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Comparison between Two Different Manufactured Forms of β-Tricalcium Phosphate Bone Graft in Immediate Implant Placement

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Abstract

Objectives: The aim of this study was to compare the efficacy of using the synthetic β-TCP bone grafting material in two different manufacturing forms (putty and granular) in grafting the jumping zone around immediate implant. **Patients and Method:** A randomized controlled clinical and radiographic trial was conducted on 24 male patients aged from 45 - 55 with badly decayed non-restorable teeth in the posterior mandibular area and seeking for receiving immediate dental implant directly after extraction. Vertical bone height and bone density were taken at time of implant placement and 6 months postoperatively. **Results:** The Putty form group and the Granular form group did not differ statistically in terms of age, post-operative complications, or implant outcome six months postoperatively. Additionally, there was a statistically significant increase in Putty form group compared to the Granular form group regarding Marginal bone loss 6 months postoperatively, but there was no statistically significant difference between the Putty form group and the Granular form group regarding Bone density by CBCT. **Conclusion:** The β-TCP Putty material, compared to β-TCP granular, displayed better surgical handling properties, and both forms had no adverse effect on bone formation, bone tissue maturation or graft volume stability, The β-TCP granular material, compared to β-TCP putty, displayed less marginal bone loss 6 months post-operatively.

Keywords

β-Tricalcium Phosphate Bone Substitute, Putty Form and Granular Form, Grafting the Jumping Zone around Immediate Implant

1. Introduction

Immediate implant placement has social as well as financial benefits. Because it decreases the number of surgical procedures by integrating extraction, implant insertion, and bone grafting into one appointment, the overall treatment duration is reduced, a second surgical intervention is avoided, and rehabilitation therapy time is reduced. Using β-TCP (β tricalcium phosphate) as a bone substitute which is biocompatible and has several criteria: Bio-inertia (is defined as the absence of a Physico-chemical reaction of the product in direct contact with bone). Bioactivity (the capacity to develop reactions favoring osseointegration of the product and the adaptation of the receiving tissue) avoids the morbidity observed with harvesting autogenous bone and widens the operative indications [1]. β-TCP grafting material can be produced in different forms and gives a wide range of use. The Putty form gives much easy manipulation of the material to be injected in many types and forms of sockets and no need to use a collagen membrane, and the granular form is produced in a different and wide range of sizes to fill most socket sizes, both forms of this grafting material actively supported the bone formation and matrix mineralization in different situations [2].

2. Patients and Method

1) 24 male patients aged 45 - 55 with badly decayed non-restorable teeth in the posterior mandibular area and seeking for receiving immediate dental implant directly after extraction selected from those attending the outpatient clinic of the Department of Oral and Maxillofacial Surgery, Faculty of Dental Medicine, Al-Azhar University (Assiut), Egypt.

2) All patients had signed an informed consent form after being fully informed about study protocol, treatment plan, and alternative treatment approaches.

3. Eligibility Criteria

1) Inclusion criteria for participants:

All patients were medically free, according to Cornell Medical Index. Should have a badly destructed hopeless tooth and seek implant placement. Patients aged between 45 and 58 years with badly decayed non-restorable teeth in the posterior mandibular region.

2) Exclusion criteria for participants:

Any patient with acutely infected socket, any socket with wall defect, infected socket, heavy smokers, alcoholism, uncontrolled systemic diseases which affect bone healing or presence of any pathology in the site of operation.

3) Sample size:

All data were collected, tabulated and statistically analyzed using SPSS 26.0 for Windows (SPSS Inc., Chicago, IL, USA). Qualitative data were described using number and percentage. Quantitative data were described using range (minimum and maximum), mean, standard deviation and median. All statistical comparisons

were two-tailed with significance Level of p-value ≤ 0.05 indicates significance. $P < 0.001$ indicates a highly significant difference while $p > 0.05$ indicates a non-significant difference.

4) Patients grouping and intervention:

Patients were classified randomly into two equal groups:

Group I: Patients with fresh defective extraction sockets received an immediate dental implant with β-TCP bone grafting material in the Putty form to fill the jumping zone around the dental implant (Figure 1).

