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Evaluation of Immediate Dental Implant Augmented with Biphasic Calcium Phosphate Coated by Polylactide-co-Glycolide Versus to Immediate Dental Implant Only

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Abstract

Objectives: Numerous bone grafts have been studied for augmentation of the healing outcomes of dental implants. The aim of this study was designed to compare the clinical and radiographic evaluation between immediate dental implant augmented with biphasic calcium phosphate (BCP) coated with polylactide -co- glycolide (PLGA) and immediate dental implant alone.

Materials and Methods: Twenty adult male patients with endodontic failure, root fracture, decayed tooth, retained deciduous teeth and teeth with internal/external root resorption were selected and categorized into the followings; Group 1(G1); received immediate implant only and group 2 (G2); received immediate implants augmented with (BCP/PLGA). The patients were evaluated at baseline, 6 and 12 months, clinically; by using plaque index (PI), gingival index (GI) and Pocket depth (PD). In addition, radiographic evaluation of marginal bone level (MBL) and measurement of bone density (BD).

Results: Clinical improvement of GI and PI were observed in both groups, the statistical analysis were non-significant in comparisons at different time intervals. PD was significantly reduced in G1 at 6 months versus baseline and highly significant at 12 months compared to baseline, in G2 the comparisons at 6 and 12 months contrast to baseline was highly significant, and whereas the differences at 12 months were significant reduced in G2 than G1. Radiographically, MBL was showing highly statistical significant in comparing the baseline versus 12 months in both groups, but at the difference at 6 months compared to baseline was highly significant in G1, while insignificant in G2. Moreover, there is no significant difference in G1 against G2 at 6 and 12 months. In addition, the bone density was showing highly statistical significant in comparing the baseline contrast to 6 and 12 months in both groups, and highly significant differences were observed in G2 compared G1 at 6, and 12 months.

Conclusion: Immediate dental implant augmented with BCP/PLGA achieved significant improvements in clinical and radiographic outcomes rather than immediate dental implant only.

Keywords: Immediate, Dental Implant, Biphasic Calcium Phosphate

Introduction

Immediate implant was defined as placement of the implant immediately into fresh extraction socket. To increase peri-implant

bone healing and achieve an esthetic final outcome, the use of barrier membranes and/or different graft materials to fill in residual

peri-implant defects has been widely documented [1].

A variety of regenerative techniques using combinations of bone grafts and barrier membranes have been suggested to promote bone regeneration in localized defects at implants placed into extraction sockets [2]. Many types of bone graft material have been used in dentistry namely: autogenous, allograft, xenografts and alloplast [3]. A variety of synthetic bone grafts (alloplast) have been tried, including ceramics, collagen, non-collagenous proteins, bioactive glasses, and biodegradable polymers; they are used in approximately 10% of bone graft procedures performed worldwide [4].

Calcium phosphate ceramics have been widely applied as bone substitutes, coatings, cements, drug delivery systems and tissue engineering scaffolds due to their resemblance to the mineral portion of the bone tissue, relative ease in processing and good cell attachment [5]. Its biocompatibility, safety, predictability, unlimited availability, lower morbidity for the patient and cost effectiveness represent important advantages over autograft and allograft [6].

Among the calcium phosphate ceramics, the biphasic calcium phosphates (BCP), which are composed of different concentrations of the stable phase, hydroxyapatite (HA), and the more soluble phase, usually composed of β -tricalcium phosphate (β -TCP), have presented significant advantages over other calcium phosphate ceramics due to their controlled bioactivity and balance between resorption/solubilization which guarantees the stability of the bio-material while promoting bone ingrowths [7].

Calcium phosphate ceramic bone substitutes are more brittle and have less tensile strength than bone and known as slowly biodegradable materials [8].

Different methods have been applied to overcome these drawbacks. One of the effective methods for enhancing the mechanical properties and bioactivity of ceramic scaffolds is coating the struts of scaffolds with biocompatible materials [9]. Interestingly, the use of BCP was effective in preserving buccolingual dimensions of alveolar ridges in immediate implant surgeries [10].

