"COMPARATIVE EVALUATION OF DEMINERALIZED FREEZE DRIED BONE ALLOGRAFT (DFDBA) AND GENGIGEL ALONG WITH A GUIDED TISSUE MEMBRANE FOR THE TREATMENT OF GRADE II FURCATION DEFECTS : A RANDOMISED CONTROLLED CLINICAL TRAIL"

By

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Dissertation

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of the requirements for the degree of

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PERIODONTICS
(Branch II)

Under the guidance of

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DEPARTMENT OF PERIODONTICS
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Dr. ROHITA PENDYALA

LIST OF ABBREVIATIONS

DFDBA	Demineralized Freeze Dried Bone Allograft
GTR	Guided Tissue Renegeration
RC	Root Concavity
RT	Root Trunk
FI	Furcation Involvement
CAF	Coronally Advanced Flap
CEJ	Cemento Enamel Junction
SBI	Sulcus Bleeding Index
PPD	Probing Pocket Depth
RAL	Relative Attachment Level
HFI	Horizontal Furcation Involvement
VFI	Vertical Furcation Involvement
UNC	University Of North Carolina
BOP	Bleeding On Probing
BMP	Bone Morphogenic Protein
FRP	Fixed Reference Point
GF	Growth Factor
TGF-β1	Transforming Growth Factor - β1

ABSTRACT

Background: Successful management of furcation involved tooth is a clinical challenge. Closure of furcation defects is the most desirable outcome of therapy to ensure optimal maintenance and long-term success. Attempts at regenerative therapy based on the concept of guided tissue regeneration (GTR) can result in significant improvements in clinical parameters, bone fill and closure of defects. Various biomaterials like DFDBA which has both osteoconductive and osteoinductive properties have been employed over years to achieve this goal . Various newer materials have also been used for this purpose. One such material is 0.8% hyaluronic acid (Gengigel®) which showed regenerative potential and also improvement in clinical parameters like clinical attachment level, pocket probing depth etc.

Objective: To compare and evaluate the use of DFDBA and 0.8% Gengigel® along with a GTR for the treatment of Grade II furcation defects.

Materials and methods: Thirteen patients presenting bilateral mandibular Grade II furcations were included. Sites were allotted either Group A (DFDBA+GTRcollagen membrane (HEALIGUIDE®) or Group B (0.8%Gengigel®+GTR collagen membrane (HEALIGUIDE®). Clinical Parameters such as Sulcus Bleeding Index (SBI), Probing Pocket Depth (PPD),Relative Attachment Level (RAL) were assessed at baseline, 1 month, and 6 months. Horizontal Furcation Involvement and Vertical Furcation Involvement were assessed at baseline, 1month and 6 months.

Results: Intra group comparison showed statistically significant improvement in all clinical parameters with mean bone fill of 1.45±0.86 and 1.50±0.58 in Group-A and

Group-B respectively. Inter group comparison showed no statistically significant difference when the two groups were compared at 6 months.

Conclusion: 0.8% Gengigel gives promising results that are comparable and almost equivalent to DFDBA .

Keywords: Grade II furcation, Demineralized Freeze Dried Bone Allograft (DFDBA), 0.8% Gengigel®, Guided Tissue Regenerative Membrane (GTR), Healiguide®, bone regeneration.

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INTRODUCTION

Periodontitis is defined as “an inflammatory disease of supporting tissues of teeth caused by specific microorganisms or groups”[1]. This will result in a progressive destruction of the periodontal ligament and alveolar bone which leads to the appearance of the clinical signs of periodontitis. Periodontal diseases are considered to be one of the most prevalent diseases and are the major cause of tooth morbidity and mortality. Hence, “the ultimate goal of periodontal therapy is to arrest the disease progression and to achieve a healthy and functional periodontium that helps in the long term maintenance of the dentition throughout lifetime”[2].

Furcation involvement is one of the major consequence of the progression of periodontitis and increases the risk of tooth loss. . Furcation involvement is common with an incidence of 35% in mandibular molars and 90% in maxillary molars. Bacterial invasion and subsequent destruction of the surrounding structures leading to furcation invasion making it inaccessible for proper maintenance and long-term stability of the tooth. Furcation involved tooth shows greater amount of clinical attachment loss as compared to single rooted teeth[3] .

The extent of furcation involvement is often difficult to diagnose, and therefore a combination of radiographs, clinical probing with Nabers probe, and bone sounding must be done simultaneously[4]. The management of multi-rooted teeth demonstrating furcation involvement is one of the greatest clinical challenges to the periodontist. The suggested treatment modalities for furcation defects include odontoplasty, open flap debridement, regeneration, root resection, and extraction.

Regenerative therapies have been aimed at not only closing the furcation by filling it, but more specifically by attaining a gain in periodontal attachment apparatus to reduce and eliminate the defect[5]. With the introduction of bioactive agents, such as platelet concentrates (PCs), enamel matrix derivatives (EMD), bone morphogenic proteins (BMP), and matrix macromolecules such as hyaluronic acid (HA) the scope for better outcomes in furcation treatment has been surfaced.

Regeneration of new bone, cementum and periodontal ligament has also been documented histologically in humans by Bower in 1989[6]. Bone allografts has been reffered to as a gold standard for grafting procedures but their use is limited because of insufficient intra-oral graft and post-operative complication due to secondary donar site[4].

Urist and Strates (1965) stated that demineralising and freeze drying the bone increases the osteogenic potential by removing the mineral content and exposing the BMP present. Among them demineralised freeze dried bone allograft (DFDBA) has shown a potential to reconstruct the intraosseous periodontal and furcation defects clinically as well as histologically[7].

Demineralized freeze-dried bone allograft was first used by LIBIN in 1975 and has been used for more than three decades from then. Thus, they have been used to reconstruct intraosseous periodontal and furcation defects[8].

Despite the presence of BMP in DFDBA, direct clinical comparison of treatment success using mineralized freeze–dried bone allografts and DFDBA yielded similar results. So, DFDBA if not osteoinductive can be considered atleast osteoconductive scaffold with limited bone inductive proteins [9].

In 1976, Melcher presented the basic concepts of compartmentalisation, which led to the development of the clinical technique known as guided tissue regeneration (GTR). The use of barrier membrane enhances the regeneration by grafting which excludes gingival fibroblasts and epithelium from the healing site[10]. This treatment modality allows for the formation of bone, cementum, and periodontal ligament in the degranulated periodontal defects by placement of a membrane which acts by selective prevention of epithelial cells from populating and thus enhancing the healing process.

Various non-resorbable and resorbable barrier membranes have been used for this purpose which forms a seal over the underlying bone graft which inhibits epithelial cell migration and promotes connective tissue attachment[11]. Therefore, guided tissue regeneration using a membrane holds to be promising for increasing the success of bone grafting. When nonabsorbable membranes are used for guided tissue regeneration (GBR), second surgeries are required for membrane retrieval. In addition, these types of membranes show a high incidence of flap sloughing and membrane exposure that often lead to infection and unfavourable results. Absorbable barriers such as collagen membranes were developed to overcome these drawbacks.

Management of grade II furcation defects with osseous grafting and guided tissue regeneration enhances the response to membrane-only therapy[8],with bone restoration via the conductive effect of the graft. In human Grade II furcations the addition of a bone graft in combination with a barrier has demonstrated improved bone density, probing depth reduction, and clinical attachment gain.

In cases of furcation involvement various new materials have been used for the advancement of naturally occuring extracellular matrix of connective tissue, synovial fluid and other tissues .Hyaluron has structural and physiological function

within tissue including cellular and extracellular interactions, growth factor interactions ,regulation of osmotic pressure and tissue lubrication which helps in maintaining homeostatic intergation of all tissues. Hyaluronate has shown anti-inflammatory, anti edematous, and anti-bacterial properties, which suggests their use for resolution of gingivitis and periodontitis. Hyaluronic acid have shown osteoconductive potential by accelerating bone regeneration with means of chemotaxis, proliferation and successive differentiation of mesenchymal cells. Bone induction characterstics are comparable to BMP–2 and osteopontin[12].

Hyaluronin(gengigel) is available in two formulations (0.2% & 0.8% concentration). 0.2% is used for the treatment of gingivitis where as 0.8%when used after mechanical debridement has major clinical benefits of improved healing after non-surgical therapy[13]. The regenerative potential of gengigel has been tested for vertical bony defects, extraction sockets, wound healing and so on.

The present study is therefore undertaken to comparatively evaluate the Demineralized Freeze Dried Bone Allograft (DFDBA) and GENGIGEL® along with a guided tissue membrane for the treatment of Grade II furcation defects.

AIMS AND OBJECTIVES OF THE STUDY

AIM OF STUDY

To compare and evaluate the use of Demineralized Freeze Dried Bone Allograft(DFDBA) and Gengigel® (0.8%) along with a Guided Tissue Regenerative Membrane(GTR) for the treatment of Grade II furcation defects.

OBJECTIVES OF STUDY

- To clinically evaluate Bleeding Index, Relative Attachment Level, Pocket Probing Depth with the use of Demineralized Freeze Dried Bone Allograft(DFDBA) and Guided Tissue Regenerative Membrane(GTR) for treatment of Grade II furcation defects.
- To radiographically evaluate the percentage of bone fill with the use of Demineralized Freeze Dried Bone Allograft(DFDBA) and Guided Tissue Membrane(GTR) for treatment of Grade II furcation defects
- To clinically evaluate bleeding index, relative attachment level, pocket probing depth with the use of Gengigel® (0.8%) of and Guided Tissue Regenerative Membrane(GTR) for treatment of Grade II furcation defects.
- To radiographically evaluate the percentage of bone fill with the use of Gengigel® (0.8%) and Guided Tissue Regenerative Membrane(GTR) for treatment of Grade II furcation defects.
- To compare the effect of Demineralized Freeze Dried Bone Allograft(DFDBA) andGengigel® (0.8%) along with a Guided Tissue Regenerative Membrane(GTR) for treatment of Grade II furcation defects .

REVIEW OF LITERATURE

FURCATION DEFECTS

A furcation invasion / involvement (FI) has been defined by the American Academy of Periodontology as the pathologic resorption of bone in the anatomic area of a multi-rooted tooth where the roots diverge. It typically occurs due to the progression of chronic or aggressive periodontitis[14].

In a landmark study by Hirschfeld and Wasserman, it was observed that teeth with furcation involvement exhibited a higher rate of tooth loss (31%) compared to teeth without furcation defects (7%) over a period of ≥15 years[15]. In addition, several studies have demonstrated that FI tooth responded less favourably to non-surgical therapy than tooth without FI.

Prevalence and distribution:

Furcation involvement is frequently more common in maxillary molars than in mandibular molars (Ross & Thompson 1980, Svardstrom & Wennstrom 1996, Dannewitz et al., 2006)[16]. A study by Ross and Thompson (1980) found that the prevalence of furcation involvement in maxillary molars was 90%; compared with 35% in mandibular molars[17]. Studies on dry skulls have found that maxillary first and second molars have a higher risk for furcation involvement than mandibular molars. Moreover, first molars were more frequently affected than second molars (Larato 1970, Tal & Lemmer 1982)[19]. According to Svardstrom (1996), highest frequency of furcation involvement is the distal of maxillary 1st molar (53%) and lowest frequency of furcation involvement is the mesial of the maxillary 2nd molar(20%)[20].

Etiology

The etiology of furcation involvement maybe classified into three major groups[21].

1. Primary factor - Bacterial plaque, most common etiologic factor
2. Predisposing factors - Location relative to cementoenamel junction (CEJ), root trunk length, root length, root form, interradicular dimension, furcation shape,location of entrance, furcation entrance diameter, facial and lingual radicular bone, enamel projections, enamel pearls, bifurcation ridges, root concavities, and carious lesions.
3. Contributing factors - plaque-associated inflammation, trauma from occlusion, pulpal pathology, vertical root fractures, and iatrogenic factors.

Diagnosis

1. Clinical Assessment
2. Probing: Buccal and lingual furcation can be easily probed. Proximal furcations are difficult for probing particularly when broad contacts are present in adjacent teeth. Nabers Probe and Columbia curette 4R/4 L are used for probing the furcation area
3. Bone Sounding or Transgingival probing: It may aid in the diagnosis of furcation defects more accurately determining the underlying bone contours.
4. Radiographic Assessment- Radiographs have been used to determine the presence or absence of FI with different results (Rees et al., 1971, Deas et al., 2006)[22]. Rees et al., found that 86% of the buccal and lingual furcation can be diagnosed with the aid of radiographs. Deas et al., found that the agreement on detection of proximal FI between clinical and radiographic examination.

Classification[23]

A number of classifications have been proposed to categorize furcation involvement.

Various Classifications proposed for Furcation Involvement

AUTHOR(S)	CLASSIFICATION
1958 Glickman[24]	Grade I: soft tissue lesion extending to the entrance of the furcation but no furcal bone loss Grade II: loss of furcal bone to varying degrees but not through and through Grade III: through and through but not clinically visible (presence of granulomatous tissue) Grade IV: through and through visible clinically (tunnel)
1958 Goldman[25]	Grade I: incipient Grade II: cul-de-sac (pouch) Grade III: through and through
1969 Staffileno[26]	Grade I: soft tissue lesion extending to the entrance of the furcation with minor degree of bone loss Grade II: loss of furcal bone but not through and through Grade III: through and through
1969 Easley and Drennan[27]	Class I: incipient involvement, entrance of the furcation detectable with no horizontal bone loss Class II, Type 1: horizontal bone loss but no vertical component Class II, Type 2: horizontal bone loss and vertical bone loss Class III, Type 1: through-and-through bone loss with no vertical component Class III, Type 2: through-and-through bone loss with vertical component
1975 Hamp et al[28]	Degree/Class I: horizontal loss of periodontal tissue support <3 mm Degree/Class II: horizontal loss of periodontal tissue support >3 mm but not

	through and through Degree/Class III: through-and-through defect
1979 Ramfjord[29]	Degree 1: horizontal penetration <2 mm Degree 2: horizontal penetration >2 mm but not through and through Degree 3: through and through
1982 Ricchetti [30]	Class I. 1 mm of horizontal measurement; the root furrow. Class Ia. 1–2 mm of horizontal invasion; earliest damage. Class II. 2–4 mm of horizontal invasion. Class IIa. 4–6 mm of horizontal invasion Class III. > 6 mm of horizontal invasion
1984 Tarnow and Fletcher[31]	Uses Grades I, II, III proposed previously by Glickman with an additional sub-classification based on vertical invasion from the furcation fornix: A: VPD, 1 to 3 mm B: VPD, 4 to 6 mm C: VPD, >7 mm
1998 Hou et al[32]	Three classes (Class I, II, and III): Classes are the same as Grades in the classification by Hamp et al., Two subclasses (Subclass a and b): a: for suprabony defects b: for infrabony defects Three types (A, B, and C): A: root trunk represents the cervical one-third of the root complex B: root trunk represents half of the root complex C: root trunk represents the cervical two-thirds of the root complex

The present study deals with Grade II furcation defects, as classified by Glickman, demonstrating loss of furcal bone to varying degrees but not through and through. Nevertheless, the classification by Hamp et al., is probably the most universal one. This is likely attributable to its simplicity and the correlation between the proposed degrees of severity and commonly found clinical scenarios; also, it is the most commonly used classification in periodontal research.

Management

The treatment or correction of a furcation invasion is dependent on several factors such as, the severity of furcation invasion, amount of remaining bone support, status of abutment teeth, and strategic importance of the involved tooth. Grade I lesions frequently respond well to conservative therapy that involves odontoplasty, non-surgical therapy, and minimal flap surgery. Grade III/ IV lesions are managed by surgical therapy such as Widman flaps or tunnel preparations, root resections, and hemisection. Grade II furcation defects respond well to regenerative therapies[33].

In a recent systematic review by Avila-Ortiz et al., (2015)[34] it was concluded that the indication of regenerative approaches for the treatment of furcation defects is predictable in certain clinical scenarios, particularly in maxillary facial or interproximal and mandibular facial or lingual Class II furcation defects. Regenerative therapy in maxillary molars presenting Class III furcation defects and in maxillary premolars affected by Class II or III furcation defects is not predictable based on current available evidence. The authors also stated that, novel approaches such as, tissue engineering-based approaches consisting of the application of biologic agents, growth factors, scaffolds, pluripotential cells or a combination.

Regeneration is defined as the reproduction or reconstitution of a lost or injured part in such a way that the architecture and function of the lost or injured tissues are completely restored[3]. Although many attempts have been made to regenerate alveolar bone support and the attachment apparatus, predictable success has proved elusive. Osseous grafts are the only material for which ample histologic evidence is available for periodontal reconstruction in humans, including new cementum, alveolar bone, and a functional periodontal ligament.

Periodontal bony defects are treated because they complicate the definitive elimination of active pocket defects, compromise the support of the tooth and the tooth's ability to withstand functional stresses and complicate maintenance of an arrested pocket defect. The ideal result is correction of bony defects by regeneration of lost supporting bone and periodontal ligament. Furthermore, there is evidence that supracrestal bone regeneration is possible when certain bone replacement grafting materials are used. This has not been observed with other forms of regenerative periodontal therapy, which attempt to eliminate bony defects without a bone replacement graft material.

The objectives of periodontal bone grafts are[35]:

1. Probing depth reduction
2. Clinical attachment gain
3. Bone fill of the osseous defects
4. Regeneration of new bone, cementum and periodontal ligament.

The ideal graft material remains to be found, such a material induces osteogenesis and cementogenesis that would result in regeneration of a new periodontal attachment complex at a more coronal level. It would be completely biocompatible and would not be carcinogenic, toxic or antigenic or effect round-cell infiltration responses. It would also be easily obtainable, relatively inexpensive and would not cause the patient or the therapist unnecessary inconvenience.

