ORIGINAL RESEARCH

Evaluation of the relative efficacy of copolymerized polylactic–polyglycolic acids alone and in conjunction with polyglactin 910 membrane in the treatment of human periodontal infrabony defects: A clinical and radiological study

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ABSTRACT

Background: Absorbable synthetic biopolymers have been used as bone filler in Periodontology, proving effective stimulants to bone regeneration.
Aim: Copolymerized polylactic and polyglycolic acid is used as a bone filler and polyglactin 910 as a guided tissue regeneration (GTR) membrane to achieve regeneration in periodontal infrabony defects.
Materials and Methods: Forty patients with two- or three-walled infrabony defects were selected and randomly divided into two groups. Group A included patients treated with polylactic–polyglycolic acids 50:50 (Fisiograft®,Ghimsa SPA,Via Fucini, Italy) alone and Group B included patients treated with polylactic–polyglycolic acids (PLA-PGA)50:50 in conjunction with polyglactin acid 910 (Vicryl Mesh® Johnson&Johnson , U.S.A). Evaluation of clinical parameters probing depth and attachment level and radiographs was done preoperatively and 12 and 24 weeks postoperatively.
Results: Both the groups showed statistically significant mean reduction in probing depth and gain in clinical attachment level and linear bone fill.
Conclusions: Within the limit of this study, both the treatment modalities are beneficial for the treatment of infrabony defects.

Key words: Polylactic–polyglycolic acids 50:50, polyglactin 910, GTR, regeneration

Bringing of the periodontium to its prediseased state is the optimal therapeutic goal of the periodontal surgeon, allowing the patients to preserve their dentition in a state of health, comfort, and function.[1-4]

Procedures for the treatment of diseased periodontal tissue ranges from scaling and root planning, curettage, open flap debridement to regenerative therapies.[5,6] The latter include the bone graft materials or bone replacement grafts, guided tissue regeneration (GTR) procedures, and/or both. Synthetic grafts are frequently used in clinical practice, which are osteoconductive, as exhibited by their ability to enhance bone formation through a defect and by acting as a scaffold in periodontal therapy.[7] Synthetic bioabsorbable polymers represent one of the principal innovations in biomaterial sector. Among these, PLA and PGA have been used in the fields of orthopedics and maxillofacial surgery for more than a decade, proving highly effective in osteosynthesis.[8-10]

In recent years, absorbable synthetic biopolymers have been used as bone filler in Periodontology, proving effective stimulants to bone regeneration. One such copolymer in current use is the copolymerized poylactic and polyglycolic acid as bone filler.[7,9,10]

PLA–PGA functions as an absorbable space maintainer

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between the plane of the bone defect and the above-lying connective tissue, permitting the osteocytes and bone cells to replace it in a relatively short period of time. This material is available in sponge, powder, and gel form. The gel form is the latest synthetic filler. Due to greater intrinsic stability of the gel at the recipient site, it is especially suitable for filling irregular cavities where flap is unable to close the defect completely.

Upon contact with an aqueous medium, that is, saline or blood, the gel loses its excipient PEG, which is hydro-thermo-labile and assumes the appearance and consistency of a soft porous plaster. This constitutes an ideal matrix for stabilizing the coagulum originating from periosteal bone, which when isolated from the bone and membrane will evolve into bone.[7,9-11]

The polymer is biocompatible, non-allergenic and does not produce any inflammatory response. It is well tolerated as it is reabsorbed and degraded in Kreb's cycle with end products as carbon dioxide and water. Because of its lower molecular weight as compared with other well-known polymers, it permits a more rapid biological degradation estimated to be a minimum of 3–4 months to a maximum of 6–8 months.[7,11-14]

Polyglactin 910 is a bioabsorbable membrane made from a copolymer of glycolide and lactide and is also available in a woven or a knitted mesh. The knitted mesh has a larger pore size and better handling properties, degrades over a period of 3–12 weeks, is easily available, cost-effective, easy to manipulate, and produces no adverse immunologic response. It is being used as a barrier membrane for GTR allowing only the progenitor cells from the periodontal ligament to repopulate at the surgical site.[15-18]

In this study, an attempt has been made clinically and radiographically to evaluate the relative efficacy of copolymerized polylactic–polyglycolic acids alone and in conjunction with polyglactin 910 membrane in the treatment of human periodontal infrabony defects.

