatment.

All clinical and radiographic parameters were recorded as Baseline readings. The patients were recalled for surgical procedures. They were asked for a pre-procedural rinse with 10 ml of 0.2% chlorhexidine gluconate solution for 1 minute. The surgical procedure was performed under aseptic conditions.

The operative sites were anesthetized with a solution of 2% lignocaine with 1:200,000 adrenaline. Incisions were given for a CAF procedure. A sulcular incision was made at the recession and extended with two vertical releasing incision in correspondence to the line angles of adjacent teeth; the interdental papilla was preserved as much as possible. A full thickness flap was elevated up to the alveolar crest, and then a partial thickness flap was raised extending beyond the muco-gingival junction to facilitate flap mobility and easy coronal positioning. Puros Dermis was trimmed according to the size of the defect, hydrated in a saline solution for 60 seconds as per manufacturer's instructions, and placed over the root surface. A 5-0 silk suture secured the flaps to the allograft and simultaneously to the surface of the neighboring papillae and Coe pack dressing was placed.

For patients in Group B, similar incisions for CAF were given. To obtain PRF, 10 ml blood was drawn from the median cubital vein from the cubital fossa and was placed in sterilized test tubes without anticoagulant and centrifuged immediately at 3000 rpm for 10 min using the centrifuge (Remi centrifuge R303). The resultant product consisted of the following three layers

1. Topmost layer – a cellular platelet poor plasma
2. Middle – Leukocyte and Platelet Rich Fibrin (L-PRF)
3. Bottom layer – Red blood corpuscles



The acellular plasma layer was discarded and the PRF clot was retrieved along with the associated RBC layer with tweezers from the test tube. The RBC Layer just below PRF-RBC junction was cut using scissors. The PRF clot was then placed on a glass slab over a gauze piece and gently compressed using another glass slab to remove excess serum. The

ARMAMENTARIUM FOR DIAGNOSIS, SCALING & ROOT PLANING

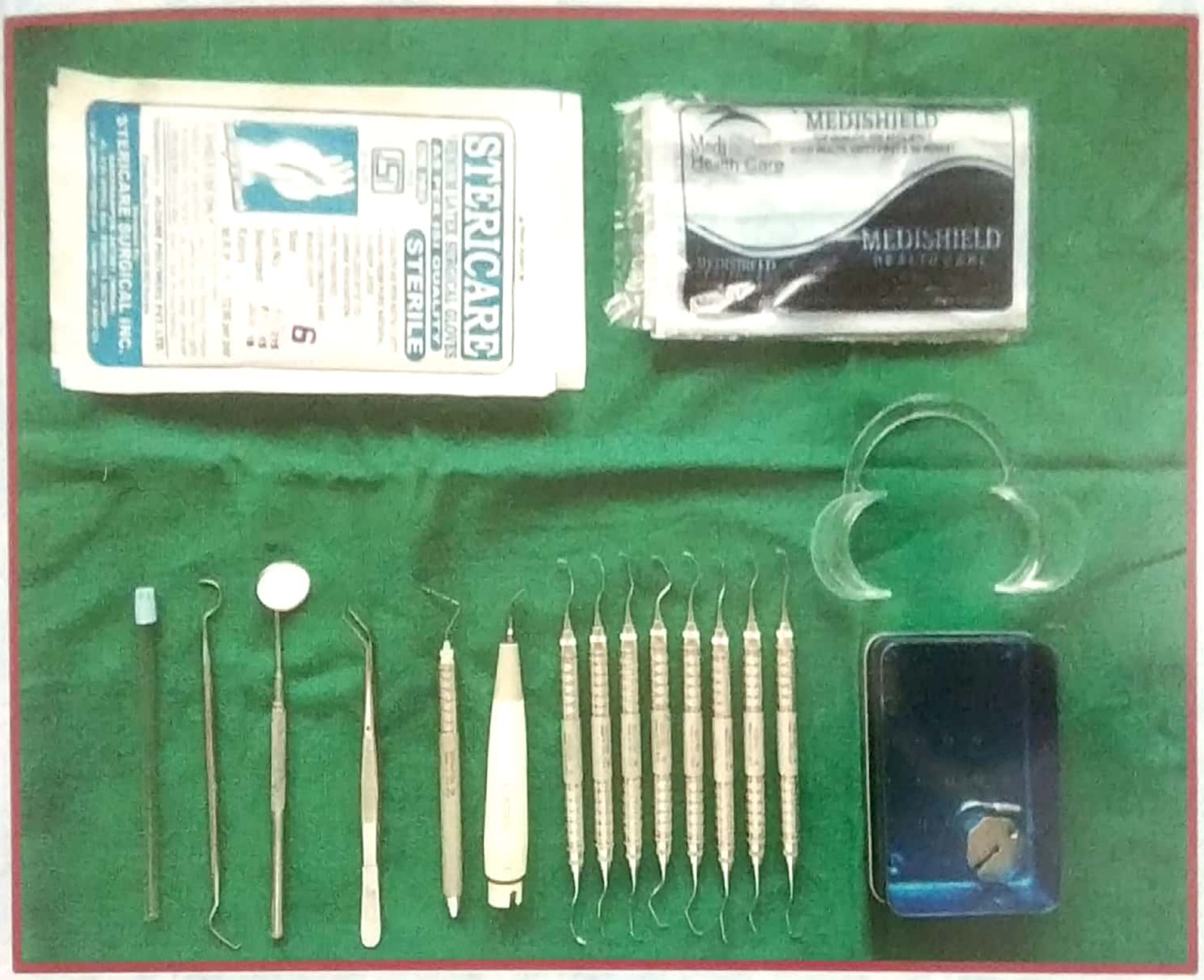


PLATE NO. I

ARMAMENTARIUM FOR SURGICAL PROCEDURE

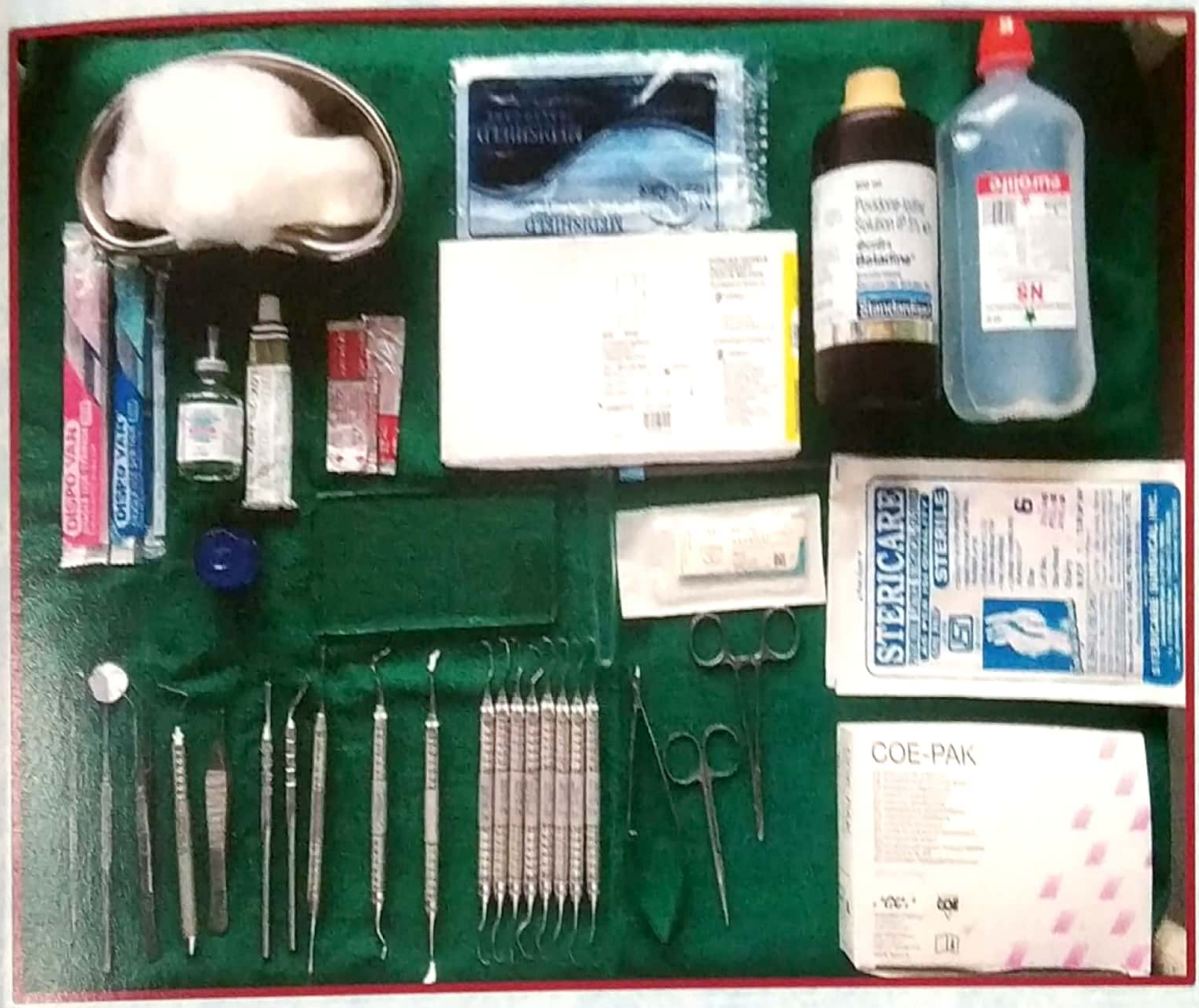
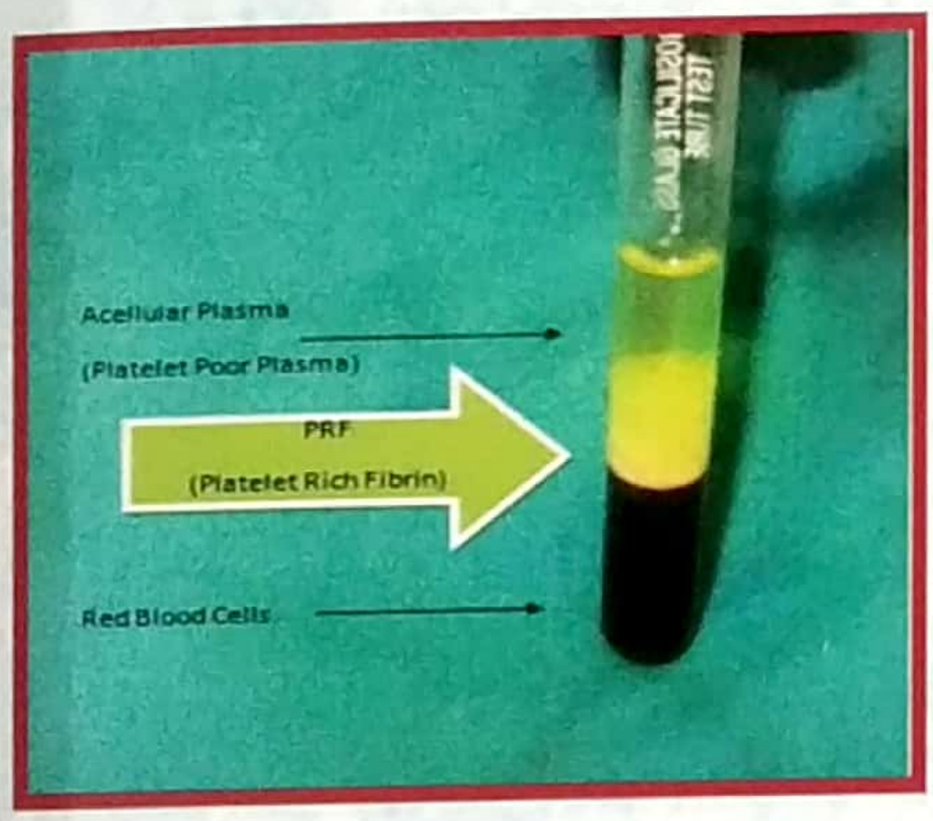


PLATE NO. II

L-PRF PREPARATION



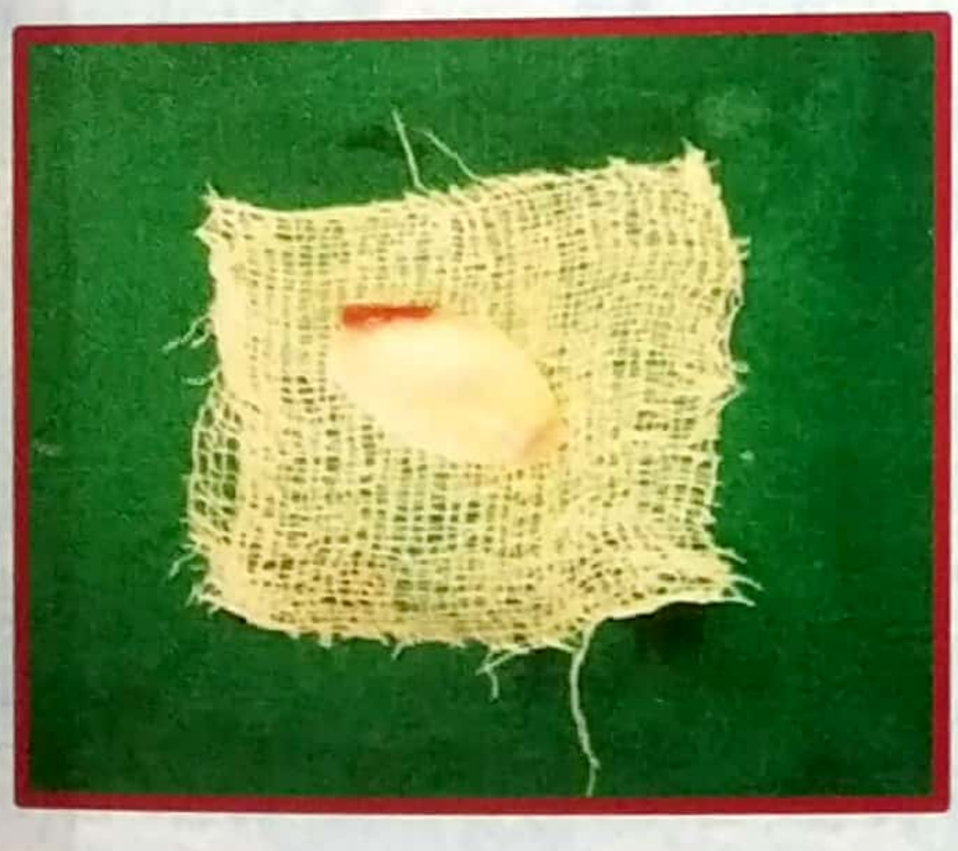


PLATE NO. III

PUROS DERMIS

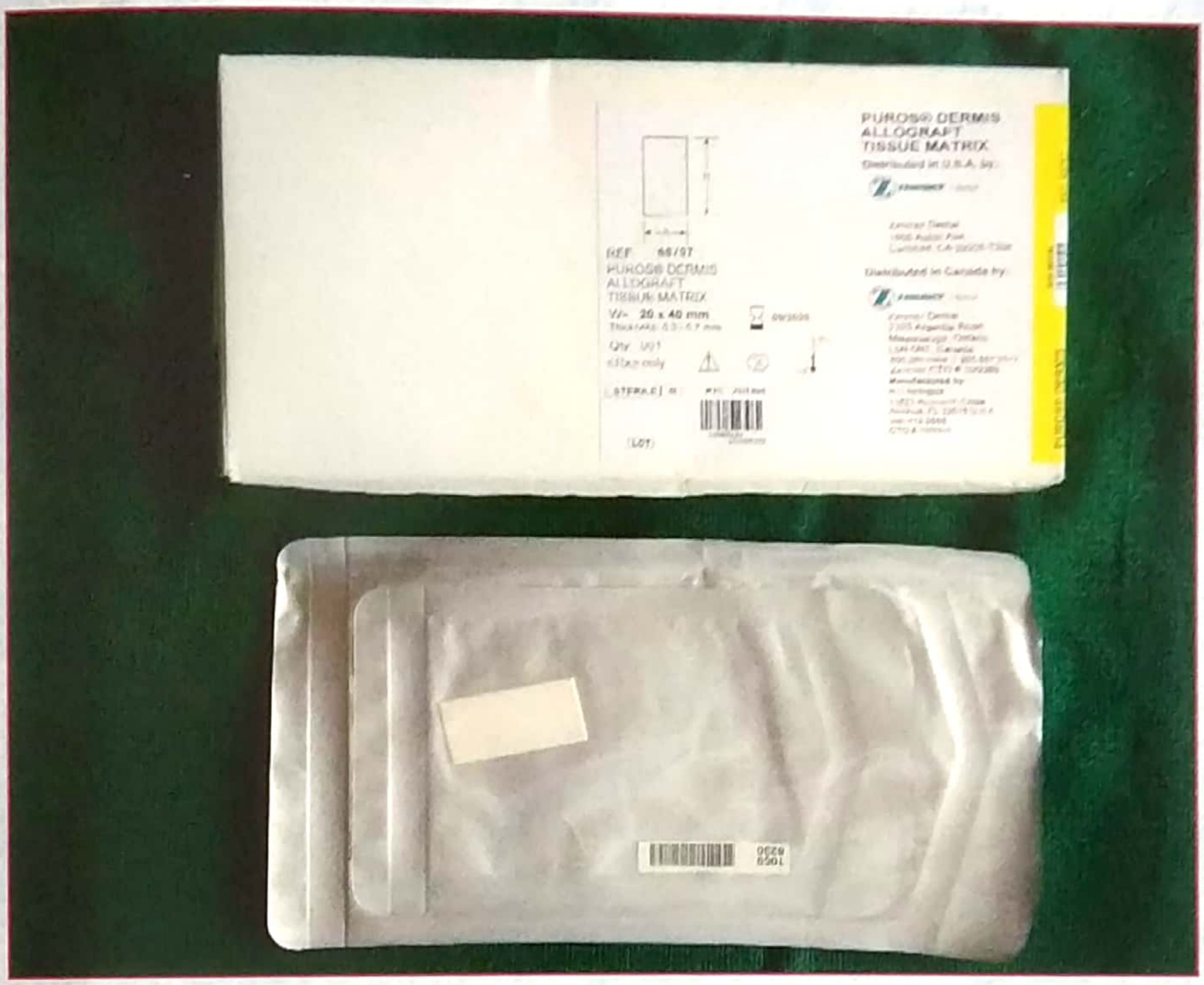
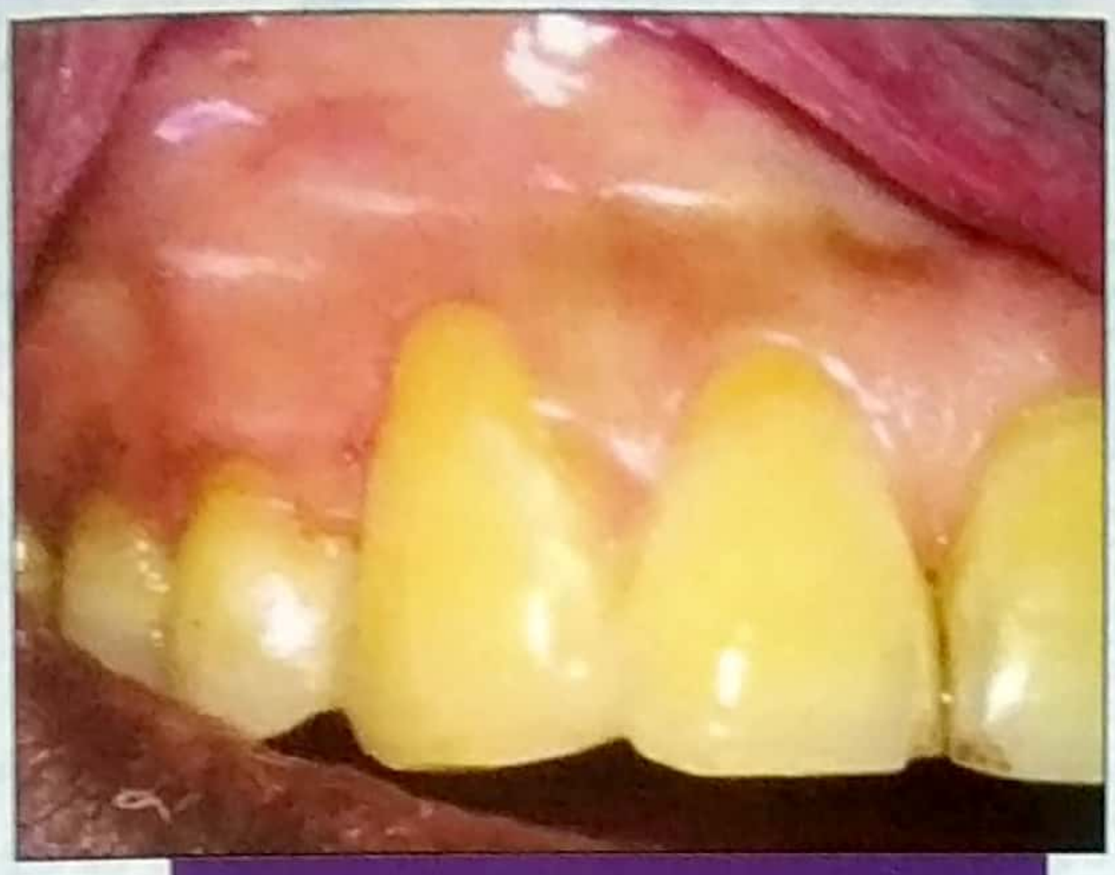
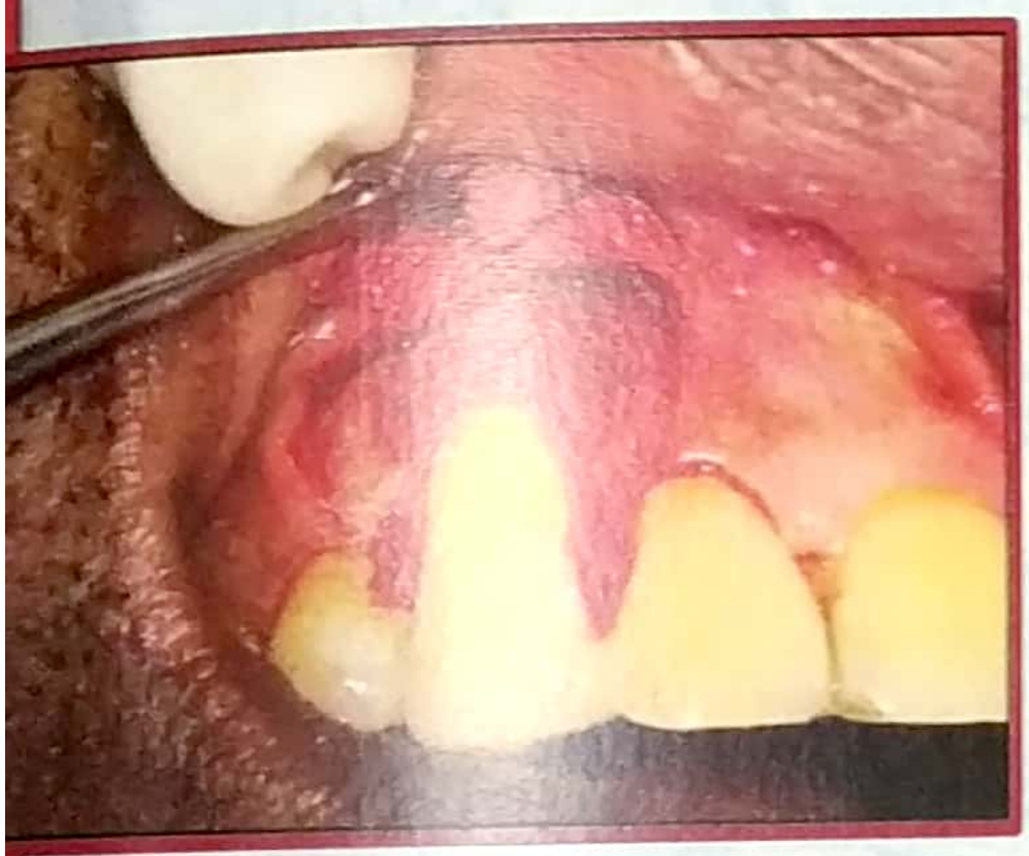