The three types of grafts being used most frequently today in periodontics are autogenous grafts, allografts and alloplasts[35].

Allografts are grafts transferred between genetically dissimilar members of the same species. Demineralized freeze-dried bone allograft induces host mesenchymal cells to differentiate into osteoblasts (Harakas). Urist etal showed that demineralization and freeze- drying of cortical bone graft material greatly enhances its osteogenic potential. HCl demineralization exposes the bone morphogenic proteins that are composed of acidic polypeptides. The bone morphogenic proteins are located in the bone matrix and therefore are abundant in cortical bone where bone matrix is more abundant. The use of DFDBA in human periodontal defects was first reported by Libin et al (Libin et al 1975)[36].

Particle size of DFDBA ranging from 45µ to 1000µ are currently available and in use. Factors related to particle size that cause differences in healing include interparticle spacing, surface area and exfoliation of osseous graft particles. Shape and size of the particles can affect interparticle spacing of approximately 40µ - 200µ is necessary for the ingrowth of vascular and bony tissue (Zaner DJ et al 1984)[37]. A greater surface area to volume ratio could potentially expose more of the growth and differentiation factors in the collagenous matrix of the graft and enhance the early

stages of healing. Narrower spaces may inhibit revascularization and retard healing.However particle size did not correlate with the ability to induce bone. Commercial DFDBA preparations differ in both size and ability to induce new bone formation, but these two are not related[38].

STUDIES ON DFDBA

Barry M. Libin et al (1975)[39]presented three reports of patients with severe periodontal defects treated with a decalcified, lyophilized bone allograft prepared as described by Urist. Two patients received grafts of cancellous bone and one patient received a cortical bonegraft. The patients were observed up to 2 years following implantation. Clinical and histological data concluded that the implantation of decalcified, lyophilized bone allograft of both the cortical and cancellous bone types resulted in new bone formation and a gain in attachment level and no evidence of rejection of graft material for up to 2 years following implantation.

GE Pearson, S.Rosen and D.A Deporter (1981)[40]performed a controlled pilot study to evaluate the effectiveness of decalcified freeze-dried cancellous bone allograft material in the treatment of intrabony periodontal defects in humans. 22 defects were selected for the study, out of which 16 defects were randomly selected for grafting while the remaining 6 served as controls. Significant gains in attachment were achieved with the allografting procedure but not with the control procedure, which consisted of flap and curettage only.

Quintero et al (1984)[41]evaluated the osteogenic potential of DFDBA in the treatment of human periodontal osseous defects over a 6-month period. Cortical bone obtained under sterile conditions from a human donor within 24 hours after death, was

decalcified, freeze dried and grounded to particle size of 250-500 microns. 27 osseous defects with one, two and wide three wall morphology were treated. Clinical measurements were made before surgery, at the time of surgery and re-entry. The combined mean osseous regeneration for all defects was 2.4mm. This represented a 65% mean bone fill of the original defect. In conclusion DFDBA has a potential as an osseous grafting material in periodontal therapy.

Mellonig et al (1984)[42]compared open flap debridement plus DFDBA (32defects) versus open flap debridement alone (15 defects) for the treatment of intrabony defects. Grafted defects had an average depth of 4.0 ± 1.6mm, clinical attachment level gain at an average 2.9 ± 1.3mm and bone gain 2.6 ± 1.4mm, which were significantly better than open flap debridement.

Gerald M Bowers et al (1985)[43]this study was designed to evaluate the potential for regeneration of a new attachment in patients whose attachment apparatus has been destroyed by periodontal disease. In each of the three parts of the investigation, the most apical level of calculus on the root served as a histologic reference point to measure regeneration. In part I, attempts were made to initiate the formation of new attachment by surgical debridement, crown removal and submersion of the vital root below the mucosa. In part II the debrided intra bony defects were treated with or without DFDBA and the associated vital roots were submerged. Part III evaluated the potential for regeneration of a new attachment in non-submerged roots with and without use of DFDBA. Gingival grafts were placed. Biopsies were obtained in 6 months and regeneration was evaluated histometrically. Preliminary results in 24 defects indicated that new attachment is possible on pathologically exposed roots surfaces in a submerged environment with and without the incorporation of DFDBA.

New attachment was observed on pathologically exposed root surfaces in a submerged environment when intrabony defects were grafted with DFDBA. New attachment was not observed on non-grafted, non-submerged defects irrespective of placement of gingival grafts over the defects.

Marvin Werbitt (1987)[44]presented several case reports where DFDBA had been used to treat advanced intrabony defect and where new bone formation had occurred. A total of 20 defects were treated, and at the nine-month evaluation, the six cases presented in this report had minimal probing depth and showed radiographic evidence of substantial bone fill. The amount of repair ranged from 75% to 95% of the original defect. Bone fill was achieved on both vital and non-vital teeth and in same cases there was a radiographic evidence of a lamina dura and a discernable periodontal ligament space. Furthermore, the teeth that were initially mobile showed a decrease in mobility.

James A Bowen et al (1989)[45]compared healing potential of the osteoinductive DFDBA with an osteoinductive porous hydroxyapatite (HA). 6 patients were selected for the study. Soft and hard tissue measurements were taken at baseline and 6 months re-entry. There was no significant difference in any of the soft tissue measurements when DFDBA and HA were compared. There was a defect fill of 61% for DFDBA and 53% for HA. These values were likewise not statistically different.

Gerald M Bowers et al (1989)[27]compared the healing of intrabony defects with and without the placement of DFDBA in a submerged environment. Biopsies were obtained at 6 months and evaluated histometrically. Data from 9 patients with 30 grafted defects and 13 non-grafted defects showed results indicating that in a submerged environment, significantly more new attachment apparatus and new bone

was formed at grafted than non-grafted sites. Significantly greater loss of alveolar crest height occurred at non-grafted than grafted sites; regeneration of new attachment apparatus, new bone and new cementum occurred more frequently at grafted than non-grafted defects.

Gerald M Bowers et al (1989)[46]compared the healing of intrabony defects with and without the placement of DFDBA in a non-submerged environment. Free gingival grafts were placed over grafted and non-grafted defects to retard epithelial migration. Biopsies were obtained at 6 months and regeneration was evaluated histometrically. Data from 12 patients with 32 grafted and 25 non-grafted defects showed results indicating, new attachment apparatus was observed when treated with DFDBA. Significantly more new attachment, new cementum, new connective tissue and new bone formed in intrabony defects treated with DFDBA than in non-grafted defects. Free gingival grafts did not enhance regeneration of new attachment apparatus, new cementum or new connective tissue. New cellular cementum formed on old cementum. Periodontal ligament was more frequently oriented perpendicular to the root. There was greater loss in alveolar crest height in non-grafted than grafted defects. Extensive root resorption, ankylosis and pulp death were not seen in both the grafted or non-grafted defects.

J.M Rummelhart et al (1989)[47] compared freeze-dried bone allograft (FDBA) with demineralized freeze-dried bone allograft (DFDBA). 22 defects in 9 patients were grafted with either DFDBA or FDBA. Evaluations were based on standardized radiographs, presurgical and post surgical measurements using the cementoenamel junction as fixed reference point and osseous measurements at the time of surgery. At reentry after 6 months a mean osseous repair of 59% occurred with DFDBA and 66%

with FDBA. Findings revealed significant differences between the two materials in primarily intraosseous defects when evaluated at a minimum 6 months post surgery.

James.T.Mellonig, Annamarie.B.Prewett & Mary Pat Moyar (1992) [48]conducted the study to obtain direct evidence that the processing of a DFDBA would render the allograft safe for human use. In part I, human cortical bone was obtained from a cadaveric source and tested to be free of HIV contamination. In part II, cortical bone was procured from a donor who died of AIDS. Test samples were treated with a virucidal agent and demineralized with HCl. Control samples were left untreated. All samples were co cultivated. Treated samples were negative when assayed for HIV. Bone samples in part II HIV infected bone, were positive by polymerase chain reaction. Replication of viable HIV could not be demonstrated after treatment. It was concluded that demineralization and treatment with a virucidal agent inactivates HIV in spiked and infected bone.

Stephen E. Fucini et al (1993)[49]conducted a study to compare the bony defect resolution obtained using 2 different particle size of DFDBA. Cortical bone from a single donor was processed and grounded to final particle sizes of 250µ to 500µ or 850µ to 1000µ. Paired interproximal intrabony periodontal defects in 11 patients were grafted with DFDBA. Soft and hard tissue measurements were made using an electronic constant force probe at the initial and reentry surgeries. Treated sites in 10 patients were reevaluated by reentry approximately 6 months post operatively. Mean bony defect fill was 1.66 mm for large particle group and 1.32 mm for the small particle group. There was no statistically significant difference in bony fill between defects grafted with the different particle sizes of DFDBA when used in humans.

Craig L Meadows et al (1993)[50]compared the effectiveness of polylactic acid granules as an alloplastic grafting material to that of DFDBA and a flap procedure for debridement without graft (FPD). 10 patients with at least 3 similar periodontal osseous defects were included in the study group. Soft tissue and hard tissue measurements were determined at baseline and 6 months re-entry. No statistically significant differences were found in soft tissue recession between groups or in osseous defect measurements between polylactic acid granules and FPD. A statistically significant improvement was found in the fill of the osseous defects when using DFDBA compared to the other 2 groups. DFDBA produced the greatest amount of osseous defect fill, FPD less fill, and PLA the least amount of fill.

Yoichiro Shigeyama (1995)[28]the studies described here focused on establishing biological activity of proteins extracts prepared from commercially obtained bone graft material in vitro. Furthermore, the biological activity of these proteins extracts in vitro was compared with similar extracts prepared from freshly obtained human bone. Biological activities of the bone matrix proteins examined included their ability to promote proliferation, attachment, and migration of gingival fibroblasts using in vitro system. Slot blot analysis revealed that commercially available material contains Type I collagen; fibronectin and BMP- 2, 4 &7.The freshly prepared bone extracts appeared to have higher BMP concentrations. The ability of commercial extracts to promote cell proliferation, while significant was limited and less when compared to freshly obtained bone. All extracts promoted cell attachment significantly while none of these extracts promoted cell migration. Thus commercially prepared material retained proteins having capacity to influence cell behavior in vivo.

Francis et al (1995)[51]evaluated an allogenic bone matrix (ABM) as a graft material for the treatment of periodontal osseous defects. Paired osseous defects in 11 patients were randomized to receive ABM or DFDBA. Soft tissue and hard tissue measurements were determined at baseline and 6 months reentry procedure. Standardized radiographs were taken. Results of radiographic analysis suggested similar density changes with each graft. These results demonstrated that both the treatments were effective and that ABM may be a useful graft material in the treatment of periodontal osseous defects.

Mark A Reynolds et al (1996)[52]conducted a study to histologically examine the fate of DFDBA used for regeneration in intrabony defects. Histologic sections obtained from 12 patients with 32 grafted defects revealed that 72% of the grafted defects exhibited residual DFDBA particles. Data from 5 patients with 14 grafted sites permitted an intra subject comparison of the amount of regeneration in relation to the presence or absence of residual graft material. Defects harboring residual graft particles exhibited significantly greater amounts of new attachment apparatus formation. No apparent differences were seen in the nature of the new attachment apparatus or component tissues, other than in amount of formation.

J. de La Fontaine (1997)[53]conducted a study to assess variability in osteoconduction of demineralized freeze dried bone allograft (DFDBA) obtained from multiple bone banks, and to develop an in vitro assay for predicting osteoinduction in vivo. Twelve lots of DFDBA obtained from six bone banks, were evaluated for osteoinduction in vivo following graft placement in mice. 8 lots were inductive, while 4 induced neither bone nor cartilage. An in vitro assay system for DFDBA induction activity was developed by first characterizing the response of the mesenchymal cell line 2T9 to an

established induction factor. Based on this study osteoinduction by DFDBA varies between bone banks as well as between lots of the same bank. The variation may be the results of factors, which affect the availability of bone induction proteins present in DFDBA. Alternatively, DFDBA may contain factors, which modify the response of target cells to bone induction proteins.

Parashis et al (1998)[54]performed a study to compare clinically and radiographically the effectiveness of guided tissue regeneration, using a bioabsorbable polylactic acid softened with citric acid ester barrier and commercially available DFDBA in the treatment of 2 and 3 wall intrabony defects. 12 patients, each with one treated defect comprised each group. Soft tissue measurements and hard tissue measurements were taken and were comparable in both the groups at baseline. They were repeated at 12 months. Results showed no statistical significant differences between the 2 groups, only the exception was in the radiographic resolution of defect, which was significantly greater in the GTR group.

Graig D Brown et al (1998)[55]conducted a study to determine the potential of hydroxyapatite cement for the treatment of periodontal osseous defects. 16 patients with 2 bilaterally symmetrically vertical defects received initial therapy followed by treatment with calcium phosphate cement, flap curettage (f/c) or debridement plus DFDBA. Soft tissue, hard tissue, measurements and standardized radiographs were taken at base line and 12 months. Results showed that mean probing depth reduction, clinical attachment level gain and defect fill at sites treated with calcium phosphate cement were minimal when compared to sites treated with DFDBA and (f/c). Based on this study there was no rationale available to support the use of hydroxyapatite

cement implant in its current formulation for the treatment of vertical intrabony periodontal defects.

Lars Laurell et al (1998)[56]reviewed the studies presented during the last 20 years on the surgical treatment of intrabony defects. The treatments included open flap debridement, open flap debridement with DFDBA, freeze- dried bone allograft (FDBA) or autogenous bone and guided tissue regeneration (GTR). The review included only those studies that presented baseline and final data on probing depths, intrabony defect depth as measured during surgery, clinical attachment level gain and or bone fill. Result of meta-analysis showed that open flap debridement alone resulted in limited pocket reduction, clinical attachment level gain averaged 1.5mm and bone fill 1.1mm. Open flap debridement plus bone graft resulted in limited pocket reduction; clinical attachment level gain and bone fill averaged 2.1mm. Guided tissue regeneration resulted in significant pocket reduction, clinical attachment level gain of 4.2mm and bone fill averaging 3.2mm.

Staurt Froum et al (2002)[57]compared healing extraction sockets 6 to 8 months post implantation of a bioactive glass or DFDBA to an unfilled socket control. 30 sockets in 19 patients were randomly divided into 3 treatment groups. 10 sockets received bioactive glass, 10 sockets DFDBA, and 10 sockets served as unfilled controls, and histological cores of the treatment sites were obtained. Results concluded that although the differences in percent vital bone were not statistically significant among the 3 treatment group, bioactive glass material was observed to act as an osteoconductive material and had a positive effect on socket healing at 6 to 8 months post extraction. Residual implant material was significantly higher in DFDBA treated sockets versus bioactive glass treated sockets.

Mark A Reynolds et al (2003)[58]systemically reviewed the efficacy of bone replacement grafts in proving demonstratable clinical improvements in periodontal osseous defects compared to surgical debridement alone. The therapeutic end points examined included changes in bone level, clinical attachment level, probing depth, gingival recession and crestal resorption with respect to the treatment if intrabony defect, the results of meta-analysis supported the following conclusions;

1. Bone grafts increased bone level, reduced crestal resorption, increased clinical attachment level, and reduce probing depth compared to open flap debridement (OFD) procedures. 2)Bonegrafts in combination with barrier membranes increased clinical attachment level and reduced probing depth compared to graft alone 3)Histologically DFDBA, supported the formation of a newattachment apparatus in intrabony defects, whereas OFD resulted in repair characterized by long junctional epithelium. The results of this systemic review indicated that bone replacement grafts provided demonstrable clinical improvement in periodontal osseous defects compared to surgical debridement alone.

Gurinsky BS et al (2004)[59]conducted a study to evaluate the use of DFDBA in combination with Enamel matrix derivative compared to enamel matrix derivative alone in the treatment of human periodontal osseous defects. 40 patients with a total of 67 sites were selected for the study; each subject received either enamel matrix derivative alone, (34 sites) or enamel matrix derivative in combination with DFDBA (33sites). Both soft tissue and hard tissue measurements were taken at baseline and 6months. Results showed significant improvements in soft tissue parameters for both

treatment groups as compared to preoperative measurements. There was no statistical difference between the two groups.

Mary.E.Aichelmann-Reidy, Carlette.D.Heath & Mark.A.Reynolds (2004)[60]conducted a study to establish whether there was a significant difference in hard tissue fill of intrabony defects following treatment with either calcium sulphate or ePTFE in combination with DFDBA. 19 patients with 38 defects were selected for the study. Soft tissue and hard tissue measurements were recorded at baseline and 6 months. Defects were randomly treated with either a combination graft of DFDBA with calcium sulphate covered by a calcium sulphate barrier or with DFDBA and fitted with an ePTFE barrier. Results of this study indicated that calcium sulphate, when used as a binder and barrier in combination with DFDBA, supported significant clinical improvement in intrabony defects. Calcium sulphate represented an alternative to non-resorbable ePTFE barrier in combination with DFDBA for the treatment of intrabony defects.

Maragos, et al (2002)[61]had conducted a study to compare the effectiveness of three methods using calcium sulfate as a graft/barrier for the treatment of Class II mandibular furcation defects. A total of 36 defects in 17 patients were treated with a graft/barrier of pure calcium sulfate, calcium sulfate plus doxycycline, or demineralized freeze-dried bone allograft (DFDBA) in a 2:1 ratio by volume. The parameters recorded were vertical and horizontal probing depth , defect volume and vertical clinical attachment. Measurement parameters were standardized to a light-cured acrylic resin stent at baseline and 6, 9, and 12 months. The addition of doxycycline or DFDBA to calcium sulfate significantly enhanced the clinical outcome than calcium sulfate alone. The study concluded that the addition of DFDBA was

more effective in the treatment of Class II mandibular furcation defects than doxycycline.

