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CLINICAL AND RADIOGRAPHIC EVALUATION OF CORTICO-CANCELLOUS BONE MIX XENOGRAFT (OSTEOBIOL GEN-OS®) IN THE TREATMENT OF HUMAN PERIODONTAL INTRABONY DEFECTS

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ABSTRACT

Background and objective: Bone substitutes are widely used to promote bone formation and periodontal regeneration. The aim of this study was to compare the clinical and radiographic effectiveness of cortico-cancellous bone mix xenograft (Osteobiol Gen-Os) in the treatment of intrabony defects.

Materials and methods: Twenty systemically healthy chronic periodontitis patients, radiographic observation showed vertical intrabony defect of ≥ 5 mm after non-surgical periodontal therapy, subjects were categorized into group 1 (G1) treated by xenogrfat and group 2 (G2) treated by open flap debridement only. At baseline, 6 and 12 month after surgery the patients were evaluated clinically by: plaque index (PI), gingival index (GI), pocket depth (PD), clinical attachment loss (CAL), and radiographically to measure the bone density and reduction of intrabony defect depth.

Results: Significantly clinical improvements of PI and GI were observed in both groups. In G1, The mean values of PD and CAL were representing highly significant differences between the three time intervals (baseline, 6 and 12 month, ($P \leq 0.01$). In G2, the statistical comparisons between the mean values of PD at 3 time intervals, also CAL mean values at 6 month versus baseline were highly significant ($P \leq 0.01$). Radiographically, the bone density and reduction of defect depth were improved in G1 compared to G2. The mean values of bone density and reduction of defect depth were high significantly increased in G1 versus G2 at 6 and 12 month ($P \leq 0.01$).

Conclusions: The results of the current study indicated that cortico-cancellous xenograft (Osteobiol Gen-Os) significantly improved of clinical and radiographic outcomes over the course of the study.

INTRODUCTION

Periodontitis is a destructive inflammatory process which affect on surround and supporting structure of the periodontium leading to pocket formation, loss of attachment and alveolar bone resorption. This mechanism reproduces several bone defects; include furcation and intrabony defects. The basic purpose of periodontal therapy is to regenerate periodontal tissue that has been lost. [1]

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Numerous bone graft materials are used therapeutically, including xenografts, which are materials obtained from other species with their organic components totally removed. Removal of the organic components prevents immune reactions by the host. The remaining inorganic structure provides a natural matrix and a perfect calcium source. [2]

Heterologous cortico-cancellous bone mix xenograft (OsteoBiol Gen-Os), it is biocompatible and bioavailable, Gen-Os is gradually resorbable and provides support in bone neoformation helping to preserve the original graft shape and volume. Furthermore, advantage to its collagen content, the product enhances blood clotting and the subsequent invasion of regenerative cells. Because of its marked hydrophilia, it can be used as a carrier for selected medication and drugs. The particle sizes of the commercialized product are 250–1,000 μm and its porosity is 33%. [3]

The material exhibited good clinical findings when used for augmentation of the alveolar crest and maxillary sinus, as filler in postextractive alveolus and for implant treatment. [4,5,6] Clinical and histological study suggest that the use of collagenated porcine bone (OsteoBiol Gen Os) as a grafting material can lead to the augmentation of the alveolar crest or the maxillary sinus floor prior to or in conjunction with implant placement. [7]

Long-term assessment of bone formation in response to Gen Os xenograft in an experimental rat model was studied by ***Develioglu H et al., (2015)***; they reported that Gen Os has osteoconductive and biocompatible effects. Based on the long-term outcomes, Gen-Os xenograft is more beneficial to bone regeneration, but further studies are needed. [8]

Recently, ***Rombouts et al., (2016)*** studied the angiogenic potential of xenogenic bone grafting materials (Gen-Os of equine and porcine origins, and anorganic Bio-Oss) in periodontal ligament cells culture. Both Gen-Os materials significantly improved secretion of vascular endothelial growth factor (VEGF) by periodontal ligament cells cells. On the other hand, significant increase in endothelial cell proliferation was observed in cultures with both Gen-Os conditioned media, but not with that of Bio-Oss. [9]

According to our knowlodge there is no studies are presently available for the treatment of periodontal intrabony defects by Cortico-cancellous xenograft [Osteobiol Gen-Os].

