



CLINICAL EVALUATION OF REINFORCED NANO-HYDROXYAPATITE BONE GRAFT AND POLY-LACTIDE-CO-GLYCOLIDE (PLG) POLYMER (FISIOGRAFT) FOR MAINTAINING THE ALVEOLAR HEIGHT POST-TEETH EXTRACTION

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ABSTRACT

Objectives: To evaluate maintaining the alveolar height post- teeth extraction with nano-hydroxyapatite bone graft and Poly-Lactide-co-Glycolide (PLG) polymer (Fisiograft). **Subjects and Methods:** Randomized, controlled, clinical study was done on 20 patients divided into 2 equal groups. In Group I (study), fisiograft nano hydroxyapatite reinforced was applied in extracted socket then absorbable collagen membrane was adapted over graft and sutured while in Group II (control), the socket was closed without any graft materials for alveolar ridge preservation after tooth extraction, CBCT was done to evaluate; bone density, alveolar bone width and height at the site of extraction and bone graft addition. Alveolar bone height and width in addition to bone density was assessed immediately & 6 months post operatively. **Results:** In the NHA & PLG showed less decrease in buccal and lingual height & width & increase in bottom of socket. It was found that the NHA & PLG group had an increase in bone density measurements. **Conclusion:** Applying of reinforced nano-hydroxyapatite bone graft and Poly-Lactide-co-Glycolide (PLG) polymer (Fisiograft) to the alveolar socket showed least resorption in buccal and lingual heights as well as socket width & increase bone density, so it decreased bone resorption after 6M from grafting.

Key words: Alveolar ridge preservation, alloplast biomaterials & bone regeneration, panoramic radiography, cone beam computed tomography, bone density.

INTRODUCTION

Tooth extraction is one of the most widely performed dental treatments⁽¹⁾. After tooth extraction, blood clot gets filled within extraction socket, then slowly remodels and a suitable matrix for bone ingrowth from the surrounding buccal bone⁽²⁾. However, a significant dimensional change of the alveolar ridge is induced by this extraction⁽¹⁾. This changes of the alveolar ridge and consequently bone resorption, is one of the most widely complicated process for surgeon⁽³⁾. This resorption reaches a

mean horizontal reduction of 3.79 mm and mean vertical reduction of 1.24 mm at 6th month post teeth extraction⁽⁴⁾.

Multiple types of bone graft materials such as; autograft, allograft, xenograft, and alloplastic materials can be used for socket preservation in combination with or without a barrier membrane^(1,2). The gold-standard grafting material is the autografts but they suffer from disadvantages such as defect size limitation, increased surgical time, and also can cause donor site morbidity⁽²⁾.

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Some studies have also used synthetic polymers, such as PLA or PLGA, for bone augmentation. It can be used as a space filler⁽⁵⁾. PLGA is synthetic, biodegradable and biocompatible⁽⁶⁾, used in both oral-maxillofacial and general orthopedic applications. It's capable of delivering drugs⁽⁷⁾, proteins, and growth factors to enhance bone healing⁽⁸⁾. polymeric biomaterials has many advantage such as easy handling, good biocompatibility, and interesting biomechanical properties Without the risk of immunogenic and infectious complications⁽⁵⁾.

Similar to natural bone mineral, nanohydroxyapatite (nHA) has been studied extensively as a bioactive mineral phase additive to natural and synthetic bone biomaterials to enhance osteoblast differentiation and to improve mechanical and degradation properties of composites⁽⁹⁾.

The composite microspheres of PLGA and different matrix particles of nHA have attracted significant attention in the field of bone regeneration. Some of literatures supporting the use of poly lactic co-glycolic acid (PLGA) and nHA in maintaining ridge height after tooth extraction, but are scant. In the present study we need to assess success of nHA and fisiograft clinically and radiographically for socket preservation

PATIENTS AND METHODS

Study Population:

Twenty healthy patients were randomly selected from the Out-patient Clinic of Oral and Maxillofacial Surgery Departement, Faculty of Dental Medicine, Al Azhar University, Cairo, Boys. All patients seeked treatment for badly broken lower premolars and molars. The age of selected patients range from 18-65 years. All patients had a treatment plan for extraction of these teeth.

Study design:

Randomized, controlled, clinical trial.

Inclusion criteria: Adult patients were selected according to the following criteria, Patients with non-restorable hopeless tooth or remaining root indicated for extraction, lower premolars and molars

Exclusion criteria: Patients having debilitating uncontrolled systemic diseases, presence of acute infection, and heavy smokers.

Patient Grouping:

The patients were divided randomly according to methods of treatment into two groups:

Group A: 10 patients were subjected to extraction of badly decayed, non restorable tooth then Fisiograft-nano hydroxyapatite reinforced (GHIMAS S.P.A via D. Cimarosa 85 40033 Casalecchio di Reno (Bologna)-ITALIA) was applied and covered with absorbable collagen membrane(Parasorb resident forte, medical GmbH, Am Flachmoor, 16, Nurnberg, Germany) with suturing(vicryl 4-0) (Ethicon,USA)

Group B: 10 patients were subjected to extraction of badly decayed non restorable tooth and closed with stich without fisiograft or membrane insertion.

