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# BIPHASIC CALCIUM PHOSPHATE VERSUS BIPHASIC CALCIUM PHOSPHATE COATED WITH POLYLACTIDE –CO- GLYCOLIDE IN IMMEDIATE DENTAL IMPLANT AUGMENTATION (A COMPARATIVE CLINICAL AND RADIOGRAPHIC STUDY)

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***ABSTRACT***

The present study was designed to compare clinically and radiographicaly between immediate dental implant augmented with biphasic calcium phosphate (BCP) and it augmented with BCP coated with polylactide -co- glycolide (PLGA).This study was carried out on twenty adult male patients ,which were divided into two groups (group I included ten patients received immediate implant augmented with BCP ,while group II included ten patients were received immediate implants augmented with biphasic BCP coated with PLGA). Patients were evaluated clinically and radiographically to assess Gingival Index (GI) ,Probing pocket depth (PPD) , Marginal bone level (MBL), and Bone density measurement (BD) parameters at 3, 6, 9&12 months. Statistical analysis of GI and MBL results showed no significant difference in both groups at the different intervals while PPD results showed significant difference between both groups only at 9 and 12 months. On the same side, BD measurements showed statistical difference between groups at 3 month and highly statistical significant difference at 6, 9 and 12 months. The present study concluded that BCP coated with PLGA was significantly superior in comparison with BCP in augmentation of immediate dental implant.

## INTRODUCTION

Immediate implant is defined as placement of the implant immediately into fresh extraction socket [(1)] . It was shown that when the horizontal width of a peri-implant defect was < 2 mm, the defect had the capacity to spontaneously heal and produce new bone formation when immediate implant placement was performed [(2)] .However, gaps of 2 mm or more in the orofacial dimension show clearly reduced predictability for spontaneous bone regeneration" [(3)].

To enhance peri-implant bone healing and achieve an esthetic final outcome, the use of barrier membranes and/or different graft materials

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to fill in residual peri-implant defects has been widely documented [4]. A variety of synthetic bone grafts (alloplast) have been tried for this aim, including calcium phosphate ceramics, collagen, non collagenous proteins, bioactive glasses, and biodegradable polymers [5].

Among the calcium phosphate ceramics, the biphasic calcium phosphates (BCP), 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 biomaterial while promoting bone ingrowths [6,7] . However, Calcium phosphate ceramic bone substitutes are more brittle and have less tensile strength than bone and known as slowly biodegradable materials [8,9] .

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, while maintaining the macrospores intact and open [10] .To combine the osteoconductivity of calcium phosphates and good biodegradability of polyesters, polymer/ceramic composite scaffolds have been developed.

A few clinical studies used this composite in augmentation of immediate dental implant [11, 12]. Therefore, the present study was designed to compare between immediate placements of dental implant with BCP and immediate dental implant with BCP Coated by PLGA.

## PATIENTS AND METHODS

### I) Patients Selection

This study was carried out on twenty adult male patients. 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.

***Patients Exclusion criteria:***

- Presence of active infection around the failing tooth.
- A medical history that would complicate the outcome of the study.
- Dental history of bruxism, parafunctional habit, and/or lack of stable posterior occlusion.
- Perforation and/or loss of labial bony plate following tooth removal and/or implant osteotomy.
- Smoking patients

***Patients groups:***

Patients were divided into two groups:

- ***Group I:*** Included ten patients received immediate implant augmented with BCP
- ***Group II:*** Included ten patients were received immediate implants augmented with BCP coated with PLGA

### II) Implant Selection:

Zimmer implant® (Zimmer dental, 1900 Aston Avenue Carlsbad, CA 92008-7308.USA) was used in this study. This implant system has tapered body with double-lead threads and two-piece abutment portion

***III) Surgical Procedures:***

- Only type I extraction sites were selected in this study.
- Following administration of local anesthesia, a full-thickness flap is elevated and extended beyond the anticipated apical extension of the preplanned implant length.
- The tooth in question is then extracted using a method involving minimal trauma to the bone and surrounding soft tissues, taking care to avoid fracturing the thin buccal plate.

