

Treatment of Mandibular Grade II Furcation Defects Using Demineralized Freeze-dried Bone Allograft Alone or in Combination with Guided tissue Regeneration Membrane – A Randomized Controlled Clinical Trial.

Abstract:

Background: Periodontal disease, if not interfered, will headway further with attachment loss involving the bifurcation or trifurcation of multirooted teeth. Furcation involved molar teeth respond less favorably to conventional periodontal therapy alone resulting into tooth loss. Combining osseous grafting with guided tissue regeneration membrane may enhance the response to treatment as compared to graft – only therapy by achieving mechanical stabilization and preventing micromovement of the bone graft material.

Aim & Objective : To compare the efficacy of demineralized freeze-dried bone allograft alone or in combination with guided tissue regeneration membrane in the treatment of mandibular Grade II furcation defects.

Materials & method : In this study a total number of 20 patients with 20 mandibular sites (buccal grade II furcation involvement) were evaluated. They were divided into two groups: Control group (bone graft only) and test group (bone graft + GTR). The clinical parameters assessed were vertical probing depth, horizontal probing depth and relative clinical attachment level.

Results: In this study the statistical analyses comparing test and control sites at baseline revealed no significant differences between the two groups for any of the clinical parameters considered. At 6 month evaluation, significant difference was found between two groups regarding VPD, HPD and rCAL.

Conclusion: It was concluded that there is a significant enhanced effect of using DFDBA bone graft in combination with GTR membrane over bone graft alone for the treatment of mandibular Grade II furcation defects.

Key-words: Demineralized freeze-dried bone allograft, furcation involvement, guided tissue regeneration, repair, regeneration

Introduction:

Periodontitis is defined as “an inflammatory disease of the supporting tissues of the teeth caused by specific microorganism or group of microorganisms, resulting in progressive destruction of the periodontal ligament and alveolar bone with pocket formation, recession, or both”[1].

The progress of inflammatory periodontal disease, ultimately results in the attachment loss in the bifurcation and trifurcation of multirooted teeth. Furcation is “the anatomic area of a multirooted tooth where the root diverges” and furcation invasion refers to the “involvement of the bifurcation and

trifurcation of multirooted teeth by periodontal disease.”[1] Furcation involvement results from loss of periodontal fiber attachment and bone between the roots of multirooted teeth. The management of furcation involvement presents one of the

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greatest challenges in Periodontal therapy. Furcation – involved molar teeth respond less favorably to conventional periodontal therapy and molars are lost more often than any other tooth type.[2,3]

Conventional methods like surgical or non surgical therapy including scaling and root planing generate negative histological results with the formation of long junctional epithelium. However regeneration of new bone, cementum and periodontal ligament is considered one of the primary objectives of the periodontal therapy. The commonly used methods for regeneration of the lost periodontal tissues are Bone Grafting and Guided Tissue Regeneration (GTR) [4].

For the treatment of grade II furcation, recommended therapy includes: furcation plasty, tunnel preparation, root resection, tooth extraction, bone grafting, guided tissue regeneration and combination of bone grafts alone with GTR membrane. There are various types of bone grafts available which can be used in Grade II furcation. Materials such as autogenous bone grafts, allografts (undecalcified freeze dried and decalcified freeze dried bone allograft), xenograft and alloplast (nonbone/ synthetic graft materials) have been used.[5]

DFDBA (Demineralized Freeze Dried Bone Allograft) has been documented to have osteogenic potential and can be used as a bone graft material. Demineralization process exposes the components of bone matrix termed as bone morphogenic proteins like osteogenin, which is a bone inductive protein isolated from the extracellular matrix of human bones[1]. Clinical research has reported remarkable gains in clinical attachment level using Demineralized freeze dried bone allograft (DFDBA)[6,7] while other studies have provided histological evidence of new attachment formation achieved by the use of DFDBA[8].