Group II: Patients with fresh defective extraction sockets received an immediate dental implant with β-TCP bone grafting material in the Granular form to fill the jumping zone around the dental implant (Figure 2).

5) Surgical procedure:

Before surgery, all patients' mouths were rinsed with 20 ml chlorhexidine gluconate 0.12% solution or 30 second as a topical antimicrobial agent. A surgical site was locally anaesthetized by Artinibsa 40 mg/0.01 mg/ml (Articaine hydrochloride + Epinephrine(adrenaline)). Atraumatic tooth extraction was done using elevators to avoid any trauma during extraction, and forceps of anatomic design rotated the root in a clockwise-counterclockwise fashion to retrieve the root from the alveolus. After extraction, the socket was degranulated with curettes to remove all remnants of the periodontal ligament and granulation tissue. The drilling of implant was done in sequential manner. The implant was removed out of its vial and inserted about 2 mm apically to the extracted tooth according to determined length and width and to the analysis of each case that was done by cone beam computed tomography. Ratchet was used to insert the implant and tight in its site in a clockwise direction. A Smart peg was applied to implant fixture for determination and reading the primary stability with implant stability quotient (ISQ) ostell. The cover screw was removed from the bottom of the implant vial by a hex tool and screwed into the implant body. In group I, Beta tricalcium phosphate bone graft in the putty form was applied around dental implant as a graft material. In group II, Beta tricalcium phosphate bone graft in the granular form was applied around dental implant as a graft material. A custom healing abutment was made and applied to the surgical site to preserve the grafting material and the soft tissue dimensions of the socket.

6) Assessment:

Duration of procedure (time).

CBCT was used to evaluate bone density and marginal bone loss. Bone density (HU) immediately and 6 months postoperatively.

7) Follow-up and data collection:

- **Radiographic parameters:**

CBCT radiographic examinations were performed immediately after surgery and 6 months postoperatively. This included measurements of alveolar ridge length and recording bone density values around implants immediately and 6 months postoperatively.

