Original Article

Clinical and radiographic evaluation of periodontal intrabony defects by open flap surgery alone or in combination with Biocollagen® membrane: A randomized clinical trial

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Abstract

Background: Guided tissue regeneration (GTR) is often incorporated in regenerative periodontal surgical procedures. However, the actual benefits of adding GTR to such a procedure remain undocumented. The purpose of this randomized controlled trial was to investigate the contribution of GTR to the outcomes of open flap debridement (OFD) in the treatment of intrabony defects. **Materials and Methods:** A total of 16 patients of both sexes satisfying the criteria of chronic periodontitis and each of whom displayed one intrabony defect were randomly assigned to two groups, i.e. either treated with open flap surgery and GTR (group 1) or with open flap surgery alone (group 2), in this parallel-arm study. The soft tissue and hard tissue measurements, including probing pocket depth (PD), clinical attachment level (CAL), and bone mineral density were recorded at baseline and 3,6 and 12 months after surgery. The differences with a $P < 0.05$ were considered significant. **Results:** Results showed that the membrane group showed significant difference when compared with open flap surgery alone, in relation to the degree of periodontal pocket, clinical attachment loss, and bone density. **Conclusion:** The findings of this study suggest that biocollagen membrane could be considered as an option in the treatment of intrabony defects. Biocollagen membrane alone gives favorable clinical results in the treatment of intrabony defects. Open flap debridement resulted in acceptable clinical results in the treatment of intrabony defects.

Key words: *Biocollagen membrane, guided tissue regeneration, intrabony defects, management of infrabony pocket defects, open flap surgery*

INTRODUCTION

Periodontal diseases are a group of inflammatory diseases causing alveolar bone loss and eventually leading to loss of teeth. Periodontitis is caused by the cumulative effect of interactions between bacteria and the immune-inflammatory response of the host.[1] Periodontal surgery has been indicated to stop the progression of bone loss and regenerate lost periodontal tissues, in case non-surgical management has failed in controlling the disease activity. Different treatment modalities have been advocated in the treatment of advanced periodontitis, such as open flap surgery, osseous respective surgery, guided tissue regeneration (GTR), and bone grafting. Periodontal surgery is aimed to provide accessibility for proper removal of plaque and calculus and correction of bony irregularities occurring as a result of bone resorption. Other studies have proved that surgical treatment of

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moderate to advanced periodontitis cases often results in less periodontal breakdown over time. When coupled with post-treatment maintenance regimen, these are successful in preventing tooth loss in nearly 85% of patients.[2,3]

Chronic periodontitis is a slowly progressive disease occurring at any time, however because of its slow rate it becomes clinically significant in the mid 30's or later.[4] Albandar[5] proved that the oral hygiene level is inversely proportional to the severity of periodontitis. According to Haffajee *et al*.,[6] traditional surgical methods are the commonest time-saving methods for root planing, periodontal pocket reduction, and gain of periodontal attachment. The regenerative periodontal therapy is aimed at eliminating periodontal defects by replacement of lost periodontal tissues with new periodontal tissue and restoring their functions.[7,8] Different techniques used for periodontal tissue regeneration include root surface conditioning, GTR, CO_2 laser, growth factors as biological mediators, and a combination of two or all of these procedures.[9,10]

GTR is a treatment plan to initiate regeneration of lost periodontal tissues and prevents the development of long junctional epithelium.[11,12] The principle of GTR is based on either restitution or "healing by repair."[13] Some authors have suggested that GTR results in healing characterized by "reparative" rather than regenerative activity.[14,15] Schüpbach *et al*.[16] and Graziani *et al*.[17] concluded that the healing results obtained following GTR are regenerative. Use of GTR as a clinical periodontal surgical procedure appeared in the literature more than 40 years ago.[18,19] The membranes utilized for GTR are either resorbable or non-resorbable. In case of non-resorbable membrane, it should be removed 4–6 weeks later. The biological rationale of GTR is based on delaying the migration of the epithelial cells into the osseous defect, allowing time for bone and other attachment tissues to heal. The placement of the GTR membrane would ensure that the detached root surface becomes repopulated with cells from the periodontal ligament and becomes capable of forming bone, periodontal ligament, and cementum by preventing epithelial tissue migration. In addition, the membrane provides space for optimal wound stability that is necessary for periodontal regeneration.[20,21]