The purpose of the present study was to investigate the collagenated heterologous cortico-cancellous bone mix xenograft (osteobiol; Gen-Os) versus to open flap debridement (OFD) in treatment of human periodontal intrabony defects.

MATERIALS AND METHODS

Study Population

Twenty systemically healthy patients were enrolled in the present study aged between 20 and 50 years with moderate to advanced chronic periodontitis with radiographic evidence of angular defects were recruited for the study.

The patients received detailed written information about the treatment and signed an informed consent form. The patients were selected from Out Patient Department (OPD) of Periodontic, Faculty of Dentistry, Umm Alqura University. The patients were categorized into: Group 1 (treated by xenograft: Gen-Os) and Group 2 [treated by open flap debridement (OFD)].

Inclusion criteria

The patient must be had: 1- Moderate to severe periodontitis, diagnosed on the basis of bleeding on probing, probing pocket depth, and clinical attachment loss. 2- Pocket depth of ≥ 5 mm. 3- Radiographically showed vertical intrabony component of ≥ 5mm.

Exclusion criteria

The exclusion criteria include: 1- Any systemic disease that might affect the periodontium, 2- No recent periodontal surgery within 6 month, 3- Smoking, 4- Uncooperative patients, 5- Pregnancy or lactating period and patients not response to nonsurgical periodontal therapy.

The patients were carried out to nonsurgical periodontal therapy (Phase 1) through four weeks. Following phase I therapy a periodontal re-evaluation was performed to confirm the suitability of the sites for this study.

Clinical examination

Occlusal stent for positioning periodontal probe was fabricated with cold-cured acrylic resin on a cast model obtained from an alginate impression of each patient. The stent was made to cover the occlusal surface and the coronal third of the tooth being treated and extended to at least one tooth to the mesial and distal directions. Grooves were made on stent to ensure precise repeated probing measurements. [9]

Clinical parameters were measured prior to surgery: baseline, 6 and 12 month after surgery. Plaque index (PI) [10] and gingival index (GI) [11] were recorded, in addition measurements of PD, and attachment level (AL) [12], the PD and AL were measured by using a Marquis periodontal probe and recorded to the neatest millimeter, the measurements were repeated at the same grove which designed to the periodontal defect.

Surgical procedure

The surgical procedure was performed under local anesthesia (2% mepivacaine HCL with levonordefrin 1:20000). Buccal and lingual sulcular incisions were used and mucoperiosteal flaps were elevated. Thorough debridement of the defects was achieved with hand instruments. The surgical area was irrigated with enough amounts of sterile saline.

The xenogenic bone substitute consisted of heterologous corticocancellous bone mix (OsteoBiol Gen-Os, Tecnoss Dental, Turin, Italy) in the form of mixed granules with a diameter ranging from 250 to 1,000 μm; the product was hydrated with saline before the application into the intrabony defect, Fig (1).

After grafting, the flap was repositioned to accomplish complete interproximal closure. Then the flap was sutured with 4-0 absorbable sutures with single interrupted sutures and sling sutures if necessary. Periodontal dressings were placed over surgical areas.