MATERIALS AND METHODS

Forty patients with two- or three-walled infrabony defects as determined by clinical and radiological evaluation were selected from among those reporting at the Department of Periodontology and among each patient, only one periodontal defect was analyzed.

The patients selected were non-alcoholic and had no history of any systemic disease and allergies.

Prior to study, after an explanation of the proposed study criteria, including alternative treatments and potential risks and benefits, the patients were asked to sign consent.

After their consent, the patients were subjected to oral prophylaxis procedures, occlusal equilibration if required and routine laboratory investigations. The patient was instructed to adopt meticulous home care measures to control the dental plaque, and their oral hygiene status was reviewed until it was maintainable at a satisfactory level.

Clinical probing depths and attachment levels were recorded immediately before surgery. Radiographs were taken by a standardized technique and the defect depth was measured from a fixed reference point (the adjacent cuspal tip) to the most apical point of the base of defect. A grid was used along with the X-ray to ensure accuracy in the measurements [Figures 1–3].

The selected patients were randomly divided into two groups: Group A and Group B. Group A included the patients treated with PLA–PGA alone and Group B included the patients treated with PLA–PGA in conjunction with polyglactin 910 membrane.

Surgical procedure

The patients were premedicated using 10 mg diazepam and 0.3 mg glycopyrrolate i.m. 45 min prior and were prepared to undergo the surgical procedure.

The area to undergo surgery was anesthetized with local anesthetic solution (lignocaine hydrochloride 2% with adrenaline 1:200,000). Envelope flaps were reflected and the infrabony defects were debrided prior to regenerative procedure [Figure 4]. After this, graft alone was placed in Group A and graft along with GTR membrane was placed in Group B [Figures 5 and 6]. The flaps were repositioned and approximated with interrupted interdental sutures using 3-0 black braided silk [Figure 7].

Antibiotic therapy (amoxycillin 250 mg + cloxacillin 250 mg + lactobacillus 60 million spores) for 8 days, along with an anti-inflammatory agent for 3 days as prescribed postoperatively. The patients were asked to follow dietary instructions strictly and perform adequate plaque control by rinsing with 10 mL of chlorhexidine gluconate mouth rinse twice daily for 3 weeks postoperatively. The sutures were removed one week after surgery. Postoperative assessments were done and measurements were recorded 12 and 24 weeks postoperatively.

RESULTS

It was observed that both the materials were well tolerated by all the patients with no adverse tissue reaction, infection, or delayed healing reported during the course of the study.

The postoperative follow-up for parameters were done 12 and 24 weeks after surgery and observations thus recorded