Biodegradable polyesters such as poly (lactic acid) (PLA), poly (glycolic acid) (PGA), and their copolymers (PLGA), have been widely used for the preparation of 3D scaffolds for bone tissue engineering application because of their good biocompatibility and biodegradability [11].

Efficacy of nanocrystalline bone substitute biphasic calcium phosphate/poly-DL-lactide-co-glycolide for periodontal intrabony defects filling was studied by Stevanovic et al. 2015. They reported that significant reductions of PPD and CEJ were registered in the group with BCP/PLGA when compared to the β -TCP group [12].

A study on the effect of poly (lactide-co-glycolide) (PLGA)-coated β -tricalcium phosphate (TCP) as a scaffold on bone regeneration in rat calvaria, The result indicated that application of PLGA-coated β -TCP could promote bone regeneration to similar extent as the β -TCP [13].

The present study was designed to evaluate clinically and radiographically immediate dental implant with biphasic calcium phosphate (BCP) coated with Polyactide-co-Glycolide (PLGA) versus immediate dental implant alone.

Materials and methods

Patients Selection

Twenty adult male patients with endodontic failure, root fracture,

teeth with external/internal root resorption, decayed non restorable teeth and retained deciduous teeth (hopeless tooth). All patients were selected from those patients attending at the out-patients clinic of Oral Medicine and Periodontology Department, Faculty of Dental Medicine, Al-Azhar University (Assiut Branch). All selected patients were indicated for implant surgery according to the criteria of Cornell medical index [14,15].

Patients Inclusion criteria

1- Should be free from any systemic disease and physically able to tolerate conventional surgical and restorative procedures. 2- The recipient site of the implant should be free from any pathological conditions. 3- The implants recipient sites should have sufficient bone quantity (width & height) and adequate bone quality. 4- Should be cooperative, motivated, and have very good oral hygiene. 5- Should have sufficient vertical inter-arch space to accommodate the restorative components. 6- Should have opposing natural teeth, not drifted and over erupted to the implant site. 7- Should be non-smokers. 8- Should be free from Para functional habits such as bruxism and clenching.

Groups

Patients were divided into two groups: Group 1 [G1, ten patients received immediate implant alone], and Group 2 [G2, ten received immediate implants augmented with biphasic calcium phosphate (BCP) coated with polyactide-co-glycolide (PLGA)].

Implant Selection

Zimmer implant (Zimmer dental, 1900 Aston Avenue Carlsbad, CA 92008-7308, USA) was used in this study. It is one and two-stage self-tapping implant system designed for conventional and immediate loading applications with variable lengths and diameters according to the site of implant placement.

Periodontal Evaluation

All cases of our study were submitted to extensive course of scaling, polishing and patient motivation for improvement their oral hygiene. The following clinical parameters were used and recorded for all teeth before and after implants at intervals baseline, 6 and 12 months post-surgically: PI and GI [16, 17], in addition to propping pocket depth (PD).

Surgical Procedures

The pre-operative classification proposed by Salama and Salama [18] was used to categorize the cases and only type I extraction sites were selected.

Zimmer implant (Zimmer dental, 1900 Aston Avenue Carlsbad, CA 92008-7308, USA) was used in this study. It is one and two-stage self-tapping implant system designed for conventional and immediate loading applications with variable lengths and diameters according to the site of implant placement.

Implants were placed within the body of the alveolus. Torque wrench was used to ensure a good primary stability. In group I patients received immediate implant alone. While; Group II patients received immediate implant augmented with biphasic calcium phosphate (BCP) coated with polyactide-co-glycolide (PLGA) GUIDOR® easy-graft® (AG, Schlieren, Switzerland) CLASSIC Alloplastic Bone Grafting System is a complete system that helps clinicians provide more predictable clinical results. Each system is

comprised of Biphasic calcium phosphate (β -TCP) granules coated with a biodegradable polymer called poly(lactide-co-glycolide) (PLGA), that are mixed with N-methyl-2-pyrrolidone (NMP) liquid activator called BioLinker® to form a permeable, moldable material which hardens to form a stable, porous scaffold. (Fig. 1,2,3,4,5).