Criteria for the membranes include: Biocompatibility, cell occlusiveness, integration by host tissues, clinical manageability, and the space making functions.[22] Bioresorbable membranes need additional criteria to be fulfilled, such as minimal tissue reactions after the resorption of the membrane; these reactions should be reversed. Formation of abundantly vascularized connective tissue in the membrane-protected space is always preceded by the formation of new mineralized bone by GTR.[23]

Outcome of GTR therapy is strongly dependent upon: (i) Bacterial infections, (ii) innate wound-healing potential, (iii) characteristics of the surgical site, and (iv) surgical techniques. The main disadvantage of expanded polytetrafluoroethylene (ePTFE) membrane is that it is non-resorbable and, therefore, should be removed in a second surgical procedure.[24] Bunyaratavej and Wang[25] compared bioresorbable to non-resorbable membranes and concluded that using the ePTFE membranes resulted in more favorable bone formation compared to bioresorbable membrane. This resulted from the increased space available with ePTFE.

However, due to the paucity of studies evaluating the regenerative potential of resorbable membranes alone, we aimed to find whether these resorbable membranes had an added benefit when compared to open flap debridement (OFD) alone.

MATERIALS AND METHODS

Patient selection

The study was designed as a controlled, randomized, parallel-arm study, comparing the clinical and radiographic outcomes of bioresorbable collagen membrane (Biocollagen®) withOFD versus OFD alone in the treatment of intrabony defects of patients.

A total of 24 patients (12 males and 12 females) with age ranging from 25 to 35 yearsand witha mean range of 30 years were initially screened from the Out-patient Department of Periodontics, Oral medicine and Periodontology Department, Faculty of Dental Medicine, Al-Azhar University (Assuit branch) of these patients, four were diabetic, two were smokers, and two were non-compliant with the surgical procedure explained. Finally, 16 patients of both sexes (8 males and 8 females) satisfying the criteria of chronic periodontitis and each of whom displayed one intrabony defect were randomly assigned by a computer-generated randomization to two groups and were either treated with open flap surgery and Biocollagen (group 1) or with open flap surgery alone (group 2) in this parallel-arm study.

Ethical clearance was obtained from the Institutional Ethics Committee of Faraby College, Research Unit ref (AEC 6-014).

Patients were randomly assigned to either group 1 (test group) or group 2 (control group):

Group 1 (test group): Bioresorbable membrane + OFD
Group 2 (control group): OFD alone.

Patients who satisfied the following selection criteria were enrolled in the study.

Inclusion criteria

- Systemically healthy patients with moderate to severe chronic periodontitis, and having at least one tooth with clinical attachment level (CAL) and pocket depth (PD) ≥5 mm with radiographic evidence of angular bone loss and an intrabony defect depth of 3 mm
- Vital or treated non-vital teeth
- No history of intake of antibiotics or other medications affecting the periodontium in the previous 6 months
- No invasive periodontal therapy carried out in the past 6 months.

Exclusion criteria

- Patients suffering from systemic disease, according to the criteria of Modified Cornell Medical Index[26]
- Patients with unacceptable oral hygiene and non-compliant patients
- Current smokers
- Pregnant or lactating mothers.

All patients were explained about the study and written informed consent was obtained before the commencement of the study.

After completion of the initial cause-related therapy comprising complete full-mouth scaling and root planing, proper oral hygiene instructions were given with an advice for tooth brushing for 3–5 min, two times daily, and the use of dental floss and or wooden tips for interdental cleaning.