- Following extraction, socket was thoroughly degranulated with curettes to remove all remnants of the periodontal ligament and granulation tissue.
- The initial penetration point for the anterior maxillary teeth was approximately 2 mm coronal to the extraction apex and along the palatal wall.
- Different diameters of titanium grit-plasted implants (width of 3.7, 4.8, 5 and length of 12 mm, 14 and 16 mm) were selected.
- Implant head should be a minimum of 3 mm apical to an imaginary line connecting the cemento–enamel junctions of the adjacent teeth and apical to the interproximal and crestal bone.
- 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 augmented with BCP (DM-Bone, BDM-0505, Meta Biomed, 363-951 Chungbuk/ Korea ).
- While; Group II patients received immediate implant augmented with BCP coated with PLGA (easy- graft CRYSTAL, Dgradable solutions AG, Wagistrasse23, CH-8952 Schlieren/ Switzerland) (fig. 1a,b,c).
- Flap was sutured with 3-0 black silk interrupted sutures after graft application (fig. 1 d).
- Standard post-surgical instructions and medications were described to the patients.
- 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 (fig. 1e,f).

**IV- Periodontal Evaluation:**

The following clinical parameters were recorded for all teeth before and after implants at intervals base line, 3, 6, 9 and 12 months post-surgically:

- ***Gingival Index (GI):*** [13]

It used to measure the degree of gingival inflammation.

- ***Probing pocket depth (PPD):***

It was measured as the distance from the crest of gingival margin to the bottom of the pocket at four sites around implants (mesial, labial, distal and palatal) using graduated periodontal probe.

**V- Radiographic Evaluation:**

All patients were exposed to standardized periapical radiographs. They were taken by long-cone paralleling technique, using film holder.

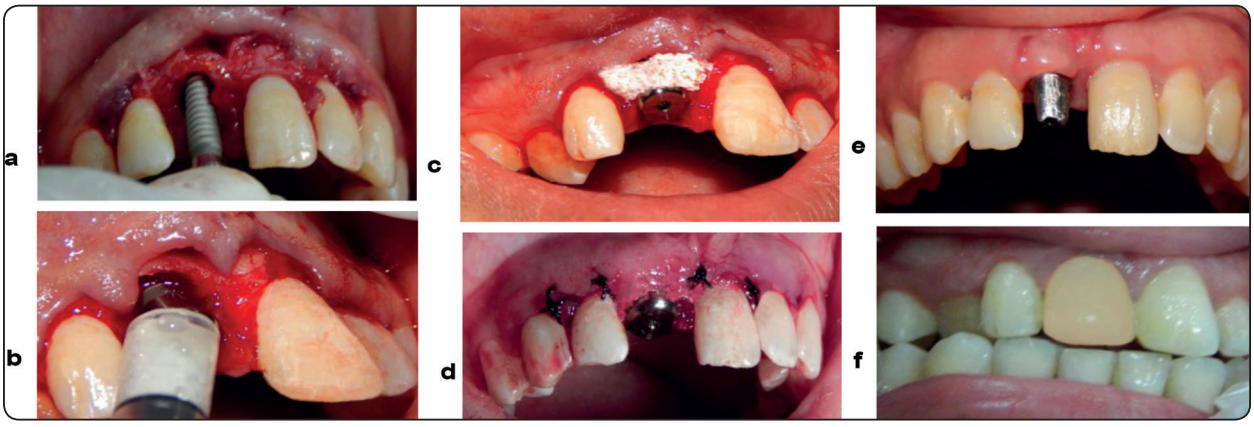


Fig. (1) a. Implant insertion b. Bone graft application c.,d. Bone graft adaptation and flap closure e. abutment preparation f. temporary restoration placement 3 weeks later

These radiographs were taken before and immediately after implant placement and at intervals of 3, 6, 9, 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® to produce the image that manipulated by Bioquant software analysis program (Durr Dental GmbH& Co. Bietigheim-Bissingen, Germany).

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 (baseline) and after 3, 6, 9 and12 months.

**Statistical analysis:**

The data were collected, tabulated and statistically analyzed by Statistical Package for Social Sciences (SPSS) version 13 that program. Graphs were performed using the Microsoft Excel 2010 program.

## RESULTS

Clinically, no adverse reactions, no complications observed during the periods of the study. No implant failed up to 12 months after insertion.

