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Research Article

Treatment of Intrabony Defects by Decortication with Cerabone™ and DFDBA - A Randomised Controlled Trial

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Abstract

Objective: Decalcified Freeze Dried Bone Allograft (DFDBA) and xenografts have shown good results in the management of intrabony defects. Decortication of the bone has shown favourable results in guided bone regeneration procedures. The goal of the present study was to check the efficacy of decortication with decalcified freeze dried bone allograft (DFDBA) and Cerabone™ bone grafts and to compare the response between the bone grafts placed using Radiovisiography (RVG) and Cone Beam Computed Tomography (CBCT) in intrabony defects.

Methodology: In this split mouth study, ten patients presenting with bilaterally intrabony defects were selected and decortication was done in all the defects. They were randomly allocated as Group I which received DFDBA and Group II received Cerabone™. Clinical parameters included Pocket Probing Depth (PPD), Relative Attachment Level (RAL), Plaque

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Index (I), Periodontal Disease Index (PDI) and Gingival Bleeding Index (GBI). Radiographically Intrabony Defect Depth (IBD) and defect resolution were measured at baseline, 3 months, 6 months and 9 months with RVG. CBCT was used at baseline and 9 months.

Results: Both the groups demonstrated statistically significant PPD reduction, attachment gain and radiographic bone fill. The differences between the groups were statistically significant and more favourable in Group II.

Conclusion: Decortication plus Cerabone™ significantly improved the clinical and radiographic parameters of intrabony defects at 9 months after treatment when compared to decortication plus DFDBA.

Keywords

Periodontal Destruction; Bone Scaffold; Alveolar Crest; Cementoenamel Junction

Introduction

Periodontitis is characterized by non-reversible tissue destruction resulting in progressive attachment loss, which in turn leads to tooth loss [1]. It is established that the sixth most prevalent disease of mankind is severe periodontitis [2]. Occasionally, overgrowth or new properties are introduced by a subset of bacterial species that contribute to periodontal destruction. Periodontitis results in osseous defects of different morphological forms and three types of defects are caused by site-specific periodontal breakdown that is suprabony (horizontal) defects, infra-bony (vertical) defects and inter-radicular (furcation) defects [3]. Vertical defects are more suitable for regenerative processes [4].

Regeneration of the lost periodontal tissues is the primary therapeutic goal for the preservation of teeth through the restoration of health, function, and aesthetics of the periodontium [5]. The limits of what is considered "regenerable" have been pushed by recent advances in periodontal regenerative techniques and materials [6]. Intra-bony defects can be more successfully regenerated with the currently available regeneration procedures and materials in the field of periodontology, but some patient factors such as plaque control, smoking and medical history, tooth mobility, restorative and endodontic condition also play a role in the prognosis [7].

The superiority of periodontal regenerative therapy in the treatment of intrabony defects over traditional procedures, such as Open-Flap Debridement Surgery (OFD), in terms of Probing Pocket Depth (PPD) and reduction of Clinical Attachment Loss (CAL) has been stated in

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several publications [8]. A number of autografts, allografts, xenografts and alloplasts have been clinically tested for favourable treatment outcomes [9]. DFDBA is an allograft with osteoconductive and osteoinductive properties. Attributable to enhanced expression of bone morphogenetic protein, it has the potential for osteoinduction (BMP) [10]. Whereas, xenograft (Cerabone^{TM}) is a graft that ensures the biomaterial's osteoconductive properties and is therefore used in combination with decortication according to the principle of Guided Bone Regeneration (GBR). On the inert absorbable bone scaffold, revascularisation, osteoblast migration and woven bone formation occur [11].