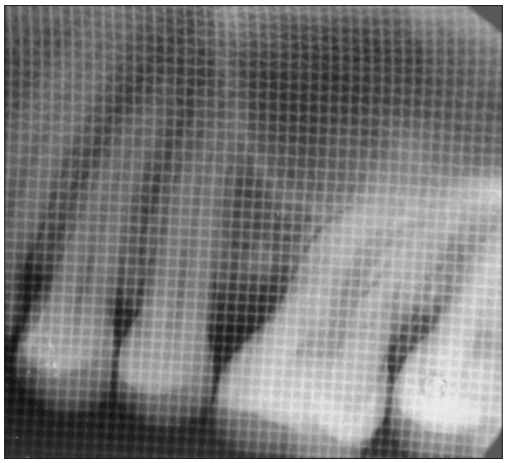

Figure 1: Preoperative infrabony defect of "Group A" between 25 and 26

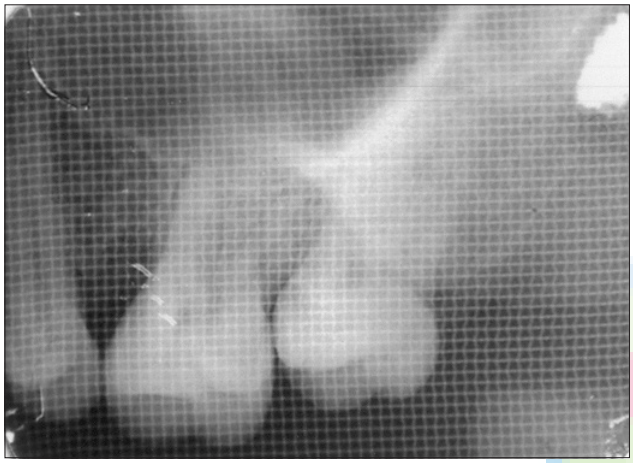

Figure 2: Postoperative infrabony defect of "Group A" 12 weeks postoperative

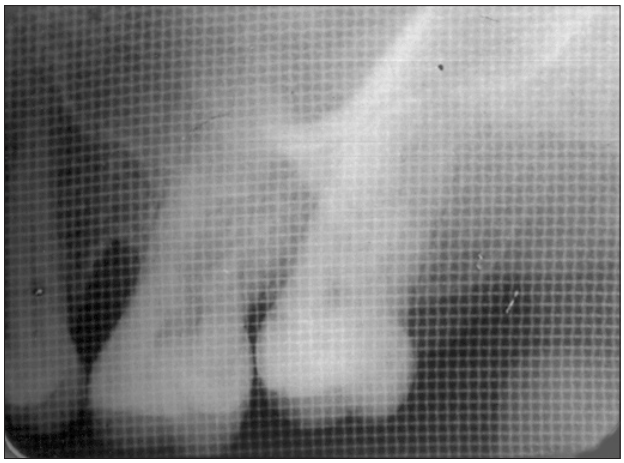

Figure 3: Postoperative infrabony defect of "Group A" 24 weeks postoperative

were subjected to statistical analysis.

The mean values of probing depths [Table 1], clinical attachment level [Table 2], and infrabony defect depths [Table 3] were recorded for Group A and Group B both preoperatively and 12 and 24 weeks postoperatively. The efficacy of the two treatment modalities at 12 and 24 weeks postoperatively were evaluated using paired Student's *t* test because the observation at the two points in time were expected to be closely related to each other.

The two groups A and B were then comparatively evaluated over the three time intervals, using the independent Student's *t* test for equal sample sizes, because sample sizes were collected from randomly selected individuals from the same population at different times.

On analyzing it was seen that both the groups: Group A and Group B have shown a significant reduction in probing depth, significant gain in clinical attachment level, and significant linear bone fill at all the three points of time, namely, 12 weeks postoperatively, 24 weeks postoperatively, and from 12 to 24 weeks postoperatively [Table 4].

On comparative evaluation of the two groups, almost a similar pattern of reduction in probing depth was experienced in both the groups, the difference in the results between two treatment modalities was found to be statistically insignificant [Table 5].

Similarly, on comparative evaluation of the two groups regarding the clinical attachment level, almost a similar pattern with regard to gain in clinical attachment level was experienced, the difference in the results between two treatment modalities was found to be statistically insignificant. Similar observations were made with regard to linear bone fill [Tables 6 and 7].

DISCUSSION

Periodontal disease is one of the most prevalent afflictions worldwide. The most serious consequence is the loss of periodontal supporting structures, which include cementum, periodontal ligament, and alveolar bone.