GUIDED TISSUE REGENERATION

With the advent of guided tissue regeneration (GTR) based on the concept given by Melcher, restoration of periodontium is being achieved more predictably. The technique using barrier was introduced by Nyman in 1982, and the term GTR was coined by Gottlow in 1986[62]. GTR is employed with the use of resorbable and non-resorbable membranes which act as a physical barrier to avoid connective and epithelial tissue down-growth into the defect, thereby favouring the regeneration of periodontal tissues[25].

The barrier membranes recommended for use in GTR must satisfy the following criteria (Greenstein G, Caton JG 1993)

1. Biocompatibility
2. Cell occlusiveness
3. Space making
4. Tissue integration
5. Clinical manageability

Membranes used for periodontal regeneration can be classified as[62]

1. Nonresorbable expanded-PolyTetrafluoroethylene(e-PTFE)GoreTex
   High density poly tetrafluoroethylene (d-PTFE)
   Titanium mesh Titanium reinforced PTFE
2. Resorbable Polymeric (vicryl, atrisor, Epiguide) & collagen derived

Wang HL, O'Neal RB, Thomas CL, et al(1994)[63]evaluated the efficacy of a type I bovine collagen membrane in the treatment of class II furcation defects. 12 patients each with bilateral mandibular furcation defects having attachment loss>6mm were randomly assigned to either control(flap debridement alone) or test group(flap debridement with collagen membrane). Both test and control group demonstrated significant improvement in clinical and intra-surgical parameters, when compared to presurgery status. A significant improvement of furcation bone repair (horizontal) and defect fill was noted in the collagen membrane treated site as compared to presurgery status. Study suggests the use of collagen membrane have beneficial effects in treatment of class II furcation defects.

Chen CC, Wang HL, Smith F, Glickman GN, Shyr Y, O'Neal RB(1995)[64]conducted a study to compare the clinical regenerative capacity of collagen membrane with or without Demineralized(DFDBA) in treating periodontal intrabony defects in 10 patients. The defects were randomly assigned to either test (collagen membrane plus DFDBA)or control group(collagen membrane alone). The results of the study indicated that the collagen plus DFDBA and the collagen alone treated groups had significant decrease of PPD, gain of CAL, and defect fill when compared to the presurgery status. Both the groups promoted significant resolution of periodontal intrabony defects. The addition of bone graft with collagen membrane appears to add on extra benefit to collagen membrane treatment.

Paulo M. Camargo, et al(2001)[65]A controlled re-entry study on the effectiveness of bovine porous bone mineral used in combination with a collagen membrane of porcine origin in the treatment of intrabony defects in humans this study employed a split-mouth design. 22 paired intrabony defects were treated and surgically re-entered

6 months after treatment. Experimental sites were grafted with bovine porous bone mineral and received a collagen membrane for guided tissue regeneration. Control sites were treated with an open flap debridement. The results concluded that clinical resolution of intrabony defects can be achieved using a combination of bovine porous bone mineral and an absorbable, porcine derived collagen membrane.

Nevins ML, Camelo M, Lynch S, Schenk RK, Nevins M (2001)[66]evaluated the clinical , radiographic and histologic response to the composite use of bone mineral; (BIO-OSS) and the autogenous bone in combination with a bilayer collagen membrane(BIO-GIDE) for the treatment of human periodontal osseous defects.Preoperative and 9 months postoperative recordings included radiographs, clinical probing depths and attachment levels. After 9 months clinical and radiographic recordings were done and histologic sections were taken which on observation revealed new cementum(with inserting collagen fibers)and new bone formation on the surface of both types of graft materials. This human histologic study demonstrated that the autogenous bone in combination with porous bone mineral matrix, and the porcine derived collagen membrane, has the potential to stimulate significant new bone and cementum formation with Sharpey's fiber attachment.

Eickholz P, Kim TS, Dorfer C, Holle R, Hausmann E (2001)[67] conducted a 5year study to clinically and radiographically evaluate the long term results after GTR therapy of Class II furcation defects using non resorbable and bio absorbable barriers.9 pairs of contralateral class II furcation defects were treated in 9 patients with advanced periodontitis. In each patient, one defect received ePTFE(control) and other polyglactin 910(test) by random assignment. At baseline 6 and 60±3months after surgery, clinical parameters and radiographs were obtained. Gain of bone density

within furcation areas was assessed using substraction radiography. Results showed CAL-H gain achieved after GTR therapy in class II furcation was stable after 5 years in 16 of 18 defects. The study failed to show a statistically significant difference in stability of CAL -H gain between control and test groups 5 years after GTR therapy.

Sculean A , Chiantella GC, Windish P, Arweiler NB, Breex M, Gera I(2005)[68]conducted the study to compare clinically the treatment of deep intra-bony defects with a combination of a composite bovine-derived xenograft(BDX Coll) and a bioresorbable collagen membrane (GTR) to access flap surgery only. Within the limits of this present study, it was concluded that the combination of BDX Coll+GTR resulted in significantly higher CAL gains than treatment with access flap surgery alone, and thus appears to be suitable alternative for treatment intra-bony periodontal defects.

HYALURONIC ACID GEL

HISTORICAL BACKGROUND

Hyaluronic acid was discovered in 1934 by Karl Meyer and his colleague John Palmer, scientists at Columbia University, New York, who isolated a chemical substance from the vitreous jelly of cow's eyes.They proposed the name hyaluronic acid as it was derived from Greek word hyalos (glass) and contained two sugar molecules one of which was uronic acid[70].

STRUCTURE

Hyaluronic acid (HA) is naturally occurring non sulphated glycosaminoglycan with high molecular weight of 4,000- 20,000,000 daltons. HA structure consists of polyanionic disaccharide units of glucoronic acid and N-acetylglucosamine connected

by alternating β1–3 and β1–4 bonds[69] . It is a linear polysaccharide of the extracellular matrix of connective tissue, synovial fluid, embryonic mesenchymal cells, vitreous humor, skin and many other organs and tissues of the body. Most cells of the body are capable of synthesizing hyaluronic acid and synthesis takes place in the cell membrane. Hyaluronan binds to many other extracellular matrix molecules, binds specifically to cell bodies through cell surface receptors, and has a unique mode of synthesis in which the molecule is extruded immediately into the extracellular space upon formation. Extensive studies on the chemical and physicochemical properties of HA and its physiological role in humans have proved that it is an ideal biomaterial for cosmetic, medical, and pharmaceutical applications[70].

In the field of dentistry, preliminary clinical trials have been conducted by Pagnacco and Vangelisti in 1997[71]. HA has shown anti-inflammatory, anti-edematous, and anti-bacterial effects for the treatment of periodontal disease, which is mainly caused by the microorganisms present in subgingival plaque. It has been found that the equilibrium between the free radicals/reactive oxygen species (ROS) and antioxidants is the major prerequisite for healthy periodontal tissue. Individuals suffering from periodontitis might be at a higher risk of developing other systemic inflammatory diseases like cardiovascular diseases and diabetes.

PROPERTIES[69,70]

1. **Hygroscopic nature**

Hyaluronic acid is one of the most hygroscopic molecules known in nature. When HA is incorporated into aqueous solution, hydrogen bonding develops between adjacent carboxyl and N-acetyl groups; this feature allows hyaluronic acid to maintain

conformational stiffness and to retain water. One gram of hyaluronic acid can bind up to 6 L of water. As a physical background material, it has functions in space filling, lubrication, shock absorption, and protein exclusion (Sutherland IW 1998).

2. **Viscoelastic properties**

The viscoelastic properties of the material may slow the penetration of viruses and bacteria, a feature of particular interest in the treatment of periodontal diseases. Hyaluronan as a viscoelastic substance assists in periodontal regenerative procedures by maintaining spaces and protecting surfaces[(64)]. Through recognition of its hygroscopic and viscoelastic nature, hyaluronic acid can influence the cell functions that modify the surrounding cellular and extracellular micro and macro environments.

FUNCTIONS

1. **Modulation of inflammation**
    - Enhanced inflammatory cell and extracellular matrix cell infiltration into the wound site
    - Elevation in pro-inflammatory cytokine production by inflammatory cells and extracellular matrix cells.
    - Organization and stabilization of granulation tissue matrix.
    - Scavenges reactive oxygen species, such as superoxide radical ($\cdot O_2$) and hydroxyl radical ($\cdot OH$) thus preventing periodontal destruction.
    - Inhibition of inflammatory cell-derived serine proteinases (Weigel PH et al., 1988)

2. **Stimulation of cell migration, proliferation, and differentiation**

The remarkable hydrophilicity of hyaluronic acid makes the coagulum more receptive and thus more likely to undergo colonization by the cells committed to the reconstruction of the damaged tissue by migration, proliferation and differentiation of mesenchymal and basal keratinocytes (Toole BP 2001).

3. **Effect on angiogenesis**

Deed R et al., 1997 , studied the effect of hyaluronan on angiogenesis and stated that low molecular weight hyaluronic acid has a marked angiogenic effect whereas, surprisingly, high molecular weight has the opposite effect.

4. **Osteoconductive potential**

Hyaluronic acid accelerates the bone regeneration by means of chemotaxis, proliferation and successive differentiation of mesenchymal cells. Hyaluronic acid shares bone induction characteristics with osteogenic substances such as BMP-2 and osteopontin (Mendes RM et al., 2008).

5. Carrier function

Hyaluronic acid may act as biomaterial scaffold for other molecules, such as BMP-2 and PDGF-BB, used in guided bone regeneration techniques and tissue engineering research (Hunt DR et al., 2001)

6. **Bacteriostatic effect**

Recent studies on regenerative surgical procedures indicate that reduction of bacterial burden at the wound site may improve the clinical outcome of regenerative therapy.

The high concentration of medium and lower molecular weight hyaluronic acid has the greatest bacteriostatic effect, particularly on Aggregatibacter actinomycetemcomitans, Prevotella oris and Staphylococcus aureus strains commonly found in oral gingival lesions and periodontal wounds (Pirnazar P et al., 1999)

CLINICAL APPLICATIONS IN PERIODONTICS

- Topical application of subgingival hyaluronic acid gel can be used as an adjunct to scaling and root planing.
- Bone regeneration in periodontal bony defects.
- Guided Bone Regeneration.
- In non-surgical therapy of peri-implant pockets.
- Peri-implant maintenance of immediate function implants.
- As autologous cell hyaluronic acid graft gingival augmentation in mucogingival surgery.
- As a carrier for newer molecules in various regenerative procedures.
- As a biomaterial scaffold in tissue engineering research.

CLINICAL STUDIES

Pirnazar P et al., 1999[71] suggested that the clinical application of hyaluronic membrane, gels or sponges during surgical therapy reduces bacterial contamination of surgical wound site, thereby, lessening the risk of postsurgical infection and promoting more predictable regeneration.

According to **Hunt DR et al., 2001**[72], hyaluronan is thought to be the best carrier for the Bone Morphogenic Proteins (BMP), the growth factors commonly documented to stimulate the formation of new bone tissue.

Pistorius Alixander et al., 2005[73], evaluated the efficacy of topical application of HA for treatment of gingivitis and found that topical application of HA containing preparation was potentially useful adjunct in the therapy of gingivitis. Gengigel® (Ricerfarma s.r.l, Milano, Italy) is a topically applied anti-inflammatory product that has been specifically developed for dental use. It contains high molecular weight fractions of hyaluronic acid in gel formulation with 0.2% concentration.

According to **Koshal A et al., 2007**[74], the adjunctive use of Gengigel® after thorough mechanical debridement has major clinical benefits in terms of improved healing after non-surgical therapy and demonstrates significant improvements in bleeding on probing and pocket depth measurements.

Vanden Bogaerde L. 2009[75], treated periodontal intra-bony defects with esterified hyaluronic acid. A full-thickness flap was raised and the roots were accurately planed; hyaluronic acid in the form of fibers was then packed into the defect to completely fill the space. One year after treatment, the mean PPD was reduced by 5.8 mm (range, 0 to 10 mm), gingival recession had increased by 2.0 mm (range, 0 to 6 mm), and attachment gain was 3.8 mm (range, 0 to 7 mm).

Pilloni et al., 2011[76], in their randomized controlled clinical pilot study, evaluated the efficacy of an esterified form of HA gel on periodontal clinical parameters. The periodontal clinical parameters were plaque index (PI), BOP, PPD, gingival index (GI), and probing attachment level. In the end of the study, they concluded that an esterified gel form of HA has shown an effect in reducing the gingival inflammation when used as an adjunct to mechanical home plaque control and that it could be successfully used to improve the periodontal clinical indexes.

Fawzy El‑Sayed et al., 2012[77], in a randomized controlled trial evaluated the effect of local application of 0.8% Hyaluronan gel in conjunction with periodontal surgery and noted statistically significant differences in clinical attachment level ($P < 0.05$) in favor of the test sites though non-significant results were obtained regarding probing depth.

Sandhu GK et al., 2015[80] reported the regenerative capacity of HA gel (Gengigel®) in conjunction with PRF in a patient with Grade II furcation defect, through surgical re‑entry after 6 months. The furcation area was reassessed clinically with the help of Q2N Naber's probe to assess the bone fill. Healing was uneventful and at 6 months of follow‑up, there was substantial defect fill in the furcation area with a residual horizontal dimension of <1 mm at 6 months, representing a significant percentage of bone formation. Hence it was observed that the combined approach resulted in significant furcation defect fill on re‑evaluation at 6 months.

Kalra et al., in 2015[81] reported the radiographic assessment of the regenerative capacity of HA gel (Gengigel®) in conjunction with bioactive amnion GTR membrane in a patient with Grade II furcation defect. Roentgenographic assessment was done at 4 months and 6 months postoperatively. It resulted in complete defect fill and loss of radiolucency at 6 months. The authors stated that the surgical placement of HA gel along with amnion membrane in the furcation defect can significantly improve the periodontal defect morphology.

Sugandha Gupta et al., 2017[82], evaluated the role of Gengigel® (0.8% hyaluronic acid) as a potential material for regeneration of lost attachment apparatus. A total of 20 sites with Grade II furcation defects from 10 patients were selected using random

sampling technique. These were divided into Group A (placement of hyaluronic acid) and Group B (without placement of hyaluronic acid) according to treatment modality. Furcation defect assessment was done in vertical and horizontal depth preoperatively and postoperatively at six months through surgical re-entry. The results showed that mean plaque index, gingival index and bleeding index score were statistically significant for both the groups at baseline and six months. Mean difference in probing pocket depth and Relative Attachment Level (RAL) were statistically highly significant, whereas, mean difference of gingival position margin was not significant for both the groups, at baseline and six months. Mean difference in horizontal component at baseline and six months was statistically highly significant for both the groups. Mean difference in vertical component at baseline and six months was statistically significant for both the groups. On comparison, the mean difference in vertical and horizontal component of Group A and Group B at six months was statistically not significant. It was concluded that both Gengigel® with coronally positioned flap and coronally positioned flap alone were effective in the treatment of Grade II furcation defects. The combination of Gengigel® with coronally positioned flap leads to better results in hard tissue measurement as compared to coronally positioned flap alone.

MATERIALS AND METHODS

SOURCE OF DATA:

The study was conducted in the Department of Periodontics, KAHER's KLE V.K. Institute of Dental Sciences, Belagavi. It was a randomized controlled clinical trial which was carried out over a period of 6 months. An ethical clearance (Annexure I) was obtained before conducting the study from the Ethical Committee, KAHER's KLE V.K. Institute of Dental Sciences, Belagavi.

The sample size was calculated by using the following formula:

Npairs = $\frac{2(s^2)}{d^2}(Z_{1-\alpha/2} + Z_{1-\beta})^2$

Where,

S = S2-S1 = 1.05-0.72=0.33

Zα= 1.96

Zβ=0.842

d= 0.9765

Power(%) = 85

α Error (%) = 5

β error (%) = 20

Thus, a total of 13 patients with a total of 26 sites having bilateral Grade II furcation involvement, reporting to the outpatient unit, Department of Periodontics, KAHER's KLE V.K. Institute of Dental Sciences, Belagavi were selected for the study.

Informed consent (Annexure II) was taken from all the subjects after explanation of the nature, risks and benefits of the clinical procedure.

Patients who met the following criteria were included in the study:

INCLUSION CRITERIA:

- A total of 26 mandibular molars with grade II furcation involvement (buccal or lingual) according to Hamp et al classification of furcation (1975), Naber's probe marking 3-4mm.
- Patients aged between 25-60 years .
- Pocket probing depth of ≥5mm.
- Patients with no medical history.
- Patient who have not received any type of periodontal therapy in the past 6months.

EXCLUSION CRITERIA:

- Systemic conditions affecting bone density e.g. osteoporosis, Paget's disease.
- Use of anticoagulants and immunosuppressive agents or any other drugs that interfere with the healing process.
- History of drug intake in the past 6 months that can affect bone metabolism.
- Pregnant or lactating women.
- Patients who have undergone any periodontal treatment or received antibiotic therapy in the last 3 months.

STUDY DESIGN

13 subjects with 26 sites of mandibular bilateral Grade II furcationswere selected. A thorough phase I therapy (supragingival and subgingival scaling) was done for all the subjects. Subjects were recalled after three weeks for regenerative procedure. Laboratory investigations such hemoglobin level, bleeding time and clotting time, random blood sugar level were assessed prior to the surgery. Pre-operative photographs were taken.

They were divided into 2 groups by lottery method of randomization. The groups were as follows:

- Group A –Grade II furcation defects treated with Demineralized Freeze Dried Bone Allograft (DFDBA) and Guided Tissue Regenerative Membrane(HEALIGUIDE®)
- Group B - Grade II furcation defects treated with 0.8% GENGIGEL® and Guided TissueRegenerative Membrane (HEALIGUIDE®)

  A proforma (Annexure III) was designed for the study to enable methodological recording of all the observations and information. The relevant data comprising of personal details of the patient, chief complaint, past dental history were recorded before starting the surgical procedure.