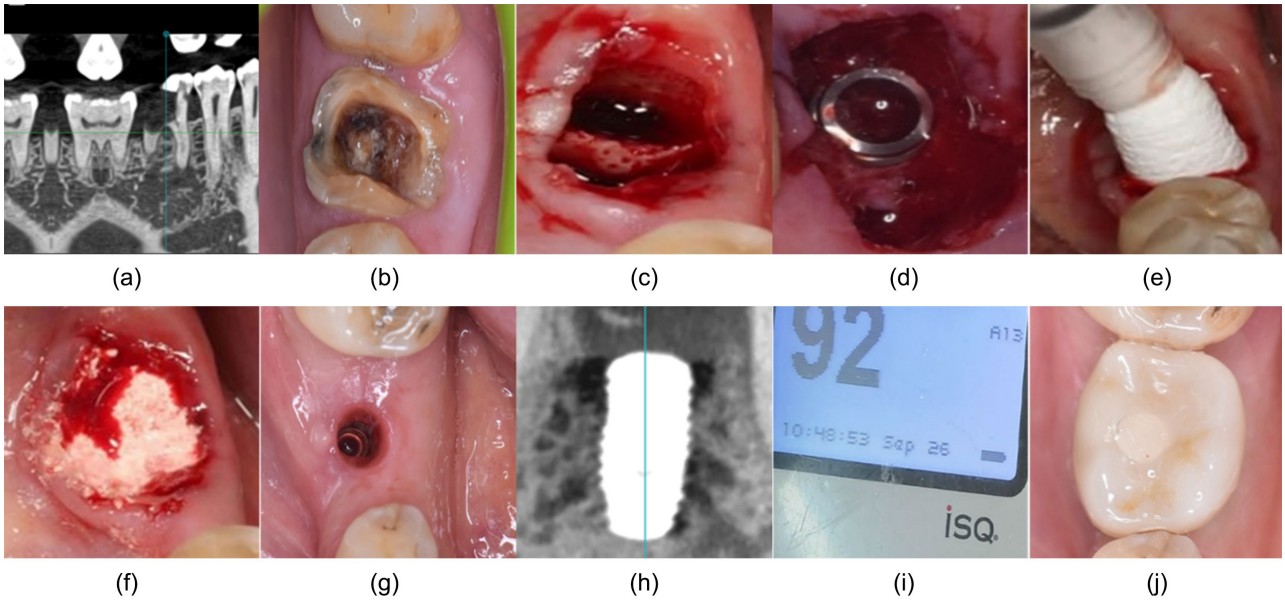

Figure 1. Putty group (GI): (a) CBCT, non-restorable L6, (b) non-restorable L6, (c) fresh socket, (d) immediate implant, (e) application of putty β-TCP bone graft, (f) putty β-TCP bone graft in place, (g) soft tissue healing after 3 months, (h) post-operative radiograph 6 months postoperatively, (i) secondary stability reading by OSTELL, (j) final prosthesis.

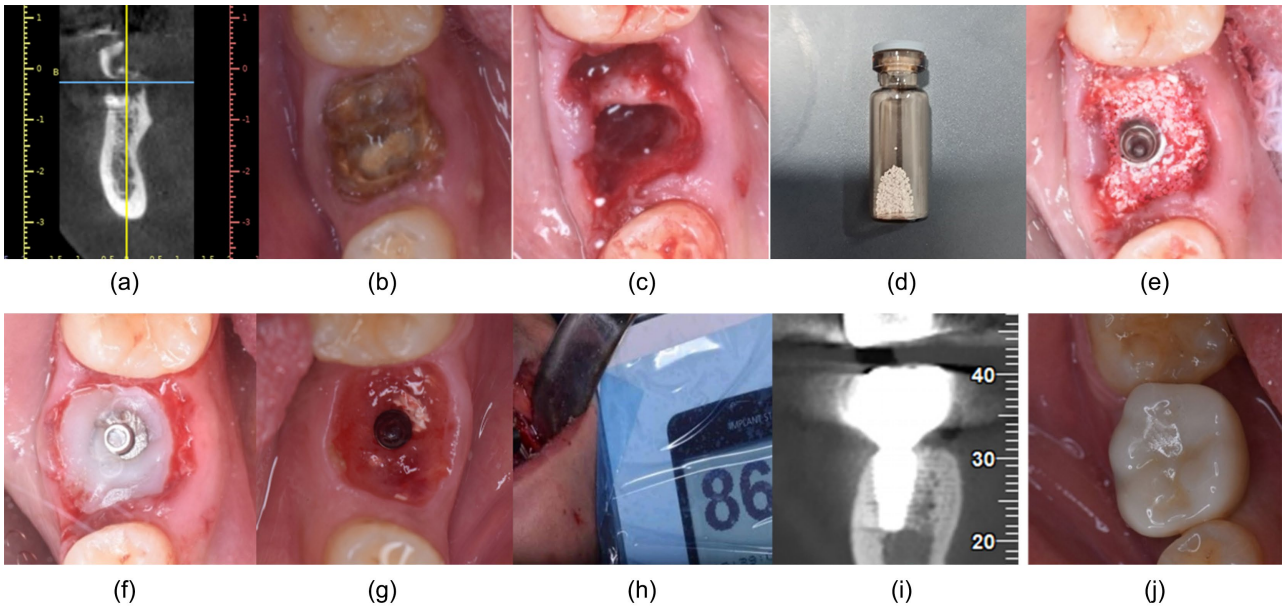

Figure 2. Granular group (GII): (a) CBCT, pre-operative radiograph of non-restorable lower 6, (b) tooth before extraction, (c) fresh socket, (d) Granular form of β-TCP bone graft, (e) bone graft in place around implant, (f) custom made healing abutment, (g) soft tissue healing after 3 months, (h) secondary stability reading by OSTELL, (i) post-operative radiograph after 6 months, (j) prosthesis after placement.