Postoperative instructions

Standard post-surgical instructions and medications were given to

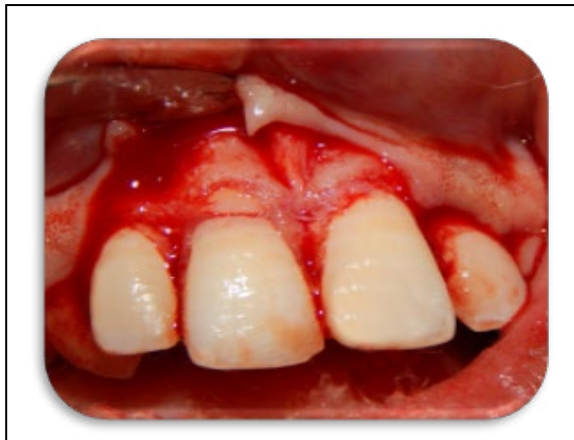


Fig. (1): Showing flap reflection



Fig. (2): Showing extracted tooth



Fig. (3): Showing Implant insertion



Fig. (4): Seating of graft at peri-implant defect

the patients as the following: Post-operative therapy consisted of antibiotics, analgesics, anti-inflammatory drugs and chlorhexidine mouth rinsing for 10 days.

The patients were instructed to avoid incising food in the operated sites for 6 weeks. Transmucosal one-stage implants delayed occlusal loading technique was used. First, the cover screw placed over implant fixture after initial placement. After three weeks implant was uncovered and temporary restoration was reconstructed and at 6 month final restoration was constructed.

Radiographic Evaluation

All patients were exposed to standardized periapical radiographs. They were taken by long-cone paralleling technique, using film holder. These radiographs were taken before and immediately after implant placement and at intervals of 6, and 12 months post-operatively. Customized bite acrylic templates were fabricated for each case and used in conjunction with radiographic film holder to standardize geometry, film placement, angulations of the beam, and source to film distance for periapical radiographs.

The exposure from x ray machine were received by image plate sensor size 2 that analyzed by photon collection system of vistascan® (Durr Dental GmbH& Co. Bietigheim- Bissingen, Germany) (Fig -3) to produce the image that manipulated by Bioquant® software analysis program (Bioquant Image Analysis Corporation, Nashville, TN, USA).

Bone height from fixed point on implant was assessed. In this study, the fixed point is the apical boarder of implant shoulder. The length of the implant fixture was measured and compared to the real fixture length to determine the magnification factor in the image. Two points mesial and distal to the implants from the end of the implant shoulder to the first visible bone to implant contact (BIC) were measured. The mean was calculated in mm according to the magnification factor of the image immediately following implant placement at baseline, 6, and 12 months. In addition, the bone density also measured at time intervals of study.

Imaging Analysis

To measure the bone density around the implant was occurred by using the Bioquant image analysis software that is used for different analysis applications. In this software, the area to be measured,

Table 1: Means and Standard deviations of periodontal parameters in the two groups during different intervals.

		PI	GI	PD
		Mean ± SD	Mean ± SD	Mean ± SD
Group 1	Baseline	0.3±0.48	0.4±0.51	4.4±0.80
	6 Month	0.2±0.42	0.3±0.48	2.5±0.70
	12 Month	0.3±0.48	0.2±0.42	2.9±0.99
Group 2	Baseline	0.2±0.42	0.3±0.48	4.6±0.68
	6 Month	0.3±0.48	0.3±0.48	2.0±0.48
	12 Month	0.3±0.48	0.3±0.48	2.1±0.31

G1= Immediate implant only G2= Immediate implant augmented with (BCP/PLGA)
 PI= Plaque index GI= Gingival Index PD= Pocket depth

Table 2: Statistical comparisons of Mean ±SD values for periodontal parameters among studied groups at each evaluation period.