In GBR, decortication, also known as intra-marrow penetration (i.e. cortical bone perforation), is used to promote bone regeneration by stimulating osteoblast migration to the region of the bone defect and avoiding cell migration that impedes bone formation [12]. The compact bone acts as a physical barrier to cell and tissue migration from medulla that mediates bone formation. Perforation reduces this obstruction and will enhance the physical binding between the recipient sites and grafting materials. The decortication of the walls of the intrabony defect has demonstrated dramatically improved clinical and radiographic performance [12]. Local tissue regeneration with release of osteoprogenitor cells and osteoinductive agents has been triggered by this Regional Accelerated Phenomenon (RAP) [13]. The intramarrow penetration of cortical bone may affect the quality of regenerated bone by facilitating the migration of osteoprogenitor cells from the bone marrow into the isolated space created [13].

The present study was undertaken to evaluate, the efficacy of decortication with Decalcified Freeze Dried Bone Allograft (DFDBA) and Cerabone™ (xenograft) and also to compare the response between the osseografts placed in the treatment of Intrabony Defects (IBD), clinically and radiologically using Radiovisiography (RVG) and Cone Beam Computed Tomography (CBCT).

Materials and Methods

Ethics

The study protocol was approved by the institutional ethical review board of Krishnadevaraya College of Dental Sciences and Hospital, affiliated to Rajiv Gandhi University of Health Sciences. The study was conducted in accordance with the principles of the World Medical Association Declaration of Helsinki (Version VI2002) on experimentation involving human participants and consort 2010. The present study has been registered under Clinical Trial registration with protocol ID 02_D012_54500.

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Study Design

The study design is a single centred, prospective, randomized controlled clinical trial comparing the clinical and radiographic outcome at baseline and 9 months after periodontal intervention. This study is split mouth with parallel design having allocation ratio of 1:1. Ten patients having bilateral intrabony defects were decorticated and randomly allocated into two groups, Group I- Demineralized Freeze-Dried Bone Allograft (DFDBA) and Group II- Cerabone™. The randomization was carried out by computer generated random sequence allocation (Fig. 1). The study was conducted between November 2014 and September 2015 on patients reporting in dental OP of Department of Periodontology, Krishnadevaraya College of Dental Sciences and Hospital.

