Original Article

Comparative clinical and radiographic evaluation of mineralized cancellous bone allograft (puros®) and autogenous bone in the treatment of human periodontal intraosseous defects: 6-months follow-up study

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Abstract

Aims: Several materials have been introduced as bone grafts, i.e., autografts, allograft, xenografts, and alloplastic grafts, and studies have shown them to produce greater clinical bone defect fill than open flap debridement alone. The aim of this clinical and radiological 6-month study was to compare and evaluate the clinical outcome of deep intraosseous defects following reconstructive surgery with the use of mineralized cancellous bone allograft (Puros®) or autogenous bone. **Materials and Methods:** Ten patients with 12 sites exhibiting signs of moderate generalized chronic periodontitis were enrolled in the study. The investigations were confined to two and three-walled intra bony defects with a preoperative probing depth of ≥5 mm. Six of these defects were treated with Puros® (group A) the remaining six were treated with autogenous bone graft (group B). Allocation to the two groups was randomized. The clinical parameters, plaque index (PI), gingival index (GI), probing pocket depth (PPD), clinical attachment level (CAL), and bone fill, were recorded at different time intervals at the baseline, 1 month, 3 months, and 6 months. Intraoral radiographs were taken using standardized paralleling cone technique at baseline, 1, 3, and 6 months. Statistical analysis was done by using the one-way analysis of variance (ANOVA) followed by Tukey highly significant difference. **Results:** Both groups resulted in decrease in probing depth (group A, 3.0 mm; group B, 2.83 mm) and gain in clinical attachment level (group A, 3.33 mm; group B, 3.0 mm) over a period of 6 months, which was statistically insignificant. **Conclusion:** Within the limitations of the present study, it can be concluded that both mineralized cancellous bone allograft (Puros®) or autogenous bone result in significant clinical improvements.

Key words: *Bone substitutes, grafts, intraosseous defects, periodontal disease, periodontal regeneration*

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INTRODUCTION

Periodontitis is an inflammatory disease of the supporting tissues of teeth caused by specific microorganisms or group of specific microorganisms resulting in progressive destruction of the periodontal ligament and alveolar bone with pocket formation, recession, or both.[1] The rationale of periodontal therapy is not only to control inflammation but also to reduce periodontal pockets and regeneration of alveolar bone, cementum, and periodontal attachment.[2,3] Autogenous grafts are considered to be the gold standard among graft materials[4] because they are superior at retaining cell viability, contain osteoblasts and osteoprogenitor stem cells and heal by osteogenesis, avoid the potential problems of histocompatibility differences and risk of disease transfer.[5] Allografts, such as DFDBA, exposes the bone inductive proteins located in the bone matrix such as bone morphogenetic protein-2 (BMP2) and BMP7,[6] which are capable of inducing mesenchymal cells to differentiate into osteoblasts *in vivo*.[7,8] The ultimate goal of periodontal therapy is the regeneration of alveolar bone, cementum, and periodontal ligament. Therefore, the shift in therapeutic concepts from conventional therapy to regeneration has significantly impacted the practice of periodontology with greater efforts being directed towards the establishment of a new attachment apparatus in intrabony defects.[9] The aim of the present study was to compare and evaluate clinically, as well as radiographically, the efficacy of Mineralized Cancellous Bone Allograft (Puros®) and Autogenous Bone in human periodontal intra osseous defects over 6 months period.

MATERIALS AND METHODS

Ten patients with 12 intrabony defect sites who attended the outpatient Department of Ragas Dental College and Hospital, Chennai were included in the study. Patients were randomly assigned to two study groups, i.e., A and B. Patients within the age group of 35–50 years diagnosed with generalized chronic periodontitis exhibiting multiple intrabony defects (two wall and three wall defects), probing depth of >5 mm, sufficient keratinized tissue to allow complete tissue coverage of the defect, a radiographic evidence of vertical osseous defect with base at least 3 mm coronal to the apex of tooth, and patients who had not undergone any type of periodontal therapy in the past 6 months were included in the study. Patients with any systemic conditions which would compromise the outcome of periodontal therapy, pregnant or lactating women, teeth exhibiting mobility, patients known to be allergic to antibiotics/drugs, smokers and patients who were unable to maintain periodic recall visits were excluded from study.