Comparisons		PI		GI		PD	
		<i>P</i>	<i>T</i>	<i>P</i>	<i>T</i>	<i>P</i>	
<i>T</i>							
G1	<i>Baseline Vs 6 M</i>	0.557	0.591	0.429	0.678	2.209	0.04*
	<i>Baseline Vs 12 M</i>	0.000	1.000	0.802	0.443	4.700	0.001**
G2	<i>Baseline Vs 6 M</i>	0.429	0.678	0.000	1.000	7.293	0.000**
	<i>Baseline Vs 12 M</i>	0.557	0.591	0.000	1.003	16.69	0.000**
Baseline	<i>G1 Versus G2</i>	0.493	0.628	0.447	0.660	0.577	0.577
6 M	<i>G1 Versus G2</i>	0.493	0.628	0.000	1.000	0.739	0.470
12 M	<i>G1 Versus G2</i>	0.000	1.000	0.493	0.628	2.420	0.03*

G1= Immediate implant only G2= Immediate implant augmented with (BCP/PLGA)
 PI= Plaque index GI= Gingival Index PD= Pocket depth

Table 3: Revealed Means and Standard deviations of Marginal Bone Level and Bone Density in the two groups at different time intervals.

		MBL	Bone Density
		Mean ± SD	Mean ± SD
Group 1	Baseline	3.73±0.70	81.0±6.12
	6 Month	4.06±0.66	90.0±6.03
	12 Month	4.33±0.68	101.4±7.42
Group 2	Baseline	3.85±0.84	84.0±4.69
	6 Month	3.62±0.79	100.8±5.24
	12 Month	3.97±0.81	118.1±5.97

G1= Immediate implant only G2= Immediate implant augmented with (BCP/PLGA)
 MBL= Marginal bone level

Table 4: Demonstrate the statistical analysis of Mean values for Marginal Bone level (MBL) and Bone Density among studied groups at different time intervals.

Comparisons		MBL		Bone Density	
		<i>P</i>	<i>T</i>	<i>P</i>	
<i>T</i>					
G1	<i>Baseline Vs 6 M</i>	9.85	0.000**	6.09	0.000**
	<i>Baseline Vs 12 M</i>	15.21	0.000**	9.320	0.000**
G2	<i>Baseline Vs 6 M</i>	4.64	0.001**	12.31	0.000**
	<i>Baseline Vs 12 M</i>	2.167	0.04*	14.78	0.000**
Baseline	<i>G1 Versus G2</i>	0.347	0.733	1.22	0.235
6 M	<i>G1 Versus G2</i>	1.343	0.196	4.27	0.000**
12 M	<i>G1 Versus G2</i>	1.068	0.299	5.54	0.000**

G1= Immediate implant only
 G2= Immediate implant augmented with (BCP/PLGA)

which called Regions of Interest (ROI) was selected (color density selection). A single pixel that represents a specific color (white pixels in radiographs) is selected or threshold allowing for automatic selection of all other pixels in the ROI that threshold areas are traced and counted as a number of pixels that can be calculated as a ratio of the whole ROI (Fig. 6).

Bioquant was used for calculation of the average density of the marginal and crystal bone. Average density is determined based on



Fig. (5): Showing flap suturing

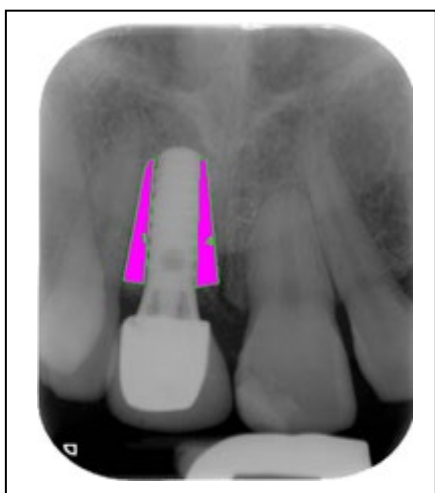


Fig. (6): The region of interest for bone density measurement

a scale of 0-256 and the number 256 (8 bits) stands for the whitest pixel on the screen while number 0 represents the areas of the darkest pixels on the screen, the ROI of these radiographs was a rectangle of a fixed size to contain the critical size defect precisely. The program calculates every pixel in the image and then performs the calculations necessary to get one number representing the average density of all the pixels and this number must be between the 0 and 256 values.