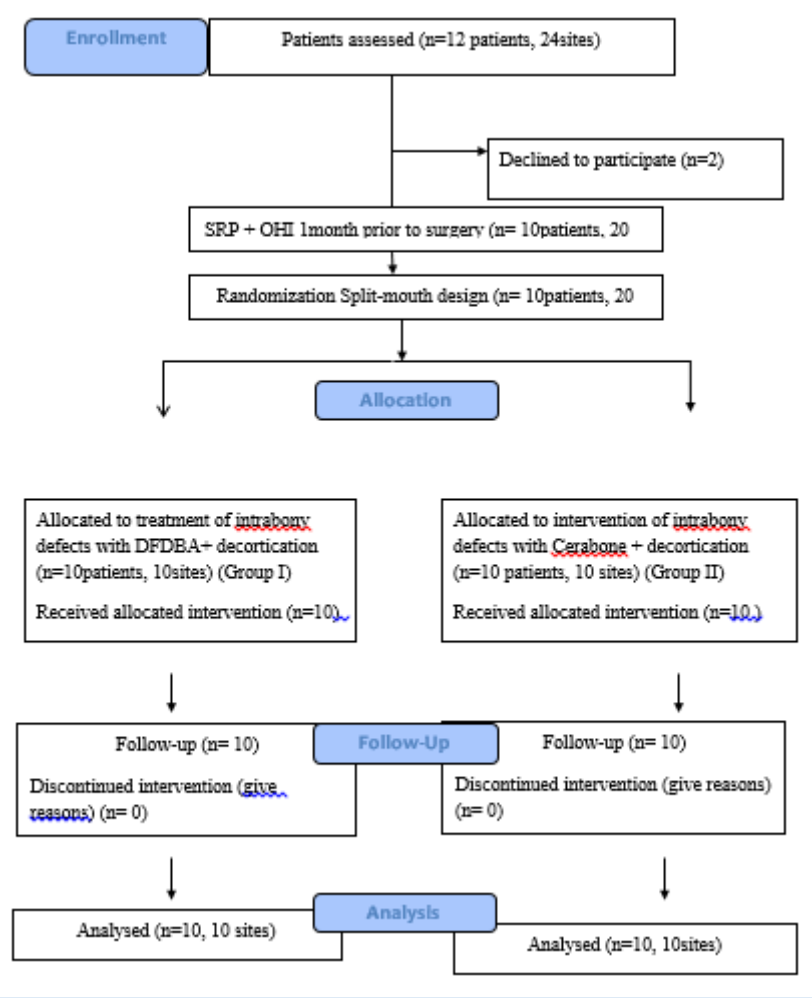

Figure 1: CONSORT flow diagram.

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Patients satisfying following criteria were included, moderate to severe localised periodontitis, Pocket Probing Depth (PPD) of ≥ 5mm and at least two similar intrabony defects as detected by transgingival probing. Radiographically, Intrabony Defect Component (IBD) ≥3 mm as detected on Radiovisiography (RVG) and CBCT. Full-mouth plaque score (FMPS) < 20% at baseline and Full-Mouth Bleeding Score (FMBS) < 20% at baseline. Clinical parameters recorded were Plaque Index (PI), Periodontal Disease Index (PDI), Gingival Bleeding Index (BI), Pocket Probing Depth (PPD) with UNC-15; Relative Attachment Level (RAL) is recorded using customized acrylic stent. It is the distance measured from a fixed reference point on the stent at the selected tooth site to the bottom of the defect.

In radiographic analysis, RVG was taken at baseline, 3 months, 6 months and 9 months follow up using paralleling technique. The radiographs were standardized using positioning device (Rinn Positioner, KKD, Germany) and radiographic grid (X-ray Mesh Gauge, Dental, Shimizu, Japan). For measurement, calibrated measurement software called Digimizer (version 4.0) was used. The Cementoenamel Junction (CEJ), the crest of Alveolar Crest (AC) and the base of the defect (BD) were marked on the image. A line was drawn from CEJ to BD. The software then displayed the distance between these two points. Intra-Bony Defect (IBD) (Fig. 2). At the time of surgery, after debridement of the surgical site, following measurements were taken [14].

- Distance from CEJ to the bottom of defect (CEJ-BD)
- Distance from the CEJ to the most coronal extension of alveolar bone crest (CEJ-BC)
- The intra bony component of the defects was measured as (CEJ-BD)-(CEJ-BC)
- Angle was defined as the angle between lines 1 to 2 and 2 to 3
- Defect resolution = Initial bone defect- 9months post op bone defect X 100 [15]

Initial Bone Defect

Radiographic analysis of defect morphology was done using Cone Beam Computed Tomography (CBCT) (3DKodak Dental Imaging Software, Carestream Health Inc. NY USA) and Radiovisiography (RVG) (SOPIX Digital X-ray sytem, ActeonsoproLaciatat, France). Defect morphology was assessed at base line and at 9 month follow-up. Using the software, points were marked on the Cementoenamel Junction (CEJ), Base of the Defect (BD), and Alveolar Crest (AC) and the defect depth was measured using (CEJ to BD)-(CEJ to AC). The total bone fill was measured subtracting the depth of the osseous defect at 9 months from the baseline measurement using CBCT. All clinical and radiographic measurements were performed by examiner who was masked to the surgical procedures performed (Fig. 2).