OCCLUSAL STENT FABRICATION:

Customized acrylic stent using cold-cure acrylic resins will be prepared on the stone models by taking alginate impression of the patients. Extent of the Stent will be on one adjacent tooth in the mesial and distal direction and will cover the coronal third of tooth crowns. Vertical groove will be made in relation to the involved tooth,

which will guide the probe while recording the measurements. This technique provides a fixed reference point(FRP) and fixed angulations for measurements of parameters pre operatively as well as post operatively. All the customized acrylic stents should be stored on the prepared study cast throughout the study period to minimize distortion.

The following clinical parameters were measured with the aid of a William's graduated periodontal probe in millimetres:

- Probing Pocket Depth (PPD): It was measured from gingival margin to base of the sulcus.

- Sulcus Bleeding index (BI) :It is developed by MUHLEMANN H.R and SON.S in 1971.The purpose of this index is to locate areas of gingival sulcus bleeding upon gentle probing.

- Relative Attachment Level (RAL): It is measured from the fixed reference point(occlusal stent) to the base of the pocket.

  Along with the previous mentioned clinical parameters, the radiographic parameters weremeasured at baseline, 1 month and 6 months after surgery.

  The horizontal component of the furcation was evaluated using a Nabers probe and the vertical component is measured on a radiograph. The radiographic assessment was done using RADIOVISIOGRAPHY with grid in position.

CLINICAL ARMAMENTARIUM

1. Surgical drape
2. Disposable head cap
3. Disposable Mouth mask
4. Disposable gloves
5. Cotton swabs and gauze
6. 2% Lignocaine HCl containing 1:80,000 adrenaline with sterile and disposable syringe
7. Kidney tray
8. Mouth mirror
9. Straight probe
10. Tweezers
11. Explorer
12. William's periodontal probe
13. Nabers probe
14. Bard Parker handle with 11,12,15
15. Molts Periosteal Elevator
16. Gracey curettes
17. Castroviejo scissors
18. Adson tissue holding forceps
19. Needle holder
20. Saline with sterile and disposable irrigating syringes
21. Dappen dish
22. DFDBA(Tata Tissue Bank, Mumbai, Maharashtra) as graft material
23. Syringe loaded with GENGIGEL® (RICERFARMA ,Milano, ITALY)

24. Collagen membrane (HEALIGUIDE®)
25. Suture material - 4-0 Vicrylresorbable suture (Ethicon, Jhonson and Jhonson PVT Ltd.)
26. Black braided silk suture.
27. Periodontal pack (Coe Pak™,GC America Inc, USA)

SURGICAL TECHNIQUE

GROUP A

Demineralized Freeze Dried Bone Allograft (DFDBA) +Guided Tissue Regenerative Collagen Membrane

- The operative site was local anaesthetised (2% Lignocaine HCl with 1:80,000 Adrenaline),.
- Horizontal incisions were given using a no.15 blade and a full thickness mucoperiosteal flap was reflected using a periosteal elevator.
- The granulation tissue was debrided and root planning was performed using Gracey curettes.
- Required quantity of DFDBA was transferred into a Dappen dish and mixed with saline.
- Small increments of the material was placed at the defect site, condensed and completely filled followed by placement of GTR collagen membrane (HEALIGUIDE®)
- The collagen membrane was stabilized with 4-0 Vicrylresorbable suture(Ethicon, Jhonson and Jhonson PVT Ltd.)
- Following this, the mucoperiosteal flap was repositioned andinterrupted sutures were placed using silk suture(3-0)
- After which periodontal dressing (Coe Pak™) was given.

GROUP B

Gengigel®+Guided Tissue Regenerative Collagen Membrane

- Adequate quantity of localanaesthesia was administered (2% Lignocaine HCl with 1:80,000 Adrenaline).
- Using a no.15 blade horizontal incisions were given and a full thickness mucoperiosteal flap was reflected using aMolts no 9 periosteal elevator.
- Debridement and root planning was performed using Gracey curettes.
- Required quantity of 0.8%Gengigel® was taken in a disposable syringe and placed at the defect site.
- Following this, the GTR collagen membrane (HEALIGUIDE®) was placed and stabilized with 4-0 Vicrylresorbable suture(Ethicon, Jhonson and Jhonson PVT Ltd.)
- The mucoperiosteal flap was then repositioned and interrupted sutures were placed using silk suture(3-0).
- After which periodontal dressing (Coe Pak™) was placed over the surgical site.

The post-operative pharmacological regime included antibiotics (combination of Amoxicillin 500 mg and Clavulanic acid 125 mg twice daily for 5 days) & analgesics (Ketorolac 10 mg twice daily for 3 days) along with betadinemouth rinse.

Following post-operative instructions were given to the patients

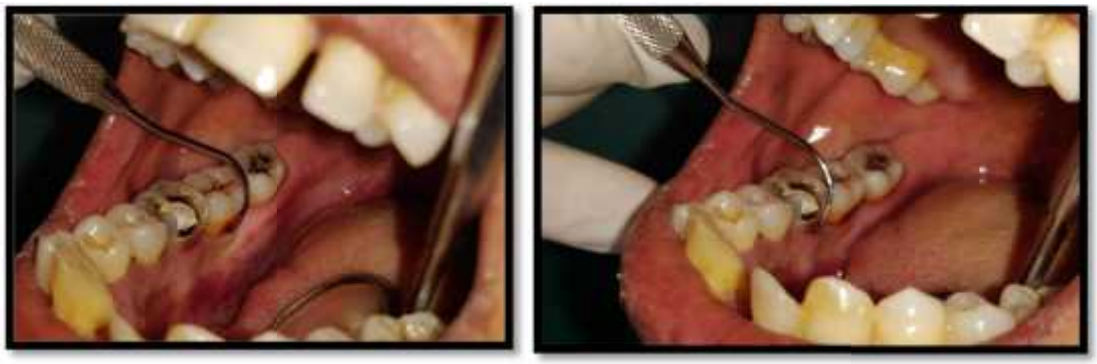
1) Avoid spitting and rinsing for first 24 hrs after the surgery.
2) Avoid brushing vigorously in the operated area.
3) Avoid touching the operated area with tongue or finger.
4) Consume semi-solid or liquid diet for first 24 hrs after the surgery.
5) Apply ice intermittently on the face over the operated area on the day of the surgery.
6) Avoid too hot or spicy food.
7) In case of any excessive bleeding, report to the clinician as soon as possible.
8) Rinse with 10ml of 0.2% chlorhexidine mouth rinse twice daily for 7 days.
9) Take the medication as prescribed by the dentist.

All the patients were recalled for suture removal after 7 days of the surgery. Clinical parameters were recorded for all patients at a follow-up of 1 month, 3 months and 6 months subsequently.

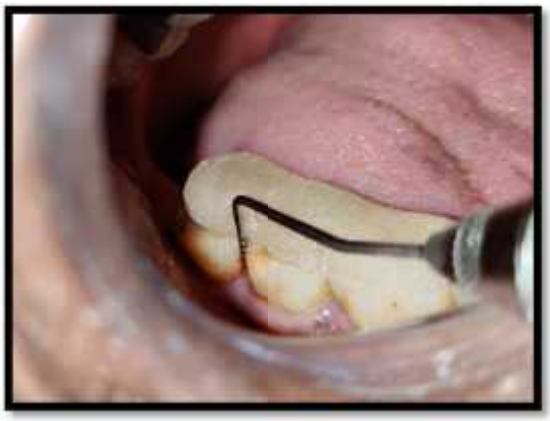
FIG 1: ARMAMENTARIUM

FIG 2: MATERIALS USED FOR THE STUDY

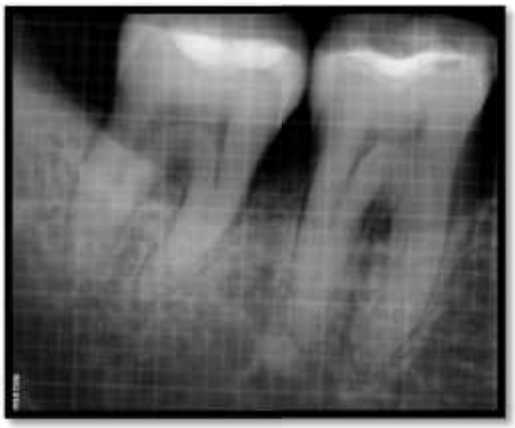
FIG 3: GROUP A (DFDBA+GTR)



Pre-operative Evaluation of Grade II furcation Using Nabers Probe



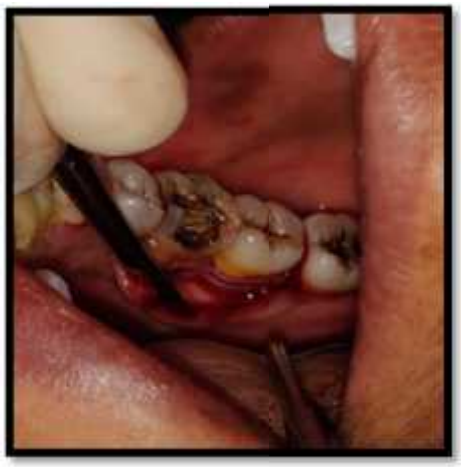
Measuring Probing Depth Using Pre-Fabricated Stent



RVG at baseline

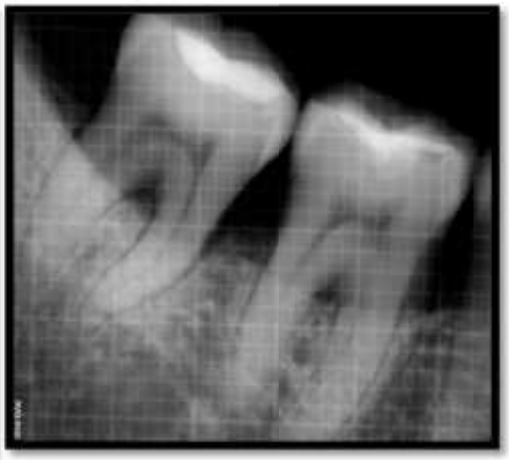
Mucoperiosteal Flap Elevation

Placement of Bone Graft (DFDBA)

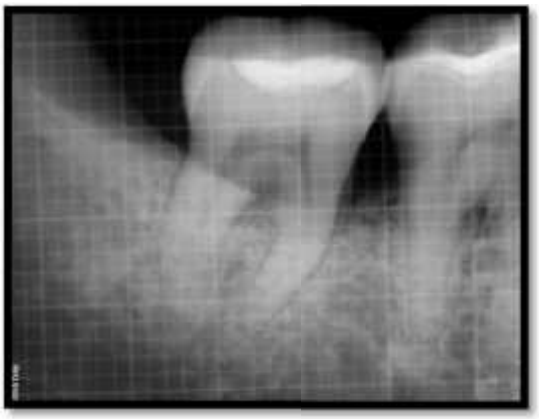


Collagen membrane placed and sutured

Flap approximated and sutured



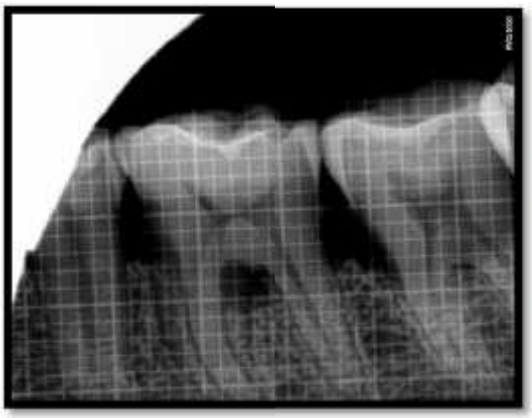
Post Operative1 Month follow- up
CLINICAL AND RADIOGRAPHIC ASSESSMENT



Post Operative6 Month follow up
CLINICAL AND RADIOGRAPHIC ASSESSMENT

FIG 4: GROUP B (GENGIGEL +GTR)

Pre- Operative Measurements At Baseline



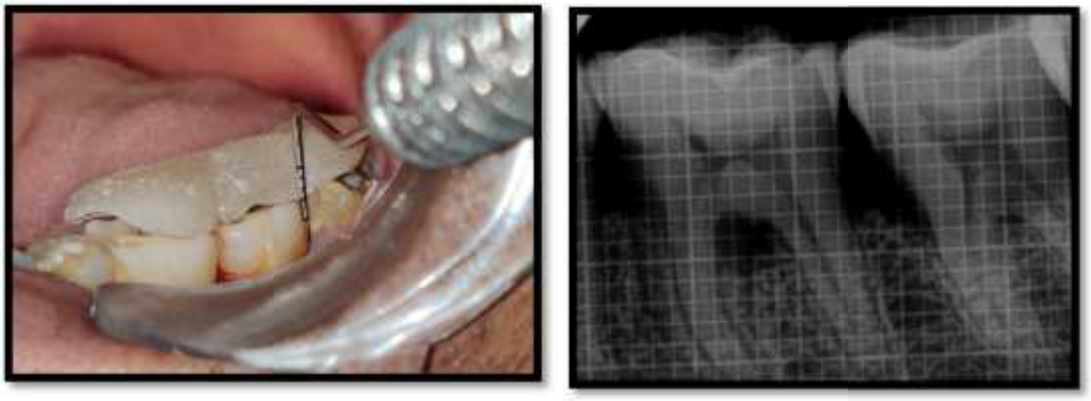
RVG At Baseline

Mucoperiosteal flap elevation

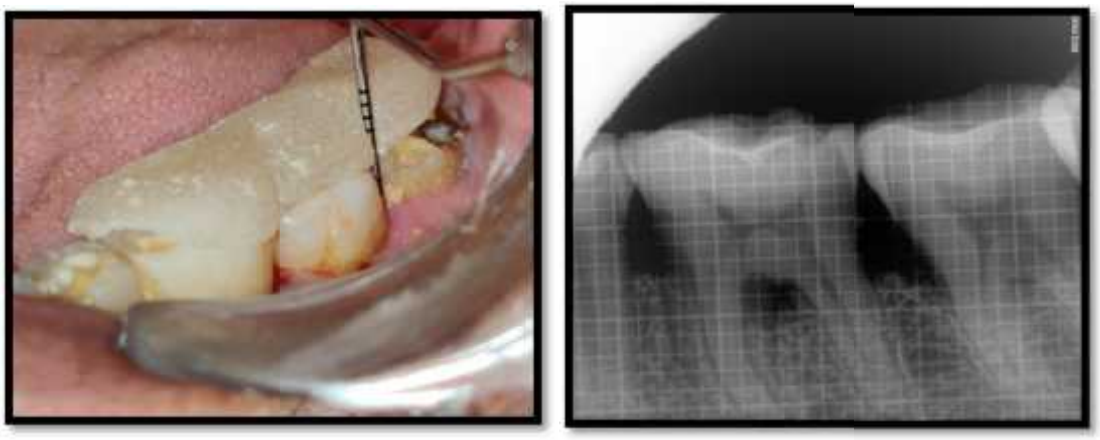
Placement ofGengigel

Collagen Membrane Placed and Sutured

Suturing Done



Post – Op 1 Month follow up (Clinical and Radiographic Photographs)



Post – Op 6month Follow Up (Clinical and Radiographic Photographs)

RESULTS AND OBSERVATIONS

A total of 13 patients with mandibular Grade II furcation defects were treated with either DFDBA and guided tissue regeneration (DFDBA + GTR) (Group A) or 0.8% GENGIGEL and guided tissue regeneration (0.8% GENGIGEL + GTR) (Group B) .All the patients were recalled at 1 month and 6 months for follow-up out of which 3 patients could not report for follow up and hence were considered drop outs due the current situation of covid-19. Therefore, the statistical analysis was carried out for 10 patients who reported at subsequent follow-ups.

The data was entered in Microsoft excel and subjected to statistical analysis using SPSS software version 20.0.

Baseline data for both the groups was almost the same as the study was carried out with a split mouth design. Of the 10 patients, 6 were females and 4 were males with a mean age of37.93±6.02.(Table1 and Table 2).

The scores of variables – Sulcus Bleeding Index(SBI) ,Probing Pocket Depth (PPD), Relative Attachment Level(RAL), Horizontal Furcation Involvement, Vertical Furcation Involvement at different time points in Group A and Group B were recorded. Independent t- test was applied for intergroup comparison between Group A and Group B and Kolmogorov Smirnov test was applied for intra group comparison.

Table 1 : Gender wise distribution.

Gender	Number	Percent
Male	4	40.00
Female	6	60.00
Total	10	100.00

Table 2: Comparison of Group A and Group B with mean age by Independent t-test

Groups	Mean	SD	SE	t-value	P-value
Group A	37.93	6.02	1.12	0.0000	1.0000
Group B	37.93	6.02	1.12		

Table 3 :Comparison of Group A and Group B with Sulcus Bleeding Index at baseline, 1month and 6months time points by Independent t-test.