- **Measuring of marginal bone loss:**

CBCT was used to quantify the crestal bone loss at the mesial, distal, buccal, and lingual surfaces of each implant. Marginal bone height was assessed at the mesial and distal surfaces of each implant in the panoramic window of the CBCT software. The marginal bone height at the buccal and lingual surfaces of each

implant was measured in the CBCT software's cross-sectional window. Using the ruler measurement feature of the software, the distance between the implant-abutment junction and the bone contact with the implant was measured to determine the marginal bone level. Alveolar bone heights during subsequent visits were subtracted from the bone level at the baseline (prosthesis delivery) to assess crestal bone loss.

All implants' mesial, distal, buccal, and lingual bone loss measurements were added up, and the average was employed in the analysis of Radiographic images showing measurements of implant marginal bone loss.

- **Measuring of bone density:**

The change in bone density around implant was measured in Hounsfield units using BlueSky Bio (software) (HU). On buccal, lingual, mesial, and distal sides of implant, measurement sites were positioned at the top, middle, and apical parts. The average density was calculated using mean values of bone density along each side implant. This procedure was carried out at each postoperative follow-up interval (immediate and 6 months).

8) Prosthetic phase:

Following a second surgical exposure six months after implant placement, gingival formers were placed for 2 weeks to establish proper gingival shape at implants' collar region. The impression was taken using an open tray impression technique with implant impression coping and implant analogues. Zircon screw-retained crowns were delivered to all patients for both groups and abutments were screwed to implants with a torque of 35 N/cm, and implants were functionally loaded. Patients were instructed about maintenance of oral hygiene by means of dental floss, interdental brush, and mouth wash.

9) Statistical analysis:

Version 20.0 of the IBM SPSS software program (Armonk, NY: IBM Corp.) was used to analyze the data once they were loaded into the computer. Number and percentage were used to describe qualitative data. The normality assumption was checked based on the Shapiro-Wilk Test.

The range (minimum and maximum), mean, standard deviation, and median were used to characterize quantitative data. For qualitative data, the Chi-square test was used.

To compare two groups under study, the following tests were used:

- Independent t-test for typically quantitative two variables.
- Mann Whitney U was used to determine the significant test for nonparametric data between the two groups.

For comparison of typically quantitative data of more than two variables, a One-way ANOVA test was used. At the 5% level, the significance of the results was determined.

4. Results

1) Implant stability (Table 1).

There was a statistically significant difference between (Baseline) and (6 mon) where ($p < 0.001$) in both groups.

Relation between Groups: There was no statistically significant difference at (baseline) between (Group I) and (Group II) where ($p = 0.860$). There was a statistically significant difference at (6m) between (Group I) and (Group II) where ($p = 0.024$).

Table 1. Implant stability among the study population.

Variables	Implant stability								*p*-Value
	Group I				Group II				
	Mean	SD	Min	Max	Mean	SD	Min	Max	
Baseline	70.71^{Ba}	2.97	60.00	85.00	71.57^{bA}	3.72	59.00	84.00	0.860ns
After 6m	76.57^{aA}	2.58	67.00	88.00	85.71^{aA}	2.43	77.00	95.00	0.024ns
p-Value	<0.001*				0.001*				

Means with different small letters in the same column indicate significant differences, means with different capital letters in the same row indicate significant difference. *: Significant ($p < 0.05$) ns; non-significant ($p > 0.05$).

2) Bone density and marginal bone loss (Table 2).

Table 2. Bone density and marginal bone loss.