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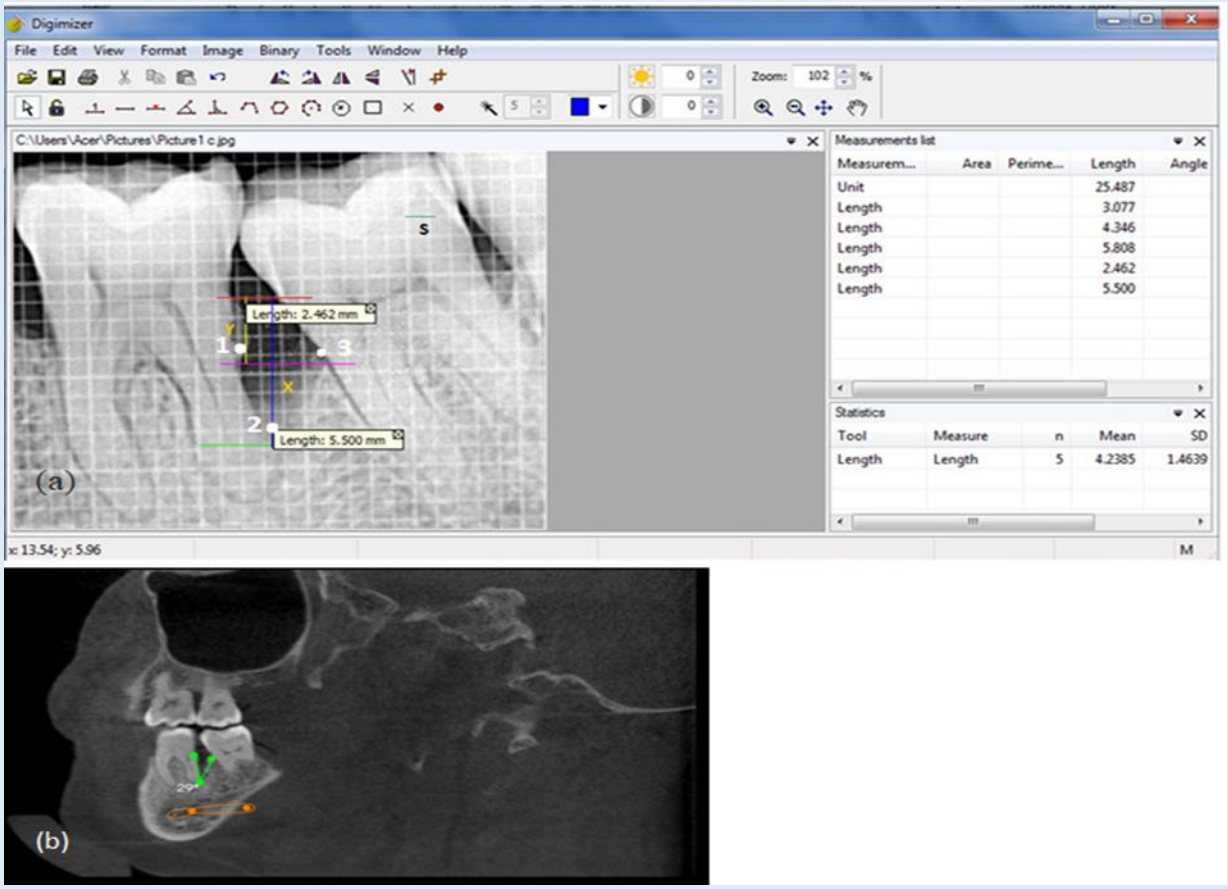

Figure 2: (a) Preoperative Radiovisiography. CEJ (red line), AC (violet line), BD (green line) 1 = Alvelolar bone Crest (AC), 2 = Intrabony defect base (BD), 3 = Bone Crest at defect width. (BC) (b) Pre-operative assessment of Defect angle using CBCT.

Surgical Technique

Prior to surgery all patients were given pre surgical rinse of 0.2 % Chlorhexidine for 30 seconds. The operative site was anaesthetised using local anaesthesia with 2% lignocaine HCL and 1:80000 adrenaline. Buccal and lingual crevicular incisions were made and mucoperiosteal flaps were reflected one tooth mesial and distal to the defect. The defect was thoroughly debridement and root planning was performed. The surgical area was carefully irrigated with saline.

For the Group I, decortication was performed by penetrating the cortical walls of the intrabony defect by using a round carbide bur of 0.2 mm diameter to reach the marrow space. Multiple perforations were performed not closer than 1mm from each other and deep enough to obtain bleeding from the spongiosa [16]. The intrabony defects in Group I were treated with DFDBA allograft. The graft material was placed into the defect with an amalgam carrier followed by

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firm pressure with an amalgam condenser. The defect was filled to the existing alveolar crest. Primary soft tissue closure was obtained by performing a modified vertical mattress suture over the grafted site using 3-0 non absorbable black braided silk suture.