Conventional periodontal treatments, such as scaling and root planning, and gingival curettage are highly effective at repairing disease-related defects and halting the progression

Table 1: Probing depth of Group A (copolymerized polylactic–polyglycolic acids alone) and Group B (copolymerized polylactic–polyglycolic acids in conjunction with polyglactin 910 membrane) (in mm)

	Group A			Group B		
	Preoperative	12 weeks postoperative	24 weeks postoperative	Preoperative	12 weeks postoperative	24 weeks postoperative
Mean ± SEM	6.40 ± 0.32	3.75 ± 0.24	3.05 ± 0.25	7.25 ± 0.40	4.25 ± 0.37	3.10 ± 0.25

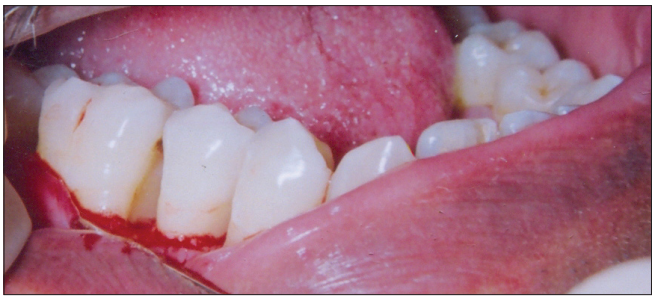

Figure 4: The exposed site of the infrabony defect

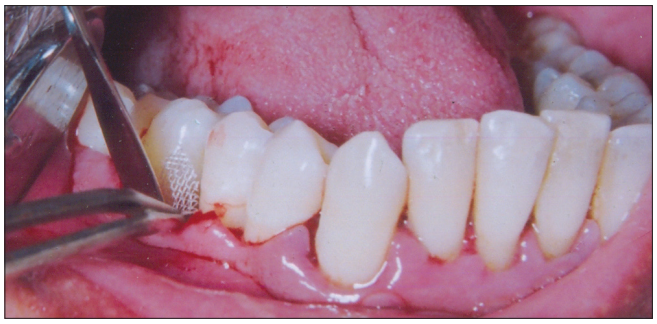

Figure 5: The placement of copolymerized PLA-PGA 50:50 at the infrabony defect

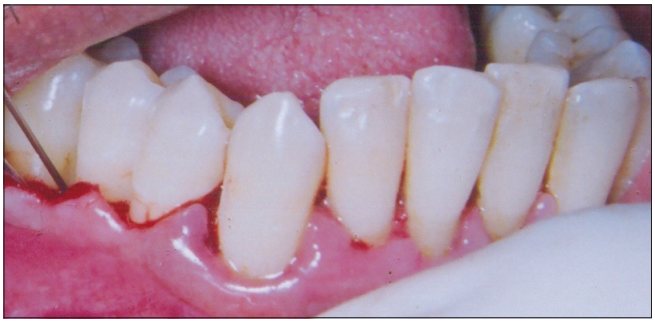

Figure 6: The placement of an absorbable polyglactin 910 membrane at the site

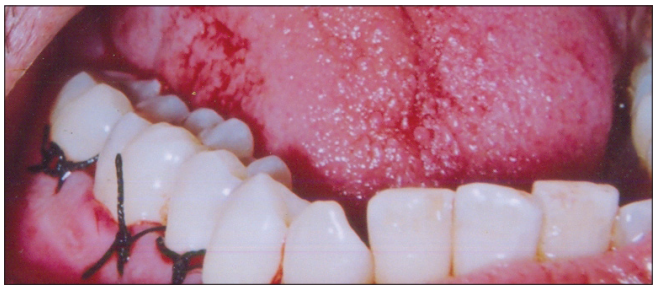

Figure 7: The operated site after suturing

Table 2: Clinical attachment level of Group A (copolymerized polylactic–polyglycolic acids alone) and Group B (copolymerized polylactic–polyglycolic acids in conjunction with polyglactin 910 membrane) (in mm)

	Group A			Group B		
	Preoperative	12 weeks postoperative	24 weeks postoperative	Preoperative	12 weeks postoperative	24 weeks postoperative
Mean ± SEM	6.30 ± 0.40	3.75 ± 0.26	2.95 ± 0.23	6.50 ± 0.43	3.95 ± 0.47	3.20 ± 0.40