Time points	Group A		Group B		t-value	p-value
	Mean	SD	Mean	SD		
Baseline	1.84	0.37	1.72	0.33	0.7660	0.4536
1 month	1.29	0.37	1.27	0.31	0.1046	0.9179
6 months	0.89	0.20	0.86	0.19	0.3493	0.7309
BL-1M	0.55	0.38	0.45	0.35	0.6389	0.5309
BL-6M	0.96	0.40	0.87	0.37	0.5215	0.6084
1M-6M	0.40	0.26	0.42	0.26	-0.1209	0.9051

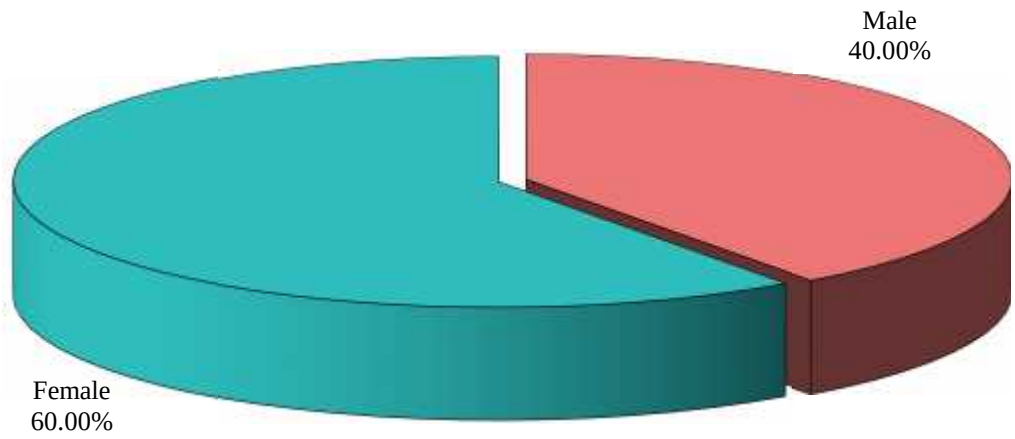
SD- Standard Deviation

Table 4 : Comparison at baseline , 1month and 6months time points with Sulcus Bleeding Index in Group A and Group B by Kolmogorov Smirnov

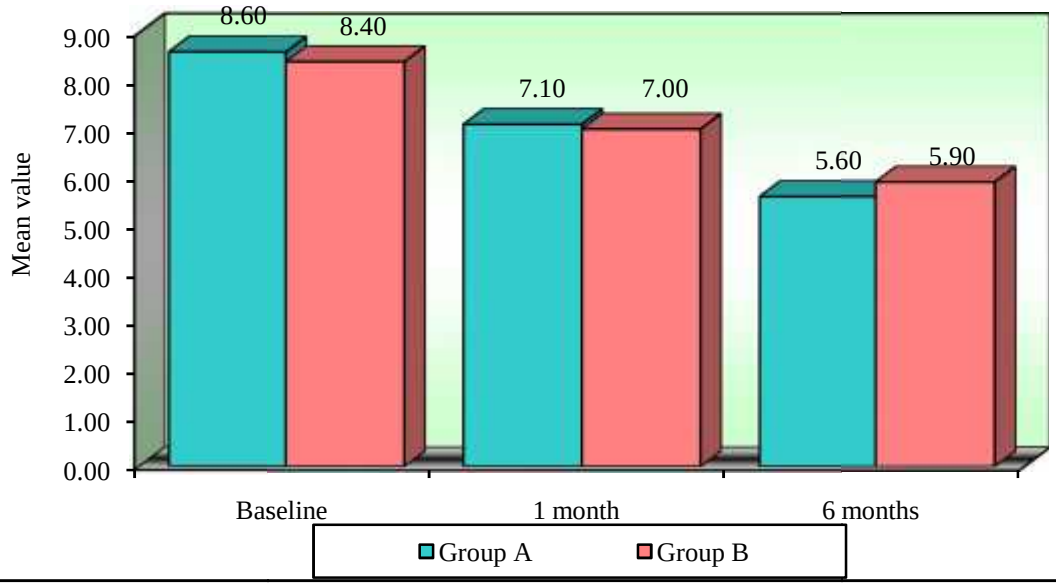
Groups	Time points	Mean	SD	Mean Diff.	SD Diff.	% of change	Paired t	P-value
Group A	Baseline	1.84	0.37					
	1month	1.29	0.37	0.55	0.38	30.04	4.6403	0.0012*
	Baseline	1.84	0.37					
	6 months	0.89	0.20	0.96	0.40	51.95	7.6055	0.0001*
	1 month	1.29	0.37					
	6 months	0.89	0.20	0.40	0.26	31.32	4.9744	0.0008*
Group B	Baseline	1.72	0.33					
	1month	1.27	0.31	0.45	0.35	26.10	4.0667	0.0028*
	Baseline	1.72	0.33					
	6 months	0.86	0.19	0.87	0.37	50.35	7.3577	0.0001*
	1 month	1.27	0.31					
	6 months	0.86	0.19	0.42	0.26	32.81	5.0617	0.0007*

*p<0.05, MD- Mean Difference, SD- Standard Deviation.

Graph 1: Gender wise distribution



Graph 2: Comparision of group A and group B with relative attachment level (mm) at baseline, 1 month and 6 months time points



SULCUS BLEEDING INDEX(SBI) (Table 3,4; Graph 1,2)

The mean sulcus bleeding index at baseline for control group was 1.84 with S.D ± 0.37, whereas values at 1 month was 1.29 ± 0.37 and 0.89± 0.20 at 6 months. The mean sulcus bleeding index when compared from baseline to 6 months was 0.96 ± 0.40 which was statistically significant.

The mean sulcus bleeding index at baseline for experimental group was 1.72 with S.D ± 0.33, whereas values at 1 month was 1.27 ± 0.31 and 0.86 ± 0.19 at 6 months. The mean sulcus bleeding index when compared from baseline to 6 months was 0.87 ± 0.37 which was statistically significant.

The mean sulcus bleeding depth when compared between the control and experimental groups at 6 months post surgery was 0.03, which was not statistically significant. The comparison showed no much difference between the experimental group and the control group.

Table 5: Comparison of group A and group B with Probing Pocket Depth at baseline , 1month and 6months time points by Independent t test.

Time points	Group A		Group B		t-value	p-value
	Mean	SD	Mean	SD		
Baseline	7.00	0.94	7.20	0.79	-0.5145	0.6132
1 month	5.50	1.08	6.00	0.94	-1.1028	0.2846
6 months	2.50	1.08	2.40	0.84	0.2308	0.8201
BL-1M	1.50	0.53	1.20	0.79	1.0000	0.3306
BL-6M	4.50	1.18	4.80	1.32	-0.5369	0.5979
1M-6M	3.00	1.25	3.60	1.07	-1.1523	0.2643

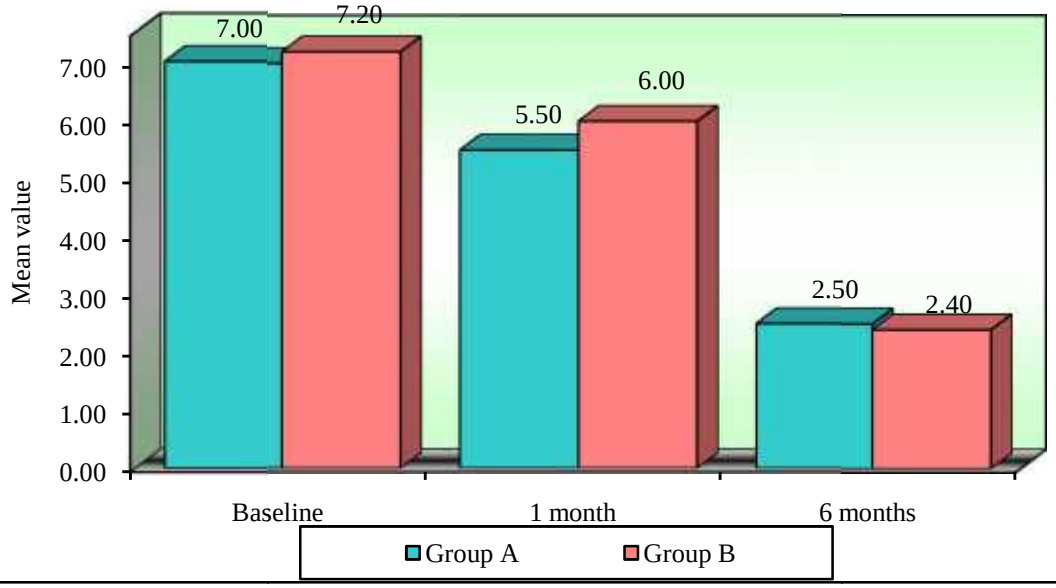
MD- Mean Difference, SD- Standard Deviation.

Table 6 : Comparison of baseline, 1 month and 6months time points with Probing Pocket Depth in Group A and Group B by Kolmogorov Smirnov

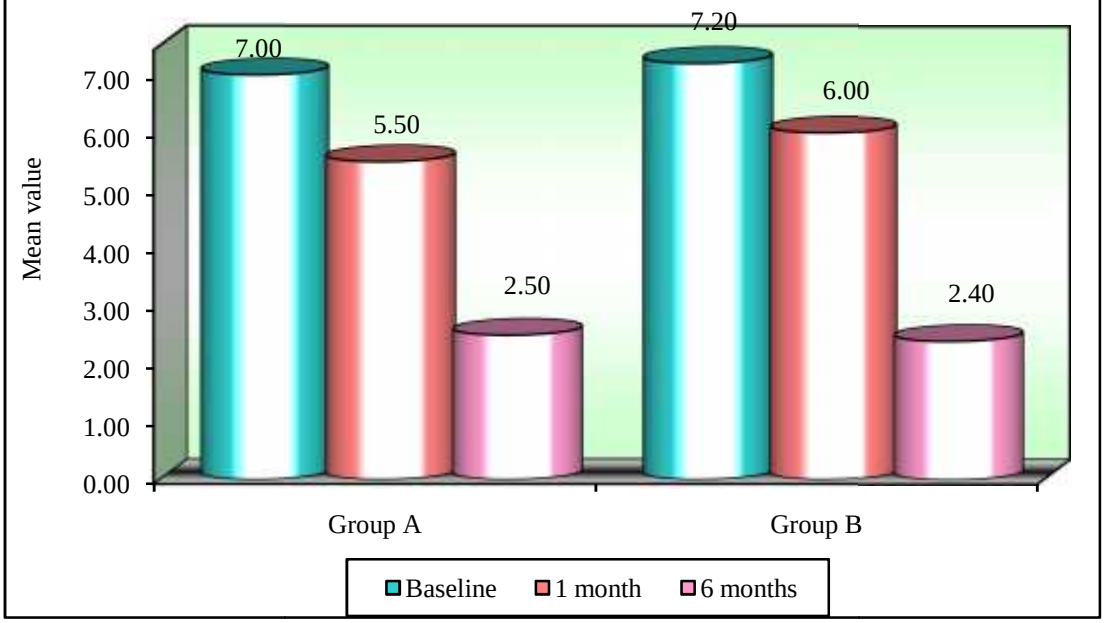
Groups	Time points	Mean	SD	Mean Diff.	SD Diff.	% of change	Paired t	P-value
Group A	Baseline	7.00	0.94					
	1month	5.50	1.08	1.50	0.53	21.43	9.0000	0.0001*
	Baseline	7.00	0.94					
	6 months	2.50	1.08	4.50	1.18	64.29	12.0748	0.0001*
	1 month	5.50	1.08					
	6 months	2.50	1.08	3.00	1.25	54.55	7.6064	0.0001*
Group B	Baseline	7.20	0.79					
	1month	6.00	0.94	1.20	0.79	16.67	4.8107	0.0001*
	Baseline	7.20	0.79					
	6 months	2.40	0.84	4.80	1.32	66.67	11.5292	0.0001*
	1 month	6.00	0.94					
	6 months	2.40	0.84	3.60	1.07	60.00	10.5903	0.0001*

*$p<0.05$, MD- Mean Difference, SD- Standard Deviation.

Graph 3: : Comparision of group A and group B with pocket probing depth (mm) at baseline, 1 month and 6 months time points



Graph 4: Comparision Of At Baseline,1 Month And 6 Months Time Points With Pocket Probing Depth (mm) in group A and group B



PROBING POCKET DEPTH (Table 5,6; Graph 3,4)

The main pocket depth at baseline was 7.00mm with S.D ± 0.94 for the control group, whereas values at 1 month were 5.50 ± 1.08 and 2.50 ± 1.08 at 6 months post surgery. The mean pocket depth reduction when compared from baseline to 6 months was 4.50 ± 1.18 which was statistically significant.

The main pocket depth at baseline was 7.20mm with S.D ± 0.79 for the experimental group, whereas values at 1 month were 6.00 ± 0.94 and 2.40 ± 0.84 at 6 months post surgery. The mean pocket depth reduction when compared from baseline to 6 months was 4.80 ± 1.32 which was statistically significant.

The mean pocket depth reduction when compared between the experimental and control group at 6 months post surgery was 0.5mm which was not statistically significant. The comparison showed pocket depth reduction for the control group as compared to experimental group.

Table 7 : Comparison of Group A and Group B with Relative Attachment Level at baseline , 1month and 6months time points by Independent t test.

Time points	Group A		Group B		t-value	p-value
	Mean	SD	Mean	SD		
Baseline	8.60	1.43	8.40	1.35	0.3216	0.7514
1 month	7.10	0.99	7.00	1.25	0.1982	0.8451
6 months	5.60	0.97	5.90	1.29	-0.5896	0.5628
BL-1M	1.50	0.97	1.40	0.70	0.2641	0.7947
BL-6M	3.00	1.15	2.50	0.71	1.1677	0.2581
1M-6M	1.50	0.85	1.10	0.57	1.2377	0.2317

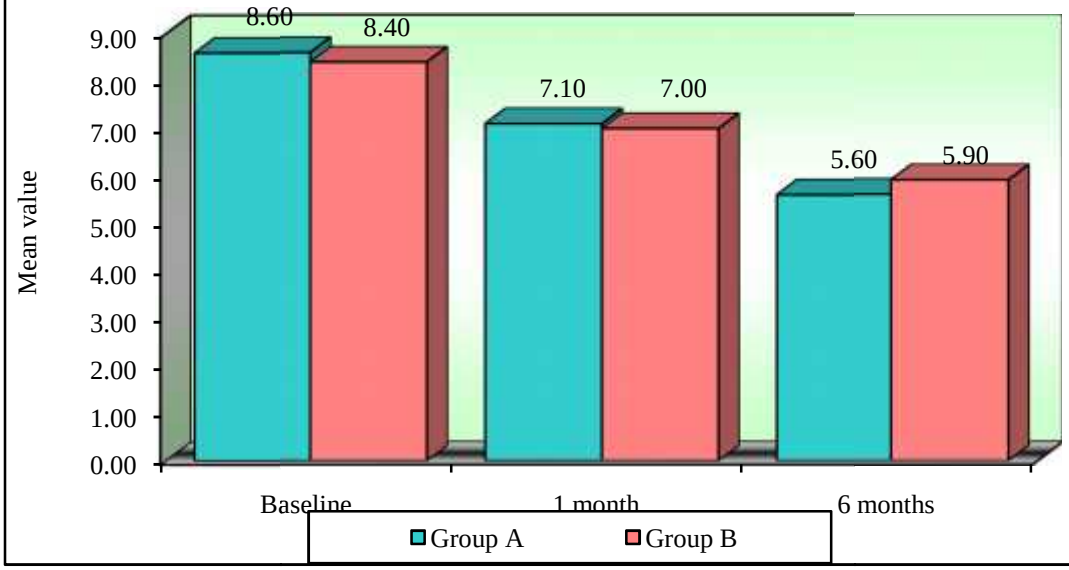
SD- Standard Deviation.

Table 8 : Comparison of baseline, 1month and 6months time points with Relative Attachment Level in Group A and Group B Kolmogorov Smirnov

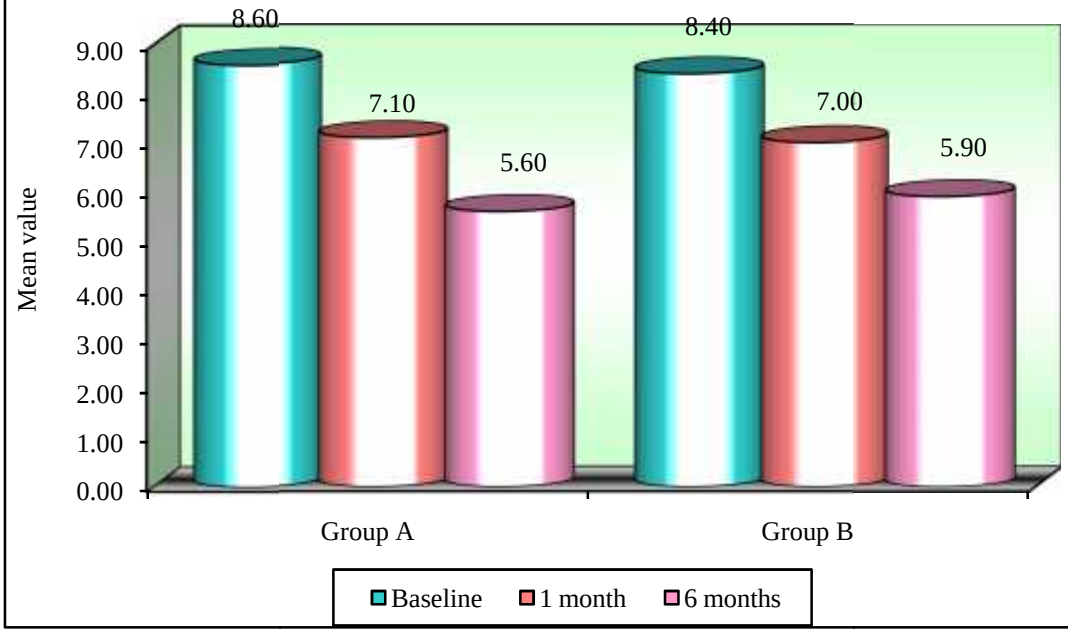
Groups	Time points	Mean	SD	MD	SD Diff.	% of change	Paired t	P-value
Group A	Baseline	8.60	1.43					
	1month	7.10	0.99	1.50	0.97	17.44	4.8809	0.0009*
	Baseline	8.60	1.43					
	6 months	5.60	0.97	3.00	1.15	34.88	8.2158	0.0001*
	1 month	7.10	0.99					
	6 months	5.60	0.97	1.50	0.85	21.13	5.5816	0.0003*
Group B	Baseline	8.40	1.35					
	1month	7.00	1.25	1.40	0.70	16.67	6.3317	0.0001*
	Baseline	8.40	1.35					
	6 months	5.90	1.29	2.50	0.71	29.76	11.1803	0.0001*
	1 month	7.00	1.25					
	6 months	5.90	1.29	1.10	0.57	15.71	6.1279	0.0002*

*$p<0.05$, MD- Mean Difference, SD- Standard Deviation.