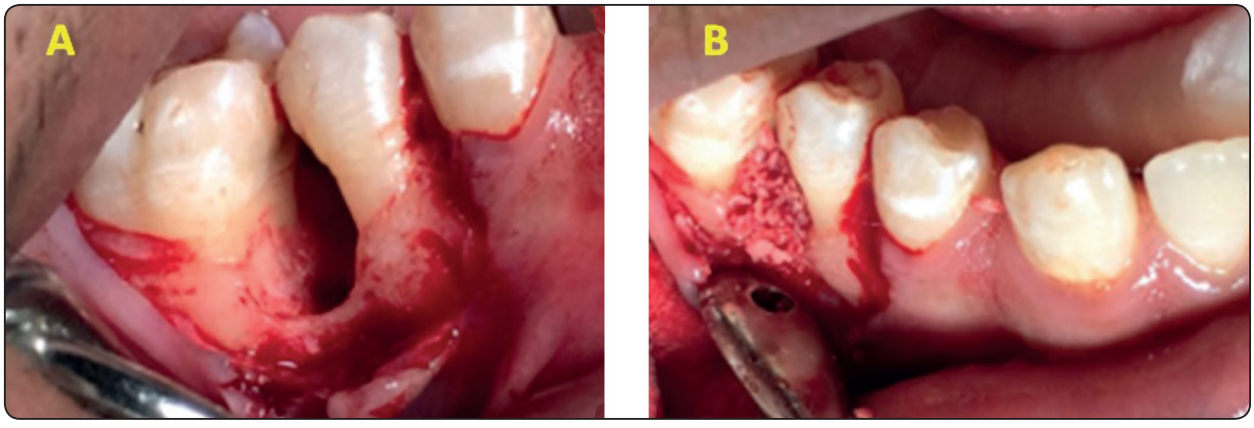

Fig (1) Demonstrate the flap of intrabony defect; (A) before grafting and (B) after grafting by xenograft (Gen-Os)

Postoperative care

All patients were prescribed 500 mg amoxicillin/125 mg clavelonic acid and Ibuprofen 400 mg twice daily for 1 week, and instructed to rinse with 0.12% chlorhexidine for at least 2 weeks, twice a day. Dressing and sutures (if still not adsorbed) were removed 2 weeks postoperatively. Patients received professional prophylaxis every 2 weeks in the first 2 month and were followed-up at 6 and 12 month after surgery.

Radiographic examination

Radiographs were taken using the RINN XCP system® (Dentsply, USA) by the standardized paralleling technique with the digital radiovisiography (RVG) (VixWin, platinum, Gendex system) at baseline, 6 month and 12 month post operatively. The patient radiographic images were stored reopened by computerized R4 system (CS R4 Clinical, Carestream Dental Ltd) and used in measurement of the defect depth. All radiographic measurements were made to the nearest 0.01 mm. Defect resolution was calculated as a difference the distance from the alveolar crest to the base of the defect through the periods of evaluation; base line, 6 and 12 month.

Bone density of intrabony defect was detected by determined the region of interest (ROI) on each radiograph as the region that begins at the cement-enamel junction and down toward the root apex 7 mm in length (Fig 2). The bone density was measured by using the mean values of gray levels were carried out using the computer graphic software Adobe Photoshop CC 2015, version 7 (Adobe Systems Incorporated, 345 Park Avenue, San Jose, California 95110, USA). [13]

The Bone density and defect depth values were measured at three time intervals; baseline, 6 and 12 month after surgery.

Statistical analysis

The collected data of clinical and radiographic parameters were statistically analyzed by SPSS (Statistical Package for Social Sciences) version 22 that programmed to produce: 1- Descriptive analysis. 2- Unpaired t-test used for comparison between the base line reading and the subsequent readings within the same group. 3- Paired t-test used for comparison between the two groups: significant ($P< 0.05$) and highly significant ($P< 0.01$). Graphs were performed using the Microsoft Excel 2010 program.

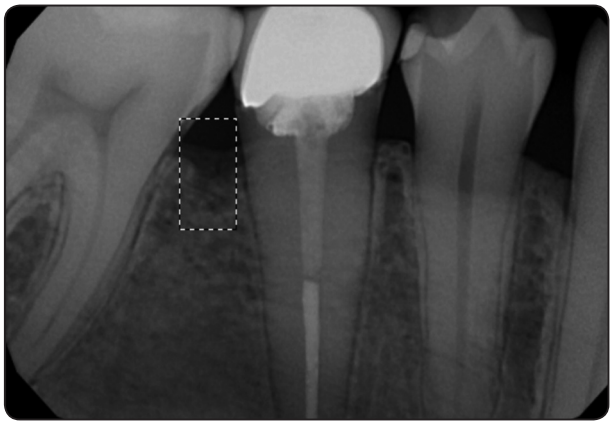

Fig. (2) Demonstrate the traced area (region of interest) that evaluated bone density at baseline, 6 and 12 month after surgery.

RESULTS

Twenty chronic periodontitis patients have intrabony defects (IBD) were participated in the present study, the patients were carried out to phase 1 therapy (scaling and root planning) and they classified into two groups according to management of IBD into the following: Group 1 [treated by cortico-cancellous bone graft (Gen - Os)] and Group 2 (treated by open flab debridement only).

During the periods of the study there was no abnormal reaction and complications were observed after periodontal therapy.