PLATE NO.IV

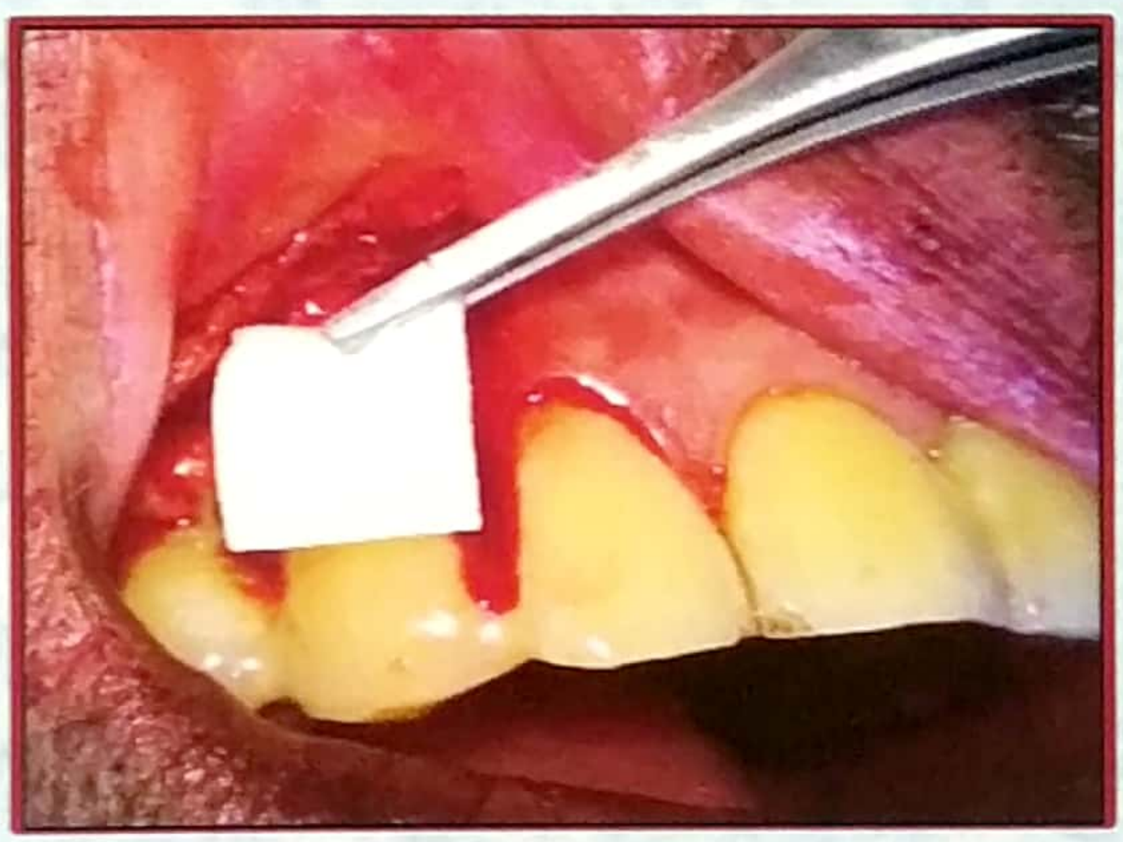
Surgical procedure – GROUP A



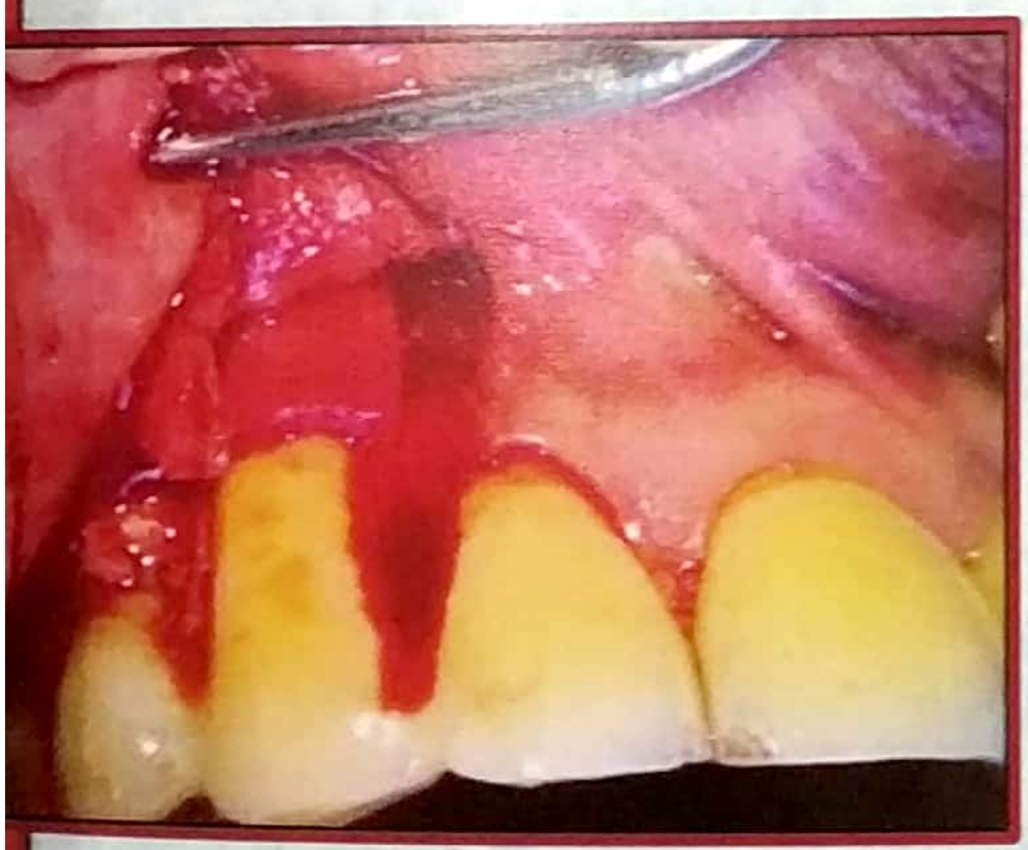
Pre-op



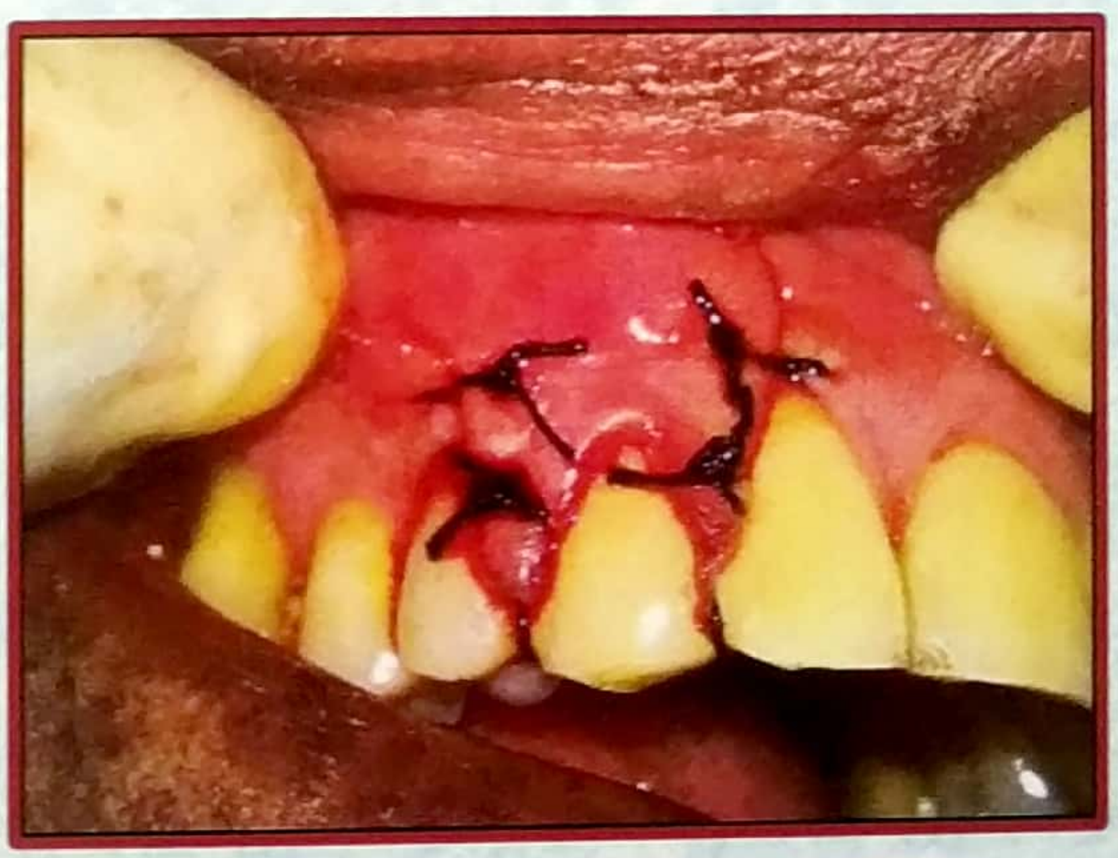
Flap reflection



Puros Dermis trimmed



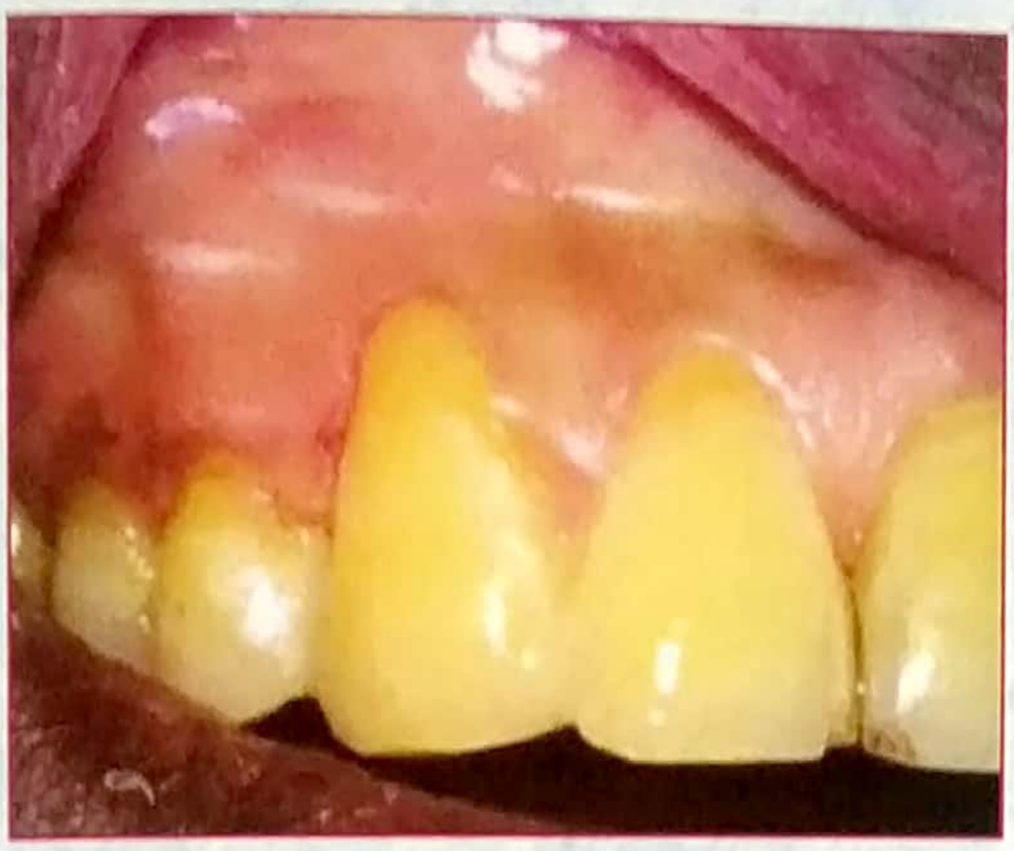
Puros Dermis placement



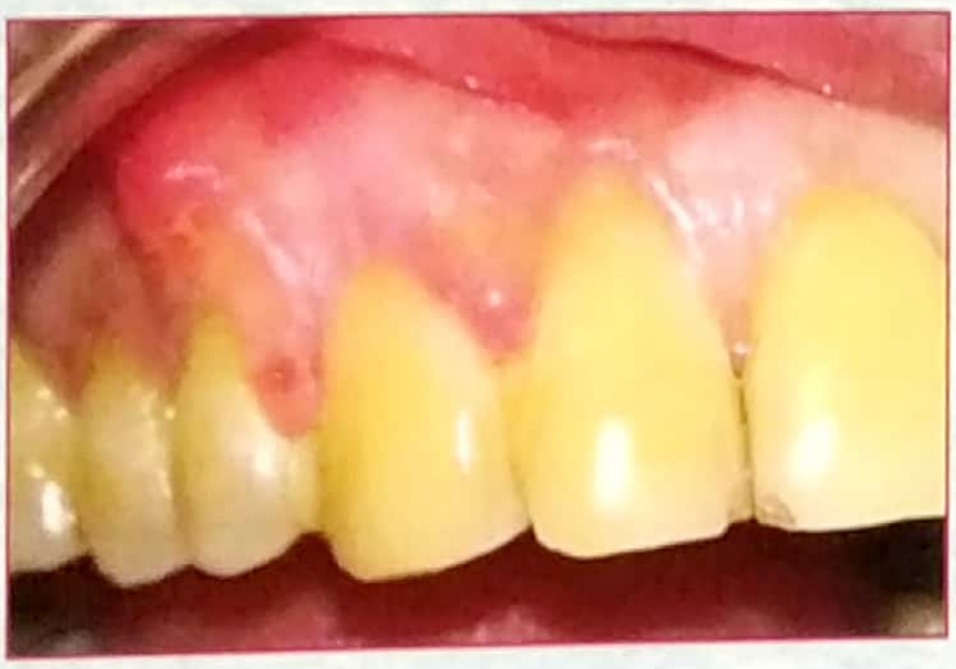
Suture placement

PLATE NO.V

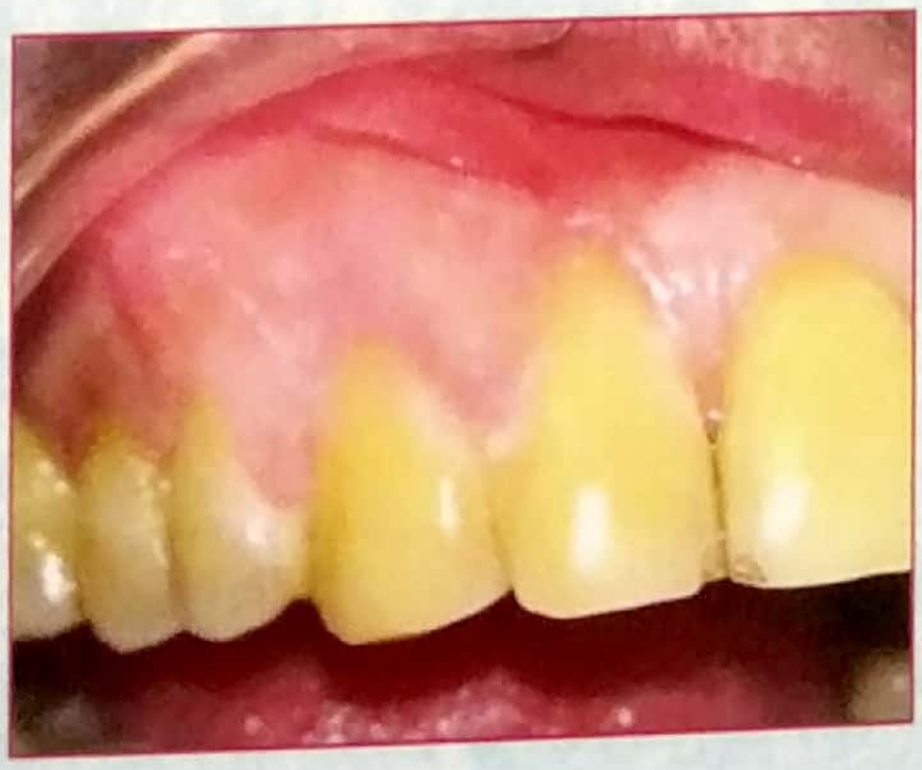
RECESSION COVRAGE GROUP A



Baseline



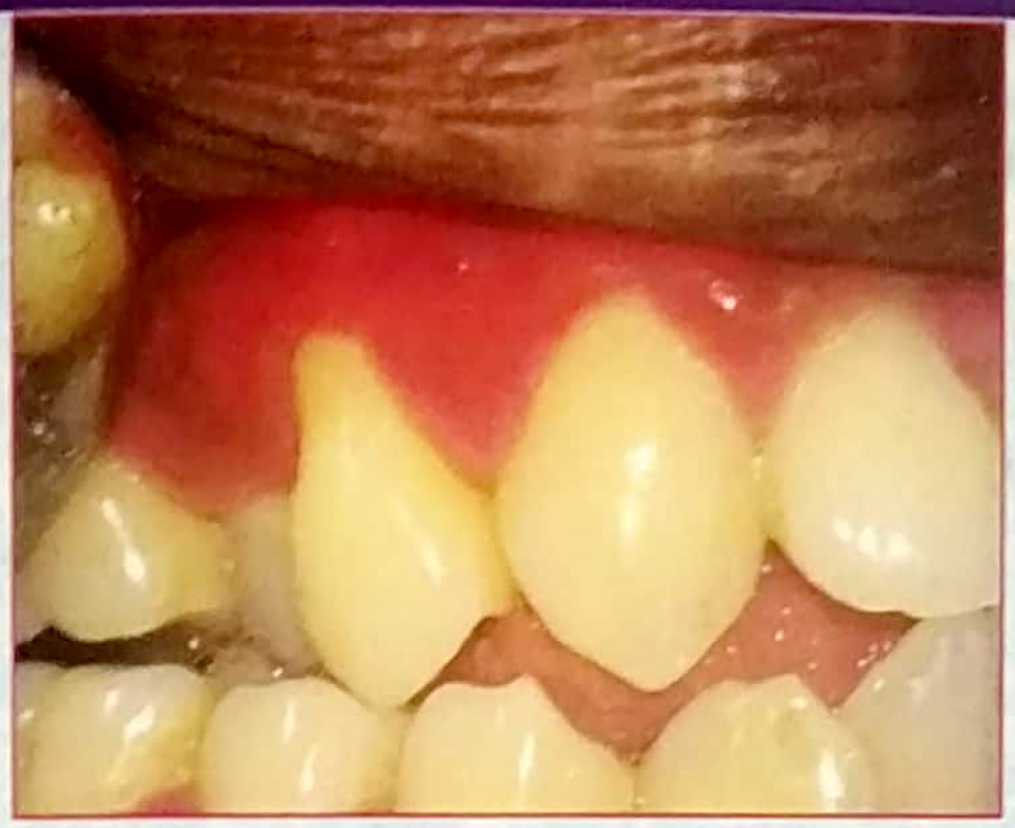
3 months Post-operatively



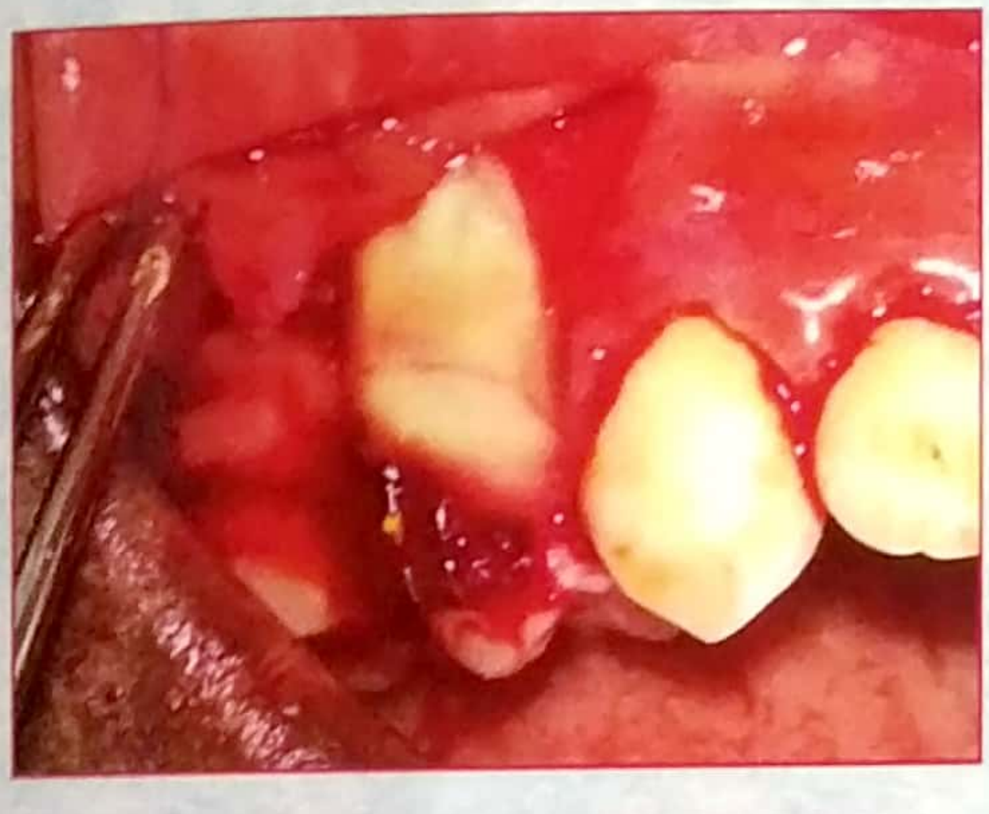
6 months Post-operatively

PLATE NO. VI

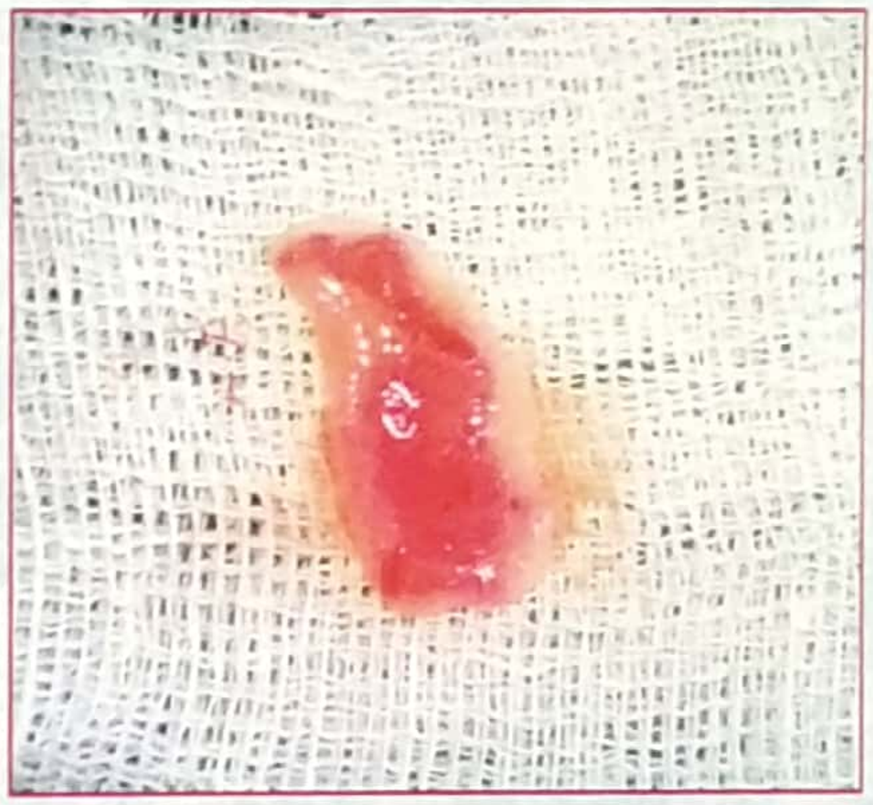
Surgical procedure - GROUP B



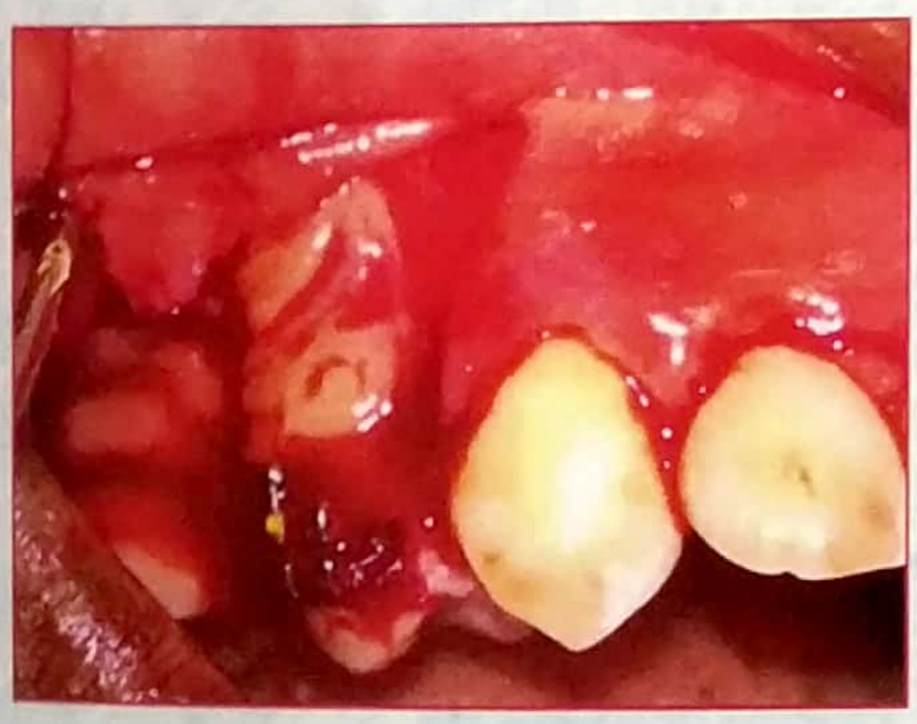
Pre-op



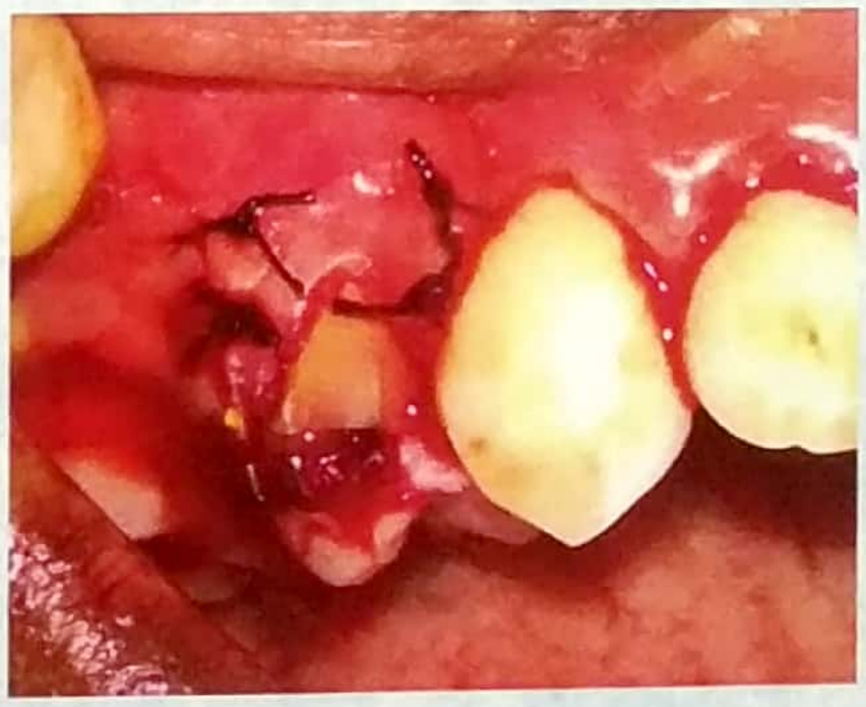
Flap reflection



PRF prepared



PRF placement



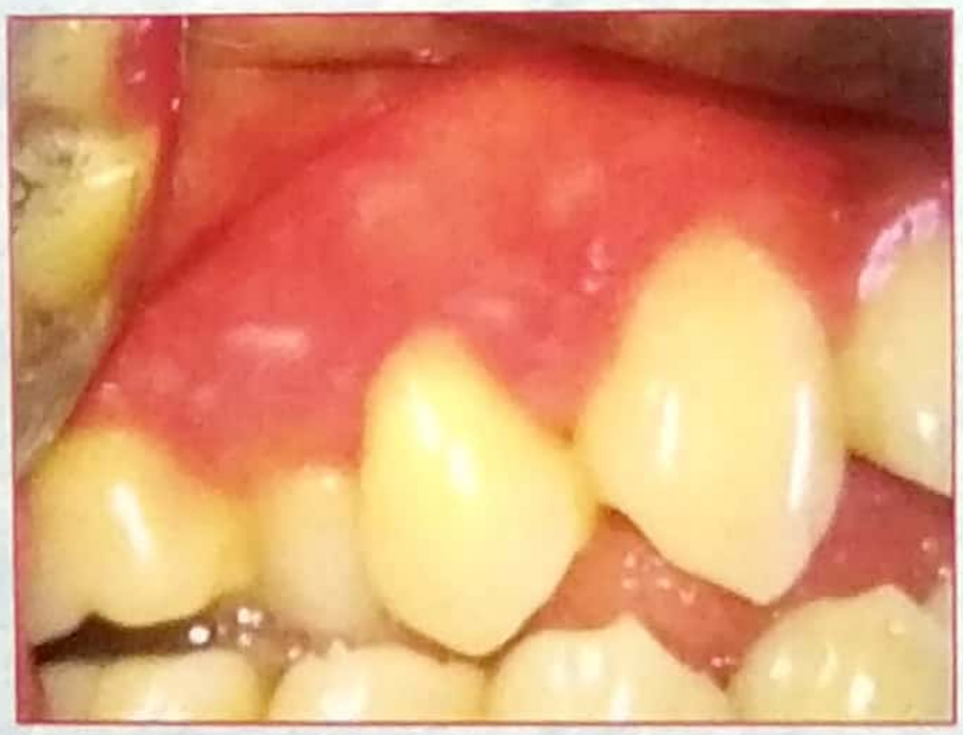
Sutures placed

PLATE NO.VII

RECESSION COVERAGE GROUP B

Baseline

3 months Post-operatively



6 months Post-operatively

PLATE NO. VIII

Observations & Results

Statistical analysis

The results are presented in mean±SD. The Unpaired t-test was used to compare the study parameters between the groups. The Paired t-test was used to compare the mean change in study parameters from baseline to subsequent time periods. The p-value<0.05 was considered significant. All the analysis was carried out on SPSS 16.0 version (Chicago, Inc., USA). All details are enclosed in Appendix - VI

Clinical parameters

1. Comparison of PI between Group A and Group B at Baseline, 3 months and 6 months (post- operatively)

Inter-Group (Table 1a, Graph 1a):-

PI score were recorded at these time intervals in both the groups.

At baseline, the mean PI reading for Group A was 2.05±0.55 and Group B was 2.21±0.67. The p-value for this was 0.46, which is statistically non-significant.

3 months post-operatively, the mean PI reading for Group A was 1.20±0.19and Group B was 1.71±0.52. The p-value for this was 0.001 which is statistically significant.