GRAPH 5: Comparision of group A and group B with relative attachment level (mm) at baseline, 1 month and 6 months time points



Graph 6: Comparision of at baseline, 1 month and 6 months time points with relative attachment level (mm) in group A and group B



RELATIVE ATTACHMENT LEVEL(Table 7,8; Graph 5,6)

The mean relative attachment level at baseline for control group was 8.60mm with S.D ± 1.43, whereas value at 1month was 7.10 ± 0.99 and 5.60 ± 0.97 at 6 months post surgery. The mean relative attachment level when compared from baseline to 6 months was 3.00 ± 1.15 which was statistically significant.

The mean relative attachment level at baseline for experimental group was 8.40mm with S.D ± 1.35, whereas value at 1 month was 7.00 ± 1.25 and 5.90 ± 1.29 at 6 months post surgery. The mean relative attachment level when compared from baseline to 6 months was 2.50 ± 0.71 which was statistically significant.

The mean relative attachment level when compared between the experimental and control group at 6 months post surgery was 0.3mm, which was not statistically significant. The comparison showed higher relative attachment level gain for the experimental group as compared to control group.

Table 9 :Comparison of Group A and Group B with Horizontal Furcation Involvement at baseline, 1month and 6months time points by Independent t- test

Time points	Group A		Group B		t-value	p-value
	Mean	SD	Mean	SD		
Baseline	4.20	0.63	4.30	0.67	-0.3419	0.7364
1 month	3.90	0.74	4.10	0.74	-0.6061	0.5520
6 months	1.50	0.85	1.30	0.95	0.4966	0.6255
BL-1M	0.30	0.48	0.20	0.42	0.4932	0.6278
BL-6M	2.70	0.67	3.00	0.94	-0.8182	0.4240
1M-6M	2.40	0.52	2.80	1.03	-1.0954	0.2878

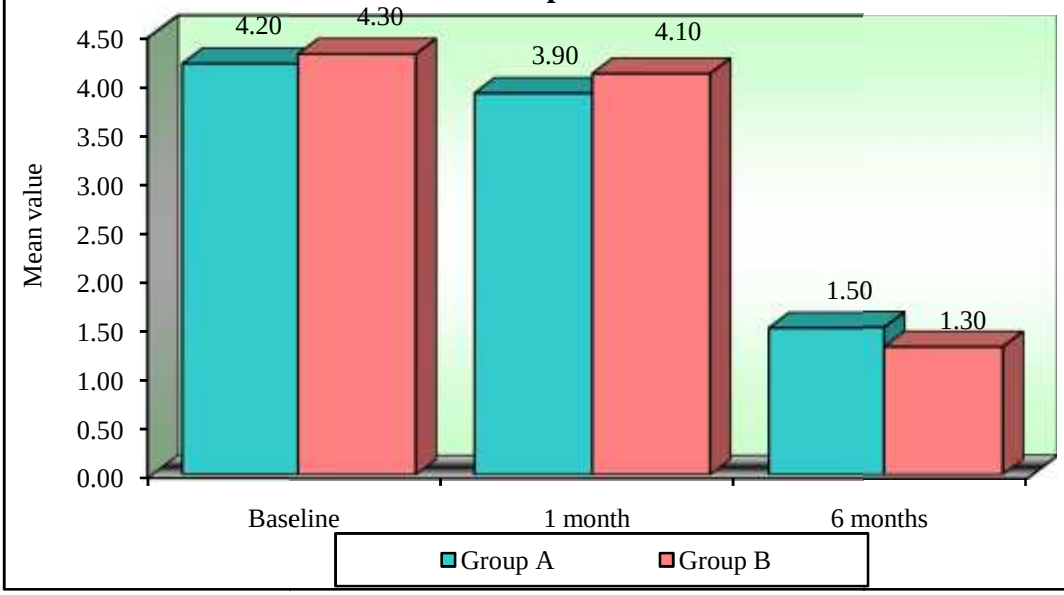
SD- Standard Deviation.

Table 10: Comparison of baseline, 1month and 6months time points with Horizontal Furcation Involvement in Group A and Group B by Kolmogorov Smirnov

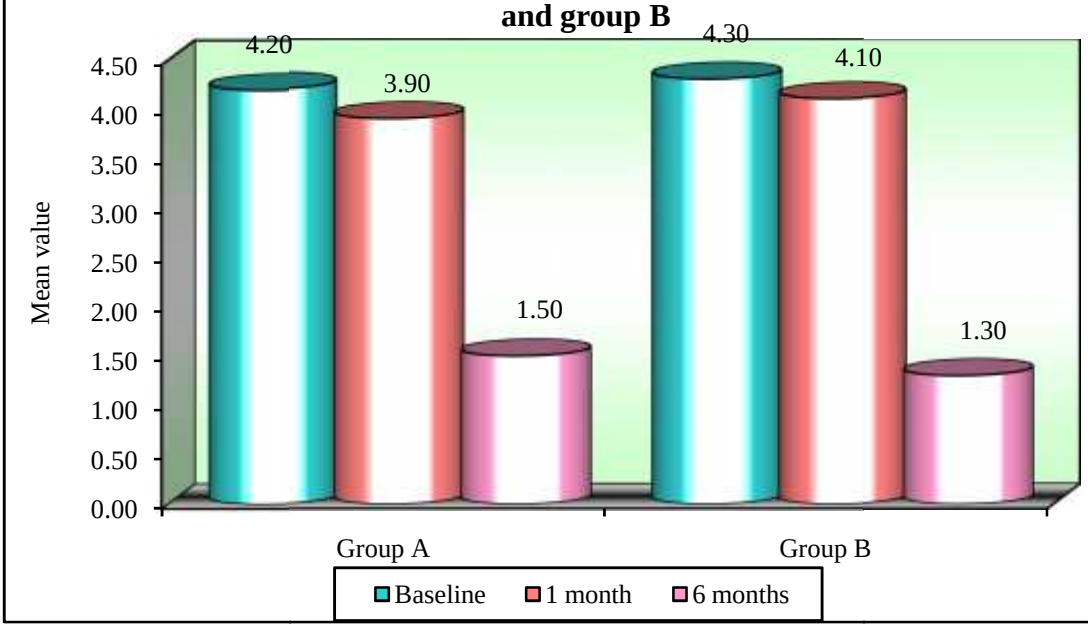
Groups	Time points	Mean	SD	Mean Diff.	SD Diff.	% of change	Paired t	P-value
Group A	Baseline	4.20	0.63					
	1month	3.90	0.74	0.30	0.48	7.14	1.9640	0.0811
	Baseline	4.20	0.63					
	6 months	1.50	0.85	2.70	0.67	64.29	12.6501	0.0001*
	1 month	3.90	0.74					
	6 months	1.50	0.85	2.40	0.52	61.54	14.6969	0.0001*
Group B	Baseline	4.30	0.67					
	1month	4.10	0.74	0.20	0.42	4.65	1.5000	0.1679
	Baseline	4.30	0.67					
	6 months	1.30	0.95	3.00	0.94	69.77	10.0623	0.0001*
	1 month	4.10	0.74					
	6 months	1.30	0.95	2.80	1.03	68.29	8.5732	0.0001*

*p<0.05, MD- Mean Difference, SD- Standard Deviation.

Graph 7: Comparision of group A and group B with horizontal furcation involvement at baseline, 1 month and 6 months time points



Graph 8: Comparision of at baseline, 1 month and 6 months time points with Horizontal furcation involvement in group A and group B



HORIZONTAL FURCATION INVOLVEMENT (Table 9,10; Graph 7,8)

The mean horizontal furcation involvement at baseline for control group was 4.20mm with S.D ± 0.63mm, whereas values at 1 month was 3.90 ± 0.74 mm and 1.50 ± 0.85 at 6 months post surgery. The mean horizontal furcation involvement at baseline to 6 months was 2.70 ± 0.67mm which was statistically significant.

The mean horizontal furcation involvement at baseline for experimental group was 4.30mm with S.D ± 0.67mm, whereas values at 1 month was 4.40 ± 0.74 mm and 1.30 ± 0.95 at 6 months post surgery. The mean horizontal furcation involvement at baseline to 6 months was 3.00 ± 0.94mm which was statistically significant.

The mean horizontal furcation involvement when compared between the control and experimental group at 6 months post surgery was 0.2mm which was not statistically significant. The comparison showed reduction in the mean horizontal furcation involvement for the experimental group as compared to control group.

Table 11 :Comparison of Group A and Group B with Vertical Furcation Involvement at baseline , 1month and 6months time points by Independent t-test.

Time points	Group A		Group B		t-value	p-value
	Mean	SD	Mean	SD		
Baseline	5.05	0.69	5.00	0.58	0.1765	0.8619
1 month	5.05	0.69	5.00	0.58	0.1765	0.8619
6 months	3.60	0.77	3.50	0.71	0.3015	0.7665
BL-1M	0.00	0.00	0.00	0.00	--	--
BL-6M	1.45	0.86	1.50	0.58	-0.1521	0.8808
1M-6M	1.45	0.86	1.50	0.58	-0.1521	0.8808

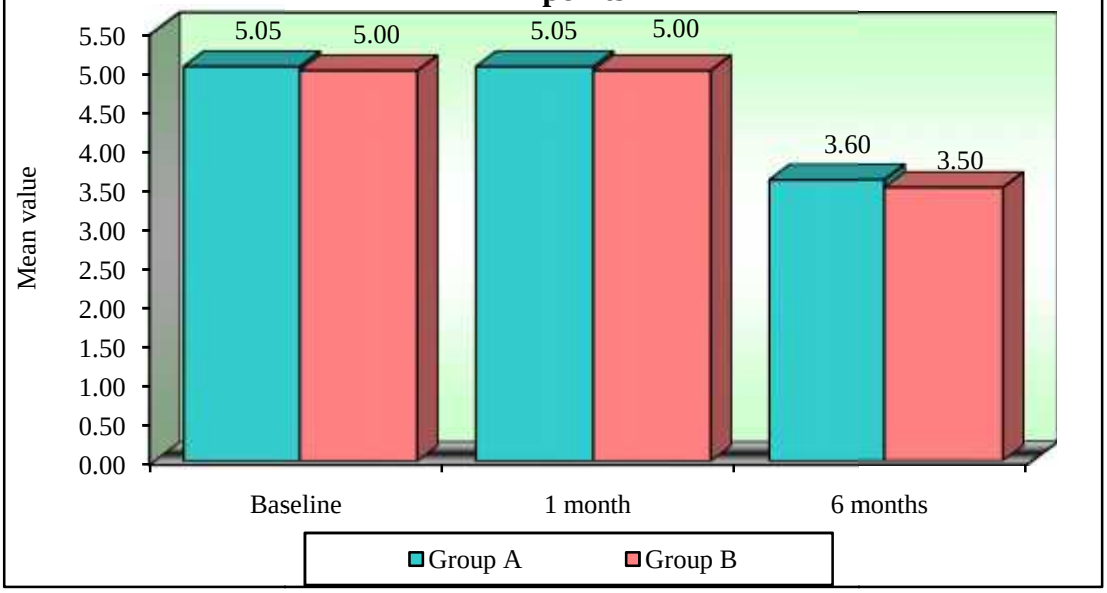
SD- Standard Deviation.

Table 12 : Comparison of baseline, 1month and 6months time points with Vertical Furcation Involvement in Group A and Group B Kolmogorov Smirnov

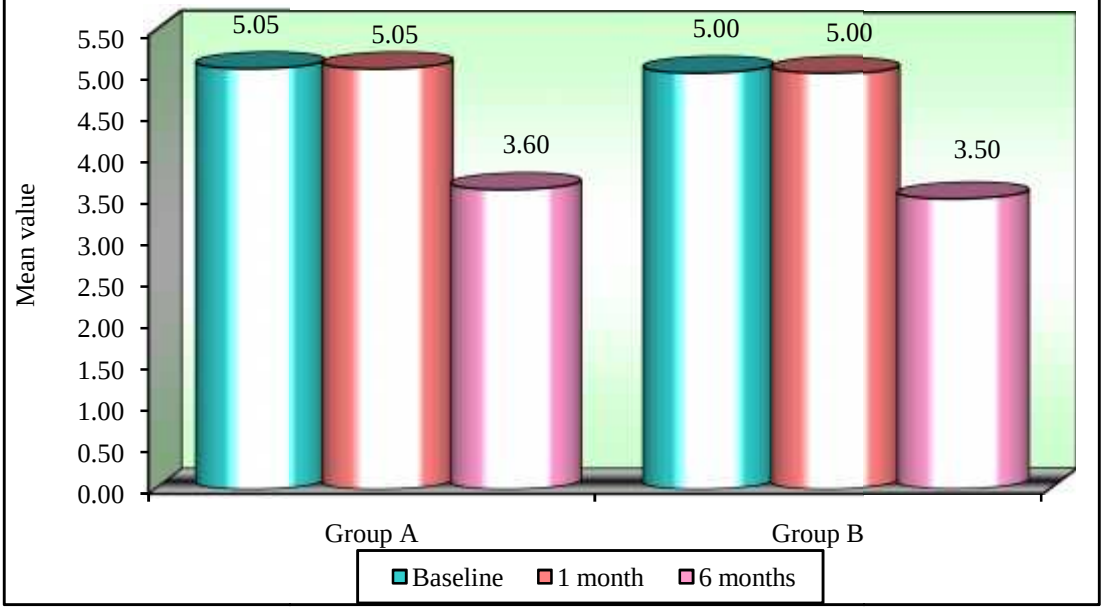
Groups	Time points	Mean	SD	Mean Diff.	SD Diff.	% of change	Paired t	P-value
Group A	Baseline	5.05	0.69					
	1month	5.05	0.69	0.00	--	0.00	--	--
	Baseline	5.05	0.69					
	6 months	3.60	0.77	1.45	0.86	28.71	5.3045	0.0005*
	1 month	5.05	0.69					
	6 months	3.60	0.77	1.45	0.86	28.71	5.3045	0.0005*
Group B	Baseline	5.00	0.58					
	1month	5.00	0.58	0.00	--	0.00	--	--
	Baseline	5.00	0.58					
	6 months	3.50	0.71	1.50	0.58	30.00	8.2158	0.0001*
	1 month	5.00	0.58					
	6 months	3.50	0.71	1.50	0.58	30.00	8.2158	0.0001*

*p<0.05, MD- Mean Difference, SD- Standard Deviation.

Graph 9: comparision of group A and group B with vertical furcation involvement at baseline, 1 month and 6 months time points



Graph 10: comparision of at baseline, 1 month and 6 months time points with vertical furcation involvement in group A and group B



VERTICAL FURCATION INVOLVEMENT(Table 11,12; Graph 9,10)

The mean vertical furcation involvement at baseline for control group was 5.05mm with S.D ± 0.69mm, whereas values at 1 month was 5.05 ± 0.69 mm and 3.60 ± 0.77 at 6 months post surgery. The mean horizontal furcation involvement at baseline to 6 months was 1.45 ± 0.86mm which was statistically significant.

The mean vertical furcation involvement at baseline for experimental group was 5.00mm with S.D ± 0.58mm, whereas values at 1 month was 5.00 ± 0.58 mm and 3.50 ± 0.71 at 6 months post surgery. The mean horizontal furcation involvement at baseline to 6 months was 1.50 ± 0.58mm which was statistically significant.

The mean vertical furcation involvement when compared between the control and experimental group at 6 months post surgery was 0.1mm which was not statistically significant. The comparison showed reduction in the mean vertical furcation involvement for the experimental group as compared to control group.

The percentage of bone fill in Group A from baseline to 1month was statistically not significant as there is no change in the amount of bone fill that has been observed at the end of 1month and 30 % (1.50±0.58) of bone fill was observed at the end of 6months.

Similarly, in Group B there was no change that has been observed at the end of 1month but on comparsion from baseline to 6months about 29%(1.45±0.86) of bone fill was observed.

On intergroup comparision , 1% of difference in bone fill was observed between the groups treated with DFDBA and Gengigel which was not statistically significant.

DISCUSSION

The primary objective of the periodontal treatment is that "it helps in the maintenance of the natural dentition in good health and comfortable function"[3,4]. When there is an attachment loss due to periodontal disease the optimal care is necessary to regenerate the periodontium to its state that has been present before the disease has occurred. Regeneration has been defined as "The reproduction or reconstruction of a lost or injured part to restore the architecture and function of the periodontium"(AAP Definition)[5]

A material or a technique which has to be considered as a regenerative modality is that it should demonstrate histologically the formation of cementum, alveolar bone and periodontal ligament on a diseased root. Different bone grafts and also their substitutes have been used to regenerate the lost structures. Use of bone grafts for this purpose i.e. the regenerating the osseous defects produced by periodontal disease in 1923 by Hegedus and was reviewed by Nabers and O'Leary in 1965[83]. Ever since that period of time a various number of techniques and materials have been employed for regeneration.

Complete regeneration of the functional attachment apparatus has remained an elusive goal of the periodontal therapy, and currently the major progress is being made to achieve this end by utilizing various regenerative procedures such as bone grafting, GTR techniques and combination therapy[84]. Both animal and human studies have shown that the combination of GTR procedure and bone grafting greatly enhances the regenerative outcome.