The sites belonging to Group II were treated similarly as Group I and the same surgical protocol were followed except that the intrabony defects were treated with xenograft (Cerabone^{TM}) (Fig. 3). Non-steroidal anti-inflammatory drug and antibiotics were prescribed. Patients were advised to consume only soft food during the first week. After this period, patients were reinstructed in mechanical cleaning of the treated teeth using a soft toothbrush and roll technique of brushing for 1 month. Patients were recalled for reinforcement of oral hygiene instructions and light debridement with ultrasonic scalers supragingivally was carried out. Sutures were removed 10 days post operatively. All the patients were recalled at 3, 6 and 9 months for periodic rechecking.

Figure 3: a) Flap reflection and debridement and surgical exposure of intrabony defect. b) Decortication. c) Cerabone graft placed in intrabony defect. d) Sutures placed.

Statistics

Power of the study was set at 90% and α maintained at 0.5, was determined using G power software with sample size of 20 (10 in each group). Statistical analyses were performed using the Statistical Package for Social Science (SPSS version 10.5) software using Shapiro-Wilks test was done to test the normalcy of the data. Parametric statistical tests were applied for all parameters except for Gingival bleeding Index that was evaluated using non parametric test i.e. Mann Whitney U test for intergroup analysis. The parametric tests applied were unpaired t test was for intergroup and One Way Analysis of Variance (ANOVA) followed by Turkeys Post hoc test for intragroup analysis. Kruskal-Wallis test for performed for intragroup analysis. P value ≤ 0.05 was considered to be statistically significant.

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Results

A total of ten patients in the age range of 25-55 years, 4 males and 6 females were enrolled in the study. The mean age was 38.70±5.31. The split mouth study conducted included a uniform distribution of defects in both the study groups (10 in each group).

Primary outcome measure: On evaluating the mean difference of PPD and RAL from baseline to 9 months was similar with p value <0.001 which was statistically highly significant (Table 1). Radiographic bone fill assessed through CBCT had p value 0.021 which was statistically significant.

Radiographic bone gain assessed by RVG: There was significant reduction in IBD from baseline to 9 months both in Group I and Group II was significant with p value of 0.013(Table 2). Both analytical methods showed higher defect resolution in percentage for group II when compared to group I. (Fig. 4).

Parameter	Group	N	Mean	Std. Deviation
PPD	Group I	10	3.1	1.19
	Group II	10	5.9	0.99
RAL	Group I	10	3.1	1.19
	Group II	10	5.9	0.99
Defect resolution	Group I	10	1.53	0.535
CBCT	Group II	10	1.01	0.378
Statistically significant $p \leq 0.05$				

Table 1: Mean difference of PPD and RAL and Radiographic bone fill assessed through CBCT.

Parameter	Visit	Group	N	Mean	(Std. Deviation)	p value
	Baseline	Group I	10	5.61	0.834	0.919
		Group II	10	5.65	0.863	
	3 months	Group I	10	4.66	0.712	0.039*
Defect resolution (RVG)		Group II	10	4	0.607	
	6 months	Group I	10	3.09	0.477	0.006*
		Group II	10	2.21	0.743	
	9 months	Group I	10	1.51	0.506	0.013*
		Group II	10	0.97	0.365	
Statistically significant $p \leq 0.05$						

Table 2: Radiographic bone gain assessed by RVG.