***Changes in Gingival Index (GI):***

Table (1) showed means, standard deviations, t-values and p-values within each group at different intervals. *Paired t-test* values proved that no statistical significant difference in both groups at the different intervals when compared to the baseline. On the same side, unpaired *t-test* for comparing the two groups showed no statistical significant difference during different observation periods of the study (fig.2).

TABLE (1) Comparison between GI of study groups and within each group at different intervals

| Periods / Groups | Baseline | 3 Month | 6 Month | | 9 Month | | 12 Month | |
|---|---|---|---|---|---|---|---|---|
| | Mean± SD | Mean± SD | Mean± SD | | Mean± SD | | Mean± SD | |
| Group I | 0.40±0.5164 | 0.20±0.4216 | 0.30±0.4830 | | 0.30±0.4830 | | 0.20±0.4216 | |
| Group II | 0.30±0.4830 | 0.10±0.3162 | 0.30±0.4830 | | 0.30±0.4830 | | 0.30±0.4830 | |
| t- value | 0.447 | 0.600 | 0.00 | | 0.00 | | 0.493 | |
| p-value | 0.660 | 0.556 | 1.00 | | 1.000 | | 0.628 | |
| | 3 Month VS Baseline | | 6 Month VS Baseline | | 9 Month VS Baseline | | 12 Month VS Baseline | |
| | t- value | p -value | t- value | p -value | t- value | p -value | t- value | p -value |
| Group I | 0.802 | 0.443 | 0429 | 0.678 | 0.429 | 0.678 | 0.802 | 0.443 |
| Group II | 1.000 | 0.343 | 0.000 | 1.000 | 0.000 | 1.000 | 0.000 | 1.000 |

TABLE (2) Comparison between PPD of study groups and within each group at different intervals

| Periods / Groups | Baseline | 3 Month | 6 Month | | 9 Month | | 12 Month | |
|---|---|---|---|---|---|---|---|---|
| | Mean± SD | Mean± SD | Mean± SD | | Mean± SD | | Mean± SD | |
| Group I | 4.40±0.8090 | 3.4±0.8432 | 2.50±0.7071 | | 2.60±0.6992 | | 2.90±0.9944 | |
| Group II | 4.60±0.6875 | 3.90±0.7378 | 2.30±0.4830 | | 2.00±0.000 | | 2.1±0.3162 | |
| t- value | 0.577 | 1.411 | 0.00739 | | 2.71 | | 2.42 | |
| p-value | 0.577 | 0.175 | 0.470 | | 0.02 | | 0.03 | |
| | 3 Month VS Baseline | | 6 Month VS Baseline | | 9 Month VS Baseline | | 12 Month VS Baseline | |
| | t- value | p -value | t- value | p -value | t- value | p -value | t- value | p -value |
| Group I | 0.958 | 0.363 | 2.209 | 0.04* | 3.272 | 0.01* | 4.70 | 0.001** |
| Group II | 4.12 | 0.003** | 7.293 | 0.000** | 10.90 | 0.000** | 16.69 | 0.000** |

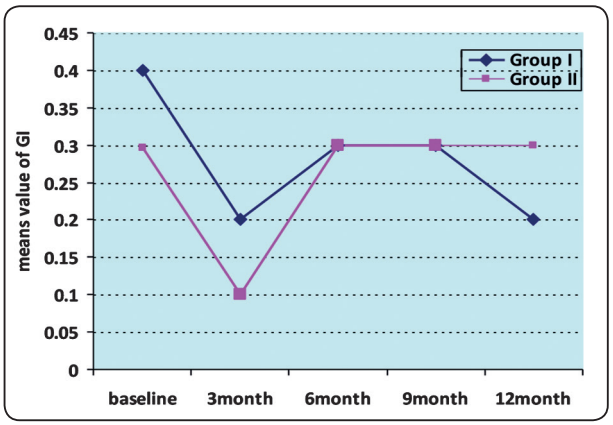


Fig. (2) Diagram showing means of GI in both groups.