GTR is the method for the prevention of epithelial migration along the cemental wall of the periodontal pocket so as to cover bone and periodontal ligament, thus temporarily separating them from the gingival epithelium and promptly regenerating the lost periodontal tissues[1]. Various non resorbable and resorbable barrier membranes have been used to facilitate a new connective tissue attachment.[9]

GTR without the combined use of bone grafts usually results

in new cementum and new connective tissue attachment, but not in new bone formation.[10,11]

Combining osseous grafting with guided tissue regeneration may enhance the response to membrane – only therapy with bone restoration via the osteoconductive effects of the graft and supporting the membrane to a more optimal position in selective sites. Similarly, the combination may enhance grafting-only therapy in selective areas via better containment of the graft and epithelial exclusion.

Therefore this study was done to evaluate the effectiveness of the combination of allograft with or without the use of a bioresorbable Guided Tissue Regeneration membrane for treatment of Grade II furcation defects.

Materials and Methods:

Source of Data:

This study was carried out in the Department of Periodontology and Oral Implantology, Rama Dental College Hospital and Research Centre, Kanpur, Uttar Pradesh. A randomized controlled clinical trial for 6 months was designed to evaluate the efficacy of demineralized freeze-dried bone allograft (From TATA MEMORIAL HOSPITAL TISSUE BANK, Mumbai[®]) alone or in combination with a resorbable collagen membrane (NEOMEM[®]) with or without for the treatment of grade II furcation defects in mandibular molars.

Sample Size:

The sample size for each group for this study was 10 sites with grade II furcation defects, with horizontal defect depth of at least 3 mm in mandibular molars. Patients were assigned to the following two groups randomly and were followed for 6 month.

1. Control group: defects were treated with bone graft only.
2. Test group: defects were treated with bone graft and GTR membrane.

Commercially available human demineralized freeze dried bone allograft was used as bone graft material, procured from TATA MEMORIAL HOSPITAL TISSUE BANK, Mumbai, with a particle size of 500 – 1000 microns used for all patients. Bioresorbable membrane used was Bovine Type I collagen membrane named NEOMEM from company CITAGENIX.

Selection Criteria:

Inclusion Criteria:

1. Subjects with Chronic Periodontitis with Grade II furcation defects with horizontal defect of atleast 3 mm in mandibular molars.
2. Individuals with good general health and with no systemic diseases like diabetes, bleeding disorders, hypertension, allergic reaction, cardio-vascular diseases were recruited to participate in this study.
3. Patients of both sexes between the age group of 30 – 50 years .
4. Teeth with functional antagonist were included.

Exclusion criteria:

1. Patients who had undergone any type of regenerative periodontal therapy 6 months prior to the initial examination.
2. Pregnant and lactating women.
3. Subjects who were taking anti-inflammatory drugs, antibiotics, immunosuppressants or oral contraceptives.
4. Chronic Smokers.
5. Subjects allergic to any medicine to be prescribed during the study.
6. Third molars were not included.
7. Inability to provide informed consent to the operator.
8. Non vital teeth.

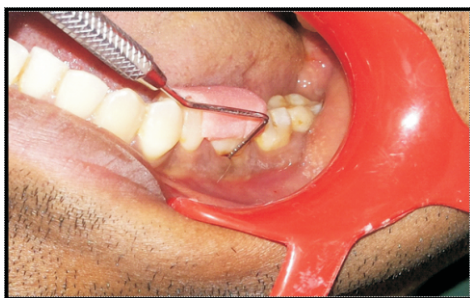


Figure -1: Vpd And Rcal At Basline (Control Group)

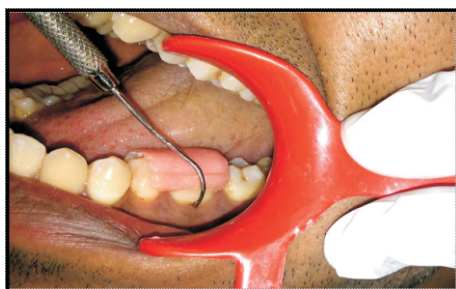


Figure- 2: Hpd At Baseline (Control Group)