Clinical evaluation

The changes in the mean values of clinical parameters during the observation periods; baseline, 6 month and 12 month of the present study were illustrated for both groups. Table (1, 2)

Table 1 was representing the comparisons of mean values of PI and GI for group 1 between three time intervals. The statistical analysis revealed highly significant differences ($P \leq 0.01$), but there is no significant difference ($P \geq 0.05$) was recorded between the mean values at two time intervals; 6 month and 12 month. Moreover, the statistical comparisons between the mean values of PD and CAL represented highly significant differences between the three time intervals ($P \leq 0.01$).

TABLE (1) Demonstrate the statistical comparisons of clinical parameters at time intervals; baseline, 6 and 12 month in group 1 (treated by xenograft).

Parameters	Comparison	Mean ± Sd	T Value	P Value
PI	Baseline 6 month	1.30±0.07 0.82±0.06	16..82	0.000***
	Baseline 12 month	0.82±0.06 0.77±0.10	11.95	0.000***
	6 month 12 month	0.82±0.06 0.77±0.10	1.35	0.209
G I	Baseline 6 month	0.91±0.07 0.66±0.09	6.01	0.000***
	Baseline 12 month	0.91±0.07 0.64±0.07	7.10	0.000***
	6 month 12 month	0.66±0.09 0.64±0.07	1.73	0.116
PD	Baseline 6 month	4.77±0.48 3.65±0.42	14.51	0.000***
	Baseline 12 month	4.77±0.48 2.75±0.34	14.80	0.000***
	6 month 12 month	3.65±0.42 2.75±0.34	9.00	0.000***
CAL	Baseline 6 month	4.98±0.29 4.31±0.41	4.42	0.002**
	Baseline 12 month	4.98±0.29 3.32±0.39	11.34	0.000***
	6 month 12 month	4.31±0.41 3.32±0.39	42.66	0.000***

PI= plaque index GI= Gingival index PD= Pocket depth CAL= Clinical attachment loss
**** = Significant (P≤ 0.05) ** = Highly significant (P≤ 0.01)***

Table 2 was demonstrating highly significant differences ($P \leq 0.01$) between the mean values of PI and GI for group 2, but there are no significant comparisons ($P \geq 0.05$) at time intervals; 6 and 12 month. Regarding to PD the statistical analysis revealed highly significant differences ($P \leq 0.01$) between all 3 time intervals. Furthermore, the comparison between the mean values of CAL at baseline versus to 6 month was highly significant ($P \leq 0.01$), whereas, there is no significant difference ($P \geq 0.05$) of mean values at 12 month compared to baseline and 6 month time intervals.

TABLE (2) Demonstrate the statistical comparisons of clinical parameters at time internals; baseline, 6 and 12 month in group 2 (OFD).

Parameters	Comparison	Mean ± Sd	T Value	P Value
PI	Baseline 6 month	1.31±0.07 0.84±0.04	13.97	0.000***
	Baseline 12 month	1.30±0.07 0.79±0.06	21.11	0.000***
	6 month 12 month	0.84±0.04 0.79±0.06	1.58	0.148
G I	Baseline 6 month	0.90±0.10 0.66±0.08	6.06	0.000***
	Baseline 12 month	0.90±0.10 0.64±0.10	6.78	0.000***
	6 month 12 month	0.66±0.08 0.64±0.10	0.87	0.403
PD	Baseline 6 month	4.68±0.81 3.74±0.55	3.51	0.007**
	Baseline 12 month	4.68±0.81 3.00±0.41	5.51	0.001***
	6 month 12 month	3.74±0.55 3.00±0.41	3.39	0.006**
CAL	Baseline 6 month	5.02±0.33 4.45±0.38	3.92	0.003**
	Baseline 12 month	5.02±0.33 4.44±1.92	0.930	0.377
	6 month 12 month	4.45±0.38 4.44±1.92	0.02	0.985

PI= plaque index GI= Gingival index PD= Pocket depth CAL= Clinical attachment loss OFD= open flap debridement
**** = Significant (P≤ 0.05) ** = Highly significant (P≤ 0.01)***

Changes in Bone Density:

The changes in average of bone density scored during the observation periods of the present study were illustrated for both groups. Table (3), Fig (3,5,6)

The statistical analysis within each group at different time intervals was represented that a high significant difference (P≤ 0.01) in both groups at the different time intervals except at the 6 versus 12 month were insignificant (P ≥ 0.05).