Table 3: Infrabony defect depth (ascertained radiographically) of Group A (copolymerized polylactic–polyglycolic acids alone) and Group B (copolymerized polylactic–polyglycolic acids in conjunction with polyglactin 910 membrane) (in mm)

	Group A			Group B		
	Preoperative	12 weeks postoperative	24 weeks postoperative	Preoperative	12 weeks postoperative	24 weeks postoperative
Mean ± SEM	10.73 ± 0.48	8.71 ± 0.44	8.05 ± 0.44	11.75 ± 0.56	9.41 ± 0.32	8.68 ± 0.34

of periodontitis. These are important steps, however, the conventional therapy results in the development of long junctional epithelium rather than regeneration.[1,5]

Bone grafting with GTR is the most common form of regenerative therapy today and is usually essential for restoring all types of periodontal supporting tissues.

Various graft materials have been recommended from time to time for achieving the desired results. Because the availability of autogenous bone is limited and requires additional surgical intervention, various materials derived from other sources have been used as substitutes with varying degrees of success. Allografts have been successfully used to regenerate the supporting periodontal tissues, but carry the risk of disease transmission. This explains the shift toward the use of synthetic grafts, which are safer, biocompatible, and can be easily available.[4]

The technique of GTR employs physical barriers, such as occlusive membrane, which if interposed between the connective tissue of periodontal flap and curetted root surface delays the epithelial down growth during healing and provides an opportunity to the progenitor cells of periodontal ligament to migrate coronally and form a new connective tissue attachment on previously denuded root surfaces. Barrier membranes have been successfully used to treat various periodontal defects. Initially non-resorbable membranes were used which required a second surgery for their removal. This caused unnecessary stress to the patient, increased treatment cost, and possibly traumatize the immature, newly generated periodontal tissues. In order to overcome these drawbacks, a variety of absorbable barriers have been tried alone and\or in combination with various bone graft materials.[2,15,16]

The bone grafting and GTR procedures have proved to be

Table 4: Reduction in probing depth of Group A (copolymerized polylactic–polyglycolic acids alone) and Group B (copolymerized polylactic–polyglycolic acids in conjunction with polyglactin 910 membrane) (in mm)

S. no.	Group A			Group B		
	Preoperative–12 weeks postoperative	Preoperative–24 weeks postoperative	12–24 weeks postoperative	Preoperative–12 weeks postoperative	Preoperative–24 weeks postoperative	12–24 weeks postoperative
1.	2	2	0	3	3	0
2.	2	2	0	2	2	0
3.	2	4	2	4	4	0
4.	2	2	0	6	6	0
5.	2	3	1	4	5	1
6.	4	5	1	2	4	2
7.	2	3	1	2	4	2
8.	6	7	1	0	2	2
9.	2	2	0	2	4	2
10.	0	0	0	2	4	2
11.	4	4	0	5	5	0
12.	2	3	1	5	6	1
13.	0	2	2	6	6	0
14.	3	3	0	5	5	0
15.	3	0	-1	3	6	3
16.	2	4	2	0	2	2
17.	5	5	0	5	5	0
18.	4	7	3	5	7	2
19.	2	3	1	2	4	2
20.	4	4	0	0	0	0
Mean ± SEM	2.65 ± 0.33	3.35 ± 0.38	0.70 ± 0.21	3.00 ± 0.41	4.15 ± 0.39	1.15 ± 0.27
t value[$]	7.919**	8.684**	3.199**	7.310**	10.572**	4.196**

[$]Student's t ratio through paired t test at 19 degrees of freedom, **Values are statistically significant at 1% probability level (critical value of Student's t at 1% level of significance and at 19 degrees of freedom is 2.861)

Table 5: Gain in attachment level of Group A (copolymerized polylactic–polyglycolic acids alone) and Group B (copolymerized polylactic–polyglycolic acids in conjunction with polyglactin 910 membrane) (in mm)