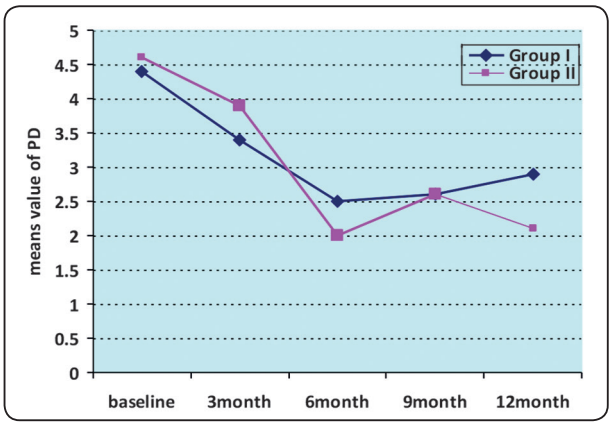


Fig. (3) Diagram showing means of PD in both groups

***Probing pocket depth measurement (PPD)***

Means, standard deviations, t-values and p-values within each group at different intervals were illustrated in table (2).

The mean value of probing depth in group I was 4.40± 0.8090 at base line that reduced to 2.9 ± 0.9944 after 12 months of implant placement. In group II, the mean value of probing depth in group II was 4. 600 ± 0.6875 at baseline that reduced to 2.10 ± 0.3162 after 12 months of implant placement. The difference within the group was highly statistical significant difference at 3, 6, 9 and 12 months when compared with base line. ***Unpaired-test*** for comparing pocket depth between both groups showed highly statistical significant difference at 9, 12 months (fig. 3).

***Marginal bone level (MBL)***

Means, standard deviations, t-values and p-values within each group at different intervals were illustrated in table (3) **.** In group I the mean value of marginal bone level was 3.85 ± 0.840 at base line that increased to 3.97± 0.756 after 12 months of implant placement and the difference within the group was highly statistically significant at 3,6, 9 and 12 months when compared with base

line. In group II the mean value of marginal bone level was 3.73 ± 0.700 at base line that increased to 4.33 ± 0.668 after 12 months of implant placement and the difference within the group was highly statistically significant at 3, 6, 9 and 12 months when compared with base line. ***Unpaired t-test*** for comparing the two groups showed no statistical significant difference during different observation periods of the study (fig.4)

***Bone Density Measurements (BD):***

The changes in bone Density (in pixels) during the observation periods of the present study illustrated in table (4). In group I 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, 9 and 12 months when compared with base line table. In group II 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 3, 6,9,12 months when compared with base line (fig 5). ***Unpaired-test*** illustrated in table (4) showed statistical difference at 3 month and highly statistical difference at 6, 9 and 12 month table (4)**.**

TABLE (3) Comparison between MBL of study groups and within each group at different intervals

| Periods / Groups | Baseline | 3 Month | 6 Month | | 9 Month | | 12 Month | |
|---|---|---|---|---|---|---|---|---|
| | Mean± SD | Mean± SD | Mean± SD | | Mean± SD | | Mean± SD | |
| Group I | 3.73±0.700 | 3.95±0.694 | 4.06±0.665 | | 4.16±0.665 | | 4.33±0.688 | |
| Group II | 3.85±0.84 | 3.98±0.839 | 3.62±0.794 | | 3.72±0.813 | | 3.97±0.813 | |
| t- value | 0.347 | 0.087 | 1.343 | | 1.343 | | 1.068 | |
| p-value | 0.733 | 0.932 | 0.196 | | 0.203 | | 0.299 | |
| | 3 Month VS Baseline | | 6 Month VS Baseline | | 9 Month VS Baseline | | 12 Month VS Baseline | |
| | t- value | p -value | t- value | p -value | t- value | p -value | t- value | p -value |
| Group I | 11.00 | 0.000*** | 9.85 | 0.000*** | 12.83 | 0.000*** | 15.21 | 0.000*** |
| Group II | 6.09 | 0.000*** | 4.64 | 0.001** | 1.948 | 0.083 | 2.167 | 0.04* |

TABLE (4) Comparison between BD of study groups and within each group at different intervals

| Periods / Groups | Baseline | 3 Month | 6 Month | | 9 Month | | 12 Month | |
|---|---|---|---|---|---|---|---|---|
| | Mean± SD | Mean± SD | Mean± SD | | Mean± SD | | Mean± SD | |
| Group I | 81.0±6.12 | 82.3±5.69 | 90.0±6.03 | | 94.90±6.04 | | 101.4±7.42 | |
| Group II | 84.0±4.69 | 88.6±4.71 | 100.8±5.24 | | 108.2±5.24 | | 118.1±5.97 | |
| t- value | 1.22 | 2.693 | 4.27 | | 5.25 | | 5.54 | |
| p-value | 0.235 | 0.01 | 0.000** | | 0.000** | | 0.000** | |
| | 3 Month VS Baseline | | 6 Month VS Baseline | | 9 Month VS Baseline | | 12 Month VS Baseline | |
| | t- value | p -value | t- value | p -value | t- value | p -value | t- value | p -value |
| Group I | 0.987 | 0.349 | 6.09 | 0.000** | 9.212 | 0.000** | 9.320 | 0.000** |
| Group II | 6.40 | 0.000** | 12.31 | 0.000** | 16.94 | 0.000** | 14.78 | 0.000** |