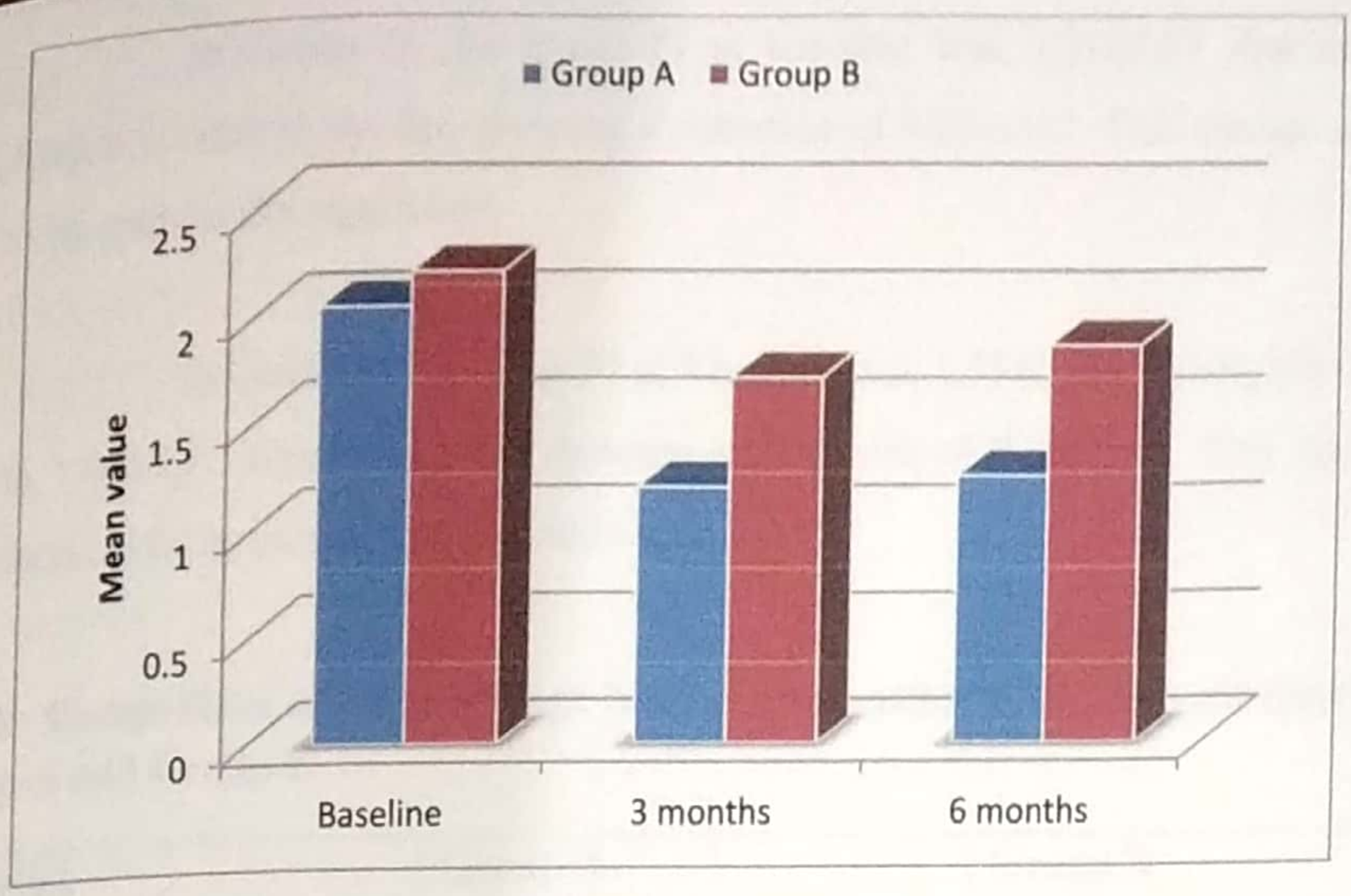
At 6 months post-operatively the mean PI reading for Group A was 1.25±0.16 and Group B was 1.86±0.51. The p-value for this was 0.0001 which is statistically significant.

Table-1a: Comparison of PI between the groups across the time periods

Time period	Group A (n=15)	Group B (n=15)	p-value[1]
Baseline	2.05±0.55	2.21±0.67	0.46
3 months	1.20±0.19	1.71±0.52	0.001*
6 months	1.25±0.16	1.86±0.51	0.0001*

[1]Unpaired t-test, *Significant

Table-1a & Graph-1a shows the comparison of PI between the groups across the time periods. There was no significant ($p>0.05$) in PI at baseline between the groups. PI became significantly ($p<0.01$) lower in Group A than Group B at 3 months and 6 months.



Graph- 1a: Comparison of plaque index between the groups across the time periods

<u>Intra-Group</u> (Table 1b, Graph 1b)

In Group A, the mean PI at baseline was 2.05±0.55 that reduced to 1.20±0.19 after 3 months, showing a reduction of 0.85±0.46. This change was found to be statistically significant.

In Group A, the mean PI at baseline was 2.05±0.55 that reduced to 1.25±0.16 after 6 months, showing a reduction of 0.80±0.54. This change was found to be statistically significant.

In Group A, the mean PI at 3 months was 1.20±0.19 that slightly increased to 1.25±0.16 after 6 months, showing an increase of 0.05±0.19. This change was found to be statistically non-significant.

In Group B, the mean PI at baseline was 2.21±0.67 that reduced to 1.71±0.52 after 3 months, showing a reduction of 0.50±0.48. This change was found to be statistically significant.

In Group B, the mean PI at baseline was 2.21±0.67 that reduced to 1.86±0.51 after 6 months, showing a reduction of 0.35±0.47. This change was found to be statistically significant.

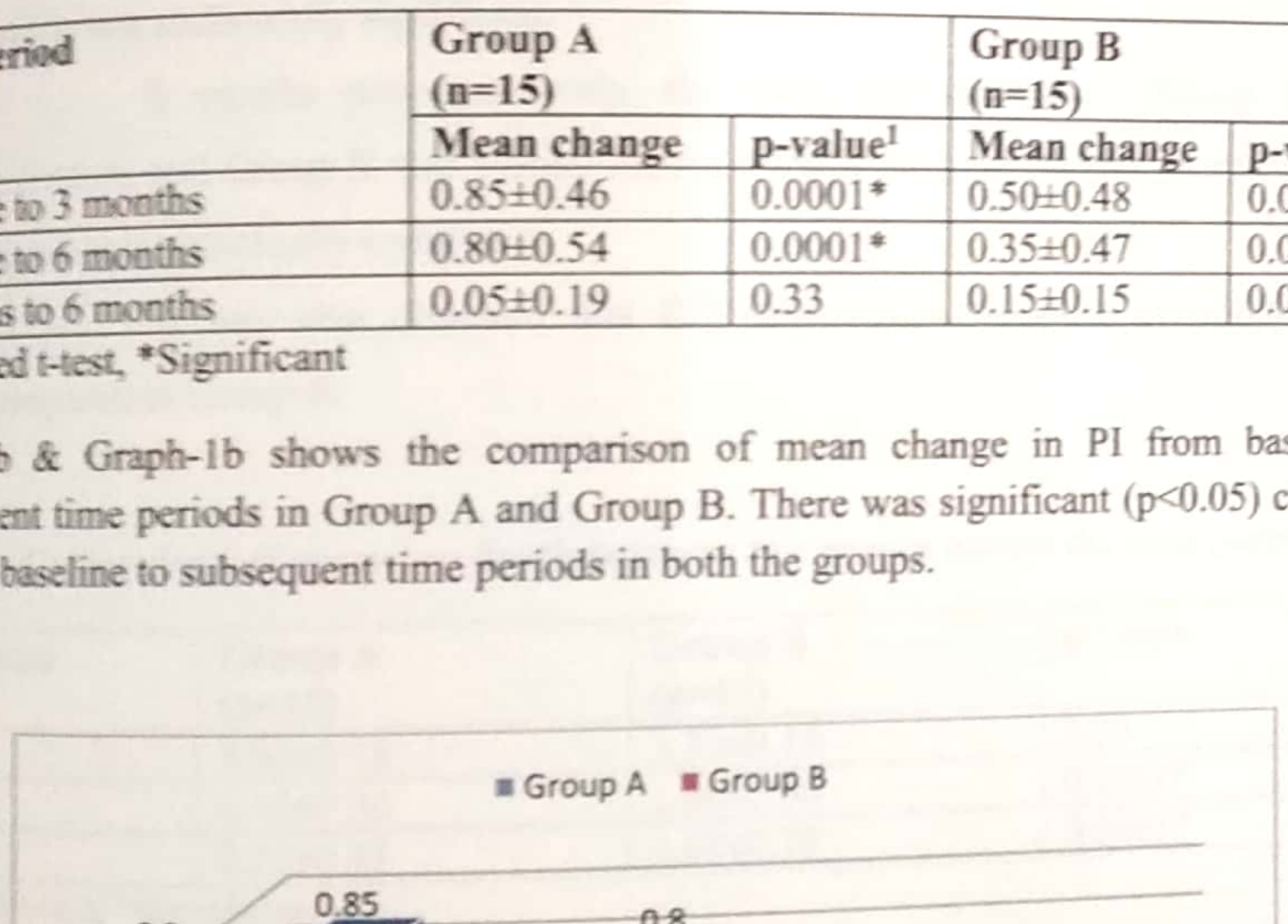
In Group B, the mean PI at 3 months was 1.71±0.52 that slightly increased to 1.86±0.51 after 6 months, showing an increase of 0.15±0.15. This change was found to be statistically significant.