Evaluation was carried out at the end of initial phase of periodontal therapy. The study protocol is depicted in Figure 1

Surgical procedure

Open flap was performed in both groups: Group 1 [Figure 2] and group 2 [Figure 3]. Figures 2 and 4-6 depict the surgical procedures for group 1, while Figures 3,7,8 depict the surgical procedures for group 2.

Following administration of local anesthesia, buccal and lingual mucoperiosteal flaps were raised. Following proper debridement of the intrabony defect, a bioresorbable collagen membrane of equine origin (Biocollagen; Bioteck: Stab Prod, Turin, Italy) was cut according to the morphology of the defect using a template. The material was applied with tweezers into the defect, such that the margins of the barrier were extended 3–5 mm beyond the defect onto the alveolar bone for stability. Sutures were not necessary as the defect morphology allowed a better adaptation of the membrane. The mucoperiosteal flaps were repositioned to cover the membrane completely. The flaps were sutured with 3-0 silk suture.

Postoperative wound management

Immediately after surgery, all the patients were prescribed 500 mg Amoxicillin every 6 h for 5 days, Ibuprofen 400 mg every 8 h, as needed, for pain, and 0.2% Chorhexidinegluconate twice daily for 4 weeks post-surgically to aid in plaque suppression. Patients were reviewed for symptoms such as discomfort, pain, and sensitivity, if any.

Sutures were removed after 7 days. The patients were asked to refrain from mechanical plaque control at the surgical site for at least 4 weeks. Postoperative appointments were conducted at 7, 14 and 21 days.

At 3, 6, 9 and 12 months post-surgically, both hard tissue and soft tissue measurements were taken.

Statistical analysis

All data were transferred and stored in Microsoft Excel 2003®. Data analysis was performed using statistical test files. The calculations that were performed using the statistical program SPSS version 13 were: 1. Descriptive analysis: For comparison between the baseline reading and the subsequent readings; and 2. unpaired *t*-test for analysis within the same group. For comparison between the two groups, we used paired *t*-test. $P < 0.05$ were considered significant and < 0.01 as highly significant. Graphs were drawn using the Microsoft Excel 2003 program.

RESULTS

The results showed no significance difference between both the groups in relation to changes in plaque and gingival indices. In relation to PD changes [Tables 1 and 2, Figure 9], when group 1 was compared with group 2, there was a significant difference at 3, 6, and 9 months post-surgery and a moderately significant difference at 12 months post-surgery.