Once the patients were included into the study, the entire study protocol was explained in detail to the patient, after which a consent form was signed. The study was approved by the Institutional Review Board of Ragas Dental College and Hospital. Initial therapy scaling and root planing were performed in a two sessions. Plaque control was assessed at the end of each scaling and root planing session and oral hygiene instructions were reinforced. After completion of the initial therapy, a re-evaluation was done after 4–6 weeks. At this point, periodontal charting was repeated to assess the response to initial therapy and to review the criteria for surgery with respect to probing depth and attachment levels. The patients were randomly allocated into groups A and B by tossing a coin.

Group A – Patients treated with mineralized cancellous bone allograft (Puros®).
Group B – Patients treated with autogenous bone.

Radiographic assessment

The following parameters were recorded:
A – Cementoenamel junction (CEJ) to the most coronal point of the alveolar crest (AC).
B – Cementoenamel junction (CEJ) to most apical point of the base of the defect (BD).

The parameters were denoted at
Baseline as A_0B_0
1 month A_1B_1
3 months A_3 B_3
Six months A_6 B_6.

Defect depth

Defect depth (DD) was measured as the distance from the alveolar crest to the base of the osseous defect, at baseline 1, 3, and 6 months using the formula.[10,11]

DD = (CEJ to BD) − (CEJ to AC)

Defect fill percentage at six months: $B_0 - B_6/B_0 \times 100$

Defect resolution percentage at six months:

$(B_0 - A_0) - (B_6 - A_6)/B_0 - A_0 \times 100$

Surgical protocol

Surgical procedures were performed under local anesthesia, sulcular incisions were given and full thickness mucoperiosteal flaps were elevated, sites were thoroughly scaled, and root planed with both hand and ultrasonic instruments. All granulomatous tissue was removed. Out of 12 sites in the study groups, 6 were randomly treated with Puros® [Figure 1] and 6 were treated with autogenous bone scrapings. In group A, Puros® was taken into a sterile dappen dish and mixed with saline [Figure 2]. A moist gauze was used to remove any excess saline and the graft was placed into the defect. Small increments of the graft material were added and condensed into the defect till the defect was filled. In group B, the mucoperiosteal flap at the defect site and adjacent tooth was extended to expose the buccal shelf area. Ebner's grafter was used in pull motion to scrape graft from the exposed bone [Figure 3]. The bone scrapings were collected into a sterile dappen dish, and the graft was placed in to the defect in increments and condensed till the defect was filled. Flaps were approximated and closed by using 4-0 black silk interrupted sutures. Periodontal dressing was given with COE-Pak®. Postoperative instructions were given.

After 1 week, sutures were removed, and if any plaque was found to be present at the surgical site, it was removed using moist gauze piece soaked in antiseptic solution. Follow up and plaque control was done on the 14th and 30th day, respectively. Periodic recall visits were scheduled at 1 month, 3 months, and 6 months time interval. At these visits, professional oral prophylaxis was done if necessary and oral hygiene reinforcements were implemented.

Figure 1: Mineralized cancellous bone allograft (Puros®)

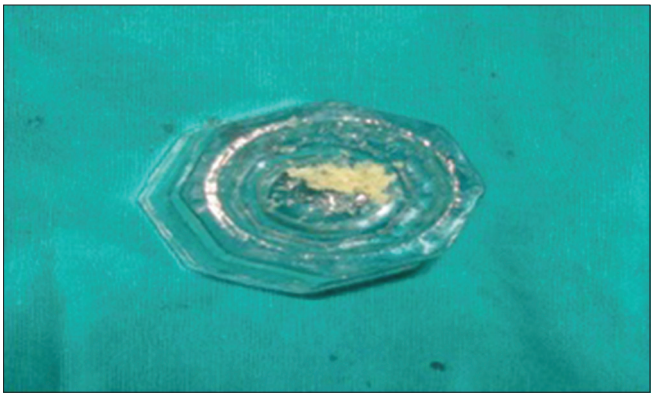

Figure 2: Puros taken in sterile dappen dish

Figure 3: Ebner's grafter

RESULTS

Clinical parameters

Plaque index for group A (Puros®)