Table-1b: Comparison of mean change in PI from baseline to subsequent time periods in Group A and Group B

Time period	Group A (n=15)		Group B (n=15)	
	Mean change	p-value[1]	Mean change	p-value[1]
Baseline to 3 months	0.85±0.46	0.0001*	0.50±0.48	0.001*
Baseline to 6 months	0.80±0.54	0.0001*	0.35±0.47	0.01*
3 months to 6 months	0.05±0.19	0.33	0.15±0.15	0.003*

[1]Unpaired t-test, *Significant

Table-1b & Graph-1b shows the comparison of mean change in PI from baseline to subsequent time periods in Group A and Group B. There was significant ($p<0.05$) change in PI from baseline to subsequent time periods in both the groups.



Graph 1b: Comparison of mean change in PI from baseline to subsequent time periods in Group A and Group B

2. Comparison of Recession Depth (RD) between Group A and Group B at Baseline, 3 months, and 6 months (post- operatively)

Inter-Group (Table 2a, Graph 2a)

Gingival recession depth was recorded at these time intervals in both groups.

At baseline the mean RD reading for Group A was 3.60±0.78 and Group B was 3.33±0.16, the p-value for both the groups was 0.33 that was statistically non-significant.

3 months post-operatively, the mean RD reading for Group A was 0.16±0.36 and Group B was 1.60±0.80, the p-value for both the groups was 0.0001, which was statistically significant.

6 months post-operatively, the mean RD reading for Group A was 0.23±0.41 and Group B was 1.66±0.79, the p-value for both the groups was 0.0001, which was statistically significant

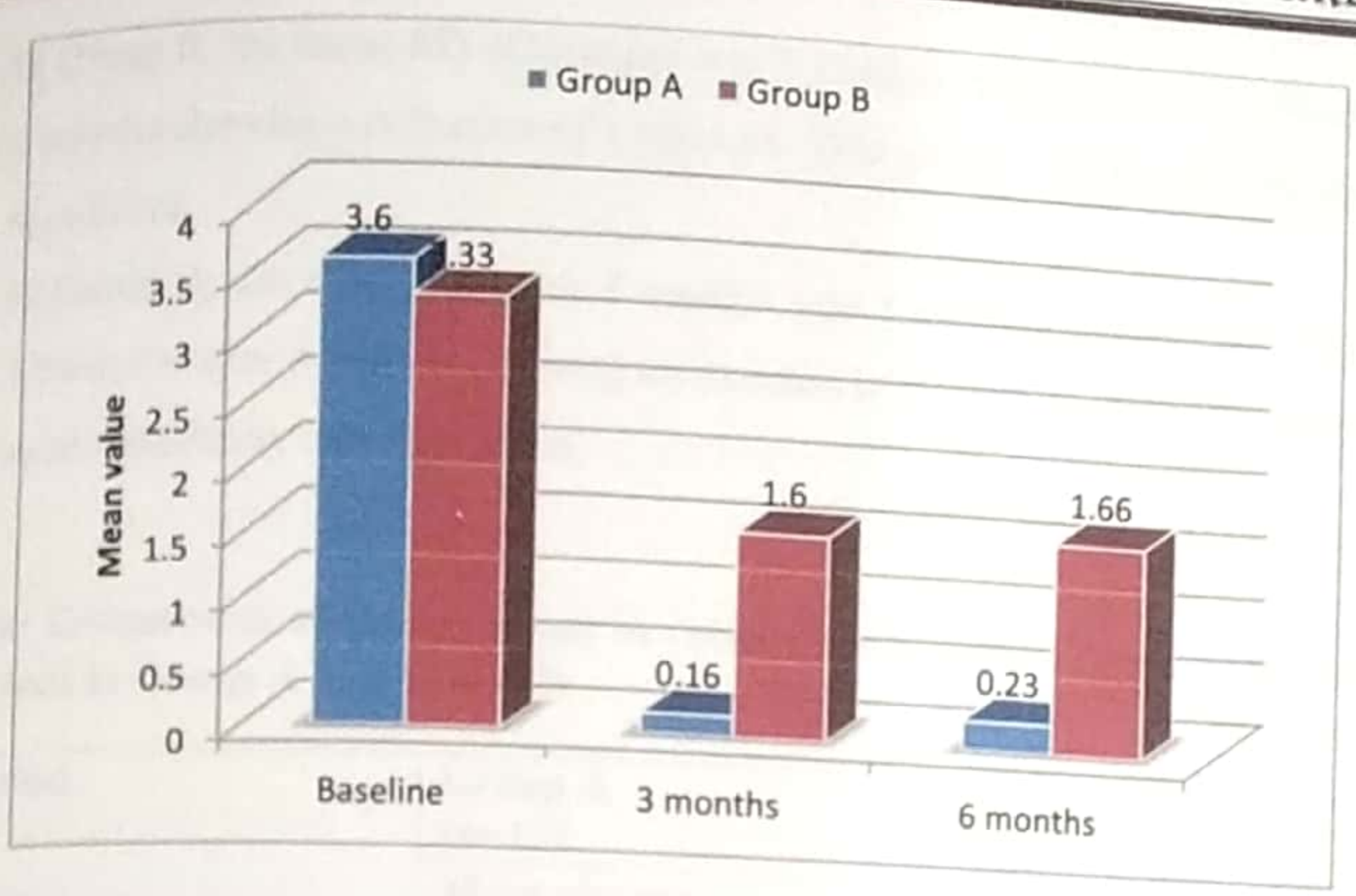
It was also observed that RD reduction was higher in Group A as compared to Group B.

ble-2a: Comparison of recession depth between the groups across the time periods

ne period	Group A (n=15)	Group B (n=15)	p-value[1]
seline	3.60±0.78	3.33±0.16	0.33
nonths	0.16±0.36	1.60±0.80	0.0001*
nonths	0.23±0.41	1.66±0.79	0.0001*

npaired t-test, *Significant

ble-2a & Graph-2a shows the comparison of recession depth between the groups across the e periods. There was no significant difference ($p>0.05$) in recession depth at baseline tween the groups. Recession depth reduced significantly ($p<0.01$) lower in Group A than oup B at 3 months and 6 months.



Graph 2a: Comparison of recession depth between the groups across the time periods

<u>Intra-Group</u> (Table 2b, Graph 2b)

In Group A, the mean RD at baseline was 3.60±0.78 that reduced to 0.16±0.36 after 3 months showing a reduction of 3.43±0.77. This change was found to be statistically significant.

In Group A, the mean RD at baseline was 3.60±0.78 that reduced to 0.23±0.41, after 6 months showing a reduction of 3.36±0.81. This change was found to be statistically significant

In Group A, the mean RD after 3 months was 0.16±0.36 that slightly increased to 0.23±0.41, after 6 months showing an increase of 0.06±0.25. This change was found to be statistically non-significant

In Group B, the mean RD at baseline was 3.33±0.16 that reduced to 1.60±0.80 after 3 months showing a reduction of 1.73±1.09. This change was found to be statistically significant.

In Group B, the mean RD at baseline was 3.33±0.16 that reduced to 1.66±0.79, after 6 months showing a reduction of 1.66±1.11. This change was found to be statistically significant.

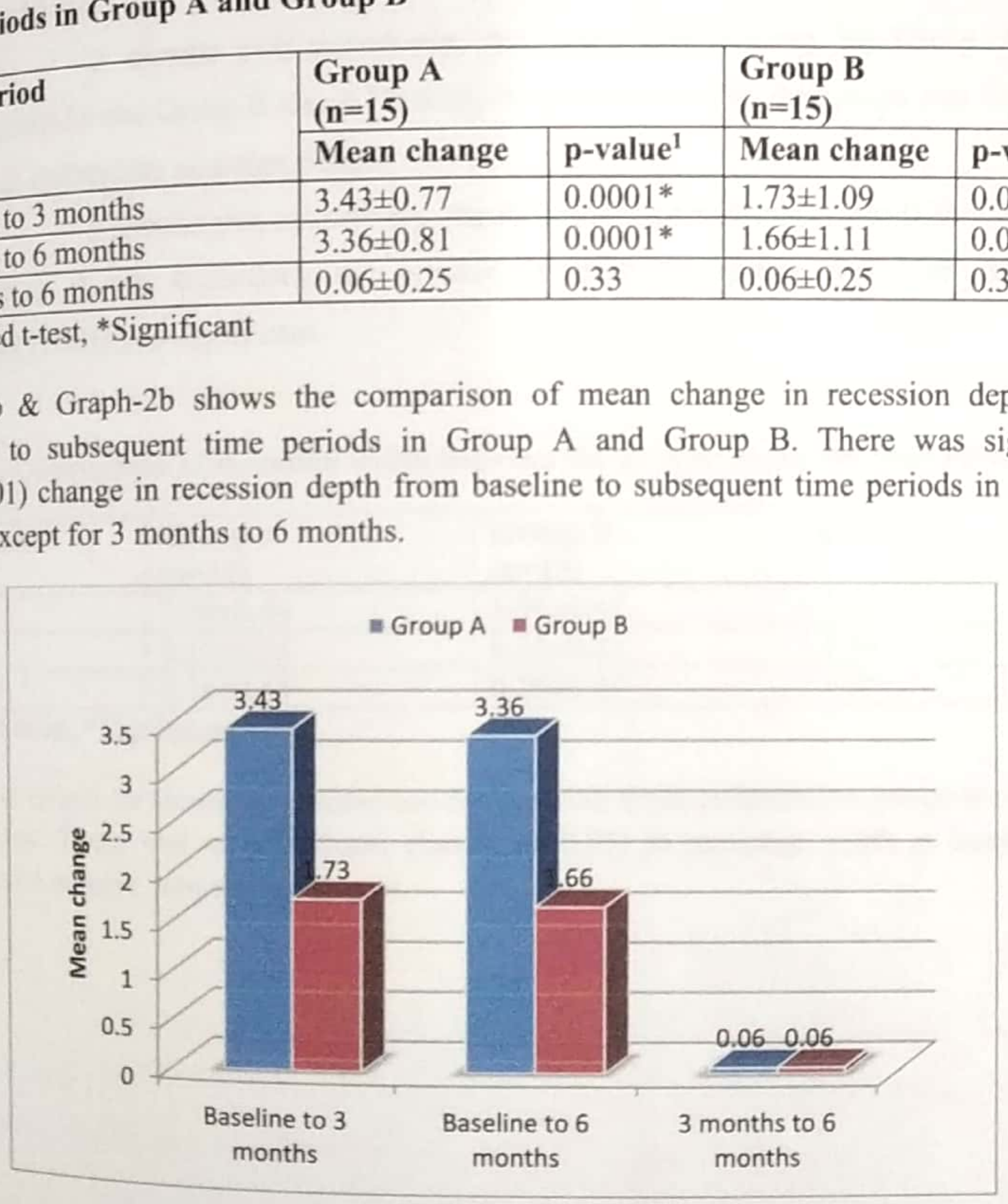
In Group B, the mean RD after 3 months was 1.60±0.80 that slightly increased to 1.66±0.79, after 6 months showing an increase of 0.06±0.25. This change was found to be statistically non-significant

Table-2b: Comparison of mean change in recession depth from baseline to subsequent time periods in Group A and Group B

Time period	Group A (n=15)		Group B (n=15)	
	Mean change	p-value[1]	Mean change	p-value[1]
Baseline to 3 months	3.43±0.77	0.0001*	1.73±1.09	0.0001*
Baseline to 6 months	3.36±0.81	0.0001*	1.66±1.11	0.0001*
3 months to 6 months	0.06±0.25	0.33	0.06±0.25	0.33

[1]Unpaired t-test, *Significant

Table-2b & Graph-2b shows the comparison of mean change in recession depth from baseline to subsequent time periods in Group A and Group B. There was significant (p=0.0001) change in recession depth from baseline to subsequent time periods in both the groups except for 3 months to 6 months.



Graph 2b: Comparison of mean change in recession depth from baseline to subsequent time periods in Group A and Group B

3. Comparison of Recession Width (RW) between Group A and Group B at Baseline, 3 months and 6 months (post- operatively)

Inter-Group (Table 3a, Graph 3a):

Gingival recession width was recorded at these time intervals in both groups.

At baseline the mean RW reading for Group A was 3.36±0.44and Group B was 3.36±0.44, the p-value for both the groups was 1.00 that was statistically non-significant.

3 months post-operatively, the mean RW reading for Group A was 0.13±0.35 and Group B was 0.13±0.35, the p-value for both the groups was 1.00 that was statistically non-significant.

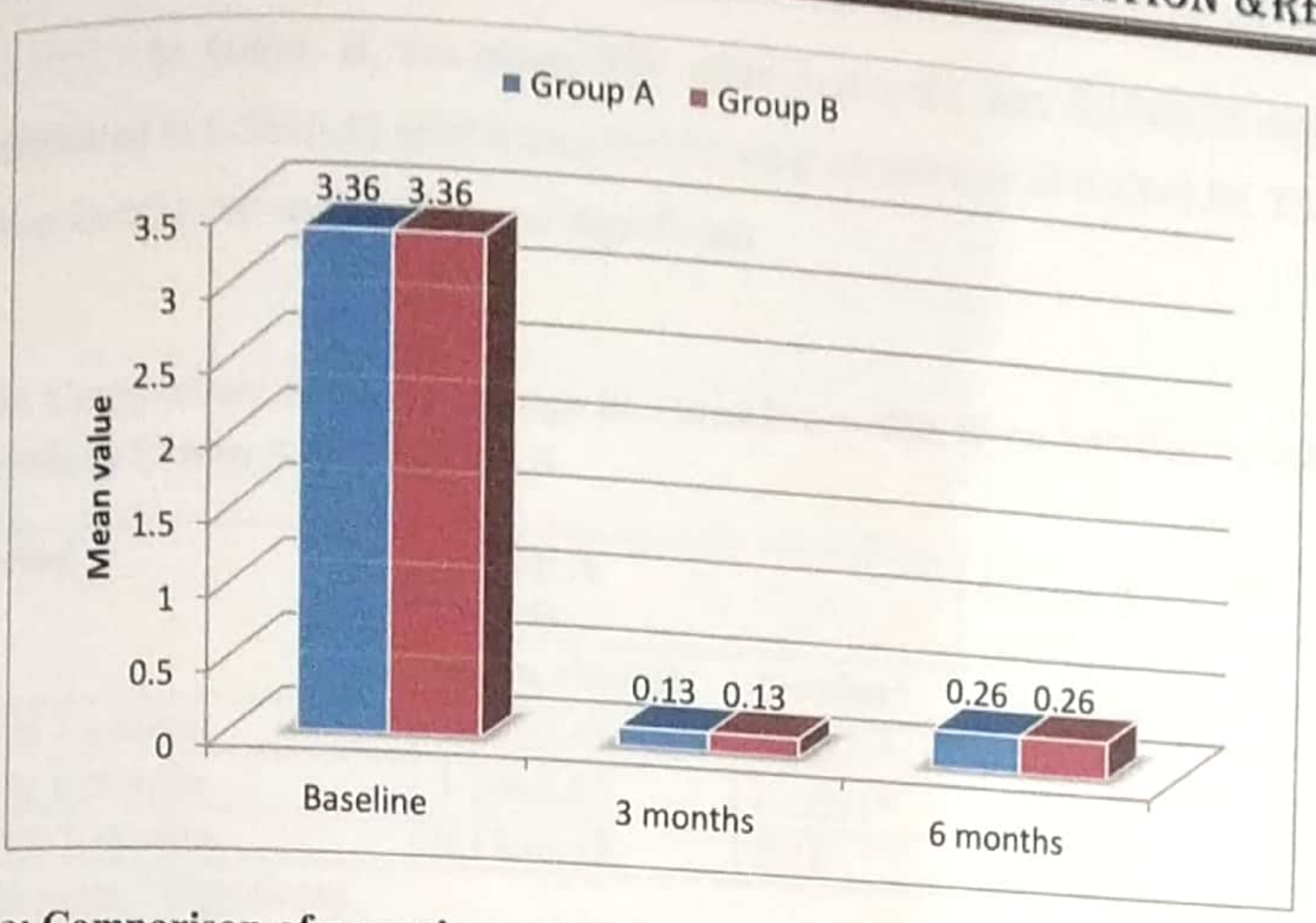
6 months post-operatively, the RW reading for Group A was 0.26±0.45 and Group B was 0.26±0.45, the p-value for both the groups was 1.00 that was statistically non-significant.

Table-3a: Comparison of recession width between the groups across the time periods

Time period	Group A (n=15)	Group B (n=15)	p-value[1]
Baseline	3.36±0.44	3.36±0.44	1.00
3 months	0.13±0.35	0.13±0.35	1.00
6 months	0.26±0.45	0.26±0.45	1.00

[1]Unpaired t-test, *Significant

Table-3a & Graph-3a shows the comparison of recession width between the groups across the time periods. There was no significant change ($p>0.05$) in recession width at baseline, 3 months and 6 months between the groups.



Graph 3a: Comparison of recession width between the groups across the time periods

<u>Intra-Group</u> (Table 3b, Graph 3b)

In Group A, the mean RW at baseline was 3.36±0.44 that reduced to 0.13±0.35 after 3 months showing a reduction of 3.23±0.65. This change was found to be statistically significant.

In Group A, the mean RW at baseline was 3.36±0.44 that reduced to 0.26±0.45 after 6 months showing a reduction of 3.10±0.63. This change was found to be statistically significant

In Group A, the mean RW after 3 months was 0.13±0.35 that increased slightly to 0.26±0.45 after 6 months showing an increase of 0.13±0.35. This change was found to be statistically non-significant.

In Group B, the mean RW at baseline was 3.36±0.44 that reduced to 0.13±0.35 after 3 months showing a reduction of 3.23±0.65. This change was found to be statistically significant.