S. no.	Group A			Group B		
	Preoperative–12 weeks postoperative	Preoperative–24 weeks postoperative	12–24 Weeks postoperative	Preoperative–12 weeks postoperative	Preoperative–24 weeks postoperative	12–24 weeks postoperative
1.	2	2	0	3	3	0
2.	3	4	1	2	3	1
3.	2	3	1	4	3	1
4.	2	4	2	3	3	0
5.	2	2	0	4	5	1
6.	4	5	1	1	3	2
7.	2	3	1	0	2	2
8.	6	7	1	0	2	2
9.	2	3	1	4	4	0
10.	0	0	0	1	3	2
11.	4	4	0	3	3	0
12.	2	2	0	6	6	0
13.	0	2	2	4	4	0
14.	4	4	0	5	5	0
15.	2	2	0	3	6	3
16.	1	3	2	0	1	1
17.	5	5	0	5	5	0
18.	3	6	3	2	2	0
19.	1	2	1	1	3	2
20.	4	4	0	0	0	0
Mean ± SEM	2.55 ± 0.35	3.35 ± 0.36	0.80 ± 0.20	2.55 ± 0.41	3.30 ± 0.34	0.75 ± 0.23
t value[$]	7.255**	9.185**	4.000**	6.075**	9.464**	3.135**

[$]Student's t ratio through paired t test at 19 degrees of freedom, **Values are statistically significant at 1% probability level (critical value of Student's t at 1% level of significance and at 19 degrees of freedom is 2.861)

reliable and consistent as far as regeneration is concerned.

In this study, both the materials were well tolerated by the patients as no unusual findings with regard to postoperative healing as well as no sign or symptom of any allergic manifestation was elicited. The graft material was well tolerated by the overlying soft tissue flap with no evidence of flap necrosis. Because of its lower molecular weight as compared with other well-known polymers, it permits a more rapid absorption.[13,19,20]

Table 6: Linear bone fill (ascertained radiographically) of Group A (copolymerized polylactic–polyglycolic acids alone) and Group B (copolymerized polylactic–polyglycolic acids in conjunction with polyglactin 910 membrane) (in mm)

S. no.	Group A			Group B		
	Preoperative–12 weeks postoperative	Preoperative–24 weeks postoperative	12–24 weeks postoperative	Preoperative–12 weeks postoperative	Preoperative–24 weeks postoperative	12–24 weeks postoperative
1.	3.30	3.30	0.00	0.66	0.66	0.00
2.	2.64	2.64	0.00	1.98	2.64	0.66
3.	2.64	1.98	-0.66	0.66	1.32	0.66
4.	3.96	5.28	1.32	3.96	3.96	0.00
5.	-1.32	0.00	1.32	3.96	4.62	0.66
6.	1.98	1.98	0.00	3.96	3.96	0.00
7.	1.32	3.30	1.98	5.94	5.94	0.00
8.	1.32	1.98	0.66	7.26	7.92	0.66
9.	1.32	1.98	0.66	3.96	5.28	1.32
10.	2.64	3.96	1.32	1.32	2.64	1.32
11.	1.32	1.98	0.66	3.30	3.30	0.00
12.	1.98	1.98	0.00	0.66	1.98	1.32
13.	2.64	3.96	1.32	2.64	3.96	1.32
14.	3.69	5.28	1.32	2.64	5.28	2.64
15.	1.32	1.98	0.66	0.00	0.00	0.00
16.	1.32	2.64	1.32	1.32	2.64	1.32
17.	3.30	3.30	0.00	1.32	2.64	1.32
18.	1.98	2.64	0.66	0.00	0.00	0.00
19.	1.32	1.32	0.00	0.66	1.98	1.32
20.	1.32	1.98	0.66	0.66	0.66	0.00
Mean ± SEM	2.01 ± 0.26	2.67 ± 0.28	0.66 ± 0.15	2.34 ± 0.45	3.07 ± 0.46	0.72 ± 0.16
t Value[$]	7.494**	9.373**	4.359**	5.206**	6.569**	4.395**