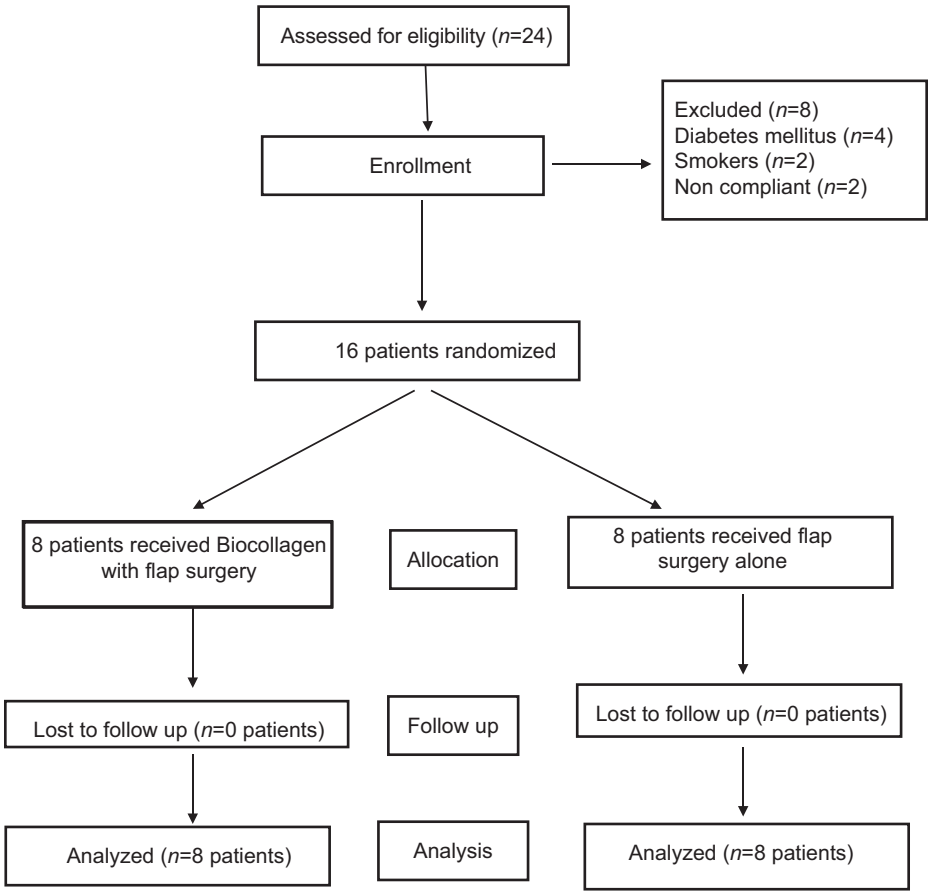

Figure 1: Depicting the study protocol

Table 1: Range, minimum, maximum, and means±standard deviations of pocket depth in the two groups during different intervals

Studied groups	Intervals	Range		Mean	SD
		Min.	Max.		
Group 1	Baseline	6	8	6.61	0.48
	3 months	3	6	4.50	0.81
	6 months	3	6	4.68	0.95
	9 months	4	6	4.42	0.78
	12 months	3	6	3.57	0.53
Group 2	Baseline	6	8	6.77	0.53
	3 months	4	7	5.23	0.37
	6 months	4	6	5.10	0.57
	9 months	4	6	4.9	0.00
	12 months	3	6	4.87	0.78

In relation to changes in the CAL or loss of attachment, as shown in Tables 3 and 4, Figure 10, when the first group was compared with the second group, there was a significant difference.

Finally, in relation to changes in bone density [Tables 5 and 6, Figure 11], there was a significant difference when the first group was compared with the second group at 9 months post-surgery and a highly significant difference at 12 months post-surgery. Radiographic changes before and after treatment in group 1 are shown in Figures 12 and 13, while the changes before and after treatment in group 2 are shown in Figures 14 and 15. Graphs were drawn using the Microsoft Excel 2003 program.

Table 2: Intergroup comparison of pocket depth

Paired samples test								
	Paired differences					*t*	df	Sig. (2-tailed)
	Mean	Std. deviation	Std. error mean	95% confidence interval of the difference				
				Lower	Upper			
Pair 1								
Group 1-group 2	−0.61800	0.43176	0.19309	−1.15411	−0.08189	−3.201	4	0.033*

**P<0.05 significant*

DISCUSSION

The present study aimed to evaluate the adjunctive benefit of the use of a biocollagen membrane in the management of intrabony defects both clinically and radiographically, compared to open flap surgery alone. Literature states that reattachment is reunion of connective tissues and epithelium with the root surface on which viable periodontal tissue is found without formation of new cementum. Whereas selective repopulation of root surfaces previously exposed to periodontal disease by periodontal ligament cells results

Figure 2: Patient before treatment (group 1)

Figure 3: Patient before treatment (group 2)