In Group B, the mean RW at baseline was 3.36±0.44 that reduced to 0.26±0.45 after 6 months showing a reduction of 3.10±0.63. This change was found to be statistically significant

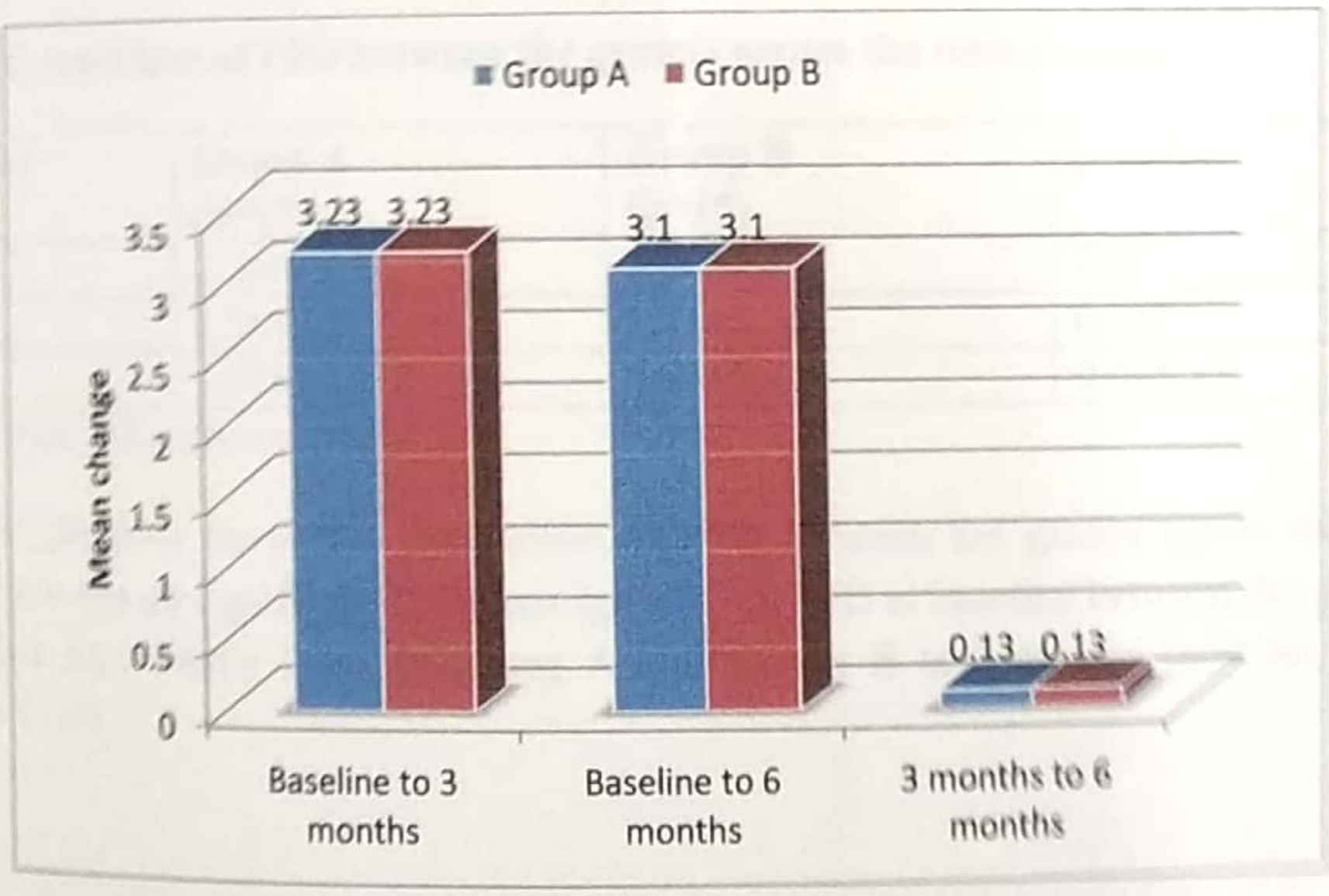
In Group B, the mean RW after 3 months was 0.13±0.35 that slightly increased to 0.26±0.45 after 6 months showing an increase of 0.13±0.35. This change was found to be statistically non-significant

Table-3b: Comparison of mean change in recession width from baseline to subsequent time periods in Group A and Group B

Time period	Group A (n=15)		Group B (n=15)	
	Mean change	p-value[1]	Mean change	p-value[1]
Baseline to 3 months	3.23±0.65	0.0001*	3.23±0.65	0.0001*
Baseline to 6 months	3.10±0.63	0.0001*	3.10±0.63	0.0001*
3 months to 6 months	0.13±0.35	0.16	0.13±0.35	0.33

[1]Unpaired t-test, *Significant

Table-3b & Graph-3b shows the comparison of mean change in recession width from baseline to subsequent time periods in Group A and Group B. There was significant (p=0.0001) change in recession width from baseline to subsequent time periods in both the groups except for 3 months to 6 months.



Graph 3b: Comparison of mean change in recession width from baseline to subsequent time periods in Group A and Group B

4. Comparison of Pocket Probing Depth (PPD) between Group A and Group B at Baseline, 3 months and 6 months (post- operatively)

Inter-Group (Table 4a, Graph 4a):

Pocket probing depth was recorded at these time intervals in both groups

At baseline, the mean PPD reading for Group A was 2.30±0.70 and Group B was 2.50±0.82. The p-value for this was 0.48 which is statistically non-significant.

3 months post-operatively, the mean PPD reading for Group A was 1.56±0.17 and Group B was 1.76±0.31. The p-value for this was 0.04, which is statistically significant.

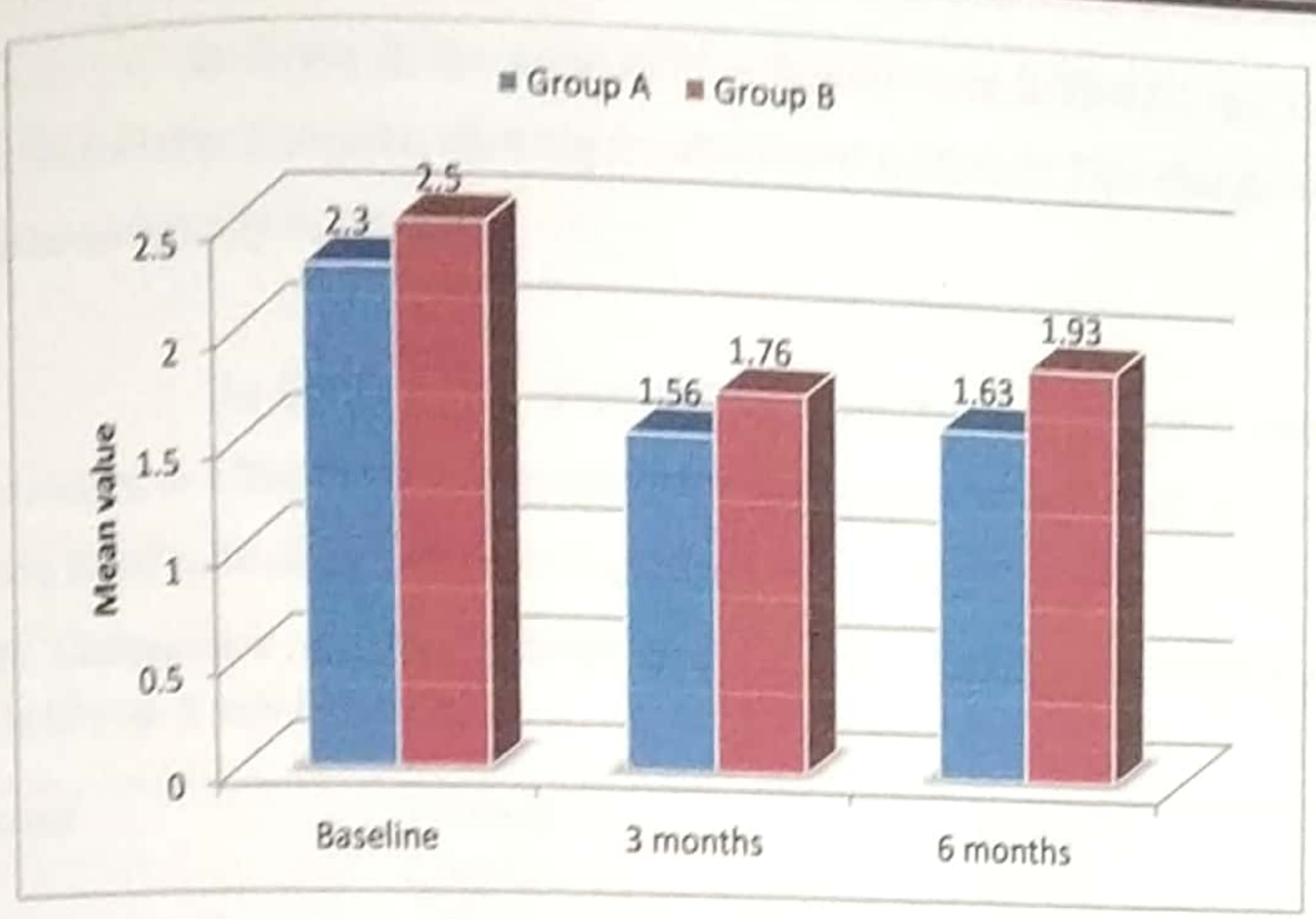
At 6 months post-operatively the mean PPD readings for Group A was 1.63±0.22 and Group B was 1.93±0.41. The p-value for this was 0.02 which is statistically significant.

Table-4a: Comparison of PPD between the groups across the time periods

Time period	Group A (n=15)	Group B (n=15)	p-value[1]
Baseline	2.30±0.70	2.50±0.82	0.48
3 months	1.56±0.17	1.76±0.31	0.04*
6 months	1.63±0.22	1.93±0.41	0.02*

[1]Unpaired t-test, *Significant

Table-4a & Graph-4a shows the comparison of PPD between the groups across the time periods. There was no significant difference (p>0.05) in PPD at baseline between the groups. PPD became significantly lower in Group A than Group B at 3 months (p=0.04) and 6 months (p=0.02).



Graph 4a: Comparison of PPD between the groups across the time periods

<u>Intra-Group</u> (Table 4b, Graph 4b)

In Group A, the mean PPD at baseline was 2.30±0.70 that reduced to 1.56±0.17 after 3 months, showing a reduction of 0.73±0.67. This change was found to be statistically significant.

In Group A, the mean PPD at baseline was 2.30±0.70 that reduced to 1.63±0.22after 6 months, showing a reduction of 0.66±0.64. This change was found to be statistically significant.

In Group A, the mean PPD at 3 month was 1.56±0.17 that slightly increased to 1.63±0.22after 6 months, showing an increase of 0.06±0.25. This change was found to be statistically non- significant.

In Group B, the mean PPD at baseline was 2.50±0.82 that reduced to 1.76±0.31 after 3 months, showing a reduction of 0.73±0.77.This change was found to be statistically significant.

In Group B, the mean PPD at baseline was 2.50±0.82 that reduced to 1.93±0.41after 6 months, showing a reduction of 0.56±0.56.This change was found to be statistically significant.

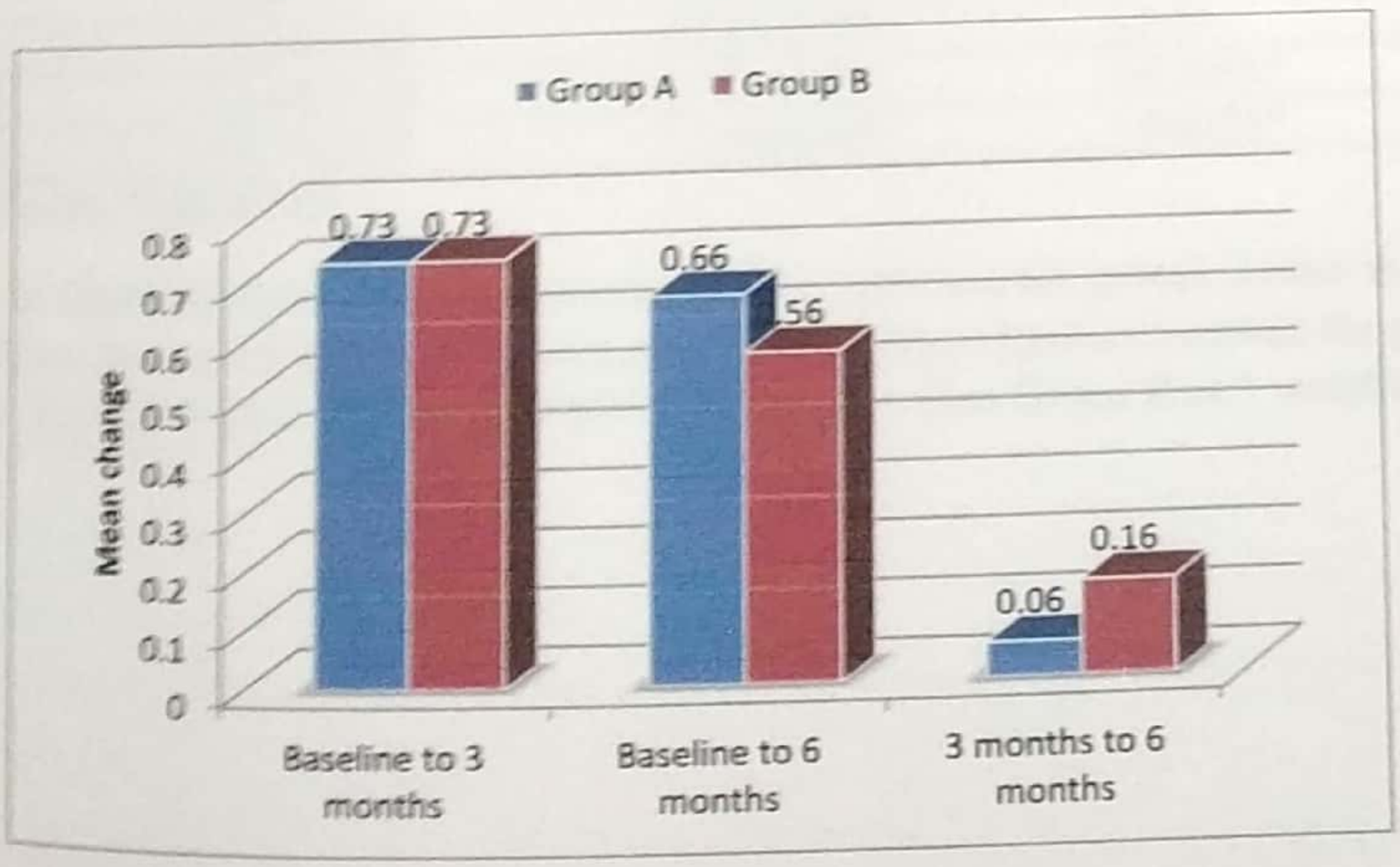
In Group B, the mean PPD at 3 months was 1.76±0.31 that slightly increased to 1.93±0.41after 6 months, showing an increase of 0.16±0.30. This change was found to be statistically non- significant

Table-4b: Comparison of mean change in PPD from baseline to subsequent time periods in Group A and Group B

Time period	Group A (n=15)		Group B (n=15)	
	Mean change	p-value[1]	Mean change	p-value[1]
Baseline to 3 months	0.73±0.67	0.001*	0.73±0.77	0.003*
Baseline to 6 months	0.66±0.64	0.001*	0.56±0.56	0.002*
3 months to 6 months	0.06±0.25	0.33	0.16±0.30	0.05

[1]Unpaired t-test, *Significant

Table-4b & Graph-4b shows the comparison of mean change in PPD from baseline to subsequent time periods in Group A and Group B. There was significant ($p<0.01$) change in PPD from baseline to subsequent time periods in both the groups except for 3 months to 6 months which was nearly significant ($p=0.05$).



Graph 4b: Comparison of mean change in PPD from baseline to subsequent time periods in Group A and Group B

5. Comparison of Clinical Attachment Level(CAL) between Group A and Group B at Baseline, 3 months and 6 months (post- operatively)

Inter-Group (Table 5a, Graph 5a)

CAL was recorded at these time intervals for both groups.

At baseline, the mean CAL reading for Group A was 5.86±0.89 and Group B was 5.83±0.87. The p-value for this was 0.91 which is statistically non-significant.

3 months post-operatively, the mean CAL reading for Group A was 1.60±0.20 and Group B was 3.36±0.97. The p-value for this was 0.0001, it was statistically significant.

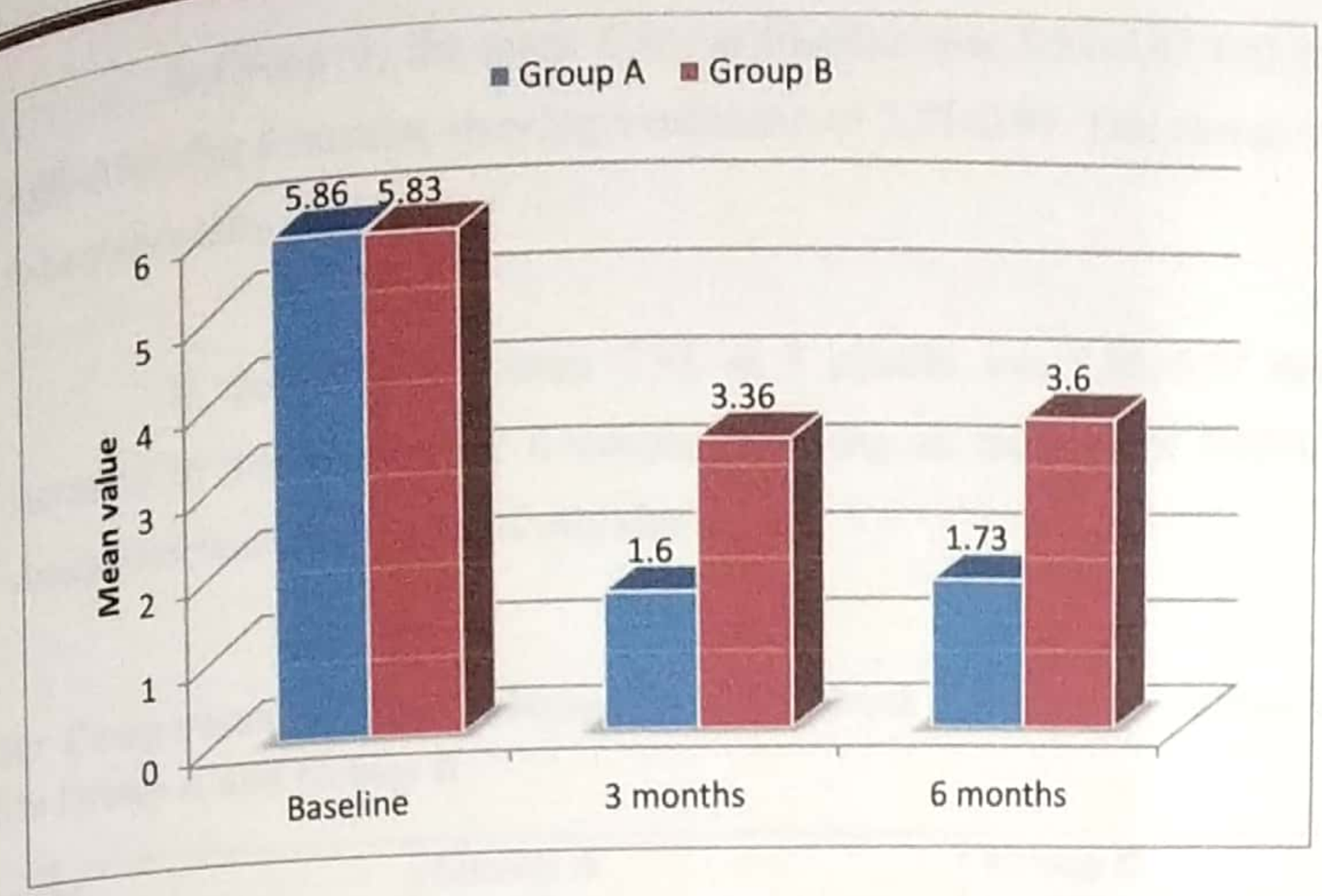
At 6 months post-operatively the mean CAL readings for Group A was 1.73±0.41 and Group B was 3.60±0.96. The p-value for this was 0.0001 that was statistically significant.

Table-5a: Comparison of CAL between the groups across the time periods

Time period	Group A (n=15)	Group B (n=15)	p-value[1]
Baseline	5.86±0.89	5.83±0.87	0.91
3 months	1.60±0.20	3.36±0.97	0.0001*
6 months	1.73±0.41	3.60±0.96	0.0001*

[1]Unpaired t-test, *Significant

Table-5a & Graph-5a shows the comparison of CAL between the groups across the time periods. There was no significant difference (p>0.05) in CAL at baseline between the groups. There was significant gain in CAL (p=0.0001) in Group A than Group B at 3 months and 6 months.



Graph 5a: Comparison of CAL between the groups across the time periods

<u>Intra-Group</u> (Table 5b, Graph 5b):

In Group A, the mean CAL at baseline was 5.86±0.89 that reduced to 1.60±0.20after 3 months, showing a reduction of 4.26±0.79. This change was found to be statistically significant.

In Group A, the mean CAL at baseline was 5.86±0.89 that reduced to 1.73±0.41 after 6 months, showing a reduction of 4.13±0.83. This change was found to be statistically significant.

In Group A, the mean CAL at 3 months was 1.60±0.20 that slightly increased to 1.73±0.41 after 6 months, showing an increase of 0.13±0.44. This change was found to be statistically non-significant.

In Group B, the mean CAL at baseline was 5.83±0.87that reduced to 3.36±0.97 after 3 months, showing a reduction of 2.46±1.12. This change was found to be statistically significant.

In Group B, the mean CAL at baseline was 5.83±0.87 that reduced to 3.60±0.96 after 6 months, showing a reduction of 2.23±0.99. This change was found to be statistically significant.