Regarding to the comparisons between groups, the mean values of both groups at time intervals; 6 and 12 month, the statistical differences were highly significantly increased in G1 versus G2 (P≤ 0.01).

Changes in defect depth

The observation of defect depth for both groups was expressed in Table (4) and Fig (4). For G1, the defect depth at 3 time intervals were; 3.64±0.52, 1.34±0.19 and 0.96±0.50 respectively. The statistical differences between 3 time intervals were highly significant (P≤ 0.01). While, in group 2 (open flap debridement), the defect depth at 3 time intervals were; 3.67±0.48, 3.00±0.46 and 2.73±0.45 correspondingly. The statistical differences between baseline and 6 month were highly significant (P≤ 0.01). Whereas, there is no significant difference between 6 month versus 12 month time intervals (P≥ 0.5).

In comparison between G1 versus G2 at 6 month and 12 month time intervals, the statistical comparisons revealed a highly significant difference (P≤ 0.01).

TABLE (3) Revealed the statistical comparison of bone density of Group 1 and 2 at time intervals: baseline, 6 and 12 month.

	BASELINE		**6 MONTH**		**12 MONTH**	
	Mean± SD		Mean± SD		Mean± SD	
Group 1	38.12±11.54		60.22±16.66		58.89±13.58	
Group 2	38.92±11.22		46.30±9.59		41.57±10.87	
Unpaired t-Test						
	T	P	T	P	T	P
G 1 Vs G2	-0.20	0.11	3.31	0.009**	3.99	0.003**
Paired t-Test						
			T		P	
G 1	Baseline Vs. 6 month		-3.53		0.006**	
	Baseline Vs. 12 month		-4.49		0.002**	
	6 month Vs. 12 month		0.67		0.514	
G 2	Baseline Vs. 6 month		-2.91		0.017**	
	Baseline Vs. 12 month		-3.42		0.008**	
	6 month Vs. 12 month		-2.56		0.300	

G 1= Treated by xenograft G 2= Treated by open flap debridement

TABLE (4) Revealed the statistical comparison of defect depth for Group 1 and 2 at time intervals: baseline, 6 and 12 month.

	BASELINE		**6 MONTH**		**12 MONTH**	
	Mean± SD		Mean± SD		Mean± SD	
Group 1	3.64±0.52		1.34±0.19		0.96±0.50	
Group 2	3.67±0.48		3.00±0.46		2.73±0.45	
Unpaired t-Test						
	T	P	T	P	T	P
G 1 Vs G2	-0.81	0.43	-11.79	0.000***	-7.34	0.000***
Paired t-Test						
			T		P	
G 1	Baseline Vs. 6 month		14.84		0.000***	
	Baseline Vs. 12 month		11.83		0.000***	
	6 month Vs. 12 month		3.57		0.000***	
G 2	Baseline Vs. 6 month		5.80		0.000***	
	Baseline Vs. 12 month		6.87		0.000***	
	6 month Vs. 12 month		3.05		0.140	

G 1= Treated by xenograft ***G 2= Treated by open flap debridement***

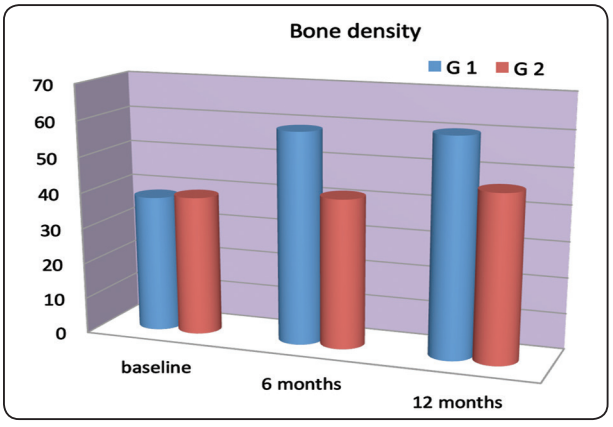

Fig (3) Illustrate the mean values of bone density of examined groups at three time intervals; baseline, 6 and 12 month.
G 1= Treated by xenograft
G 2= Treated by open flap debridement