Statistical analysis

The data were collected, tabulated and statistically analyzed by Statistical Package for Social Sciences (SPSS) version 13 that programmed to produce: 1- Descriptive analysis. 2- Paired t-test used for comparison between the base line reading and the subsequent readings within the same group. 3- Unpaired t-test used for comparison between the two groups. The level of significance at ($P <$

0.05), tables and graphs were performed by using the Microsoft Excel 2010 program.

RESULTS

The results of the present study include (twenty male adult patients, ranged in age between (18-40 years) with endodontic failure, root fracture, decayed tooth, retained deciduous teeth and teeth with root resorption (hopeless tooth) divided into two groups. The first one received immediate dental implant only, in the second group immediate dental implant augmented with biphasic calcium phosphate (BCP) coated with polyactide-co-Glycolide (PLGA). No adverse reactions, no complications observed during the periods of the study. No implant failed up to 12 months after insertion, result in a 100 % survival rate.

Changes in Plaque and bleeding index

Statistical comparisons revealed that no statistical significant changes observed at different intervals when compared to the base line in both groups. When comparing between the two groups, showing no statistical significant changes observed between both groups at different intervals (Table 1,2).

Probing pocket depth measurement

Statistical analysis of the mean values demonstrate that gradual pocket depth reduction during observation period of the study (Table 1,2). The mean values of probing pocket depth in group 1 were 4.40 ± 0.80 at base line that reduced to 2.9 ± 0.99 after 12 months of implant placement. The difference within the groups was statistically significant at 6 months and highly significant at 12 months when compared with base line. In group 2, the mean values of probing depth were 4.60 ± 0.68 at baseline that reduced to 2.10 ± 0.31 after 12 months of implant placement. The difference within the group was highly statistical significant difference at 12 months when compared with baseline. Unpaired-test for comparing pocket depth between both groups was showing highly statistical significant difference at 12 months.

Marginal bone level (MBL)

The changes in MBL scored during the observation periods of the present study was illustrated in both groups (Tables 3,4). In group 1 the mean value of marginal bone level was 3.73 ± 0.70 at baseline that increased to 4.33 ± 0.66 after 12 months of implant placement and the difference within the group was highly statistically significant at 6 and 12 months when compared with baseline.

In group 2 the mean value of marginal bone level was 3.85 ± 0.840 at baseline that increased to 3.97 ± 0.75 after 12 months of implant placement, the difference within the group was statistically significant at 6 months and high statistically significant at 6 months when compared with baseline. For comparing between the two groups at 6 and 12 months was showing no statistical significant difference during different observation periods of the study.

Bone Density Measurements (BD)

The changes in bone Density (in pixels) during the observation periods of the present study was illustrated in (Tables 3,4 Fig 7,8,9). In group 1, the mean value of bone density at base line was 81.00 ± 6.12 that elevated to 101.4 ± 7.42 at 12 months of implant placement and the difference within the group was highly statistical significant at 6, and 12 months when compared with base line. In group 2, the mean value of bone density at base line was

84.00±4.69 that elevated to 118.10 ± 5.97 at 12 months after implant placement and the difference within each group was highly statistical significant at 6, 12 months when compared with base line. For comparing of bone density between the two groups was showing highly significant difference at 6 and 12 month table.

Discussion

Immediate dental implants placed in fresh extraction sockets have several advantages since; the total treatment time and number of surgical procedures is reduced, in addition; the soft tissue height and contour are better preserved in comparison with other protocols. The placement of implant immediately following extraction permitting direct bone-to-implant contact in the apical area providing the apical osseous anchorage and result in a high degree of

initial mechanical stability. This opinion of the present work is in accordance with finding of Stafford (2009) [19].