Pre-operative evaluation:

All patients were prepared for surgery by the following

1. Clinical examination

All the patients were subjected to a complete history taking, including: name, age, gender, occupation, residency, chief complaint, general condition, life style, socioeconomic background, medical and dental history.

2. Radiographic Examination

Digital panoramic 1:1 radiograph to evaluate the condition of the teeth, the tooth to be extracted and to evaluate the alveolar bone at the site of extraction.

Surgical Procedures:

Surgical procedure was done after achievement of local anesthesia (Mepecaine-L carpule: A product of Alexandria Company for Pharmaceutics

and Chemical Industries, Alexandria. (Mepecaine HCL 2% with levonordefrin 1:20000) according to group type. In both groups, the non-restorable or badly decayed lower molars or premolars was extracted as atraumatic as possible with periosteal and suitable extraction forceps (to avoid soft tissue injuries and bone destruction). After tooth extraction, Fisiograft was applied and covered with membrane in study group and suture was done with vicryl 4-0. The socket in the control group was sutured without any bone graft

Post-Operative Instructions:

All patients were instructed to have soft diet without contact of the surgically involved zone. All patients informed to bite and presses on the gauze pack that have been placed over the surgical site and donot change for one hour, wound healing assessment together with oral hygiene had been followed up by the same investigator regularly after surgery

Medications:

Systemic Antibiotics, clavimox 1 g (Amoxicillin anhydrous 875mg / clavulanic acid 125mg produced by pharco ,pharmaceuticals Alexandria) was taken twice daily for 4 days. Anti-inflammatory, Rapidus 50mg (produced by Tabuk Pharmaceuticals) was used to relieve pain and swelling, tablet, every 8 hours for 3 days. Chlorhexidine mouth wash (product of Macro Group Pharmaceutica 0.12%) was used twice daily for 3 days Stich was removed at 7 postoperative day.

Post-operative assessment:

Patients were recalled weekly during the first month. Then after 6 months.

Clinical evaluation:

Assessment of soft tissue healing procedure was done at 1 week and for 2 weeks after surgical procedure. This was done with wound healing index score. This score revealed to;

1. Good wound healing, without detection of gingival oedema or discomfort.

2. Healing, with slight gingival oedema, discomfort and erythema.
3. Poor healing, significant gingival oedema, erythema, patient discomfort, and flap dehescence..

Radiographic Evaluation:

CBCT was done to evaluate bone density and alveolar bone height as the following;

A. Alveolar bone height and width measurements

The alveolar bone height and width were evaluated to assess alveolar bone changes after tooth extraction and bone graft application. The measurement was done immediately postoperatively and compared to measurements at 6 months after surgery. The sockets were divided into mesial, middle, and distal regions, the mean value of these points were taken and recorded. Lingual and buccal alveolar bone heights as well as alveolar bone width were measured in each region as following;

1. The distances from the bottom of the mandible to the top of the alveolar bone of the buccal side,
2. Lingual side
3. Socket floor .
4. The alveolar bone width is the distance between the reference line (1) and (2) in the mandible. The reference line was set at the bottom of the mandible. (Fig. 1) .

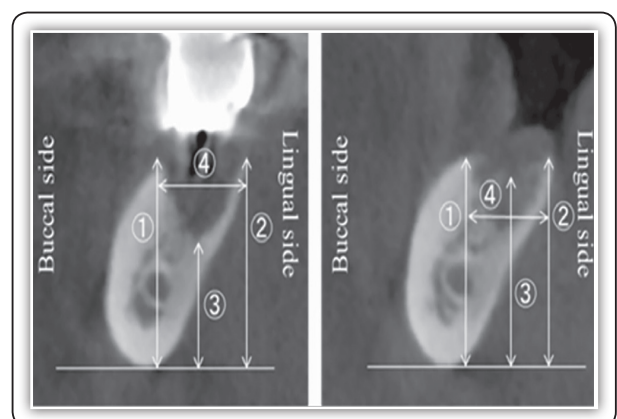


FIG (1) Coronal view CBCT of alv. bone height & width measurement at the mesial and distal side

B. Bone density measurement

Bone density was assessed at the site of extraction and bone graft application, immediately & at 6 months post operatively. Three reading were taken at the region of interest (ROI) at coronal, middle and apex of the sockets at mesial and distal side and at middle region of the sockets, measurement averages were taken and recorded fig (2) .