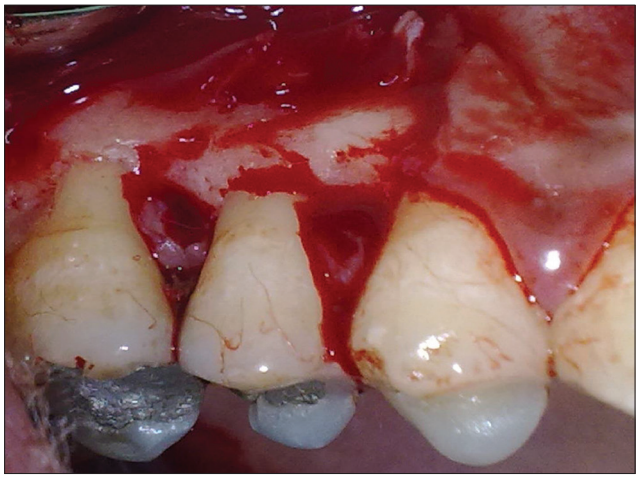

Figure 4: Flap elevation

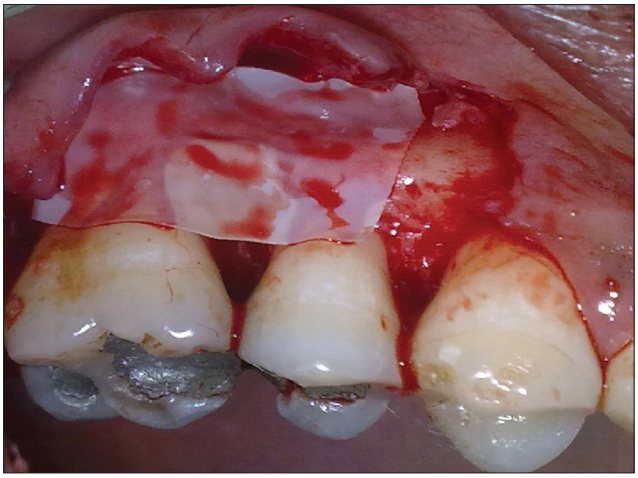

Figure 5: Membrane placement

Figure 6: Patient after treatment

Figure 7: Flap elevation

Figure 8: Patient after treatment

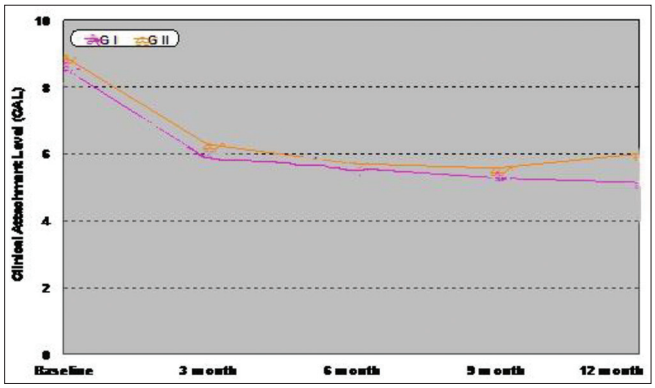

Figure 10: Graph showing means of CAL in the two groups

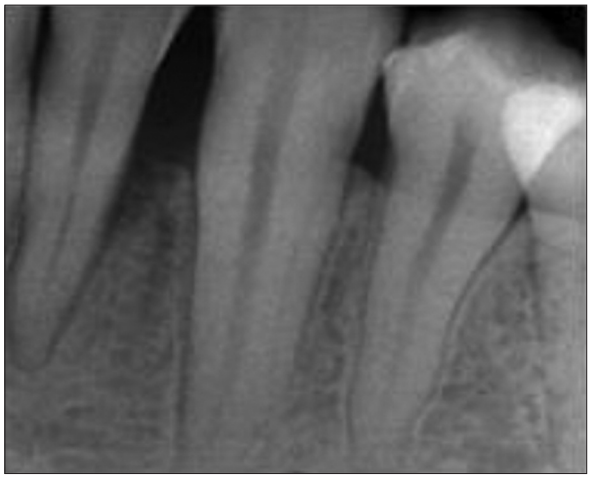

Figure 12: Radiograph of group 1 before treatment

in new connective tissue attachment, achieved by means of a biodegradable material interposed between the gingival tissue and the dental surface.[27] Hence, we opted for a collagen membrane which helps in the selective repopulation of Periodontal Ligament (PDL) cells, keeping in view the regenerative potential of collagen in periodontal procedures.