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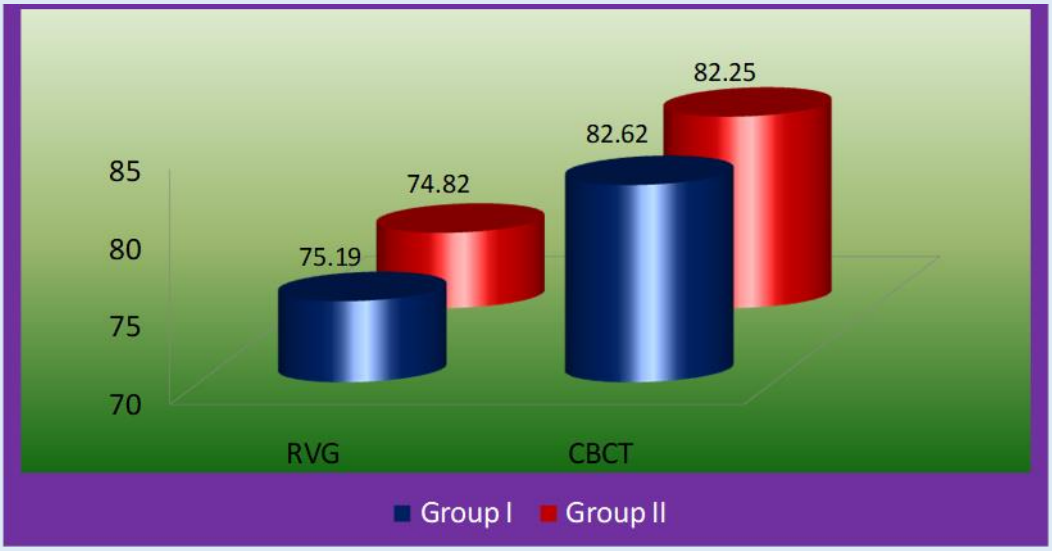

Figure 4: Comparison of defect resolution in percentage to 9 months for group I and group II according to RVG and CBCT.

The mean defect angle in Group I was 30.92±5.15 and in Group II was 31.92±3.7 with a 'p' value 0.618 which was statistically insignificant thereby suggesting that there was no difference in the angles of the defect and hence no bias.

Secondary Outcome Measure

The mean differences for plaque index and periodontal disease index showed statistically significant reduction at 9 months for both groups with p value <0.001 and 0.043 respectively, whereas the intergroup comparison of mean difference for Gingival Bleeding Index (GBI) at 9 months showed insignificant results with p value of 0.481.

Discussion

There is vast literature over the past 4-5 decades to support that healing post periodontal surgery of infrabony defects using biomaterials leading to regeneration of cementum, periodontal ligament, alveolar bone and gingiva [7]. Bone decortication is sometimes done as part of a GBR treatment prior to insertion of a bone graft, but the effect of decortication on new bone formation in GBR remains uncertain [9]. Since the addition of decortication to Open Flap Debridement (OFD) in the treatment of intrabony defects improved the clinical and radiographic bone healing parameters, it was hypothesized that a combination of decortication with bone grafts i.e., DFDBA or xenograft may positively influence the treatment of periodontal intrabony defects. According to literature the combination of decortication with OFD leads to clot formation, maturation and cell proliferation. The objective of the present

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randomized control trial was to evaluate clinically and radiographically the efficacy of allograft (DFDBA) and xenografts (Cerabone™± with decortication in the treatment of intrabony defects in chronic periodontitis patients [15,16].

In the present clinical trial, the decortication plus DFDBA group showed a PPD reduction of 3.10±1.19 mm and it was statistically significant. Similar results were seen in studies conducted by Agarwal, et al., (2014) (3.64± 0.92 mm) who treated IBD with a combination therapy of DFDBA plus PRP and Gurinsky, et al., (2004) (3.6±0.2 mm) who treated IBD with DFDBA plus EMD [17,18]. The results of the present study were contrary to a similar study with mean PPD reduction of 2.4 mm as reported by Rummelhart, et al., (1989) who performed decortication plus DFDBA in the treatment of IBD and Richardson, et al., (2.0±1.3 mm) who treated IBD with DFDBA alone [19,20]. In the decortication plus Cerabone™ group, PPD reduction of 5.90±0.99 mm was noted which was statistically significant with 'p' value of 0.001 similar to study by Aslan, et al., (2020) where PPD reduction of 6.5±2.65 mm was found when used combination of cerabone and enamel matrix proteins with papilla preservation technique [21].