The wide spread use of "DFDBA was based on the osteoinductive ability of bone graft preparation" given by Reddi, Urist. When the graft becomes demineralized it exposes the bone inductive proteins that are present in the bone matrix. DFDBA when tested histologically,have shown to be more effective in inducing the periodontal regeneration[39,45].

Hyaluronic acid, an integral part of the extracellular matrix, has been advocated for periodontal regeneration and healing. Hyaluronan interacts with fibrin clot and provides a structural framework to enable ECM cell infiltration into the inflamed site[72]. It helps in organisation of granulation tissue by promoting proliferation and migration of matrix cells. Hakansson et al, suggested the role of hyaluronan in migration and adherence of neutrophils and macrophages at the inflamed site and the resultant phagocytosis and destruction of invading pathogens. They also promote angiogenesis and enhance bone formation by their osteoconductivenature[85].

The use of type I collagen for GTR has an added advantage because, it is uniquely involved in the binding of cells, particularly fibroblasts and osteoblasts, thus promoting periodontal regeneration.

The collagen (type I) was selected as a GTR membrane in the present study was based on the following facts[86].

1. Type I collagen is the main constituent of periodontal connective tissue and therefore would seem to be an appropriate barrier in the GTR technique.

2. It is bio-absorbable so can act as a barrier analogous to a non resorbable membrane and it is either incorporated into the healing connective tissues or is degraded by macrophages in 6-8 weeks.
3. Exogenous collagen is chemotactic for periodontal ligament fibroblasts and improves fibroblast migration and attachment through its scaffold-like fibrillar structure.
4. It also creates a thrombogenic surface that stimulates platelet attachment which may accelerate fibrin and clot attachment.
5. Collagen is a hemostatic, a property that enhances wound healing.

Thus, the present study aimed to compare and evaluate the use of Demineralized Freeze Dried Bone Allograft(DFDBA) and Gengigel® (0.8%) along with a Guided Tissue Regenerative Membrane(GTR) for the treatment of Grade II furcation defects associated with mandibular posterior teeth.

The study was carried in a split mouth design with Group A- Demineralized Freeze Dried Bone Allograft (DFDBA) and Guided Tissue Regenerative Membrane (HEALIGUIDE®) or Group B- receiving 0.8% GENGIGEL® and Guided Tissue Regenerative Membrane (HEALIGUIDE®).

The clinical parameters were evaluated at baseline, 1 month and 6 month post-operative intervals.

The mean age of the study population was 37.93±6.02 years with 6 females and 4 males.

The parameters recorded wereSulcus Bleeding Index (SBI), Probing Pocket Depth (PPD), Relative Attachment Level(RAL). Horizontal Furcation Involvement

and radiographic evaluation of Vertical Furcation Involvement using RVG at baseline, 1 and 6 month intervals post surgery to evaluate the amount of bone fill.

In 1971, Muhlemann& Sons [87] had stressed that bleeding was a much more sensitive indicator of disease. It is done by gentle probing along all the surfaces of the tooth. Bleeding on probing is the objective sign of any periodontal disease and is known to be associated with the active disease.

The mean range of Sulcus Bleeding Index (Table 3.1, table 3.2 , Graph1,2) in our study was 1.72±0.37.The surgical sites showed signs of bleeding on probing and change in color.

The mean values were similar between Group A (1.84±0.37) and Group B (1.72±0.33) at baseline and the differences were not statistically significant (p=0.45). Therefore the two groups were comparable at baseline

In the present study, a gradual decrease in the Sulcus Bleeding Index was observed in both the groups from baseline to 1 month, 1 month to 6 months . The reduction in SBI may be attributed to the decrease in magnitude of the bacteria present in plaque control regime. The reduction in both the cases may be attributed to the resolution of the inflammatory component consequent to access flap surgery and mechanical, chemical plaque control regime.

The fact that collagen membrane helps in creating and maintaining a blood clot- filled space it also prevents inflammation as a result of decreased bacterial invasion [87] thus resulting in the lower SBI score. The result of our study was comparable to the study conducted by Lekovic(2003), Jepsen(2010) who showed a

decrease in SBI of 0.92±0.25 , 0.89±0.23 respectively from baseline to 6months at the end of the study.

The high concentration of medium and lower molecular weight hyaluronic acid has the greatest bacteriostatic effect, particularly on Aggregatibacteractinomycetemcomitans, Prevotellaoris and Staphylococcus aureus strains commonly found in oral gingival lesions and periodontal wounds(85). Koshal A et al., 2007[87] from his study concluded that the adjunctive use of Gengigel® after thorough mechanical debridement has major clinical benefits in terms of improved healing after non-surgical therapy and demonstrates significant improvements in bleeding on probing. Hyluronan(Gengigel®) is involved in the activation of inflammatory cells such as PMNs and macrophages, including their migration to wound site and killing the invading microbial pathogens. Pirnazar P et al. , 2011[88]suggested that the clinical application of hyaluronic membrane, gels or sponges during surgical therapy reduces bacterial contamination of surgical wound site, thereby, lessening the risk of postsurgical infection and promoting more predictable regeneration.

Similarly, a decrease in SBI score was observed by PistoriusAlixander et al., 2005 and Pilloni et al., 2011[89] of about 0.91±0.20 , 0.85±0.32 respectively at the end of 6months which were almost similar to our present study.

Periodontal pocket is a “pathologically deepened gingival sulcus and is one of the important clinical features of periodontal disease”. It is a soft tissue change that indicates an on-going inflammatory process in the gingival sulcus. The probing depth of a clinically healthy gingival sulcus is 2-3mm. The mean range of Probing Pocket

Depths (Table 4.1, table 4.2 , Graph 3,4)) in our study was more than 7 mm. Thus, it could be extrapolated that the surgical sites were inflammatory.

The mean values were similar between Group A (7.00±0.94) and Group B (7.20±0.79) at baseline and the differences were not statistically significant (p=0.61). Therefore the two groups were comparable at baseline. A statistically significant decrease in PPD was seen from 5.50 ± 1.08mm (1month) to 2.50 ± 1.08 mm (6 month) in group A and from 6.00 ± 0.94 mm (1 month) to 2.40± 0.84 mm (6 month) in Group B.

During the repair of the surgical site after flap surgery , the granulation tissue derived primarily from contiguous exposed areas of the periodontal ligament expands by proliferation onto treated root surface. It may well serve as the progenitor of the "periodontal attachment".

Use of collagen membrane as barrier had also improved properties to retard the apical migration of epithelial cells from contacting the space and facilities repopulation of the defect by regenerative cells [85] It also provides an additional wound coverage acting as a duplicate surgical flap to provide added stability and protection of the blood clot and preventing ruptures along the interface between the healing tissues and the root surface, thus promoting better wound healing[87]

Our results tally with the study conducted by Lovelace et al (1998), Froum et al (2003) and Deepa et al (2015)[85,87,90]where significant change in PPD at the end of 6 months was observed and has been attributed to the fact that tissue consistency changed throughout the study period.

In the study done by ChhayaBansal et al (2013) had shown similar results where there was reduction in PPD at the end of 9 months. He had concluded that the amount of BMP released and the particle size of DFDBA(200-500 microns) had contributed to its superior results in terms of Probing Pocket Depth.

Similarly, Toole BP 2001[91]conducted a study where he had explained the remarkable hydrophilicity of hyaluronic acid which makes the coagulum more receptive and thus more likely to undergo colonization by the cells committed to the reconstruction of the damaged tissue by migration, proliferation and differentiation of mesenchymal and basal keratinocytes.

A decrease in PPD was observed in a study conducted by Sadhu et al(2009)[80]0.08±0.39 mm (p=0.25) for Group A and 0.01±0.59 mm (p=0.10) for Group B was seen. A PPD of 3.00±1.25 mm for Group A and 3.60±1.07 mm for group B was observed at the end of 6 months. Therefore, a reduction of probing pocket depth was observed in both the groups.

Relative Attachment Level (RAL) was measured from a fixed reference point (prefabricated stent) to the base of the pocket. The mean scores for relative attachment level Table 5.1, table 5.2 , Graph 5,6) were similar between Group A (8.60±1.43 mm) and Group B (8.40±1.35 mm) and the differences were not statistically significant (p=0.75). Therefore the two groups were comparable at baseline. A statistically significant decrease was seen in the mean RAL from 8.60±1.43mm (baseline) to 7.10±0.99mm (1 month) to 6.00 ± 0.94 (6 months) 2.40 ± 0.84 in group A and from 8.40±1.35 mm (baseline) to 7.00±1.25 mm (1 month) to 2.40 ± 0.84mm (6months) in Group B.

However, both the groups showed significant gain in relative attachment level on intragroup comparison from baseline to 1month and 1month to 6months.

Changes in the Relative Attachment Level may be attributed to the reduction in gingival inflammation and also inflammatory exudate along with formation of new collagen fibers that have been achieved post periodontal flap surgery.

The additional benefit is by the use of collagen is that it is chemotactic for periodontal ligament fibroblasts and improves fibroblast migration and attachment through its scaffold-like fibrillar structure[76].

The results were in accordance with the studies conducted by Lars Laurell et al (1998), Mark A Reynolds et al (2003)[92,93]Mary.E.Aichelmann-Reidy, Carlette.D.Heath (2004)[94,95]in which a significant gain in the relative attachment level was reported from baseline to 6months , 9months and 1 year respectively. They showed an attachment gain of approximately 7.02± 0.89 which was comparable to our study.

Gerald M Bowers et al conducted a study to evaluate the potential for regeneration of a new attachment in patients whose attachment apparatus has been destroyed by periodontal disease.Results in 24 defects indicated that new attachment is possible on pathologically exposed roots surfaces in a submerged environment with the incorporation of DFDBA.

Studies carried out by Sugandha Gupta (2016), Sandhu GK et al (2015), Kalra SH et al(2015)[73,76,80]where 0.8% Gengigel was used for treatment of Grade II furcation defects showed relative attachment gain of 7.00±0.89 at the end of 6months , 7.35±0.92 at 9months and 6.99±0.87 at the end of 1year respectively.

Horizontal furcation involvement was measured with the help ofpre-fabricated stent clinically. To affirm the clinical findings, the radiographic analysis was also done using RVG.

The mean difference in the horizontal furcation involvement in both the groups at the end of 6months was statistically significant, Group A 2.40±0.52and 2.80±0.58in Group B (mean difference from baseline to 6months)(Table 6.1, table 6.2 , Graph 7,8)

This may be due the fact that DFDBA contains Osteogenin , a bone inductive protein which helped in the regeneration of intrabony defects[86]. It is believed that BMPs and other noncollagenous proteins in the exposed matrix are responsible for the osteoinductivity of DFDBA[73].

J.T .MellonigG.M .(1991)[39]et al have found improved clinical results after reentry at six months with the use of DFDBA/GTR and greater amount of bone repair with the combination technique .

Similarly in a study done by Sandeep et al (2009)[96]had done a combination therapy (DFDBA+GTR)was carried out on grade II mandibular furcation defects which showed a mean difference in horizontal furcation of 4.15±0.65 post operatively at 6months in experimental sites as compared to 3.46±0.56 in controlled sites.

Whereas in the present studyGroup B (Gengigel®) also showed an improved reduction in horizontal furcation involvement at the end of 6months.

It is because hyaluronic acid accelerates the bone regeneration by means of chemotaxis, proliferation and successive differentiation of mesenchymal cells.

Hyaluronic acid shares bone induction characteristics with osteogenic substances such as BMP-2 and osteopontin[85].

Our results tally with the study done by Sugandha Gupta et al., 2017[83], who used hyaluronic acid (Gengigel®) for regeneration in Grade II furcation defects with coronally advanced flap and assessed the sites through surgical re-entry. The authors reported statistically significant mean differences in bone fill in both the horizontal furcation (1.44±0.72)between baseline and 6 months. It was concluded that the additional use of Gengigel® leads to better results in hard tissue measurement.

The vertical component of furcation was measured from the floor of the furca to the roof of the furca. The mean defect fill was statistically significant in both the groups at the end of 6months ($p<0.05$) , Group A 1.45±0.86 and in Group B 1.50±0.58 but there was no improvement seen from the baseline to the end of 1month(Table 7.1, table 7.2 , Graph 9,10)

These findings were in accordance to study done by Mellonig et al (1984)[39]in which the defects sites treated with DFDBA showed an average of bone gain 2.6 ± 1.4mm at the end of 6months. In this the authors have concluded that demineralization removes the mineral phase of the graft material and purportedly exposes the underlying bone collagen and some growth factors , particularly BMPs which may increase its osteoinductive capabilities.

Another study done by Prathi et al (2008)[69]showed an average bone fill of about 2.0±1.2 mm at the end of 6months. DFDBA provides osteoconductive and osteoinductive factors i.e. it induces the host undifferentiated mesenchymal cell to

differentiate into osteoblasts with subsequent formation of new bone. It also contains BMP 2,4 and 7 which help stimulate osteoinduction[76].

Hyaluronic acid may act as biomaterial scaffold for other molecules, such as BMP-2 and PDGF-BB, used in guided bone regeneration techniques (Hunt DR et al., 2001).

Our results were in accordance to the study done by Kalra S H et al., 2015[83], used hyaluronic acid (Gengigel®) for regeneration in Grade II furcation defects and assessed the sites through surgical re-entry. The authors reported statistically significant mean differences the mean difference in vertical furcation involvement in Group A from baseline to 6months was 1.45±0.86 statistically significant ($p<0.05$).

Sandhu GK et al 2015[85], reported that the surgical re-entry at 6 months revealeda significant percentage of bone formation in furcation area radiographically and stated a significant improvement in defect fill.

There was no statistical difference that has been observed on intergroup comparision between DFDBA and Gengigel in terms of Sulcus Bleeding Index, Probing Pocket Depth and Relative Attachment Level.

On comparision between the percentage of bone fill between the two groups DFDBA has shown 1% higher percentage of bone fill to that of Gengigel but this value is on statistically significant.

Therefore, within the limitations of our study, it can be concluded that use of DFDBA and 0.8% Gengigel along with a guided tissue regenerative membrane had an beneficial effect in terms of Sulcus Bleeding Index , Probing Pocket Depth , Relative Attachment Level ,Horizontal Furcation Involvement and Vertical Furcation Involvement in both the groups. However, a larger sample size and a long term follow up are necessary to substantiate the results of the study. Also, further research should

be directed in order to evaluate the histological aspect of bone healing during regeneration.

SUMMARY AND CONCLUSION

The present study was a randomized controlled clinical trial that aimed to compare and evaluate the use of Demineralized Freeze Dried Bone Allograft(DFDBA) and Gengigel® (0.8%) along with a Guided Tissue Regenerative Membrane(GTR) for the treatment of Grade II furcation defects.

A total of 13 patients presenting with bilateral mandibular Grade II furcation defects , reporting to the out-patient Department of Periodontics, KAHER's KLE V.K. Institute of Dental Sciences, Belagavi were included in the study.

An informed consent was taken from all the included patients. They were randomly divided into two groups by lottery method of randomization into Group A in which defects were treated with DFDBA+ GTR and Group B with Gengigel®+GTR. The patients were clinically and radiographically evaluated at baseline, 1 month and 6 months.

The parameters, Sulcus Bleeding Index (SBI), Probing Pocket Depth (PPD), Relative Attachment Level (RAL), Horizontal Furcation Involvement (HFI) and Vertical Furcation Involvement (VFI) were assessed at baseline, 1 month and 6 months. Out of 13 patients, 3 patients couldn't report for follow-up. Hence statistical analysis was carried out for 10 patients.

Both groups showed significant improvement in all parameters. A statistically significant improvement in Sulcus Bleeding Index , Probing Pocket Depth, Relative Attachment Level, Horizontal Furcation Involvement and Vertical Furcation Involvement was seen in both the groups at the end of 6 months follow-up period .

The most desirable outcome of regenerative therapy is the closure of the furcation defects. The following conclusions were drawn from the study.

1. There was statistically significant reduction in Sulcus Bleeding Index, pocket probing depth , relative attachment level, horizontal furcation involvement in both the groups. On comparison there was statistically no significant difference between the two groups.
2. There was statistically no significant change observed in relation to percentage of bone fill at the end of 1 month. But Group A (DFDBA+GTR) showed 0.25±0.10mm amount of bone fill more compared to that of Gengigel® at the end of 6 months. But the result is not statistically significant.

   Since, hyaluronic acid shares bone induction characteristics with osteogenic substances such as BMP-2 and osteopontin it enhanced the outcome of the procedure . No histological evaluation was done in our study; hence the overall effect of Gengigel® on regeneration capacity remains undetermined.

Within the limitations of our study, it can be concluded that use of DFDBA and 0.8% Gengigel along with a guided tissue regenerative membrane had an additive effect in terms of both clinical and radiographic parameters.

However, controlled clinical trials are required with larger sample size andlong-term follow-up to validate the regenerative capabilities of these materials where,histologic evaluation and surgical re-entry would be more appropriate methods toconfirm the findings.