In the present work we used biphasic calcium phosphate (BCP) coated with polylactide -co- glycolide (PLGA) as a bone graft to promote bone regeneration. Various regenerative techniques using combinations of bone grafts and barrier membranes have been used to promote bone regeneration in localized defects around immediately placed dental implant, in these respect different regenerative techniques have been used extensively [20,21,22]. The present clinical trial was designed to compare between immediate dental implant with regenerative bone material versus immediate dental implant alone. The result of the present works showed that immediate dental implant placement with biphasic calcium phos-

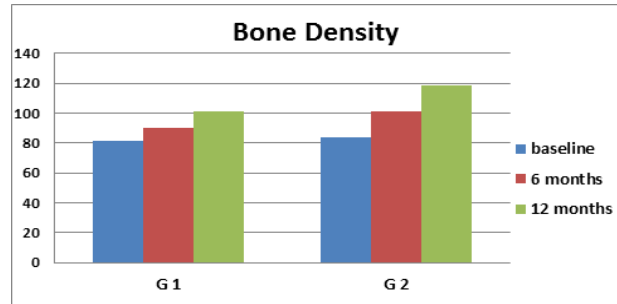


Fig. (7): Illustrate the mean values in both examined groups.

G1= Immediate implant only

G2= Immediate implant augmented with (BCP/PLGA)

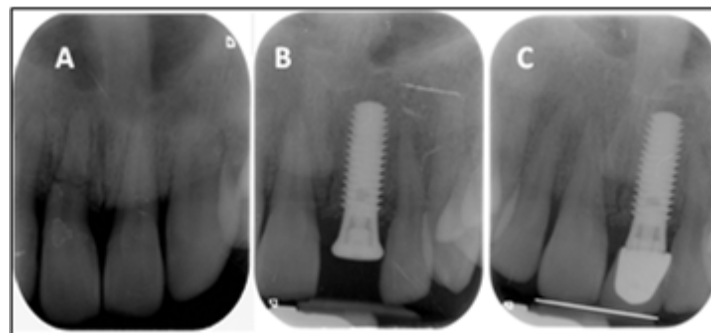


Fig. (8): Illustrate the immediate implant only (Group 1); (A) preoperative, (B) at 6 months, and (C) at 12 months.

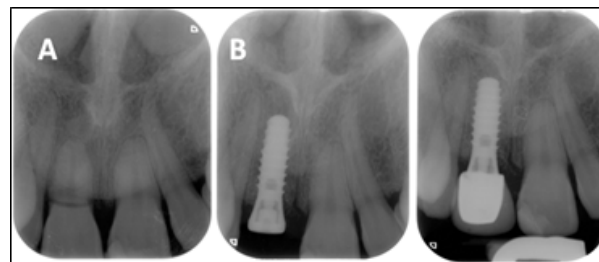


Fig. (9): Illustrate the immediate implant augmented by graft (Group 2); (A) preoperative, (B) at 6 months, and (C) at 12 months.

phate (BCP) coated with polyactide -co- glycolide (PLGA) gives better results as compared to immediate dental implant alone. These findings are in agreement with results of Koutouzis et al. (2010) [23].

In the current study, all selected cases have a single-rooted extraction socket, the multi rooted regions were excluded according to Atieh et al. (2010) [24], they concluded that the outcome of immediate implant placed in molar sites does not give a better result because of the larger extraction sockets which affect primary implant stability and implant success rate. All selected sites of the present research with four osseous walls remaining this is in accordance with the report of Salama & Salama (1993) [18], they demonstrated that type I classification with the presence of three to four remaining osseous walls is very important step for immediate implant success since; and implant failure rate significantly increase when this principle is violated. In addition Douglass & Merin (2002) [25] concluded that a bony defect with two or three missing walls is not suitable for an immediate dental implant. As regard to the socket quantity the present study used a minimum of vertical bone height more than 10 mm this is in agreement with a study of Cornelini et al (2000) [26] who recorded that the bony height of the socket (from the apex of the alveolus to the crest of bone) should demonstrate a minimum bone measurement of 7-10 mm. In the present study, a full-thickness flap surgery was used; this technique permits careful evaluation of buccal wall integrity in comparison to flapless surgery. This technique which used in the present work is in contradiction with techniques used by Vera et al. (2012) [27], they suggested that flap surgery increase amount of vertical and horizontal bone resorption and is in agreement with De Bruyn et al. (2011) [28] who concluded that there is no difference in the amount of bone resorption between flap and flapless technique.