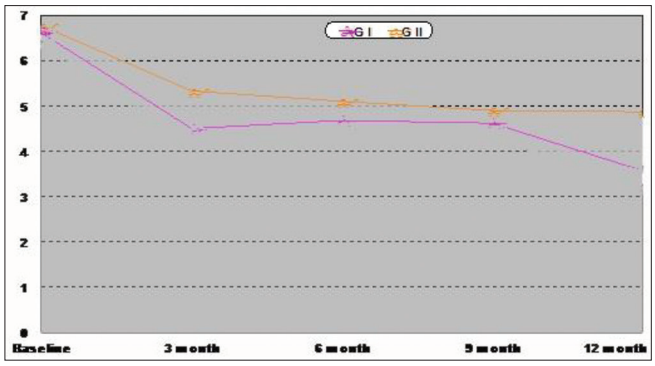

Figure 9: Graph showing means of PD in the two groups

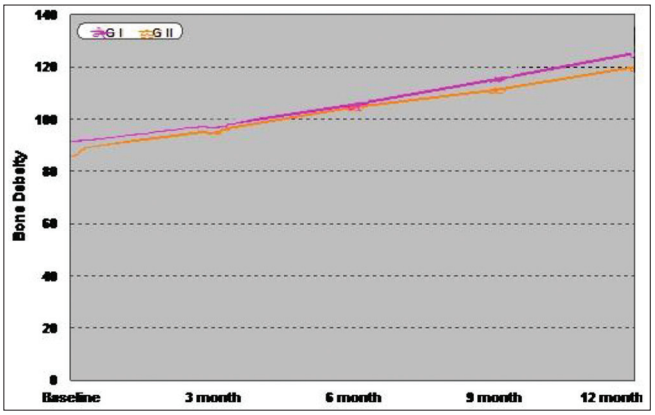

Figure 11: Graph showing means of bone density in the two groups

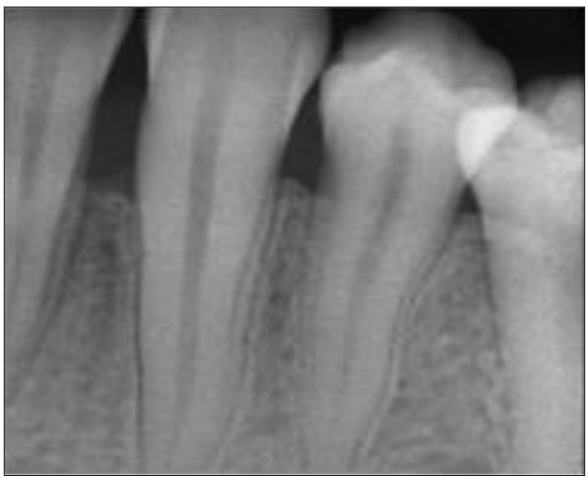

Figure 13: Radiograph of group 1 after treatment

With regard to plaque and gingival index scores, the present study showed a significant reduction prior to surgery and this reduction remained throughout the observation period of these clinical trials, which could be attributed to the effective phase I therapy and patient cooperation. A similar finding was reported by Patrick *et al*.[28] who concluded that good oral hygiene plays an important role in the management of intrabony defects before surgery. The main changes of plaque and gingival index scores that were recorded from the baseline up

to 12 months indicated that the oral hygienic status of the patients who participated in the present work was good and that patient cooperation plays an important role in periodontal regeneration. These results are in accordance with the findings of Cobb[29] and Machtei *et al*.[30] who concluded that adequate plaque control of the surgical site plays a major role in the healing of intrabony defects following the use of GTR. According to Loesche *et al*.,[31] decontamination of the root surface is essential for regeneration of the periodontal tissues. Our study substantiates this opinion with the finding that substantial improvement of the clinical symptoms after an effective cause-related therapy contributed to healing after periodontal surgery.