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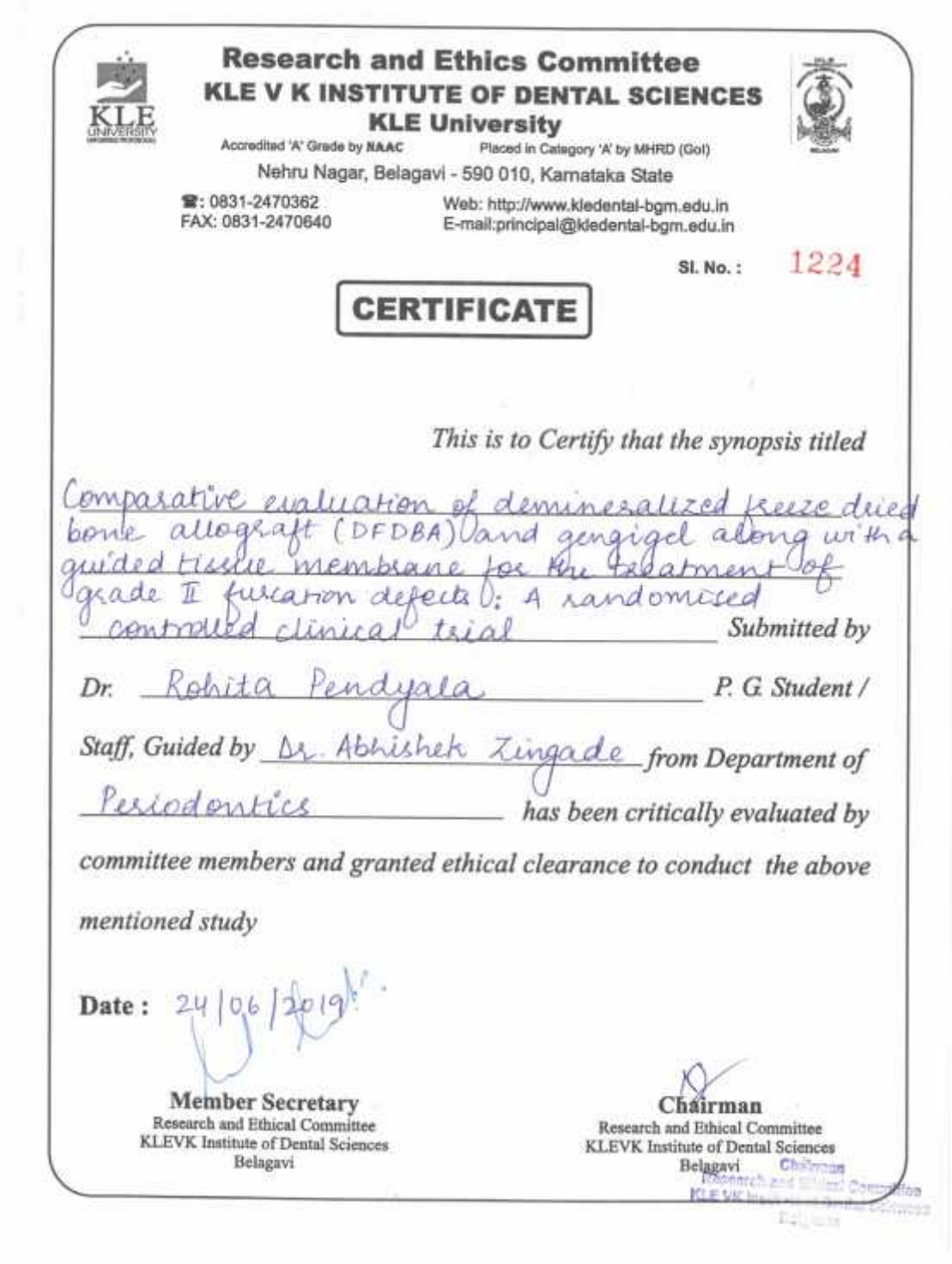
ANNEXURE-I

ETHICAL CLEARENCE



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Sl. No. : 1224

CERTIFICATE

This is to Certify that the synopsis titled

Comparative evaluation of demineralized freeze dried bone allograft (DFDBA) and gengigel along with a guided tissue membrane for the treatment of grade II furcation defects: A randomized controlled clinical trial

Submitted by

Dr. Rohita Pendyala *P. G. Student /*

Staff, Guided by Dr. Abhishek Zingade *from Department of* Periodontics *has been critically evaluated by committee members and granted ethical clearance to conduct the above mentioned study*

Date : 24/06/2019

Member Secretary
Research and Ethical Committee
KLEVK Institute of Dental Sciences
Belagavi

Chairman
Research and Ethical Committee
KLEVK Institute of Dental Sciences
Belagavi

ANNEXURE-II

DEPARTMENT OF PERIODONTICS
KLE VK INSTITUTE OF DENTAL SCIENCES, BELAGAVI

CONSENT FORM

A CLINICAL AND RADIOGRAPHIC ASSESSMENT OF DEMINERALIZED FREEZE DRIED BONE ALLOGRAFT(DFDBA) AND DFDBA WITH GENGIGEL IN TREATMENT OF GRADE II FURCATION DEFECTS: A SPLIT MOUTH COMPARITIVE STUDY

PRINCIPAL INVESTIGATOR: DR. ROHITA PENDYALA.

I _____, aged _____ years have been informed about my involvement in the study.

I agree to give my personal details like Name, Age, Gender, Residential Address, past and Present dental history and any other details if required for the study to the best of my knowledge.

I will co-operate with the dentist.

I will follow the instructions given by the dentist during study.

I will visit the dentist as and when required for the study, at the given time and date.

I permit the dentist to utilize the information given and results obtained from this study for presentation and publication without disclosing my identity.

I have understood the nature of the study and permit the dentist to carry out the required surgical procedure.

If for any reason I am unable to participate in the study, for reasons unknown, I can withdraw from the study at any given point of time.

I have been informed that the surgical procedure being performed on me for the purpose of bony defect using gengigel is a relatively newer material and after understanding the procedure, I permit the dentist to perform the same.

If by chance any complications arise during the above said procedure, I permit the dentist to take necessary actions to prevent the same.

In my full consciousness and presence of mind, after understanding all the procedures and related complications if any, in my vernacular language, I am willing and give my consent to participate in this study.

Date:
Name of the Patient:
Signature:
Address & Ph. No:
Name of witness/guardian:
Signature:

_____ _____

PRINCIAL INVESTIGATOR (Dr.ROHITA PENDYALA)
GUIDE (Dr. ABHISHEKZINGADE)

CONSENT FORM

DEPARTMENT OF PERIODONTICS

KLE V.K.INSTITUTE OF DENTAL SCIENCES

BELAGAVI.

COMPARITIVE EVALUATION OF DEMINERALIZED FREEZE DRIED BONE ALLOGRAFT (DFDBA) AND GENGIGEL ALONG WITH A GUIDED TISSUE REGENERATION MEMBRANE FOR THE TREATMENT OF GRADE II FURCATION DEFECTS:A RANDOMIZED CONTROL CLINICAL TRAIL.

Principal Investigator :Dr.RohitaPendyala

ನಾನು _____, ವಯಸ್ಸಿನ _____ ವರ್ಷಗಳಅಧ್ಯಯನದಲ್ಲಿನನ್ನತೂಡಗಿರುವಬಗ್ಗೆತಿಳಿಸಲಾಗಿದ.ನನ್ನಜ್ಞಾನದಅತ್ಯುತ್ತಮಅಧ್ಯಯನಕ್ಕೆಅಗತ್ಯವಿದ್ದರೆನನ್ನವೈಯಕ್ತಿಕವಿವರಗಳನ್ನುಹೆಸರು, ವಯಸ್ಸು, ಲಿಂಗ, ವಸತಿವಿಳಾ ,

ಹಿಂದಿನಮತ್ತುಪ್ರಸ್ತುತದಂತಇತಿಹಾಸಮತ್ತುಇತರವಿವರಗಳನ್ನುನೀಡಲುಒಪ್ಪುತ್ತೇನ.

ನಾನುದಂತವೈದ್ಯರೊಂದಿಗೆಸಹಕರಿಸುತ್ತೇನೆ.ಅಧ್ಯಯನದಲ್ಲಿದಂತವೈದ್ಯನೀಡಿದಸೂಚನೆಗಳನ್ನುನಾನುಅನುಸರಿಸುತ್ತೇನೆ.ನಾನುನಿರ್ದಿಷ್ಟಸಮಯದಲ್ಲೆಮತ್ತುದಿನಾಂಕದಂದುದಂತವೈದ್ಯರಿಗೆಮತ್ತುಅಧ್ಯಯನಕ್ಕೆಅಗತ್ಯವಿದ್ದಾಗನಾನುಭೇಟಿನೀಡುತ್ತೇನೆ.ನನ್ನಗುರುತನ್ನುಬಹಿರಂಗಪಡಿಸದೆಪ್ರಸ್ತುತಿಮತ್ತುಪ್ರಕಟಣೆಗಾಗಿಈಅಧ್ಯಯನದಿಂದಪಡೆದೆಮಾಹಿತಿಮತ್ತುಫಲತಾಂಶಗಳನ್ನುಬಳಸಿಕೊಳ್ಳಲುನಾನುದಂತವೈದ್ಯರಿಗೆಅನುಮತಿನೀಡುತ್ತೇನ

ನಾನುಅಧ್ಯಯನದಸ್ವಭಾವವನ್ನುಅರ್ಥಮಾಡಿಕೊಂಡಿದ್ದೇನಮತ್ತುಅಗತ್ಯಶಸ್ತ್ರಚಿಕಿತ್ಸಾಕಾರ್ಯವಿಧಾನವನ್ನುಕೈಗೊಳ್ಳಲುದಂತವೈದ್ಯರನ್ನುಅನುಮತಿಸುತ್ತೇನ.

ಯಾವುದೇಕಾರಣಕ್ಕಾಗಿನಾನುಅಧ್ಯಯನದಲ್ಲಿಪಾಲ್ಗೊಳ್ಳಲುಸಾಧ್ಯವಾಗದಿದ್ದರೆ, ಕಾರಣಗಳುಅಜ್ಞಾತವಾಗಿದ್ದಲ್ಲಿ,

ಯಾವುದೇಸಮಯದಲ್ಲಾದರೂಅಧ್ಯಯನದಿಂದನಾನುಹಿಂತಗದುಕೂಳ್ಳಬಹುದು.

Gengigelಅನ್ನುಬಳಸಿಕೊಂಡುಮೂಳೆಯದೋಷದಉದ್ದೇಶಕ್ಕಾಗಿನನ್ನಮೇಲನಡೆಸಿದಶಸ್ತ್ರಚಿಕಿತ್ಸಾಪ್ರಕ್ರಿಯೆಯುತುಲನಾತ್ಮಕವಾಗಿಹೊಸವಸ್ತುವಾಗಿದೆಮತ್ತುಕಾರ್ಯವಿಧಾನವನ್ನುಅರ್ಥಮಾಡಿಕೊಂಡನಂತರನಾನುದಂತವೈದ್ಯರನ್ನುಅದೇರೀತಿಮಾಡಲುಅನುಮತಿಸುತ್ತೇನ

ಎಂದುನನಗತಿಳಿಸಲಾಗಿದ.

ಮೇಲೆತಿಳಿಸಿದಪ್ರಕ್ರಿಯೆಯಲ್ಲಿಯಾವುದೇತೊಂದರಗಳುಉಂಟಾದರ,

ದಂತವೈದ್ಯರುಅದನ್ನುತಡೆಯಲುಅಗತ್ಯಕ್ರಮಗಳನ್ನುತಗದುಕೊಳ್ಳುವೆಂತನಾನುಲಿನುಮತಿ

ಸುತ್ತೇನೆ.

ನನ್ನಸಂಪೂರ್ಣಪ್ರಜ್ಞೆಮತ್ತುಮನಸ್ಸಿನಉಪಸ್ಥಿತಿಯಲ್ಲಿ,

ಎಲ್ಲವಿಧಾನಗಳುಮತ್ತುಸಂಬಂಧಿತಸಮಸ್ಯೆಗಳನ್ನುಅರ್ಥಮಾಡಿಕೊಂಡನಂತರ,

ನನ್ನದೇಶೀಯಭಾಷೆಯಲ್ಲಿ,

ನಾನುಈಅಧ್ಯಯನದಲ್ಲಿಪಾಲ್ಗೊಳ್ಳಲುನಿನ್ನಒಪ್ಪಿಗೆಯನ್ನುನೀಡುತ್ತೇನಮತ್ತುನನ್ನಒಪ್ಪಿಗೆಯ

ನ್ನುನೀಡುತ್ತೇನ.

Date:
Name of the Patient:
Signature:
Address & Ph. No:

PRINCIAL INVESTIGATOR (Dr.ROHITA PENDYALA)

GUIDE (Dr. ABHISHEKZINGADE)

Name of witness/guardian:
Signature:

CONSENT FORM

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Principal Investigator :Dr.RohitaPendyala

- मी_____,वय _____ वर्षलामाझ्यावरीलसंशोधनातसहभागीहोण्याचीकल्पनादिलेलीआहे.
- मीमाझेवैयत्तिकमाहिती, जसेनाव,वय,लिंग,घरचापत्ता, पूर्वआणिसध्याचालूअसलेलादंतइतिहासआणिसंशोधनासाठीआवश्यकअसलेलीसर्वमाहितीदेऊइच्चीतो/ते.
- मीदंतचिकित्सकांनात्यांच्या अभ्यासात सहकार्यकरीन.
- मीदंतचिकित्सकांनीदिलेल्यासर्वसूचनापाळीन.
- मीदंतचिकित्सकांनीसंशोधनाकरिताजेव्हाबोलावलंतेव्हादिलेल्यादिवशी आणिवेळेतयेईन.
- मीदंतचिकित्सकांनामीदिलेलीमाहितीआणिसंशोधनातमिळालेलेपरिणाम माझीओळखउघडनकरताप्रसारणकरण्याचीपरवानगीदेतो/ते .
- मला दंत्चिक्त्सकांचा अभ्याससमजलाआहेआणित्यासाठीआवश्यकअसलेलीशस्त्रक्रियाअमलात आणणेआणित्यासाठीदंतचिकित्सकांनामीपरवानगीआहे.
- कोणत्याहीकरणस्पतीमीसंशोधनातसहभागीहोऊशकलेनाही (अज्ञातकारणांमुळे), तरमीकोणत्याहीवेळीसंशोधनसोडूशकतो/ते.

- मलासूचितकेलेगेलेआहेकीजिंजिजेल चावापरबोनिडिफेक्ट मध्ये केला जाईल. माझ्यावरवापरलं जाणारं जिंजिजेलहेएकतुलनेनेनवीनसाहित्यआहेआणिप्रक्रियासमजूनघेतल्यानंत रमीदंतचिकित्सकयांनातसेकरण्याचीपरवानगीदेतो.
- वरील नमुद केलेल्याप्रक्रियेदरम्यानकोणतीहीसमस्याउद्भवलीतरमीदंतचिकित्सकांना झालेली समस्या टाळण्यासआवश्यककार्यवाहीकरण्यासपरवानगीदेतो.
- मीपुर्ण शुद्दीतआणिमनाच्याउपस्थिती, माझ्यामातृभाषेतसर्वप्रक्रियाआणिसंबंधितसमस्यासमजूनघेतल्यानंतर, मीयाअभ्यासातभागघेण्यासाठीमाझीइच्छाव्यक्तकरतो/ते

Date:
Name of the Patient:
Signature:
Address & Ph. No:

PRINCIAL INVESTIGATOR (Dr.ROHITA PENDYALA)

GUIDE (Dr. ABHISHEKZINGADE)

Name of witness/guardian:
Signature:

ANNEXURE-III

PROFORMA

KLE V.K.INSTITUTE OF DENTAL SCIENCES BELAGAVI.

Comparitive evaluation of demineralized freeze dried bone allograft (DFDBA) and gengigel along with a guided tissue regeneration membrane for the treatment of grade ii furcation defects :A RandomisedControl Clinical Trial.

Case No: **OPD No:**
Name:
Age: **Sex:** **Occupation:**
Address:
Chief Complaint:
Medical history:
Dental history:
Personal habits:

CLINICAL PARAMETERS

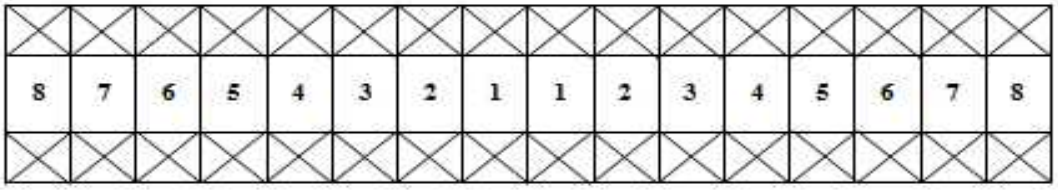
SULCUS BLEEDING INDEX:

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

POCKET PROBING DEPTH:

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

RELATIVE ATTACHMENT LEVEL:



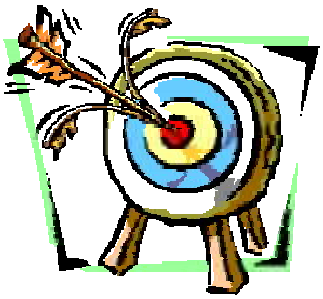
PARAMETER	BASELINE	1 MONTH	6 MONTHS
EVALUATION OF CLINICAL PARAMETERS			
RELATIVE ATTACHMENT LEVEL			
BLEEDING INDEX			
POCKET PROBING DEPTH			
EVALUATION OF FURCATION INVOLVEMENT			
HORIZONTAL COMPONENT			
VERTICAL COMPONENT			

Amount of bone fill from baseline to 6 months:

Patient Information Sheet

- I Dr.RohitaPendyala, will be conducting the study.
- In this study only the tooth with grade II furcation will be taken.
- Patient will be explained about the procedure and after their willing the study will be conducted.
- In the first appointment clinical parameters will be noted and radiograph of the tooth will be taken . Scaling will be done and after 3 weeks of phase 1 therapy the patient will be recalled. In this appointment impression will be taken .
- In the second appointment, blood investigations will be done prior to the treatment of the defective area of the tooth after which placement of bone graft on one side and gengigel on the other side along with collagen membrane will be done.
- In the third appointment and fourth appointment that is after 1month and 6 month of surgery clinical parameters will be recorded again along with radiographic assessment.
- These measurements(clinical and radiographic) taken will be used for the research study.
- Patient will have to cooperate with the dentist.

Introduction



Aim and Objectives

Review of Literature

Methodology

Results

Discussion

Summary And Conclusion

Bibliography

Annexures