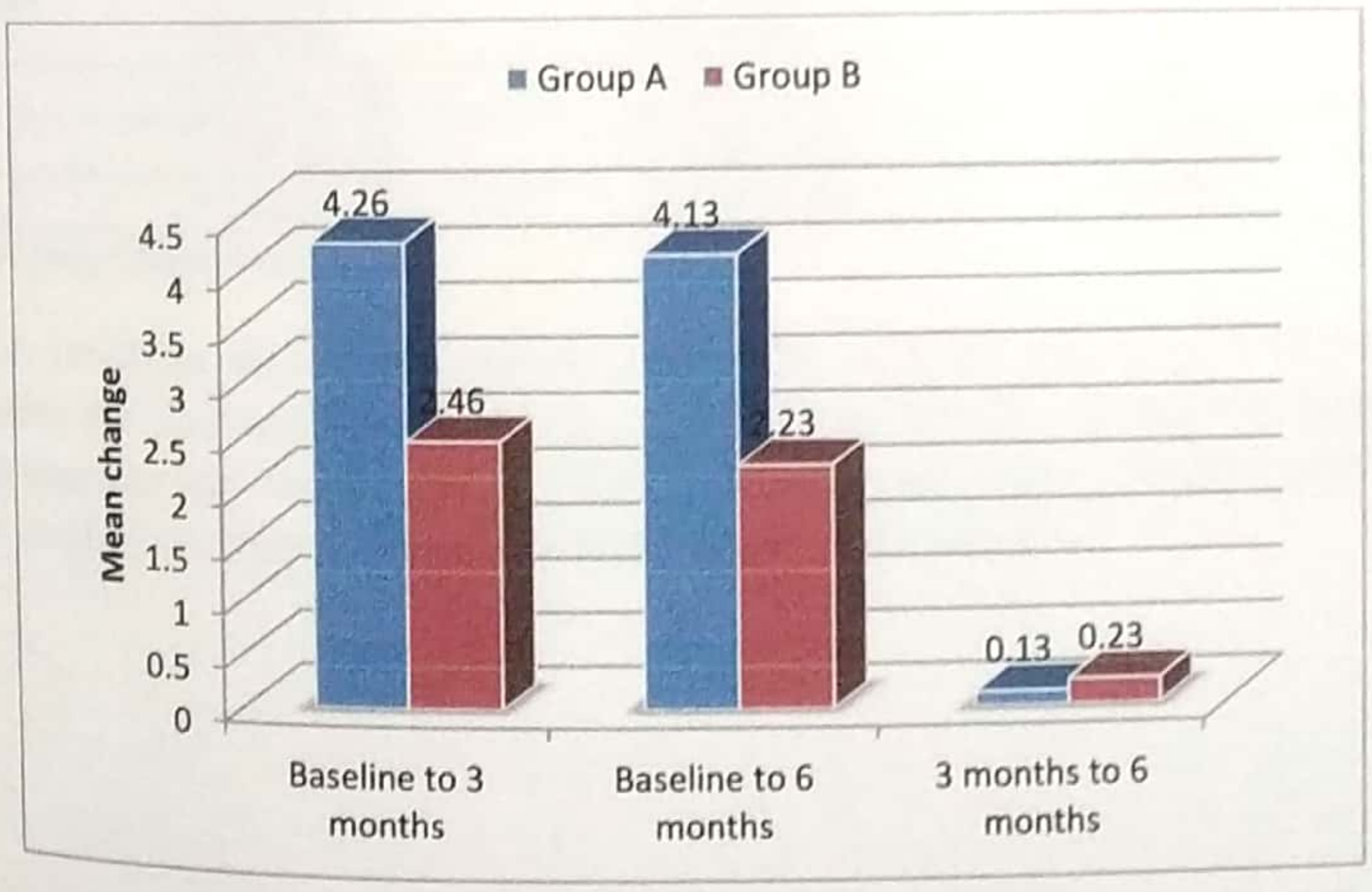
In Group B, the mean CAL at 3 months was 3.36±0.97 that slightly increased to 3.60±0.96 after 6 months, showing an increase of 0.23±0.37. This change was found to be statistically significant.

Table-5b: Comparison of mean change in CAL from baseline to subsequent time periods in Group A and Group B

Time period	Group A (n=15)		Group B (n=15)	
	Mean change	p-value[1]	Mean change	p-value[1]
Baseline to 3 months	4.26±0.79	0.0001*	2.46±1.12	0.0001*
Baseline to 6 months	4.13±0.83	0.0001*	2.23±0.99	0.0001*
3 months to 6 months	0.13±0.44	0.26	0.23±0.37	0.02*

[1]Unpaired t-test, *Significant

Table-5b & Graph-5b shows the comparison of mean change in CAL from baseline to subsequent time periods in Group A and Group B. There was significant ($p<0.05$) change in CAL from baseline to subsequent time periods in both the groups.



Graph 5b: Comparison of mean change in CAL from baseline to subsequent time periods in Group A and Group B

Comparison of Width of Keratinized Gingiva (KG) between Group A and Group B at Baseline, 3 months and 6 months (post- operatively)

Inter-Group (Table 6a, Graph 6a):-

KG was recorded at these time intervals in both the groups.

At baseline, the mean KG reading for Group A was 5.33±1.20 and Group B was 5.83±0.87. The p-value for this was 0.20, which is statistically non-significant.

3 months post-operatively, the mean KG reading for Group A was 7.80±1.13 and Group B was 6.26±0.99. The p-value for this was 0.0001 which is statistically significant.

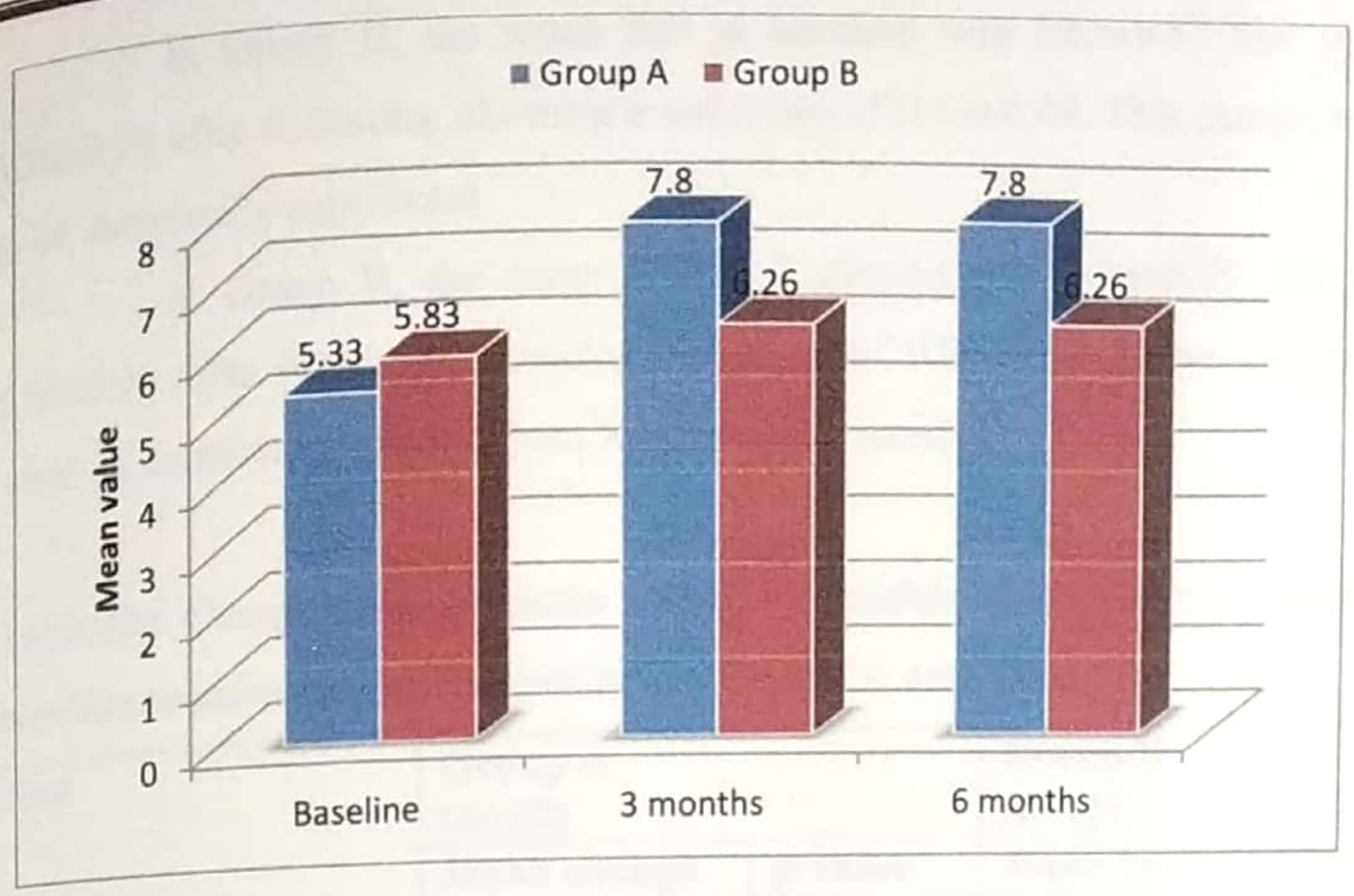
At 6 months post-operatively the mean KG reading for Group A was 7.80±1.13 and Group B was 6.26±0.99. The p-value for this was 0.0001 which is statistically significant.

Table-6a: Comparison of width of keratinized gingiva between the groups across the time periods

Time period	Group A (n=15)	Group B (n=15)	p-value[1]
Baseline	5.33±1.20	5.83±0.87	0.20
3 months	7.80±1.13	6.26±0.99	0.0001*
6 months	7.80±1.13	6.26±0.99	0.0001*

[1]Unpaired t-test, *Significant

Table-6a & Graph-6a shows the comparison of width of keratinized gingiva between the groups across the time periods. There was no significant ($p>0.05$) in width of keratinized gingiva at baseline between the groups. Width of keratinized gingiva became significantly ($p=0.0001$) higher in Group A than Group B at 3 months and 6 months.



Graph 6a: Comparison of width of keratinized gingiva between the groups across the time periods

<u>Intra-Group</u> (Table 6b, Graph 6b)

In Group A, the mean KG at baseline was 5.33±1.20 that reduced to 7.80±1.13 after 3 months, showing a reduction of 2.46±0.71. This change was found to be statistically significant.

In Group A, the mean KG at baseline was 5.33±1.20 that reduced to 7.80±1.13after 6 months, showing a reduction of 2.46±0.71. This change was found to be statistically significant.

In Group A, the mean KG at 3 months was 7.80±1.13 that remained 7.80±1.13 after 6 months, showing a change of 0.00±0.00. There was no change width of keratinized gingiva from 3 months to 6 months.

In Group B, the mean KG at baseline was 5.83±0.87 that reduced to 6.26±0.99 after 3 months, showing a reduction of 0.43±0.49. This change was found to be statistically significant.

In Group B, the mean KG at baseline was 5.83±0.87 that reduced to 6.26±0.99 after 6 months, showing a reduction of 0.43±0.49. This change was found to be statistically significant.

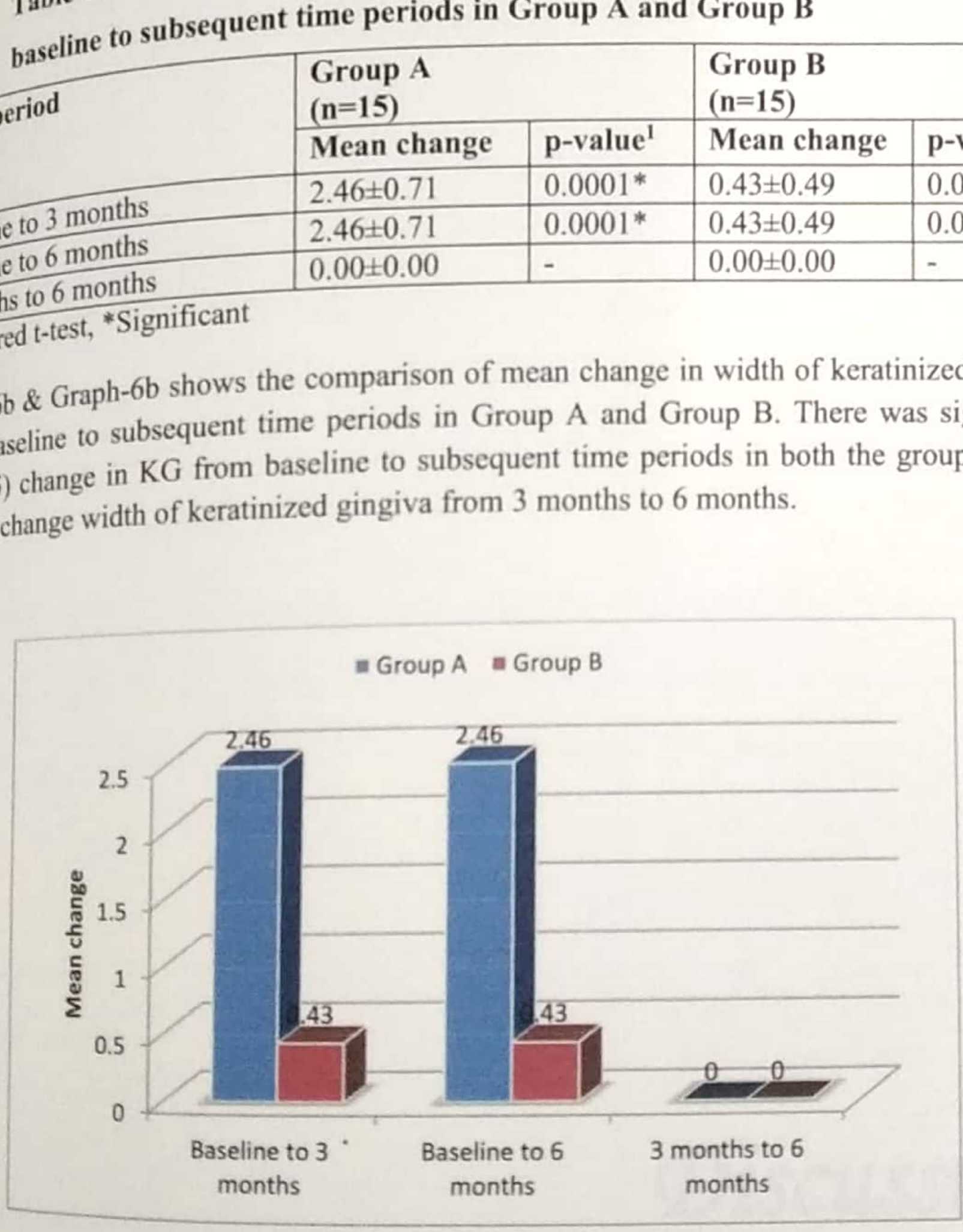
In Group B, the mean KG at 3 months was 6.26±0.99 that remained 6.26±0.99 after 6 months, showing a change of 0.00±0.00. There was no change width of keratinized gingiva from 3 months to 6 months.

Table-6b: Comparison of mean change in width of keratinized gingiva from baseline to subsequent time periods in Group A and Group B

Time period	Group A (n=15)		Group B (n=15)	
	Mean change	p-value[1]	Mean change	p-value[1]
Baseline to 3 months	2.46±0.71	0.0001*	0.43±0.49	0.004*
Baseline to 6 months	2.46±0.71	0.0001*	0.43±0.49	0.004*
3 months to 6 months	0.00±0.00	-	0.00±0.00	-

[1]Unpaired t-test, *Significant

Table-6b & Graph-6b shows the comparison of mean change in width of keratinized gingiva from baseline to subsequent time periods in Group A and Group B. There was significant ($p<0.05$) change in KG from baseline to subsequent time periods in both the groups. There was no change width of keratinized gingiva from 3 months to 6 months.



Graph 6b: Comparison of mean change in width of keratinized gingiva from baseline to subsequent time periods in Group A and Group B

Discussion

Gingival recession is defined as the exposure of the root surface due to the displacement of the gingival margin apical to the cemento-enamel junction (CEJ).[68 69] As a result, root surface exposure to the oral cavity is frequently associated with aesthetic complaints, root hypersensitivity and difficulties to achieve optimal plaque control.[70 71 72 73] The aetiology of gingival recession is complex, commonly related to over contoured tooth shape and malposition in the dental arch, alveolar bone dehiscence, thin biotype, muscle attachment, obsessive tooth brushing, localized or generalized periodontal disease, iatrogenic dental treatments.[70 71 72 73]

Successful treatment of recession-type defects is based on the use of predictable periodontal plastic surgery (PPS) procedures. As first proposed by Miller in 1988, the term PPS comprises different surgical techniques intended to correct and prevent anatomical, developmental, traumatic or plaque disease-induced defects of the gingiva, alveolar mucosa or bone.[68] Therefore, most soft tissue augmentation procedures aim not only to obtain complete root coverage (CRC) and natural tissue blending of the exposed surfaces and but also to increase gingiva width and thickness to ensure long-term stability.

Free gingival grafting (FGG), connective tissue grafts (CTGs), coronally advanced flaps (CAFs), and a combination of CTG, CAF, and guided tissue regeneration have been introduced with a high degree of predictability in Miller Class I and II recession defects. A recent systematic review of the literature demonstrated that CTG, FGG, and CAF were effective in reducing gingival recession, with concomitant improvements in attachment level. Another systematic review demonstrated that the CTG procedure optimizes results in root coverage and width of keratinized tissue.[74]

Major shortcomings of harvesting subepithelial connective tissue graft (CTG) are patient morbidity associated with the second surgical site and surgical time, as well as the limited supply of donor tissue. [75 76]

To overcome these inconveniences, new materials have been developed to replace CTG to improve patient acceptance and minimize morbidity. These have included the use of acellular dermal matrix allografts (ADMA) [44] or leukocyte and platelet rich fibrin (L-PRF) [55]

Overall comparative studies suggest that subepithelial connective tissue grafts are considered the "gold standard" procedure in the treatment of recession-type defects. The new acellular dermal matrix materials, however, do provide improved patient satisfaction and esthetics, are available in abundance, and lead to reduced postoperative discomfort and surgical time.[77]

Puros Dermis is manufactured by Zimmer Dental Inc., under its parent company Zimmer Holdings, Inc. (NYSE and SWX: ZMH) established in 1927. Zimmer Dental offers a comprehensive line of regenerative biologics with ever-expanding range of solutions to provide the breadth and depth that clinicians need to complete regenerative procedures.

Puros Dermis is recovered following the rigorous standards of both the Food and Drug Administration (FDA) and the American Association of Tissue Banks (AATB) with either a scalpel or dermatome from the back of the thighs of the deceased donor. The tissue is recovered within 24 hours of death and the multistep Tutoplast process removes all antigenicity, inactivates all kinds of pathogens, preserves tissue structure and collagen, preserves biomechanics, guarantees sterility, and results in graft healing comparable to autografts. In the span of 39 days, the process preserves the valuable minerals, collagen matrix and tissue integrity

while inactivating pathogens and gently removing unwanted materials, such as cells, antigens and viruses.

Petrungaro P in 2007 successfully used Puros Dermis to correct iatrogenic gingival recession and obtained excellent soft tissue integration.[78]

L-PRF

Periodontal wound healing requires a sequence of interactions between epithelial cells, gingival fibroblasts, periodontal ligament cells, and osteoblasts. The disruption of vasculature during wound healing leads to fibrin formation, platelet aggregation, and release of several growth factors into tissues from platelets[79] through molecular signals which are primarily mediated by cytokines and growth factors. There is evidence that the presence of growth factors and cytokines in platelets play key roles in inflammation and wound healing.[80] Platelets also secrete fibrin, fibronectin, and vitronectin, which act as a matrix for the connective tissue and as adhesion molecules for more efficient cell migration.[81]This has led to the idea of using platelets as therapeutic tools to improve tissue repair particularly in periodontal wound healing.

The use of blood-derived products to seal wounds and stimulate healing started with the use of fibrin glues, which were first described 40 years ago and are constituted of concentrated fibrinogen.[82]Consequently, the use of platelet concentrates to improve healing and to replace fibrin glues has been explored considerably in the past decade. Platelet concentrates can be classified as[83]

- pure platelet-rich plasma (P-PRP),
- leucocyte- and platelet-rich plasma (L-PRP)
- Pure platelet-rich fibrin (P-PRF)

Leucocyte and platelet-rich fibrin (L-PRF)

The initial objective of developing alternative easy-to handle methods was to make it possible to use platelet concentrates in daily practice. This led to the development of concentrated platelet-rich-plasma (cPRP). It is prepared from the patient's own blood and is activated by the addition of thrombin and calcium. The structure consists of a three dimensional biocompatible fibrin scaffold with a limited volume of plasma enriched in platelets. When PRP is activated the growth factors and proteins are released to the local environment accelerating postoperative wound healing and tissue repair.[84] But the disadvantage of using PRP is that its properties can vary depending on the concentration of platelets, amount of leukocytes, the type of activator used and time of placement of fibrin scaffold after clotting. But there are certain risks associated with the use of PRP.[85]The presence of bovine thrombin in PRP can result in the development of antibodies to the clotting factors V, XI and thrombin which can adversely affect the coagulation process. In addition, bovine thrombin preparations contain clotting factor V which can result in immune system activation when challenged with a foreign protein. Other drawbacks about the use of PRP include legal restrictions on handling the blood and also controversies in the literature regarding the benefits and clinical outcome of use of PRP. All these have led to the generation of a new family of platelet concentrate called platelet-rich fibrin which overcomes many of the limitations of PRP.[61]

Platelet-rich fibrin (PRF) described by Choukroun et al[81] is a second-generation platelet concentrate which contains platelets and growth factors in the form of fibrin membranes prepared from the patient's own blood free of any anticoagulant or other artificial biochemical modifications. The PRF clot forms a strong natural fibrin matrix, which concentrates almost all the platelets and growth factors of the blood harvest and shows a complex architecture as a

healing matrix with unique mechanical properties which makes it distinct from other platelet concentrates. PRF enhances wound healing and regeneration and several studies show rapid and accelerated wound healing with the use of PRF than without it.[54 86] Its advantages over PRP include ease of preparation, ease of application, minimal expense, and lack of biochemical modification (no bovine thrombin or anticoagulant is required). This considerably reduces the biochemical handling of blood as well as risks associated with the use of bovine-derived thrombin. PRF also contains physiologically available thrombin that results in slow polymerization of fibrinogen into fibrin which results in a physiologic architecture that is favorable to wound healing. It is advantageous than autogenous graft also because an autograft requires a second surgical site and procedure. Thus PRF has emerged as one of the promising regenerative materials in the field of periodontics.