The present study used flap surgery alone in the control group for the management of intrabony defects. This is in agreement with the study of Fleischer *et al*.[32] They observed that open root planing left the affected area more free from calculus depositions, as compared to the closed debridement technique. Moreover, the design of the flap surgery was such that it could overcome the difficulties of intrabony defect access and the complex anatomy of the defects, as Schmitt *et al*.[33] had reported in their study that it was difficult to reach the base of the vertical defect by an ordinary periodontal instrument. The present study showed no significant reduction of PD or attachment level gain, as well as improvement in bone density with OFD technique alone. These findings are in accordance with the findings of Kalkwarf *et al*.[34]

The present study was mainly directed to evaluate the efficacy of a bioresorbable collagen membrane (Biocollagen) versus open flap surgery alone. The results showed statistically significant reduction in PD as well as gain of CAL and bone density in the group treated with bioresorbable collagen membrane. These results supported the findings of Lekovic *et al*.,[35]

Table 3: Range, minimum, maximum, means±standard deviations of CAL in the two groups during different intervals

CAL	Intervals	Range		Mean	SD
		Min.	Max.		
Group 1	Baseline	8	9	8.57	0.48
	3 months	5	7	5.85	0.89
	6 months	4	7	5.57	1.13
	9 months	4	7	5.28	1.13
	12 months	4	6	5.14	0.69
Group 2	Baseline	8	9	8.92	0.48
	3 months	5	7	6.28	0.81
	6 months	4	6	5.71	0.75
	9 months	4	6	5.57	0.69
	12 months	4	5	6.00	0.48

CAL= Clinical attachment level

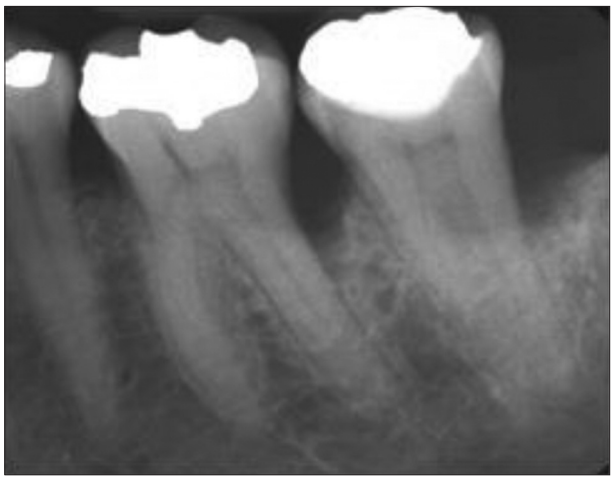

Figure 14: Radiograph o group 2 before treatment

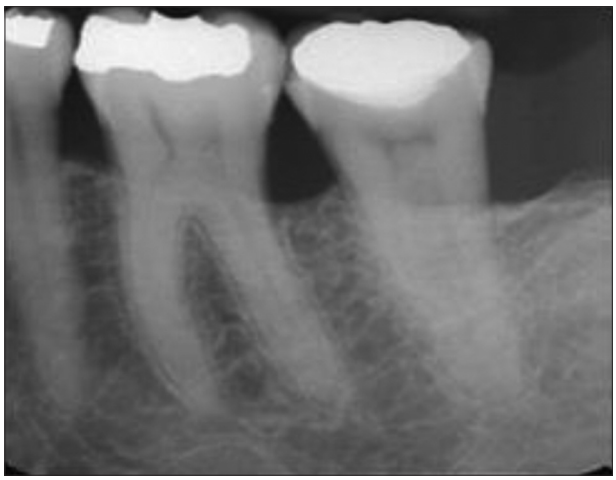

Figure 15: Radiograph of group 2 after treatment

Table 4: Intergroup comparison of clinical attachment level

Paired samples test								
	Paired differences					*t*	df	Sig. (2-tailed)
	Mean	Std. deviation	Std. error mean	95% confidence interval of the difference				
				Lower	Upper			
Pair 1								
Group 1-group 2	−0.41400	0.27098	0.12119	−0.75047	−0.07753	−3.416	4	0.027*