Figure – 3: Radiograph At Baseline (Control Group)

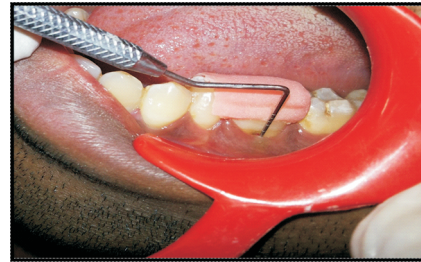


Figure -4: Vpd And Rcal At 6 Months (Control Group)



Figure -5: Hpd At 6 Months (Control Group)



Figure -6: Radiograph At 6 Month (Control Group)
Surgical Procedure Test Group (Parameters Recorded)



Figure -7: Vpd And Rcal At Baseline (Test Group)



Figure -8: Hpd At Baseline (Test Group)



Figure – 9: Radiograph At Baseline (Test Group)

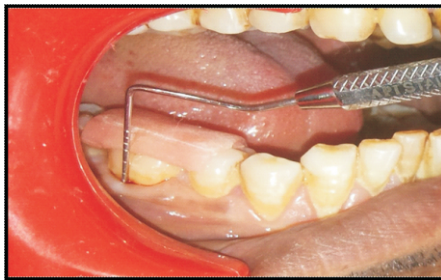


Figure -10: Vpd And Rcal At 6 Month (Test Group)



Figure -11: Hpd At 6 Month (Test Group)

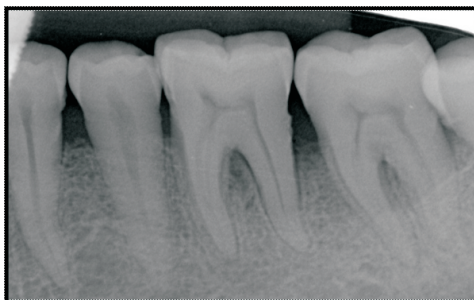


Figure – 12: Radiograph At 6 Month (Test Group)

Results:

The purpose of the present clinical trial was to evaluate the efficacy of demineralized freeze-dried bone allograft alone or in combination with guided tissue regeneration membrane in the treatment of mandibular Grade II furcation defects. In the present study, 20 patients (13 males and 7 females) with ages ranging from 30-50 years, fulfilling the inclusion and exclusion criteria, contributing to a total 20 mandibular grade II defects were recruited. These 20 defects were then randomly assigned into experimental and control sites. All patients showed good compliance and the healing period was uneventful for both treatment groups, without infection or complications.

Table -1: Changes In Vertical Probing Depth

VPD	Number	Control group			Test group		
		Mean	S.D.	P-value	Mean	S.D.	P-value
Baseline	10	4.90	1.37	0.008*	4.80	1.03	0.000*
3 months	10	3.50	0.85		2.90	1.10	
6 months	10	3.30	1.16		2.40	0.84	

Table 1 represents that VPD in control and test group remained statistically significant in control (p = 0.008) as well as test group (p = 0.000) when compared within the groups.

Table-2: Changes In Relative Clinical Attachment Level

rCAL	Number	Control group			Test Group		
		Mean	S.D.	P-value	Mean	S.D.	P-value
Baseline	10	5.10	0.99	0.006*	4.60	1.08	0.000*
3 months	10	3.80	0.79		2.70	1.06	
6 months	10	3.60	1.27		2.20	0.79	

Table 2 represents that rCAL remained statistically significant in control (p = 0.006) as well as test group (p = 0.000) when compared within the groups.

Table-3: Changes In Horizontal Probing Depth

HPD	Number	Control group			Test group		
		Mean	S.D.	P-value	Mean	S.D.	P-value
Baseline	10	3.90	0.99	0.000*	4.70	0.95	0.000*
3 months	10	2.30	0.82		2.30	0.68	
6 months	10	2.10	0.88		2.00	0.47	

Table 3 represents that HPD was statistically significant in control (p = 0.000) as well as test group (p = 0.000) when compared within the groups.