A standard protocol for PRF preparation[54] should be followed to obtain proper quantity and quality of the fibrin matrix, leukocytes, platelets, and growth factors. PRF preparation requires a PC-02 table centrifuge. A sample of blood is collected from the patient's median cubital vein from the cubital fossa in 10 ml tubes without anti-coagulant and immediately centrifuged at a rate of 3000 rpm for 10 min. During the centrifugation process, when the blood gets in contact with the test tube wall the platelet gets activated leading to the initiation of coagulation cascade. After centrifugation, the resultant product consists of three layers.

The topmost layer consisting of acellular PPP (platelet poor plasma), PRF clot in the middle and RBCs at the bottom of the test tube. The fibrin clot obtained after centrifugation is removed from the tube and the attached red blood cells scraped off from it and discarded. PRF can also be prepared in the form of a membrane by squeezing out the fluids present in the fibrin clot.

Apart from obtaining the matrix by compressing the clot between two sterile gauze, the protocol is very simple, and many PRF clots can be produced in <20 minutes. Each PRF membrane concentrates most platelets and more than half of live and functional leukocytes from a 10-ml blood harvest[81] which releases high amounts of growth factors (such as transforming growth factor-β1 [TGFβ-1], platelet derived growth factor-AB [PDGF-AB], vascular endothelial growth factor [VEGF]), and matrix glycoproteins (such as thrombospondin-1) during a period of seven days in vitro[87].

They also have advantages like less surgical time, elimination of second surgical site and potential healing difficulties associated with membranes and less resorption during healing

Anilkumar et al[88] who reported complete root coverage with excellent gingival tissue status after six months, where PRF membrane along with laterally displaced flap was used for the treatment of an isolated recession defect.

Chang et al[89] observed that PRF application exhibited pocket reduction and gain in clinical attachment along with increased postoperative radiographic density in the treated defects.

Anuroopa P et al[90] found significant reduction in PPD and CAL gain in the treatment of gingival recession with grafted sites showing rapid clinical healing, no flap reopening, and complete coverage of root with excellent tissue contour and color

CLINICAL PARAMETERS:

PLAQUE INDEX (PI):

Plaque Index was recorded to observe the patient level of plaque control. The clinical parameters changes of Group A and Group B at 3 months and 6 months are discussed as follows: the mean

change in plaque index in group A was 0.85±0.46 at 3 months and 0.80±0.54 at 6 months after surgery. Similarly, in Group B, reduction in PI from baseline to 3 months and 6 months was 0.50±0.48 and 0.35±0.47 respectively. Significant Inter group differences were observed between these two groups, with Group A having significant reduction in PI as compared to Group B.

Intra-group reduction in PI was found to be statistically significant between baseline to 3 months, and baseline to six months in both groups. However, there was no significant reduction in PI between 3 months to 6 months post operatively.

All the patients were cooperative in terms of plaque control and maintained good oral hygiene

RECESSION DEPTH:

At baseline, the recession depth in Group A was 3.60±0.78 which reduced to 0.16±0.36 at 3 months and then increased insignificantly to 0.23±0.41 at 6 months. In Group B, recession depth at baseline was 3.33±0.16 which reduced to 1.60±0.80 at 3 months and then increased insignificantly to1.66±0.79 at 6 months.

Both groups showed a non-significant relapse of recession depth at 6 months.

The mean reduction in recession depth in Group A was 3.43±0.77 after 3 months and 3.36±0.81 after 6 months of surgery. In Group B, recession depth reduced as 1.73±1.09 after 3 months and 1.66±1.11 at 6 months post-operatively. There was statistically significant difference in recession depth when Group A was compared to Group B. This reduction in recession depth can be attributed to better soft tissue improvements following placement of Puros Dermis, which is in agreement with previous studies where acellular dermal matrix was used for recession coverage[47]

Moslemi N[92] compared SCTG and ADM in the treatment of localized gingival recession of Miller's Class I or II type, and found ADM compared favorably with SCTG in reduction in recession depth which is in accordance with our findings.

A study by Hirsch A[93] concluded that sub-pedicle connective tissue graft and sub-pedicle ADM showed predictable results in terms of defect coverage, keratinized gingival gain, attachment gain, and residual probing depth.

Inter-group reduction in recession depth was found to be statistically non-significant in both groups from 3 months to 6 months.

Intra-group reduction in recession depth was found to be statistically significant in both groups from baseline to 3 months and baseline to 6 months. There was no significant change in recession depth from 3 months to 6 months in both groups.

Harris RJ[43] concluded that while short-term (mean 12.3 to 13.2 weeks) mean root coverage with ADM was found to be 93.4%; the long-term (mean 48.1 to 49.2 months) mean root coverage was 65.8% with only 32.0% remaining stable or improving over time.

Since this study has a short-term follow up period, long term results cannot be predicted with certainty.

RECESSION WIDTH:

The mean reduction in recession width was 3.23±0.65 after 3 months and 3.10±0.63 after 6 months of surgery in Group A. Similarly, in Group B the reduction in recession width was 3.23±0.65 and 3.10±0.63 after 3 months and 6 months respectively. Although both groups showed a reduction in recession width from baseline, there was no statistically significant

difference in recession width when both groups were compared which is similar to the findings of Moslemi et al[92].

Intra-group reduction in recession width was found to be statistically significant in both groups from baseline to 3 months and 6 months. There was no significant change in recession width from 3 months to 6 months in both groups.

A recent systematic review by Chambrone et al[94] has suggested the inclusion of width of recession in future randomized controlled clinical trials for better understanding of its relevance and significance to treatment success.

POCKET PROBING DEPTH (PPD):

The mean reduction in pocket probing depth in Group A was 0.73±0.67after 3 months and 0.66±0.64 after 6 months of surgery. In Group B, pocket probing depth reduced as 0.73±0.77 after 3 months and 0.56±0.56 at 6 months post-operatively. When Group A was compared to Group B, Group A showed statistically significant reduction in PPD at 3 months and 6 months.

This is in contrast with the findings of Woodyard J[43] who found no significant change in pocket probing depth when comparing treatment outcomes using coronally positioned flap alone or in combination with ADMA for gingival root coverage.

Intra-group reduction in PPD was significant in both groups from baseline to 3 months and 6 months. No significant reduction was seen between 3 months to 6 months in both groups.

CLINICAL ATTACHMENT LEVEL (CAL):

The mean reduction in CAL in Group A was 4.26±0.79 after 3 months and 4.13±0.83 after 6 months of surgery. In Group B, CAL reduced as 2.46±1.12 after 3 months and 2.23±0.99 at 6

months post-operatively. When Group A was compared to Group B, Group A showed statistically significant CAL at 3 months and 6 months.

Studies conducted by Molnar B[95] and Paolantonio M[96] have shown similar results with significant gain in CAL in their studies on treatment of gingival recession using xenogenous collagenous graft and ADMA respectively.

In contrast, studies by Novaes M[97] and Abou-Arraj RV[98] have shown non-significant changes in CAL when treating gingival recession using SCTG vs ADMA and ADMA vs Puros Dermis respectively.

Intra-group reduction in CAL was significant in both groups from baseline to 3 months and 6 months, as well as from 3 months to 6 months.

WIDTH OF KERATINIZED GINGIVA (KG):

The mean change in KG in Group A was 2.46±0.71 after 3 months and 2.46±0.71 after 6 months of surgery. In Group B, KG changed to 0.43±0.49 after 3 months and 0.43±0.49 at 6 months post-operatively. When Group A was compared to Group B, Group A showed statistically significant gain in KG at 3 months and 6 months.

The gain in KG in Group A is similar to the results reported by two studies in a meta-analysis by Gapski et al[44], favoring the root coverage achieved by ADM, and Barker et al[47] found increase in keratinized tissue using Puros Dermis as well.

Intra-group gain in KG was significant in both groups from baseline to 3 months and 6 months, and no change in KG was seen between 3 months and 6 months post-operatively.

Taken together, all our findings point towards Puros Dermis as being the better material as compared to L-PRF when treating localized gingival recession. The results found with L-PRF might be attributed to poor patient compliance and persistence of aetiology; the literature on the subject has controversial and mixed results. An advantage of using L-PRF is its autologous nature, which significantly reduces the cost of treatment. Puros Dermis, while superior in achieving root coverage, has the drawback of being financially restrictive. On the other hand, current treatment modalities for soft tissue reconstruction seem to be limited among other factors, by the applied surgical techniques. Such novel treatment approaches are best used in combination with innovative, and minimally invasive techniques.

Conclusion

CONCLUSION

- Within the limits of this 6 month long clinical study, it can be concluded that though both Puros Dermis and L-PRF can be used successfully to treat gingival recession, Puros Dermis shows far superior results when the two are compared.
- Both Puros Dermis and L-PRF have certain advantages over older techniques in that they are easy to obtain and handle, can treat multiple sites, do not require a second surgical site, account for a less invasive surgical procedure with reduced post-operative morbidity and show complete integration with host tissues.
- Puros Dermis provides a uniform thickness, can be easily trimmed, is a well adaptable material, requires a short time (<60 sec) to rehydrate before it can be used, and Puros Dermis treated sites demonstrated better esthetics.
- L-PRF treated sites can be unpredictable, but it is the cost effective option, as well as sufficient to maintain good oral hygiene and resolve persistent gingival inflammation. Further histologic studies may provide evidence for L- PRF matrix's capacity for and impact on wound healing, soft tissue reconstruction and augmentation procedures.
- The limitations of this study were its small sample size and short follow up period of six months. Further studies are necessary with larger sample size and long-term follow-up period to validate the results and for further insight into the use of and also to compare it with other recent advances in this field.

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Appendices

APPENDIX – I

INSTITUTIONAL RESEARCH COMMITTEE APPROVAL FORM

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

INSTITUTIONAL RESEARCH COMMITTEE APPROVAL

The project titled **Comparative evaluation of the effectiveness of Acellular Dermal Matrix with Leukocyte and Platelet Rich Fibrin in the treatment of localized gingival recession: A Clinical Study** submitted by **Dr. Iman Baig** Post graduate student from the Department of **Periodontics** as part of MDS Curriculum for the academic year 2015-2018 with the Accompanying proforma was reviewed by the institutional research committee present on **23rd and 24th February 2016** at BBDCODS. The Committee has granted approval on the scientific content of the project. The proposal may now be reviewed by the institutional ethics committee for granting ethical approval.

Prof. (Dr).Vivek Govila
Dean
DEAN
BBD College of Dental Sciences
BBD University
Faizabad Road Lucknow-226028
Chairperson Institutional Research Committee

APPENDIX – II

ETHICAL COMMITTE APPROVAL FORM

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 IIIrd Institutional Ethics Sub - Committee

IEC Code: 01 BBDCODS/05/2016

Title of the Project: Comparative evaluation of the effectiveness of a cellular dermal matrix with leukocyte and platelet rich fibrin in the treatment of localized gingival recession: A Clinical Study.

Principal Investigator: Dr. Iman Baig **Department:** Periodontology

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

Type of Submission: New, MDS Project Protocol

Dear Dr. Iman Baig.

The Institutional Ethics Sub-Committee meeting comprising following four members was held on 03rd May, 2016.

1.	Dr. Lakshmi Bala Member Secretary	Prof. and Head, Department of Biochemistry, BBDCODS, Lucknow
2.	Dr. Narendra Kumar Gupta Member	Prof., Department of Prosthodontics, BBDCODS, Lucknow
3.	Dr. Smita Govila Member	Reader, Department of Conservative Dentistry, BBDCODS, Lucknow
4.	Dr. Subhash Singh	Reader, Department of Pedodontics, BBDCODS, Lucknow

The committee reviewed and discussed your submitted documents of the current MDS Project Protocol in the meeting.
The proposal was reviewed, 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 12/05/16.
(Dr. Lakshmi Bala)
Member-Secretary
IEC

(Dr. Vivek Govila)
Principal
PRINCIPAL
BBDCODS
Babu Banarasi Das College of Dental Science
(Babu Banarasi Das University)
BBD City, Faizabad Road, Lucknow-226028

APPENDIX – III

Participant Information Document (PID)

Babu Banarasi Das College of Dental Sciences

(A constituent institution of Babu Banarasi Das University)

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

1. Study Title

Comparative evaluation of the effectiveness of Acellular Dermal Matrix with Leukocyte-And Platelet-Rich Fibrin in the treatment of Localized Gingival Recession: A Clinical Study

2. Invitation Paragraph

You are being invited to take part in a research study, it therefore is 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 study is to find out whether acellular dermal matrix allograft of PRF is better in treating localized gingival recession.

4. Why have I been chosen?

You have been chosen for this study as you are fulfilling the required criteria for the diseased condition.

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?

This study will last for 6 months and you will be recalled 3 times; first at the time of surgery and then 3 months and 6 months after surgery as a periodic recall. Procedure includes flap surgery along with placement of allograft and a graft like material prepared from your own blood.

7. What do I have to do?

You do not have to change your regular lifestyles for the investigation of the study. This research study is self-sponsored by the candidate. You do not have to pay for any procedures involved.

8. What is the procedure that is being tested?

Formation of new gingiva using acellular dermal matrix allograft and PRF in the treatment of localized gingival recession is being tested.

9. What are the interventions for the study?

The study includes treatment with different concentration of herbal mouthwashes, chlorhexidine along with scaling and root planing.

10. What are the side effects of taking part?

There are no side effects on patients of this study.

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

There are no possible disadvantages for the patients of this study.

12. What are the possible benefits of taking part?

Your diseased condition will be eliminated efficiently.

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 weather you want to continue in the study. If you decide to withdraw, your

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

This study will last for 6 months and you will be recalled 3 times; first at the time of surgery and then 3 months and 6 months after surgery as a periodic recall. Procedure includes flap surgery along with placement of allograft and a graft like material prepared from your own blood.

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

There are no possible disadvantages for the patients of this study.

12. What are the possible benefits of taking part?

Your diseased condition will be eliminated efficiently.

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 weather 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 IEC.

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 may be used to provide data of the periodontal health status and the treatment needs in this region of India for planning of further large scale studies. Your identity will be kept confidential in case of any report/publications.

18. Who is organizing the research?

This research study is self-sponsored by the candidate. You do not have to pay for any procedures involved.

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 Department and the IEC of the institution.

21. Contact for further information

Dr Iman Baig

Babu Banarasi College of Dental Sciences

Lucknow

chochang2004@hotmail.com

9997686276

OR

Dr. Laxmi Bala,

Member Secretary,

Babu Banarasi College of Dental Sciences

Lucknow

bbdcods_iec@gmail.com

APPENDIX - IV

Consent Form (English)

Title of the Study .....

Study Number.....

Subject's Full Name.....

Date of Birth/Age

.....

Address.....

.....

Phone no. and e-mail address.....

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 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.....

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 consent form

Signature/thumb impression of the subject or legally Date.....
Acceptable representative

APPENDIX – V
CASE SHEET

BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES, LUCKNOW

"COMPARATIVE EVALUATION OF THE EFFECTIVENESS OF ACELLULAR DERMAL MATRIX WITH LEUKOCTYE- AND PLATELET-RICH FIBRIN IN THE TREATMENT OF LOCALIZED GINGIVAL RECESSION: A CLINICAL STUDY"

CLINICAL EVALUATION:

AGE: **SEX:**

NAME:

DATE:

OPD No.:

ADDRESS:

Chief complaint:

History of present illness:

Past dental history:

Past medical history:

History of medication:

CLINICAL EVALUATION:

I. Gingiva

Color

Consistency

Size

Position

Bleeding

Suppuration

II. Examination of teeth:

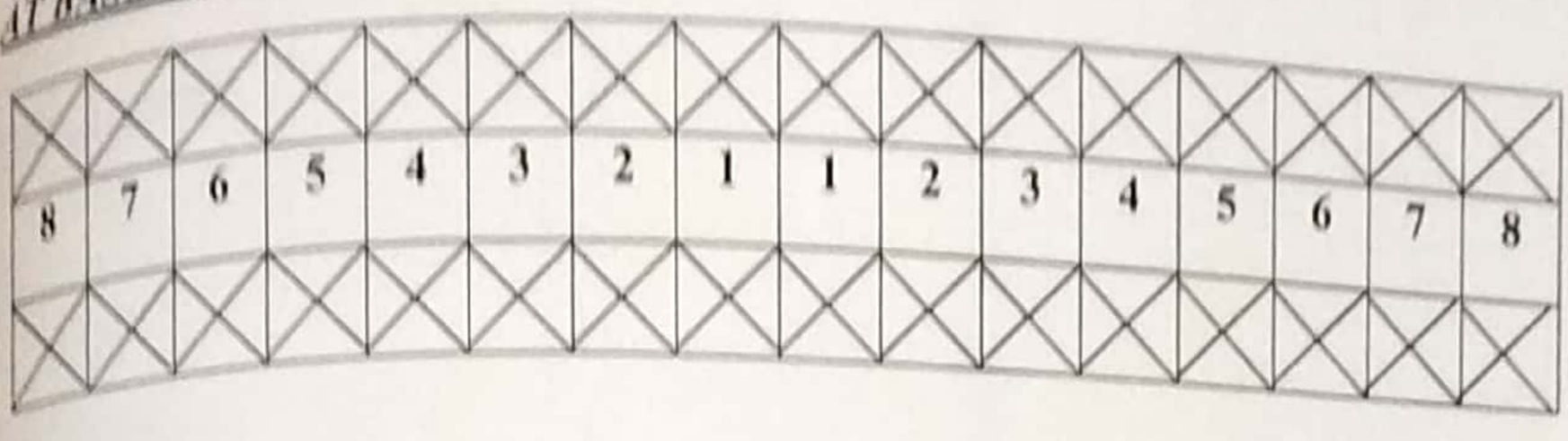
Number of teeth present

Mobility

CLINICAL PERIODONTAL PARAMETERS

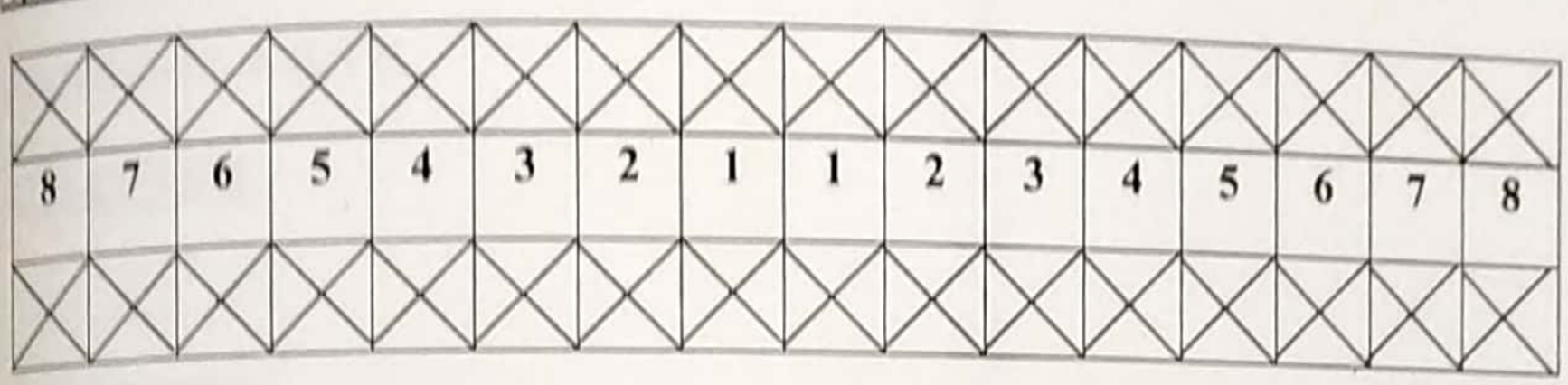
PLAQUE INDEX (Silness & Loe)