[$]Student's t ratio through paired t test at 19 degrees of freedom, **Values are statistically significant at 1% probability level (critical value of Student's t at 1% level of significance and at 19 degrees of freedom is 2.861)

Table 7: Comparison of mean of copolymerized polylactic–polyglycolic and copolymerizer polyglactic–polyglcolic and in conjunction with polyglactin 910 for the chosen parameters (in mm)

Parameters		Group A		
		Preoperative–12 weeks postoperative	Preoperative–24 weeks postoperative	12–24 weeks postoperative
Mean reduction in probing depth	Group A	2.65	3.35	0.70
	Group B	3.00	4.15	1.15
Mean gain in attachment level	Group A	2.55	3.35	0.80
	Group B	2.55	3.30	0.75
	Difference*	0.00	-0.05	-0.05
Mean linear bone fill	Group A	2.01	2.67	0.66
	Group B	2.34	3.07	0.72
	Difference*	0.26	0.40	0.06

* Stands for difference of Group A from Group B

The absorbable polyglactin 910 membrane (Vicryl Mesh) was found easy to handle and manipulate, flap shrinkage and exposure of the membrane was occasionally observed, but it did not cause any problem or require its removal. These findings concur with the findings of Nyman *et al.*,[2] Gottlow *et al.*,[14] Massato,[20] and Gottlow.[15]

The evaluation of this study requires an analysis of the results of different parameters obtained during postoperative follow-ups. Although the histologic assessment is the ideal way to verify the regeneration of new bone, cementum, and periodontal ligament after osseous grafting, it is discouraged in humans due to ethical consideration.

The assessment of the hard tissue changes after regeneration therapy can thus be done either by clinical measurement or by radiographic assessment. The clinical measurements require a second surgical intervention, which is usually not acceptable to the patient. Furthermore, it may cause disturbance of the newly formed connective tissue attachment, while radiography provides the only non-invasive method for evaluating the changes in the hard tissue.[21]

In the present study, the soft tissue parameters, namely, probing depth and attachment level were ascertained clinically, whereas hard tissue parameters, such as depth of infrabony defect, were ascertained radiographically.

Both the groups A and B showed a mean reduction of probing depth to be statistically significant at 1% probability level ($P < 0.01$) at 12 and 24 weeks postoperatively.

On comparing the mean pocket depth reduction obtained

with the two treatment modalities, we infer that the difference in their result was not significant. A similar pattern of pocket depth reduction with respect to time was experienced by both the defects. However, significant difference was presented by both the treatment modalities during each time interval (ie, preoperative to 12 weeks postoperative, preoperative to 24 weeks postoperative, and 12 weeks postoperative to 24 weeks postoperative) indicating that the reduction was taking place throughout the study.

The mean gain in clinical attachment level in both the groups was found to be statistically significant ($P < 0.01$).

On comparing the gain in mean attachment level obtained with two treatment modalities, the difference was not significant. However, significant differences were presented by both the sites during each of the time intervals indicating that gain in attachment level was taking place throughout the study.

Linear bone fill in both the groups was found to be statistically significant at 1% probability level. These findings concur with the findings of Stancari *et al.*,[10] Serinoi[9] Leghissa *et al.*[22]

On comparing the mean linear bone fill obtained with the two groups, we infer that the difference in their results was not significant. However, the rate of linear bone fill progressed in an almost uniform/similar rate over entire span of the study.

On analyzing the data generated by this study, copolymerized PLA-PGA 50:50 appears to be an alternative for bone substitute with an additional benefit of acting itself as a barrier membrane *in situ*[23] as is evident from the results of both Group A and B, which were statistically significant at 1% level of probability.

In conclusion, within the limits of this study, both the treatment modalities, namely, copolymerized PLA-PGA 50:50 alone and in conjunction with polyglactin 910 are beneficial for the treatment of periodontal infrabony defects.

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