The mean plaque index scores at baseline was 1.35 ± 0.30, reduction in the mean plaque index score at 1 month was recorded as 0.89 ± 0.16, at 3 months 0.75 ± 0.00, and at 6 months was 0.67 ± 0.13. Comparing with the baseline value, changes in the mean plaque index scores at different time intervals with a *P* value of <0.05 was statistically significant [Table 1].

Plaque index for group B (autogenous)

The mean plaque index score at baseline was 1.42 ± 0.35, reduction in the mean plaque index score at 1 month was recorded to be 0.85 ± 0.12, at 3 months 0.64 ± 0.12, and at 6 months was 0.59 ± 0.13. Comparing with the baseline value, changes in the mean plaque index scores at different time intervals with a *P* value of <0.05 was statistically significant [Table 1].

Intergroup comparison of the changes in the mean plaque index scores between the groups at 1 month, 3 months, and 6 months time intervals

had a *P* value was >0.05, which was not statistically significant [Table 3].

Gingival index for group A (Puros®)

The mean gingival index score at baseline was 1.25 ± 0.25, reduction in the mean gingival index score at 1 month was recorded to be 0.87 ± 0.12, at 3 months was 0.71 ± 0.10, and at 6 months was 0.58 ± 0.13. Comparing with the baseline value, changes in the mean gingival index scores at different time intervals with a *P* value of <0.05 was statistically significant [Table 1].

Gingival index for group B (autogenous)

The mean gingival index score at baseline was 1.28 ± 0.27, reduction in the mean gingival index score at 1 month was recorded to be 0.80 ± 0.27, at 3 months was 0.62 ± 0.13, and at 6 months was 0.58 ± 0.13. Comparing with the baseline value, changes in the mean gingival index scores at different time intervals with a *P* value <0.05 was statistically significant [Table 1].

Intergroup comparison of the changes in the mean gingival index scores between the groups at 1 month, 3 months, and 6 months time intervals had a *P* value of > 0.05, which was not statistically significant [Table 3].

Probing pocket depth for group A (Puros®)

The mean probing pocket depth scores at baseline was 6.16 ± 1.47, which reduced to 2.33 ± 0.51 at the end of 1 month, 2.83 ± 0.98 at the end of 3 months, and 3.00 ± 0.89 at the end of 6 months. Comparing with the baseline value, the changes in the mean probing pocket depth scores at different time intervals with a *P* value of <0.01 was statistically significant [Table 2].

Probing pocket depth for group B (autogenous)

The mean probing pocket depth score at baseline was 5.83 ± 0.40, which reduced to 2.50 ± 0.54 at the end of 1 month, 2.83 ± 0.75 at the end of 3 months, and 2.83 ± 0.75 at the end of 6 months. Comparing with the baseline value, the changes in the mean probing pocket depth scores at different time intervals with a *P* value of <0.01 was statistically significant [Table 2].

Intergroup comparison of changes in the mean probing pocket depth scores between the groups at 1 month, 3 months, and 6 months time intervals had a *P* value of >0.05, which was not statistically significant [Table 3].

Clinical attachment level for group A (Puros®)

The mean clinical attachment level score at baseline was 6.00 ± 1.78, the mean gain in clinical attachment level was 3.00 ± 0.63 at the end of 1 month, 3.33 ± 1.03 at the end of 3 months, and 3.33 ± 1.03 at the end of 6 months. Comparing with the baseline value, the changes in the mean clinical attachment level scores at different time intervals with a *P* value of < 0.01 was statistically significant [Table 2].