In this study, Group I showed gain in RAL with the 'p' value ≤0.001. Similar results were shown by Agarwal, et al., (2014) and Gurinsky, et al., (2004) whereas contradictory results were obtained by Rummelhart, et al., (1989) who reported a RAL gain In Group II, the RAL gain noted was 5.90±0.99 mm which was also statistically significant with 'p' value of 0.001 [17-19]. These results are better than the study conducted by Hanna, et al., (2004) who reported a RAL gain of 3.1 mm and Richardson et al. 3.5 mm [20,22].

In the current study, decortication was performed along with bone graft placement and the mean bone fill at nine months assessed radiographically with CBCT was 82.25% for xenograft (Cerabone™) and 74.84% for allograft (DFDBA) and the difference between them was statistically significant (p≤0.013). These results interpret that not only is a combination therapy beneficial but also the use of Cerabone™ xenografts as opposed to DFDBA is favorable for the treatment of IBD.

According to the systematic review of healing by defect morphology following regenerative surgery by Nibali L, et al., (2020) deeper defects with narrower angles and increased number of walls exhibit improved CAL and radiographic bone gain at 12 months post-regenerative surgery [7]. Similar observation was also made by Kao RT, (2015) where it was stated that intrabony defect depth was directly correlated with the regenerative potential. IBD depth ≥ 3 mm and defect angle ≤ 250 are more amenable to regenerative potential [23]. In the present study the mean defect angle in Group I was 30.920 as opposed to 31.920 in Group II. Wide defect angle may influence the regenerative potential in each group; however since the

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difference between the two groups is statistically insignificant with respect to defect angle, bias was eliminated.

In Group I, intrabony defect reduced from 5.61±0.83 mm (baseline) to 1.51±0.50 mm (9 months post operatively) as detected using RVG and in CBCT it reduced from 5.57 ±0.79 mm to 1.53±0.53 mm respectively whereas in Group II, defect reduced from 5.65±0.86 mm (baseline) to 0.97±0.36 mm (9 months) in RVG and it reduced from 5.66±0.86 mm to 1.01±0.37 mm as shown in CBCT and the difference between RVG and CBCT was insignificant.

Thus, based on the outcome of this study, it could be interpreted that the combination of decortication plus Cerabone™ when compared to decortication plus DFDBA did show a statistically significant difference in clinical and radiological outcome. There was notably statistically significant reduction in PPD, gain in clinical attachment and increase in radiographic bone fill when intragroup assessment was performed ($p \leq 0.001$). On intergroup comparison, Cerabone™ showed highly statistically significant results when compared to DFDBA with respect to all clinical and radiographic parameters.

This study has certain inherent limitations such as variation in defect angle and defect morphology, lack of histologic assessment and limited sample size that may have influenced the outcome of the study. Furthermore, decortication can have some minor negative consequences such as increased operative time, additional blood loss, potentially greater postoperative pain, and some bone loss if the GBR procedure fails [24].

Further studies with histologic assessment, larger sample size and longer follow ups are essential to substantiate the results which can be extrapolated to a larger population.

Conclusion

Within the limitation of the present randomized prospective study, the clinical trial showed predictable clinical and radiographic outcomes and satisfactory healing. Both the grafts showed improved clinical and radiographic parameters without post-operative complications. In conclusion, the result of this preliminary study suggests that decortication plus Cerabone™ combination therapy offered greater benefits in the treatment of IBDs. This combination can be considered effective in the treatment of IBDs.

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Clinical Trial Registration Number

Clinical trial registration number - 02_D012_54500
https://register.clinicaltrials.gov/prs/app/action/SelectProtocol?sid=S0006O1D&selectaction=Edit&uid=U0002Q0E&ts=2&cx=-kogbw4

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