AT BASELINE



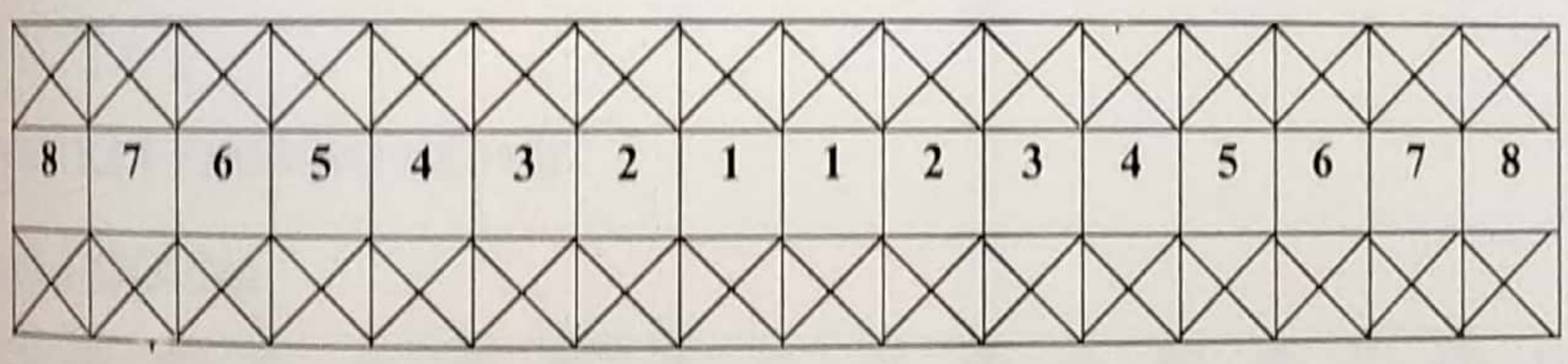
PLAQUE SCORE =

After 3 months



PLAQUE SCORE =

After 6 months



PLAQUE SCORE =

RECESSION DEPTH

AT BASELINE

After 3 months

After 6 months

RECESSION WIDTH

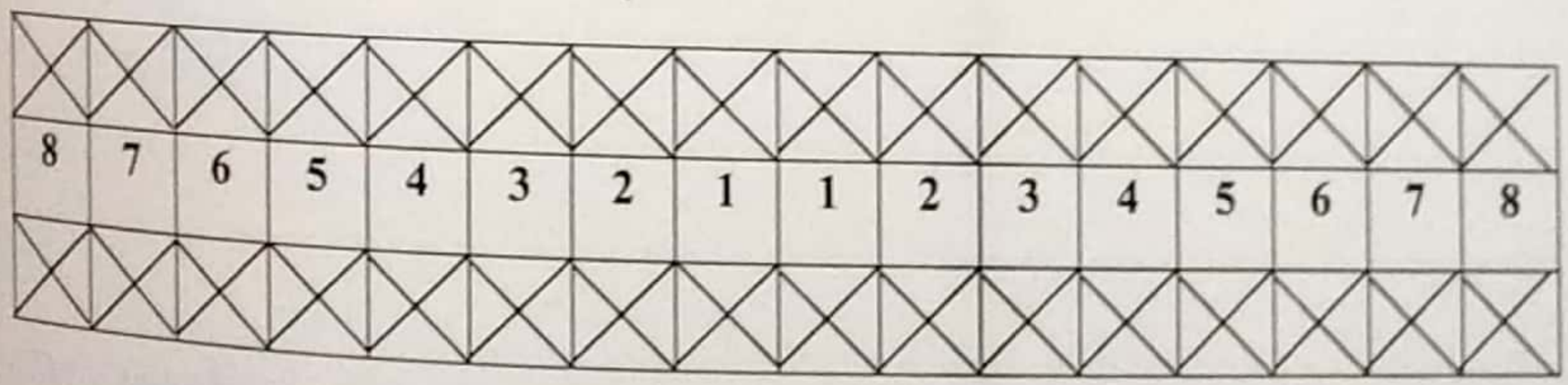
AT BASELINE

After 3 months

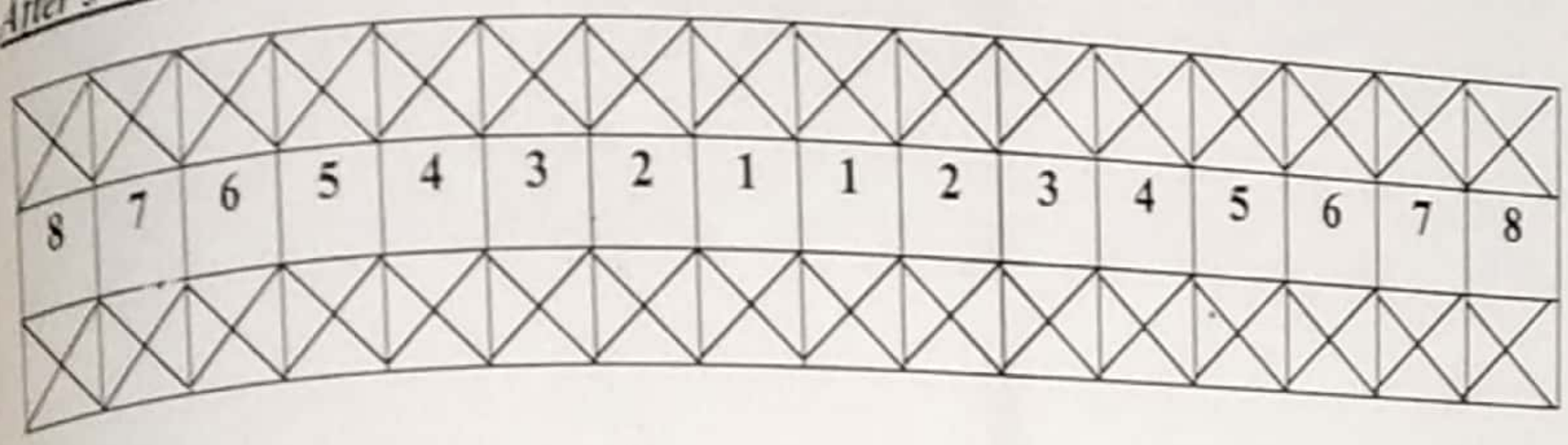
After 6 months

POCKET PROBING DEPTH

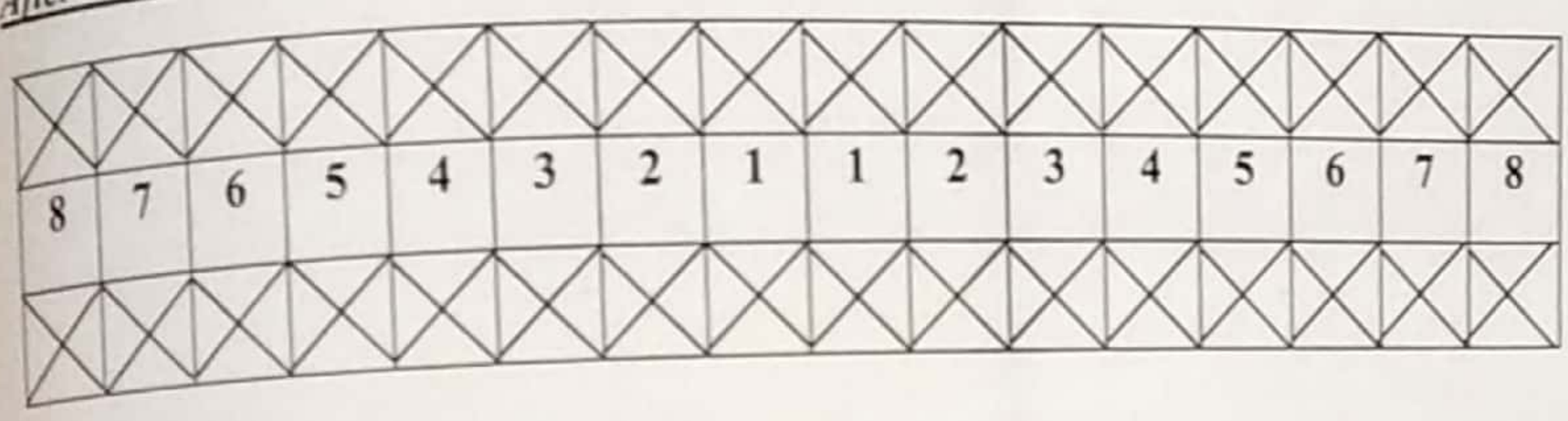
AT BASELINE



After 3 months

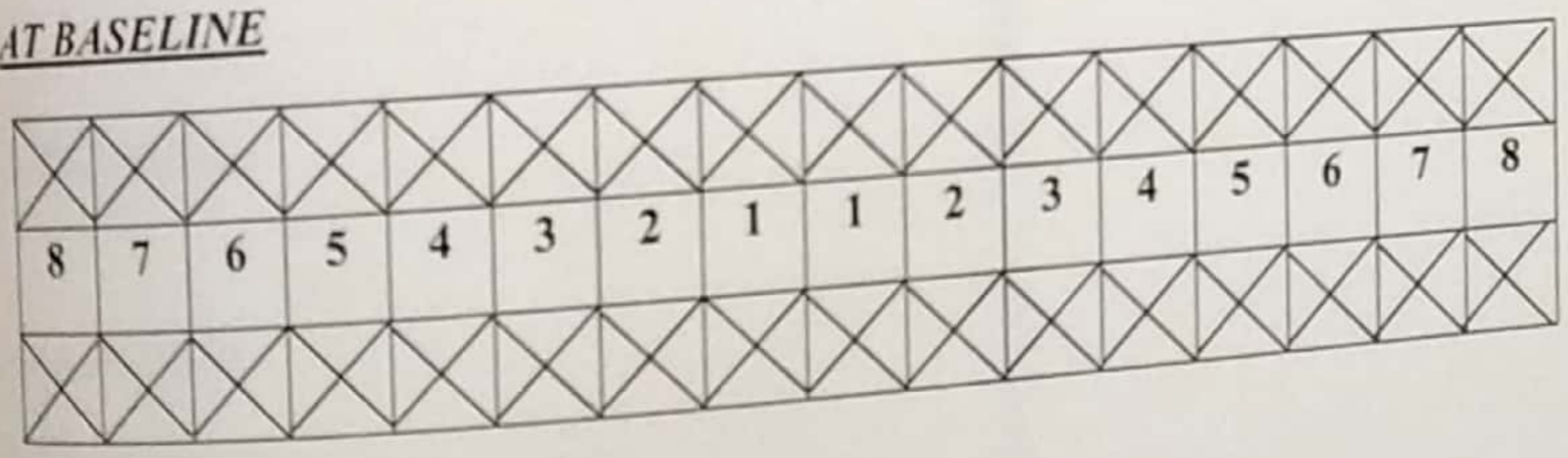


After 6 months

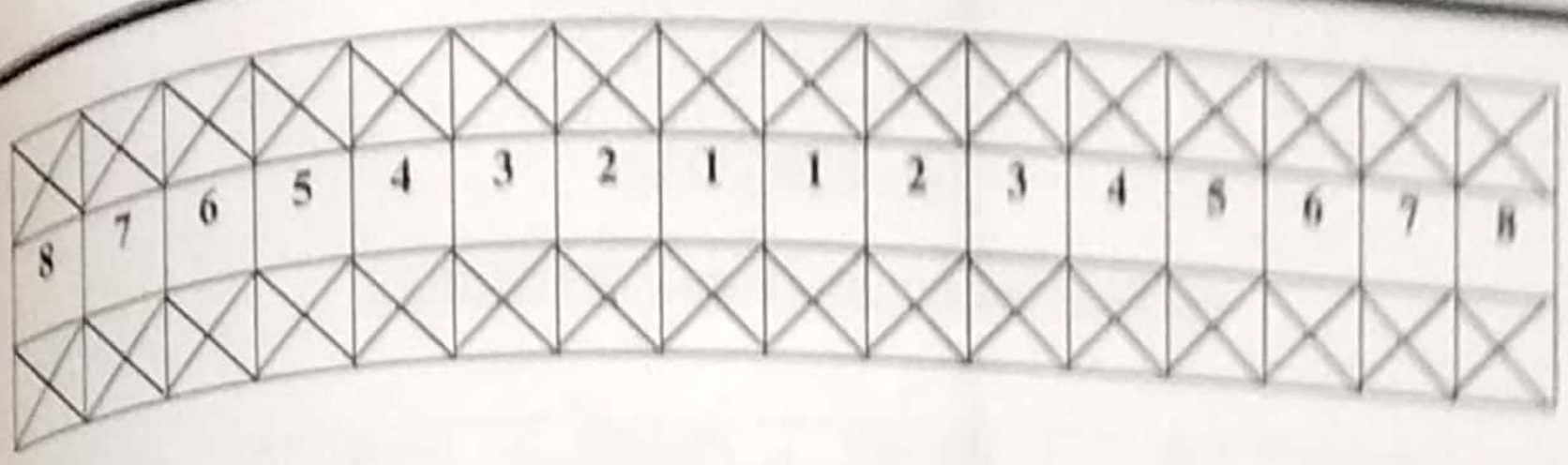


CLINICAL ATTACHMENT LEVEL

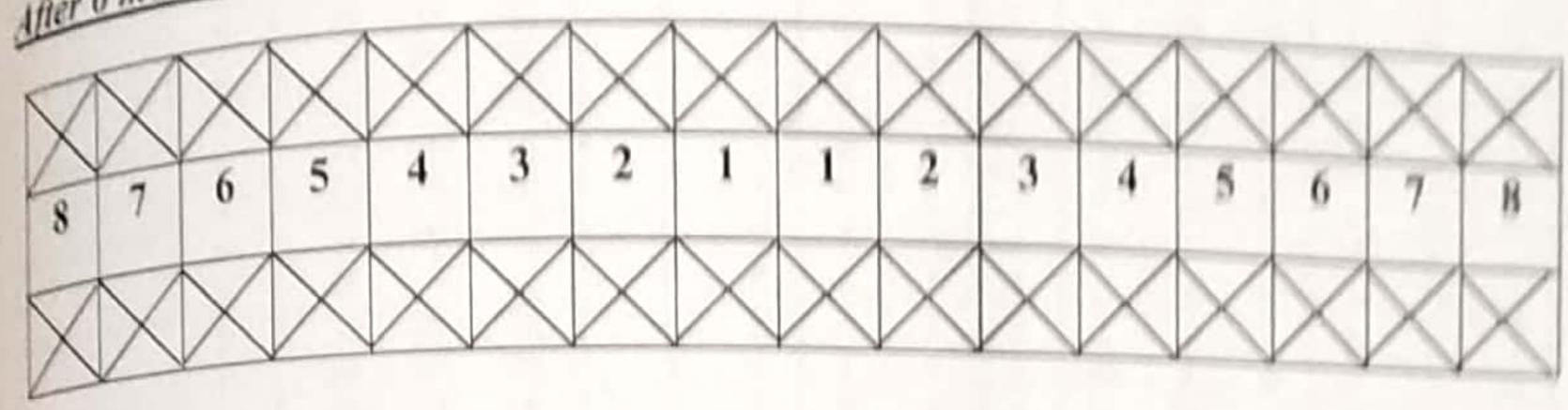
AT BASELINE



After 3 months



After 6 months



WIDTH OF KERATINIZED GINGIVA

AT BASELINE

After 3 months

After 6 months

DIAGNOSIS

PROGNOSIS

TREATMENT PLAN

TREATMENT DONE

MAINTENANCE PHASE

APPENDIX – VI

TABLES OF CLINICAL PARAMETERS

	TOOTH NO	PLAQUE INDEX			RECESSION DEPTH			RECESSION WIDTH			PPD			CAL			WIDTH OF ATTACHED GINGIVA		
		BASELINE	3 MONTH	6 MONTH	BASELINE	3 MONTH	6 MONTH	BASELINE	3 MONTH	6 MONTH	BASELINE	3 MONTH	6 MONTH	BASELINE	3 MONTH	6 MONTH	BASELINE	3 MONTH	6 MONTH
GROUP A	33	1.5	1	1	3	0	0	4	0	0	1.5	1.5	1.5	4.5	1.5	1.5	4	7	7
PURE DERMIS	32	2.25	1.25	1.25	3	0	0	3.5	0	0	2.5	1.5	1.5	5.5	1.5	1.5	5	8	8
	31	2.25	1.5	1.5	4	1	1	3	1	1	2	1.5	1.5	6	1.5	1.5	5	7.5	7.5
	41	2.5	1.5	1.25	4	1	1	3	1	1	2	1.5	1.5	6	1.5	1.5	4.5	6.5	6.5
	42	1.5	1.25	1.25	3	0	0	3	0	0	2.5	1.5	1.5	5.5	1.5	1.5	5.5	7.5	7.5
	43	1.5	1	1.25	3.5	0	0	3.5	0	0	1.5	1.5	1.5	4.5	1.5	1.5	5	8	8
	31	2.75	1.25	1.5	3.5	0	1	3.5	0	1	3	1.5	2	6.5	1.5	3	6.5	8	8
	13	1.5	1	1.25	3	0	0	4	0	0	2	1.5	1.5	5	1.5	1.5	8	10	10
	44	1.5	1.25	1.25	3.5	0	0	4	0	1	4	2	2	7.5	2	2	7.5	9	9
	45	2.5	1	1	3	0	0	3	0	0	3	1.5	1.5	6	1.5	1.5	6	10	10
	33	2.5	1.25	1.25	3	0	0	4	0	0	2	1.5	2	5	1.5	2	5	7.5	7.5
	32	2.75	1.25	1.25	5.5	0	0	3	0	0	1.5	2	1.5	7	2	1.5	4	6	6
	31	1.5	1	1.5	5	0	0	3	0	0	2	1.5	2	7	1.5	2	4	7.5	7.5
	41	1.5	1	1	4	0.5	0.5	3	0	0	2	1.5	1.5	6	2	2	5	7	7
	42	2.75	1.5	1.25	3	0	0	3	0	0	3	1.5	1.5	6	1.5	1.5	5	7.5	7.5

	TOOTH NO	PLAQUE INDEX			RECESSION DEPTH			RECESSION WIDTH			PPD			CAL			WIDTH OF ATTACHED GINGIVA		
		BASELINE	3 MONTH	6 MONTH	BASELINE	3 MONTH	6 MONTH	BASELINE	3 MONTH	6 MONTH	BASELINE	3 MONTH	6 MONTH	BASELINE	3 MONTH	6 MONTH	BASELINE	3 MONTH	6 MONTH
GROUP B	34	2.75	1.25	1.5	3	2	2	4	0	0	2	2	2	5	4	4	5	6	6
L-PRF	35	3	2.25	2.5	3	2	2	3.5	0	0	2.5	2	2	5.5	4	4	5.5	6	6
	44	3	2.25	2.5	3	2	2	3	1	1	3	1.5	2	6	3.5	4	6	7	7
	45	2.75	2.5	2.5	3	2	2	3	1	1	5	2	3	8	4	5	8	8	8
	22	1.5	1.25	1.25	3	1.5	1.5	3	0	0	2	1	1	5	2.5	2.5	5	5	5
	23	1.5	1.5	1.5	4	1.5	1.5	3.5	0	0	2	1.5	1.5	6	3	3	6	6	6
	14	1.75	1.5	1.5	3	0	0	3.5	0	1	2.5	1.5	2	5.5	1.5	2	5.5	6.5	6.5
	32	1.5	1.5	1.5	3	2	2	4	0	0	2.5	2	2	5.5	4	4	5.5	6	6
	31	1.75	1.5	1.75	3	3	3	4	0	1	2.5	2	2	5.5	5	5	5.5	6	6
	41	1.25	1	1.5	3	1	1	3	0	0	2	1.5	2	5	2.5	3	5	5.5	5.5
	31	2.75	1.5	1.5	5.5	1	1	4	0	0	1.5	1.5	1.5	7	2.5	2.5	7	8.5	8.5
	41	2.75	1.5	1.75	3	1	1	3	0	0	2	2	2	5	3	3	5	5	5
	42	1.5	1.25	1.5	3.5	1	1	3	0	0	2	2	2	5.5	3	3	5.5	5.5	5.5
	31	2.75	2.5	2.75	4	3	3	3	0	0	3	2	2	7	5	5	7	7	7
	41	2.75	2.5	2.5	3	1	2	3	0	0	3	2	2	6	3	4	6	6	6

APPENDIX-VII

FORMULA USED FOR STATISTICAL ANALYSIS

Mean and standard deviation (SD)

The simple mean is the average and is computed as the sum of all the observed outcomes from the sample divided by the total number of events. We use x as the symbol for the simple mean. In math terms,

$$\bar{x} = \frac{1}{n} \sum_{i=1}^{n} x_i$$

where n is the sample size and the x correspond to the observed valued.

We define the variance to be

$$s^2 = \frac{1}{n-1} \sum_{i=1}^{n} (x - \bar{x})^2$$

and the standard deviation to be

$$s = \sqrt{\frac{1}{n-1} \sum_{i=1}^{n} (x - \bar{x})^2}$$

Unpaired t-test

The unpaired t method tests the null hypothesis that the population means related to two independent, random samples from an approximately normal distribution are equal.

$t=x_1-x_2/(sqrt(1/n_1+1/n_2)$

$s=[sum(x_j-x_1)^2+sum(x_i-x_2)^2]/(n_1+n_2-2)$

where x_1 and x_2 are the sample means, s^2 is the pooled sample variance, n_1 and n_2 are the sample sizes and t is a Student t quantile with $n_1 + n_2 - 2$ degrees of freedom.

Paired t-test

Paired sample t-test is a statistical technique that is used to compare two population means in the case of two samples that are correlated. Paired sample t-test is used in 'before-after' studies, or when the samples are the matched pairs, or when it is a case-control study. For example, if we give training to a company employee and we want to know whether or not the training had any impact on the efficiency of the employee, we could use the paired sample test.. We collect data from the employee on a seven scale rating, before the training and after the training. By using the paired sample t-test, we can statistically conclude whether or not training has improved the efficiency of the employee. In medicine, by using the paired sample t-test, we can figure out whether or not a particular medicine will cure the illness.

$t=d/sqrt(s^2/n)$

where d is the mean difference between two samples, s^2 is the sample variance, n is the sample size and t is a paired sample t-test with n-1 degrees of freedom.