Clinical attachment level for group B (Autogenous)

The mean clinical attachment level score at baseline was 5.66 ± 1.21, the mean gain in clinical attachment

Table 1: Intergroup difference in the mean plaque index and gingival index scores between groups A and B

Groups	Baseline (Mean±SD)		1 month (Mean±SD)		3 months (Mean±SD)		6 months (Mean±SD)		*P*
	PI	GI	PI	GI	PI	GI	PI	GI	
A	1.35±0.30	1.25±0.25	0.89±0.16	0.87±0.12	0.75±0.00	0.71±0.10	0.67±0.13	0.58±0.13	0.000
B	1.42±0.35	1.28±0.28	0.85±0.12	0.79±0.28	0.67±0.12	0.63±0.11	0.59±0.13	0.58±0.13	0.000
Inter group *P* value	Plaque index								0.290
	Gingival index								1.00

Intragroup P value between baseline, 1 month, 3 months, and 6 months of <0.01 denotes statistically significant at 1% level in group A and group B. Intergroup P value is >0.05, which was not statistically significant

Table 2: Mean probing pocket depth and mean clinical attachment level at different time intervals in groups A and B

	Baseline (Mean±SD)		1 month (Mean±SD)		3 months (Mean±SD)		6 months (Mean±SD)
	PPD	CAL	PPD	CAL	PPD	CAL	PPD
Group A	6.16±1.47	6.00±1.78	2.33±0.51	3.00±0.63	2.83±0.98	3.33±1.03	3.00±0.89
Group B	5.83±0.40	5.66±1.21	2.50±0.54	2.83±0.75	2.83±0.75	3.00±1.26	2.83±0.75

Intragroup P value between baseline, 1 month, 3 months, and 6 months of <0.01 denotes statistically significant at 1% level in groups A and B

level was 2.83 ± 0.75 at the end of 1 month, 3.00 ± 1.26 at the end of 3 months, and 3.00 ± 1.26 at the end of 6 months. Comparing with the baseline value, the changes in the mean clinical attachment level scores at different time intervals with a *P* value <0.01 was statistically significant [Table 2].

Intergroup comparison of changes in the mean clinical attachment level scores between the groups at 1 months, 3 months, and 6 months time intervals had a *P* value of >0.05, which was not statistically significant [Table 3].

Radiographic measurements:

Defect depth for group A (Puros®)

The mean baseline CEJ-AC (A_0) and CEJ-BD value is 7.27 ± 2.02 and 12.01 ± 2.52, respectively [Table 4]. The mean defect depth (DD) at the baseline was 4.77 ± 1.23 at 1 month it is 2.27 ± 0.83, at 3 month it is 1.32 ± 0.35, and at 6 months it was 0.92 ± 0.22. Comparing to the baseline value, the changes in the defect depth values at different time intervals with a *P* value ≤0.01 was statistically significant at 1% level [Table 5].

Table 3: Intergroup difference in the mean probing pocket depth and clinical attachment level

	Puros	Autpgenous	*P*
PPD	3.58±1.82	3.50±1.50	0.86
CAL	3.92±1.67	3.63±1.61	0.54

Intergroup P value is >0.05 which is not statistically significant

Table 4: Mean value of alveolar crest (CEJ-AC) and base of defect (CEJ-BD) at the baseline in groups A and B

	A_o	B_o
Group -A	7.27±2.02	12.01±2.52
Group -B	6.13±1.28	10.99±1.97
P	0.27	0.45

Intergroup P value of >0.05 which is not statistically significant

Defect depth for group B (autogenous)

The mean baseline CEJ-AC (A_0) and CEJ-BD value is 6.13 ± 1.28 and 10.99 ± 1.97, respectively [Table 4]. The mean defect depth (DD) at the baseline was 6.30 ± 2.35 at 1 month it is 3.82 ± 1.52, at 3 months it is 2.77 ± 1.51, and at 6 months it was 1.74 ± 1.30. Comparing to the baseline value, the changes in the defect depth values at different time intervals with a *P* value ≤0.01 was statistically significant at 1% level [Table 5].