	Putty form group (n = 12)	Granular form group (n = 12)	Test of Sig.	*p*
Bone density by CBCT				
Mean ± SD	341 ± 36.56	342.42 ± 59.41	t = −0.07	0.945
Median (IQR)	330.5 (318.3 - 360.3)	348.5 (316.8 - 372.8)		
Range (Min-Max)	106 (298 - 404)	199 (234 - 433)		
Marginal bone loss 3 months postoperatively (mm)				
Mean ± SD	0.31 ± 0.05	0.34 ± 0.1	t = −1.03	0.318
Median (IQR)	0.3 (0.3 - 0.3)	0.4 (0.3 - 0.4)		
Range (Min-Max)	0.2 (0.2 - 0.4)	0.3 (0.1 - 0.4)		
Marginal bone loss 6 months postoperatively (mm)				
Mean ± SD	0.57 ± 0.08	0.43 ± 0.12	t = 3.317	0.004*
Median (IQR)	0.6 (0.5 - 0.6)	0.5 (0.4 - 0.5)		
Range (Min-Max)	0.3 (0.4 - 0.7)	0.3 (0.2 - 0.5)		

t: Independent T test; SD: Standard deviation; IQR: Interquartile range; p: *p*-value for comparing between the studied groups *: Statistically significant; *p*-value > 0.05: Non-significant; *p*-value < 0.05: Significant; *p*-Value < 0.001: Highly significant.

There was no statistically significant difference between the Putty form group and Granular form group regarding marginal bone loss 3 months postoperatively, while there was a statistically significant increase in Putty form group than Granular form group regarding Marginal bone loss 6 months postoperatively.

5. Discussion

Calcium phosphate ceramics have been investigated extensively because their mineral chemistry resembles that of human bone [3] [4].

The first successful application of a calcium phosphate reagent (described as "triple calcium phosphate", or tricalcium phosphate (TCP)) in humans. Biphasic calcium phosphate (BCP) is a bioactive ceramic consisting of two mixed phases: the less soluble, HA and more soluble, b-TCP where the chemical properties of BCP depend on the HA/bTCP ratio [5].

The biological response of bone substitute materials depends not only on chemical composition but also on its macro- and microstructural characteristics, such as the pore size, porosity, and interconnects [6].

β-tricalcium phosphate (*β*-TCP), hydroxyapatite (HA), and their combinations (known as biphasic calcium phosphates (BCP) are the most studied due to their composition, which is similar to the bone mineral calcium phosphate [7].

Representative calcium phosphate graft materials include hydroxyapatite (HA) and *β*-tricalcium phosphate (*β*-TCP). Due to these materials' structural and chemical similarities to the inorganic component of bone, there has been interest in using them for bone regeneration [8].

In contrast, because of its porous structure and low mechanical strength, *β*-TCP dissolves quickly in the body; however, this means that when *β*-TCP is used alone, the space needed for the bone regeneration period is frequently not maintained [9].

To maximize their benefits, HA and *β*-TCP are combined in different ratios to create biphasic calcium phosphate (BCP). The rate of degradation, mechanical characteristics, and bioactivity of these materials can all be modified [10].

The main aim of this study was to compare the efficacy of using the synthetic *β*-TCP bone grafting material in two different manufacturing forms (putty and granular) forms in the grafting of the jumping zone around the immediate implant.

The technique performed on patients were medically free according to Cornell Medical Index and should have a badly decayed hopeless tooth and seek implant placement because their tooth had become more damaged and cannot be repaired, and patients' age were 45-55 years (mean 50.5 years) more susceptible to implantation. Using synthetic *β*-TCP bone grafting material is preferred because the method is more available, sterile and reduces morbidity. *β*-TCP better biodegradability and resorption rates, which can increase the biocompatibility of the implant.

To eliminate the effect of any confounding factor that may affect the outcome

the current study enrolled two well-matched groups in baseline data, as there was no statistically significant difference between the studied groups as regards demographic data.

The current study outcome had some similarities with Knabe *et al.*, [10] study which assessed the effect of a Particulate and a Putty-Like Tricalcium Phosphate-Based Bone Grafting Material on Bone Formation, Volume Stability and Osteogenic Marker Expression after Bilateral Sinus Floor Augmentation in Humans, the study enrolled 7 patients aged from 57 - 72 years (mean 65.4 years). Four patients received Putty-Like Tricalcium Phosphate and three patients received Particulate Tricalcium Phosphate. The study revealed that sinus floor augmentation employing both kinds of materials produced enough bone volume to enable stable dental implant placement; all dental implants have been in place and functioning normally for six years.