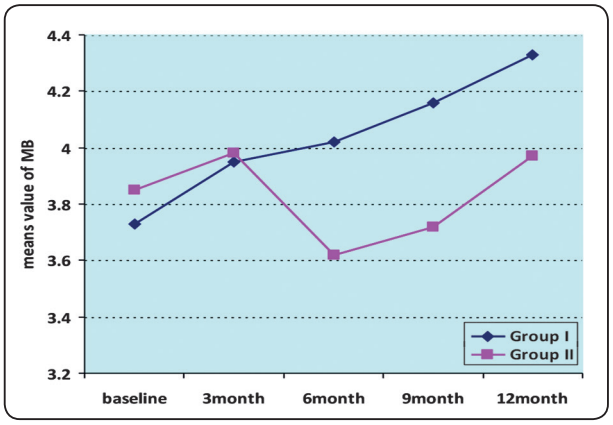


Fig. (4) Diagram showing means of MB in both groups

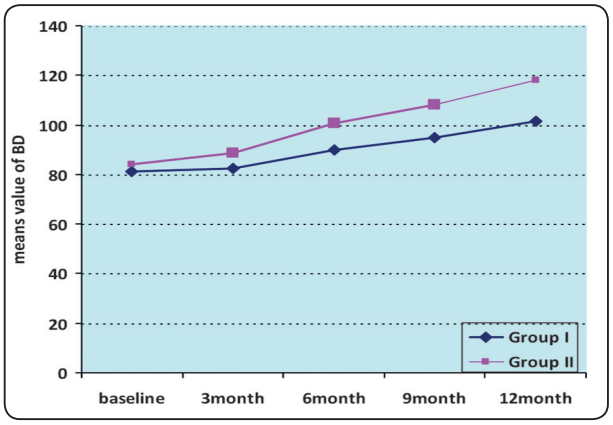


Fig. (5) Diagram showing means of BD in both groups

## 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.

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 [14-17] .

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 BCP coated with PLGA gives better results as compared to immediate dental implant alone. These findings are in agreement with results of Koutouzis et al. study [18].

In the present study, all selected cases have a single-rooted extraction socket, the multi rooted regions were excluded according to Atieh et al. [19] which concluded that the outcome of immediate implant placed in molar sites does not gives a better results 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 wall remaining this is in accordance with Douglass & Merin [20] which 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 [21] 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 which permits careful evaluation of buccal wall integrity in comparison to flapless surgery. This technique is in contradiction with techniques used by Vera et al. [22] & Barros et al. [23] .They suggested that flap surgery increase amount of vertical and horizontal bone resorption and is in agreement with De Bruyn et al. [24] who concluded that suggested there is no difference in the amount of bone resorption between flap and flapless technique.

Non submerged surgical technique was used in this study , this technique is in agreement with a study of Ericsson et al. [25] they concluded that non submerged implants do not compromise hard and/ or soft tissue integration or the long-term results of implant treatment.

In the present study, the results showed that; the mean marginal bone change after 12 month follow up was (0.6mm) in group I. However, in group II the mean marginal bone loss after follow 12 month up was (0.12mm ) .These findings is similar to a results obtained from a study by Koutouzis et al. [18] who 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.

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 group II when compared with group I. This is in agreement with a similar study by Boix et al. [14] 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 conclusion, immediate dental implants with biphasic calcium phosphate (BCP) coated with polyactide -co- glycolide (PLGA) bone substitute achieved better bone density and marginal bone level than immediate dental implants with BCP. Finally, more clinical researches are needed and should be conducted to evaluate the bone filling capacity of BCP coated with PLGA as one of the synthetic bone grafts augmenting bony defects.

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