Inter group comparison of changes in the mean defect depth values between the groups at 1 months, 3months and 6 months time intervals had a *P* value >0.05, which was not statistically significant [Table 6].

Percentage of defect fill at six months

The mean percentage of defect fill for group A was 52 ± 12.49 and for group B it was 37.75 ± 11.99. The intergroup *P* value is >0.05, which was not statistically significant [Table 7].

Percentage of defect resolution at six months

The mean percentage of defect resolution for group A was 49.28 ± 27.73 and for group B it was 65.82 ± 21.00. The intergroup *P* value was >0.05, which was not statistically significant [Table 7].

DISCUSSION

Puros® (Zimmer Dental Inc., Carlsbad, CA) is an allogenic, solvent-preserved, human cancellous bone graft material. The donor bone was subjected to the Tutoplast® Process which included delipidization,

Table 5: Mean defect depth (DD) at different time intervals in groups A and B

Group	Baseline	1 month	3 months	6 months	*P*		
					0-1	0-3	0-6
A	4.77±1.23	2.27±0.83	1.32±0.35	0.92±0.22	0.00	0.00	0.00
B	6.30±2.35	3.82±1.52	2.77±1.51	1.74±1.30	0.09	0.01	0.00

P value between baseline 1, 3, and 6 months of ≤0.01 denotes significant at 1% level

Table 6: Intergroup difference in the mean defect depth scores at different time intervals

Group	Baseline	1 Month	3 Months	6 Months	*P*			
					BL	1 M	3 M	6 M
A	4.77±1.23	2.27±0.83	1.32±0.35	0.92±0.22	0.19	0.54	0.46	0.15
B	6.30±2.35	3.82±1.52	2.77±1.51	1.74±1.30				

Intergroup P value of >0.05 was not statistically significant

Table 7: Intergroup mean percentage of defect fill and defect resolution at 6 months

	Group A	Group B	*P*
DF (%)	52.00±12.49	37.75±11.99	0.07
DR (%)	49.28±27.73	65.82±21.00	0.27

Intergroup P value of >0.05 was not statistically significant

osmotic treatment, oxidative treatment, solvent dehydration, and sterilization through limited-dose gamma radiation.[12,13] This solvent-preserved allograft (as opposed to freeze drying to extract the water component) has been shown to osseointegrate as effectively as cryopreserved material and to be equally biocompatible. Animal and human studies of this material have shown good bone formation and repair.[14] Autogenous bone has been considered to exhibit osteogenic, osteoinductive, and osteoconductive properties, and has thus, been used with the intent to improve outcomes of periodontal regenerative procedures.[4,15] In the present study, the selected sample sites in both the groups showed overall reduction in the mean probing pocket depth and marked gain in the clinical attachment level, which could be attributed to the resolution of tissue inflammation, reconstruction of the supporting periodontal structures in terms of alveolar bone, periodontal ligament in accordance with the previous studies.[16] Meta-analysis performed by Reynolds *et al*. on 12 studies showed greater clinical attachment loss gain and a significantly greater probing depth reduction was reported for bone allograft treatment 0.43 mm (SD: 2.25) compared with open flap debridement (OFD).[17,18] The regeneration of the periodontal attachment apparatus in the present study had a favorable clinical and radiological outcome while using both bone replacement grafts mineralized cancellous bone allograft (Puros®) and autogenous bone.[9] However, it is necessary to have a large sample size, greater duration of study, and assessment using surgical re-entry or advanced radiographical aids would provide more definitive information.

CONCLUSION

Both mineralized cancellous bone allograft, Puros® and autogenous bone has the potential to promote predictable periodontal regeneration in the treatment of periodontal intraosseous defects and showed significant improvement in all clinical and radiographical parameters at the end of six months. There was no statistically significant difference between group A and Group B.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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