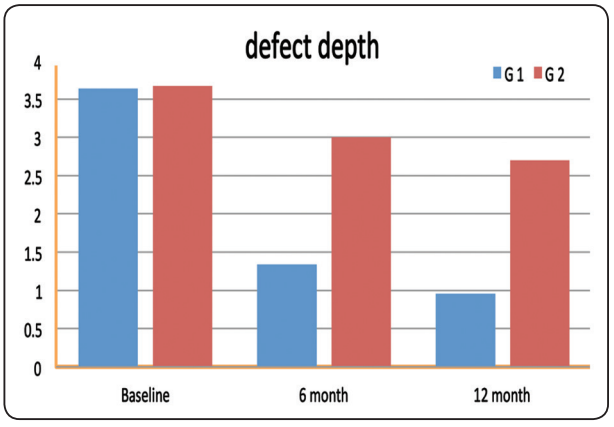

Fig. (4) Illustrate the mean values of bone density of examined groups at three time intervals; baseline, 6 and 12 month.
G 1= Treated by xenograft
G 2= Treated by open flap debridement

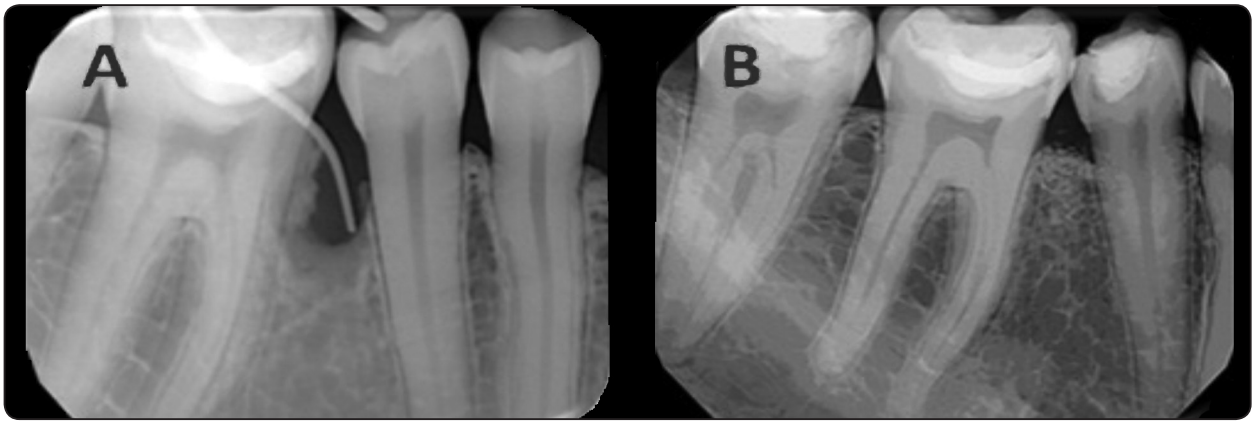

Fig. (5) Revealed the intrabony defect; (1) show defect at baseline before, and (B) after grafting by Xenograft (Gen- Os) at 12 month in group 1.

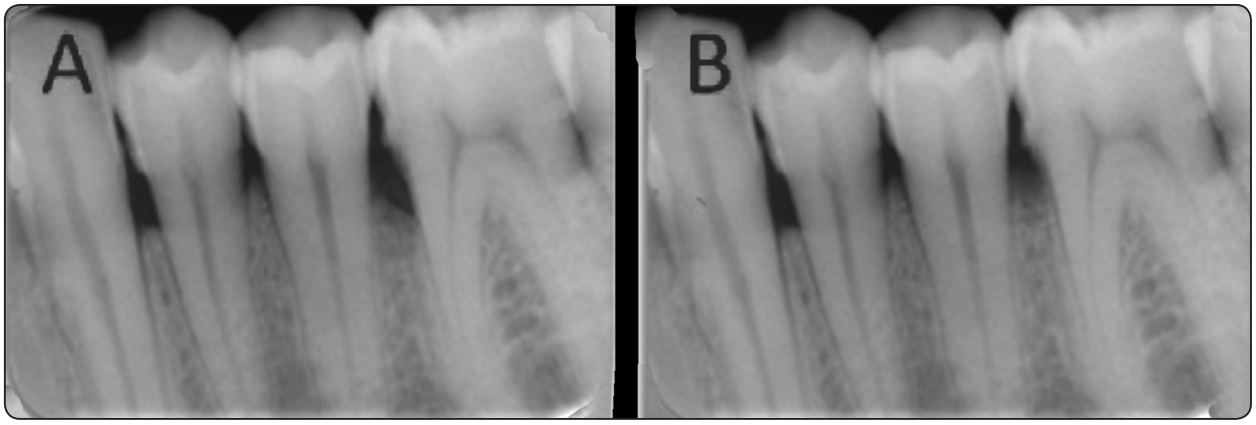

Fig. (6) Illustrate the intrabony defect; (1) show defect at baseline before, and (B) after 12 month of open flap debridement in group 2