Also, in agreement with the current study, Stiller *et al.*, [11] evaluated the clinical and osteogenic performance of β-TCP granules and a β-TCP putty bone graft material. In this study, 7 patients had 40 dental implants placed in their augmented areas. None of the patients experienced any postoperative complications. Up to two or three years after implant implantation, no implant failures were observed.

Furthermore, Merli *et al.*, [12] reported that the use of pure β-tricalcium phosphate and porcine pericardium collagen membranes for bone augmentation was associated with 100% success rate and no complications for three years postoperatively.

Regarding grafted region volume, the current study showed that directly postoperative Grafted region volume in Putty form group ranged from 1.8 to 6.1 mm with mean ± SD = 3.24 ± 1.22 while in Granular form group the Directly Postoperative Grafted region volume ranged from 2.3 to 4.3 with mean ± SD = 3.27 ± 0.72 with no statistically significant difference ($p = 0.952$) between the two groups. After six months Grafted region volume in Putty form group ranged from 1.6 to 4.9 with mean ± SD = 2.74 ± 0.93 while in Granular form group, after six months, Grafted region volume ranged from 1.8 to 2.8 with mean ± SD = 2.33 ± 0.37 with no statistically significant difference ($p = 0.172$) between the two groups.

Decrease in volume (%) in Putty form group ranged from 10 to 19.7 with mean ± SD = 14.48 ± 3.09 while in Granular form group, the Decrease in volume (%) ranged from 21.7 to 34.9 with mean ± SD = 27.91 ± 4.78 with highly statistically significant difference ($p = < 0.001$) between the two groups.

The above results established that the use of Putty form β-tricalcium phosphate was associated with higher volume stability (lower volume loss) compared to Granular form group.

Also, in concordance with the current study, Stiller *et al.*, [11] showed that both materials allowed excellent graft volume stability. Putty form β-tricalcium phosphate displayed significantly lower grafting volume reduction values compared to Granular form β-tricalcium phosphate.

Because the β-tricalcium phosphate particles used in the putty material are

packed more densely, it is possible that their smaller grain size has a positive effect on graft shrinkage [13].

Regarding changes and response at six months postoperatively the current study showed that there was no statistically significant difference between the two studied groups. No patients had complete resorption six months postoperatively. No incidence of Inflammatory response was observed six months postoperatively for any of the patients.

Regarding bone amount (%) in Putty form group ranged from 27 to 33 with mean ± SD = 30 ± 1.76 while in Granular form group the Bone amount (%) ranged from 14 to 20 with mean ± SD = 17.58 ± 2.15 with highly statistically significant difference (p = < 0.001) between the two groups.

These outcomes are consistent with research conducted by Chazono *et al.* [14] in New Zealand white rabbits implanted with TCP-blocks and a combination of TCP granules and hyaluronic acid; the TCP/hyaluronic acid group showed marginally increased bone formation. Nevertheless, they reported the presence of osteoclasts, which contrasts with our results, which did not demonstrate any osteoclastic resorption of the TCP granules. This could be connected to their research on shorter implantation times.

Furthermore, a more recent animal study by Akçay *et al.* [15] examined the efficacy of the same β-TCP bone graft in critical size calvarium defects by comparing its particulate, block, and putty forms. They concluded that the type of β-TCP bone graft greatly influences bone regeneration, with the particulate form showing the greatest degree of success in this study.

6. Conclusions

Both forms of β-Tricalcium phosphate grafting materials actively supported bone formation and matrix mineralization six months after immediate implant placement. This resulted in favorable bone regeneration and degradation of the graft material which created a sufficient volume of osseous tissue to facilitate stable dental implant placement.

The β-TCP Putty material, compared to β-TCP granular, displayed better surgical handling properties and had no adverse effect on bone formation, bone tissue maturation or graft volume stability.

Granular form group is better than putty form group regarding marginal bone loss 6 months postoperatively.

There was a statically significant increase in Putty form group than Granular form group regarding Bone amount.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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