Discussion:

The ultimate goal of periodontal therapy is the regeneration of periodontal supporting tissues that have been lost as a consequence of periodontitis. Removal of the local bacterial etiology by surgical or nonsurgical therapies results in a resolution of inflammation and an improvement in the clinical signs of periodontitis, but it does not result in the regeneration of a periodontal connective tissue attachment. The commonly used methods for regeneration of the lost periodontal tissues are Bone Grafting and Guided Tissue Regeneration (GTR). The combinations of the bone graft and the GTR membrane have been proven to give good results. Various studies have been conducted to judge the efficacy of these two biomaterials in Grade II furcation defects.

In the present trial bone graft in combination with barrier membrane was chosen as it is believed that these materials not only maintain the space, but also might provide an osteoinductive and/or osteoconductive capacity.[12] The biologic concept of guided tissue regeneration has evolved through a number of animal experiments documenting that the progenitor cells for the formation of a new connective tissue attachment to the root surface are residing in the periodontal ligament and in the present trial combined effect of bone graft and GTR was compared to bone graft alone so as to see if any added effect of GTR is available for regeneration.[13]

In this study the statistical analyses comparing test and control sites at baseline revealed no significant differences between the two groups for any of the clinical parameters considered. At 6 month evaluation, significant difference was found between two groups regarding VPD, HPD and rCAL. The test group (DFDBA+ GTR) contributed to enhanced treatment outcomes/ regeneration than the control group. This result may be attributed to selective cell repopulation underneath the barrier membrane, DFDBA might have maintained large space underneath barrier membrane leading to true connective tissue attachment.

In our study a significant reduction in HPD was seen at 3 and 6 months in the test group as compared to control group. Similar results were reported by Prathap et al[12] who used hydroxyapatite bone graft with and without collagen membrane. They also achieved significant reduction in test group (0.8 ± 0.422) and control group (0.5 ± 0.527) at 6 months

however the difference was not statistically significant in their study. Another study by Malathi et al[14] achieved statistically significant reductions in HPD from baseline to 6 months for both test (GTR+ hydroxyapatite) and control group (bone graft only.)

The gain in clinical attachment was recorded both in test group and control group. Between the groups, there was a significant difference observed both at 3 months and 6 months postoperatively. Similar results were obtained by Lekovic et al[15] who suggested an improved CAL in sites treated using combination technique(GTR + Bone graft). The results are also in agreement with the study results of Wang et al[16] in which test sites showed a CAL gain of 1.67 ± 0.22 mm and control sites showed a CAL gain of 0.67 ± 0.62 mm.

The vertical probing depth also reduced both in control and test group and this reduction between baseline and 6 months was statistically significant .However the studies done by Prathap et al[12] reported higher probing depth reduction in test group (2.9 ± 0.878) as compared to control group (2.5 ± 0.972) but the results were not statistically significant. Also the study conducted by Lamb et al[17] which compared mineralized human cancellous bone allograft with and without collagen membrane, showed a higher vertical bone fill in the group treated with bone graft alone compared with the group treated using the combination.

The present clinical trial was conducted to detect any advantageous effects of bone graft in combination with collagen membrane over bone graft alone to bring about the regeneration of lost tissues. The result of the present study indicates that both the bone graft and bone graft with guided tissue regeneration are effective treatment modalities in Grade II furcation defects and there was successful regeneration as attributed by evaluating the various clinical parameters. However the experimental group proved to be significantly better than the control group.

Conclusion:

It could be concluded that there was significant enhanced effect of using DFDBA bone graft in combination with GTR membrane (Neomem[®]) over bone graft alone for the treatment of mandibular Grade II furcation defects. This result may be attributed to several factors such as the presence of partially

resorbed particles of DFDBA hindering probe penetration; true regeneration of connective tissue attachment due to the presence of DFDBA, which may have created and maintained a larger space underneath the collagen membrane allowing for selective cell repopulation.

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