**P<0.05 significant*

who reported that a combined treatment with bone graft and membrane resulted in a significant increase in bone and clinical attachment gain. With regard to the outcome of periodontal regeneration for cases of the present study, we attribute the regeneration process to application of biocollagen membrane, which facilitates periodontal ligament cells to repopulate the root surface. A similar opinion was given by Karring *et al*.[21]

The present study was also mainly designed to evaluate the efficacy of a Biocollagen membrane alone in the treatment of intrabony defects. The results showed that there was a statistically significant reduction in PD as well as gain of CAL and bone densities, as well as more bone fill in the group treated with Biocollagen. These findings are in accordance with the results obtained in a study by Joly *et al*.[36] who had performed a similar study comparing GTR alone with an open flap surgery in the treatment of intrabony defects. Our results are also comparable with the findings of a similar study by Trejo *et al*.,[37] in had compared the regenerative potential obtained on using GTR in combination with demineralized freeze-dried bone allograft (DFDBA) to GTR alone in the treatment of human periodontal intraosseous defects and concluded that GTR had indeed shown regenerative outcome which overshadowed the additive benefit of DFDBA.

Table 5: Range, minimum, maximum, means±standard deviations of bone density in the four groups during different intervals

Studied groups	Intervals	Range		Mean	SD
		Min.	Max.		
Group 1	Baseline	84	99	90.85	5.27
	3 months	89	105	97.14	5.33
	6 months	97	114	105.42	5.59
	9 months	110	121	115.00	4.32
	12 months	121	129	120.14	2.67
Group 2	Baseline	82	96	88.57	5.62
	3 months	88	103	95.41	5.47
	6 months	94	115	104.42	7.23
	9 months	102	120	111.00	6.73
	12 months	111	126	115.85	5.52

In the present study, healing of intrabony defects in the group treated with flap procedures alone involves a process of repair by formation of junctional epithelium and this healing pattern does not represent a true regeneration as this attachment is probably not an efficient barrier to withhold bacterial products and may allow for recurrent pocket formation. These findings are in accordance with the findings of Becker.[38]

Evaluation of the patients who took part in the present study was not only dependent on clinical parameters that included PD and CAL, but also on image analysis of average bone density. In addition, periapical radiographs of the present clinical trial were standardized using the long cone technique in order to prevent errors of angulations according to the study of Reddy.[39]

The authors chose a 12-month period for evaluation in the present study; this is in accordance with the report of Rabelais *et al*.[40] who concluded that a 6-month period was short and not enough to thoroughly evaluate the outcome of periodontal therapy with grafting technique.

CONCLUSION

The success of periodontal regeneration is dependent on a multitude of factors such as patient's compliance with oral hygiene, smoking, defect depth, width, type of the barrier material used, recall maintenance, and an array of other factors. The decision to select the ideal material should indeed consider all the above-mentioned factors.

Our choice to use a resorbable biocollagen membrane in the management of intrabony defects yielded positive results. So, within the limitations of the present study, the biocollagen membrane group showed a significant difference in reduction in PD and gain in CAL and mineral density, compared to open flap surgery group.

Table 6: Intergroup comparison of deviations of bone density

Paired samples test								
	Paired differences					*t*	df	Sig. (2-tailed)
	Mean	Std. deviation	Std. error mean	95% confidence interval of the difference				
				Lower	Upper			
Pair 1								
Group 1-group 2	3.66000	3.33607	1.49193	−0.48228	7.80228	2.453	4	0.014*

**P<0.05 significant*

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