Regarding to implant selection the present study recorded that; appropriate implant diameter and length which depend on the bone crest width and height at the recipient site and ideal surgical protocol as well as wound closure technique play an important role in the success of dental implant. A similar opinion was recorded by Buser et al (2000) [29].

To achieve a higher degree of primary implant stability the osteotomy preparation in all cases of our study extended three to five millimeters beyond the base of the extraction socket. This is in accordance with Tolman et al. (1991) [30], they concluded that in most cases, placement at 3 to 5 mm beyond the apex is sufficient to gain the critical element of stability. In the present study, grafting was performed for all residual peri-implant socket horizontal defect was found to be more than 2mm, this is in agreement with Paolantonio et al. (2001) [31], they confirmed that spontaneous bone regeneration occurred in experimental peri-implant defects that were less than 2 mm in width.

Regarding to the pocket depth, this study recorded a significant reduction in the mean probing pocket depth in both groups after 12 month follow up with a statistically significant reduction in the probing pocket depth in the grafted sites when compared with the non-grafted sites, this is in agreement with the results of Pal et al. (2011) [32], in a study comparing implants placed immediately into extraction sites without grafting and delayed placement found

that in immediately placed implant the mean probing depth at 4th week was 2.88 mm, and at 12th week, it was 2.54 mm, which showed reduction in mean probing depth with time.

In the current study, the results showed that; the mean marginal bone change after 12 month follow up was (0.12mm) in augmented group. These findings is similar to a results obtained from a study by Koutouzis et al. (2010) [33], they compared bone level changes around implants placed in post extraction sockets augmented with DFDBA to implants placed in native bone. The mean marginal bone loss was a mean of (0.15 mm) for both groups at the 12 month follow-up. However, in non-augmented group the mean marginal bone loss after follow 12 month up was (0.6mm) this is in agreement with findings of De Rouck et al. (2009) [34], they evaluated the longitudinal radiographic marginal bony changes at 3, 6 and 12 months after immediate implant placement and found that from 3 to 12 months, there was a continuous loss of marginal bone from 0.51 mm to 0.95 mm at the mesial site, and from 0.52 mm to 0.79 mm at the distal site, half of the bone loss measured in the first year occurred in the first 3 months.

The results of this study showed that; the mean radiographic bone density scores were increasing in all follow up periods in both groups when compared with base line with a statistically significant increase in bone density in augmented group when compared with the non-augmented group. A similar result obtained by Daif (2013) [35] evaluated the influence of β -Tricalcium phosphate on bone density surrounding immediate dental implants using helical computer tomography. After 3 and 6 months and showed that the β -Tricalcium phosphate increased bone density in the bone defect of immediate dental implants. This is also in agreement with a similar study by Boix et al. (2004) [20] they evaluated alveolar bone regeneration for immediate implant placement using an injectable bone substitute (IBS), obtained by combining a polymer and biphasic calcium phosphate ceramic granules. Histomorphometric analysis showed that (IBS) has a significant peri-implant bone density of approximately 14.7%. After 3 months of healing.

In conclusions; 1- Immediate dental implant with biphasic calcium phosphate (BCP) coated with polyactide -co- glycolide (PLGA) was significantly superior in comparison with immediate dental implant alone. 2- Immediate dental implant with biphasic calcium phosphate (BCP) coated with polyactide -co- glycolide (PLGA) achieved higher bone density and marginal bone level rather than immediate dental implant alone. 3- More clinical researches are needed and should be conducted to evaluate the bone filling capacity of biphasic calcium phosphate (BCP) coated with polyactide -co- glycolide (PLGA) as one of the synthetic bone grafts augmenting bony defects.

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