DISCUSSION

The intimate aim of periodontal therapy is to eliminate the inflammatory processes in order to arrest the progression of the disease and keep the dentition in a state of health and function. The purpose is to arrest the destruction of soft tissue and bone caused by periodontal disease, and regenerates the lost tissue, if possible. [14] Therefore, for regeneration of periodontal intraosseous defects, combination of different materials like root conditioning agents, guided tissue regeneration procedures, bone replacement grafts and growth and attachment factors have been used with varying degrees of success. [15]

The present study compared the corticocancellous porcine-derived bone (OsteoBiol Gen-Os) for management the intarabony defects versus open flap debridement. In the current study, both treatment modalities succeeded a statistically significant reduction in the mean values of plaque and gingival scores at the treated sites during follow-up evaluations compared with baseline scores. At all evaluation periods, the reduction in PI, GI, PD and CAL in both groups may be attributed to mechanical oral hygiene procedures the PD and CAL values were improved sites treated by xenograft versus sites treated by OFD only. These results were in accordance with several studies. [16,17,18]

A natural replicate of autologous bone, (OsteoBiol® Gen-Os (Tecnoss Dental, Turin, Italy) conserves the same intimate structures (matrix and porous form) and presents a high osteoconductive activity. [18] It's gradually resorbable and provides support in bone neoformation helping to preserve the original graft shape and volume (osteoconductive property) [19], for to its collagen content, the product facilitates blood clotting and the subsequent invasion of repairing and regenerative cells. Because of its marked hydrophilia [20], it can function as a carrier for selected medications and drugs. It's also indicated for lateral access maxillary sinus lift [19, 21] and dehiscence regeneration. [22] The application of this biomaterial limits significantly the alveolar ridge width reduction that would naturally occur with spontaneous healing preserving thus the alveolar ridge volume and allowing a correct second stage implant placement .[23]

Xenograft (Gen-Os) could be proving its effectiveness in periodontal regeneration of deep intrabony defects. Due to its collagen content, once hydrated it becomes very sticky and hydrophilic [6]: it combines therefore extremely well with blood and is very stable once applied into the grafting site. Its cortico-cancellous composition allows a progressive resorption of osteoclastic type, with in parallel a similar rate of new bone formation: these unique properties allow very good graft volume preservation, a healthy new bony tissue and ultimately, successful implant rehabilitation. [18]

In the present study the mean values of defect depth of intrabony defects in group patients treated by Gen-Os versus patients treated only by open flap debridement, the clinical observation revealed that a highly significantly results through the time intervals. This result was supported by clinical findings of numerous studies. [6,7,20,22,23]

The radiographic results of this study, observed that bone mineralization and osseous healing have occurred and increased in group 1 sites more than in group 2 sites during the various periods of follow up. Also, bone height gain has increased at xenograft (Gen-Os) grafted sites compared to sites treated by open flap debridement only, particularly at 6 and 12 month after surgery, this is in consistence with the changes in probing attachment level changes.

The results of this study suggested that bone density and mineralization of alveolar bone occurred secondary to the coronal shifts of the clinical attachment level significantly in sites which treated by such xenograft material. These findings were similar to those for other studies. [13,17]

In the current study, the mean values of bone density between G 1 compared to G 2 at 6 and 12 month time intervals, the statistical comparisons expressed a highly significant difference. These outcomes were parallel to some studies which indicated that increased of bone density after using of bone substitutes. [17,24,25]

In conclusion, Xenograft (Gen-Os) improves regenerative outcomes compared to open-flap debridement only, as following; reduction of probing pocket depth, gain in clinical attachment level and resolution of intrabony defects. Good biocompatibility, excellent management properties and the better response of tissues to this material are benefits for using of that graft. Further clinical studies with more patients are needed to clarify the maximum potential effect of such xenograft for reconstructive periodontal therapy.

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