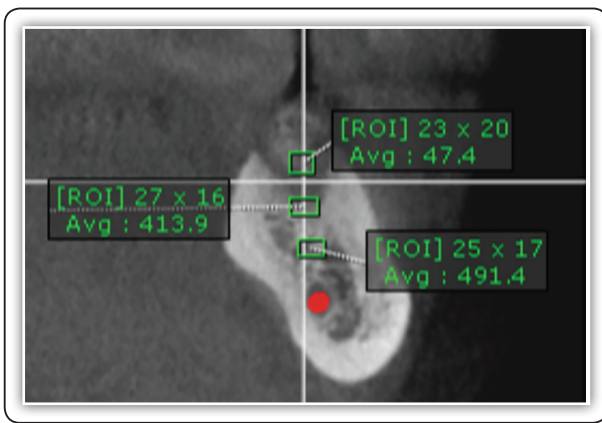


FIG (2) Coronal view CBCT showing location of alveolar bone density measurements.

RESULTS

Statistical analysis

Data were fed to the computer and analyzed using IBM SPSS software package version 20.0.

1. Demographic data

The mean age in the present study was 34.90 ± 9.39 years for control group and 35.60 ± 8.96 years for study group. Females patients represented 45% and males 55% in the two groups, while females represented 40% and males 60% in control group. at study group females 50% and males 50%. The effect of age and sex on healing was noticed but without significant difference. Changes between groups were detected without statistical significant differences.

2. Clinical evaluation

The healing of post extraction sites of all patients were un eventful and satisfactory by qualitative clinical regular intervals, no signs of infection in or around the wound sites were observed, and the soft tissue healing progressed normally. One case showed inflammation due to default of oral hygiene period of soft tissue healing, this case was treated by antibiotics and mouth wash.

3. Radiographic evaluation

Vertical bone height was assessed with CBCT to determine buccal and lingual bone height which measured from crestal alveolar height to inferior border of the mandible. Also, measurement was done from the bottom of the socket to the inferior border of the mandible. Horizontal measurement was done to determine width of bone. In addition, bone density was measured to determine the efficacy of graft material on bone formation. All measurements were done at mesial ,middle and distal of the sockets and the average measurements were taken.

1. Alveolar bone height

A. Buccal bone height

Both control and study groups; showed a statistically significant decrease in mean buccal height till 6 months. Study group showed less decrease in buccal height compared to control group (tab. 1).

Table (1) Showing buccal bone height in all groups immediately & 6 months post extraction and differences between them. U: Mann Whitney test

	Study group (n = 10)	Control group (n = 10)	U	P
Buccal Height	Mean±SD	Mean±SD		
Baseline	32.16 ±1.17	24.29 ±1.08	0.0*	<0.001*
6 months	31.53 ±1.20	22.38 ±0.55	0.0*	<0.001*

*: Statistically significant at $p \leq 0.05$

B. Lingual bone height

Both control and study groups; showed a statistically significant decrease in mean lingual height till 6 months . Study group showed less decrease in lingual height compared to control group (tab. 2).

Table (2) Showing lingual bone height in all groups immediately & 6 months post extraction and differences between them. U: Mann Whitney test

	Study group (n = 10)	Control group (n = 10)	U	P
lingual Height	Mean±SD	Mean±SD		
Baseline	32.05 ±1.35	24.66 ±0.30	0.0*	<0.001*
6 months	31.68 ±1.27	22.87 ±0.87	0.0*	<0.001*

*: Statistically significant at $p \leq 0.05$

C. Measurement of socket bottom

There was a statistically significant difference in mean bottom of socket measurements in the two groups. In study group, increasing in bottom of socket measured from inferior border of the mandible was detected in comparing to control group, that showed decrease in bottom of socket (tab. 3).

Table (3): Showing socket bottom bone height in all groups immediately & 6 months post extraction and differences between them. U: Mann Whitney test

	Study group (n = 10)	Control group (n = 10)	U	P
Socket bottom	Mean±SD	Mean±SD		
Baseline	28.73±0.73	14.89 ±1.57	0.0*	<0.001*
6 months	31.18 ±2.38	14.56 ±0.32	0.0*	<0.001*

*: Statistically significant at $p \leq 0.05$

D. Bone socket width

Non-statistically significant decrease in mean width were observed in control and study groups till 6 months. Bone width was decreased in the study group as compared to control group (tab. 4).

Table (4): Showing bone socket width in all groups at immediate & 6 months post extraction and differences between them U: Mann Whitney test

	Study group (n = 10)	Control group (n = 10)	U	P
Bone socket width	Mean±SD	Mean±SD		
Baseline	8.46±1.18	7.67 ±1.34	25.0	0.063
6 months	7.39 ±0.93	6.58 ±1.18	25.0	0.063

*: Statistically significant at $p \leq 0.05$

E. Bone density

There was a non-statistically significant increase in mean density till 6 months in Both control and study groups. Study group showed higher density compared to control group (tab. 5).

Table (5): Showing bone density in all groups at immediate & 6 months post extraction and differences between them. U: Mann Whitney test

	Study group (n = 10)	Control group (n = 10)	U	P
Bone density	Mean±SD	Mean±SD		
Baseline	387.9±75.49	402.7 ±93.0	50.0	1.000
6 months	646.9 ±38.71	568.5 ±101.1	3.419*	0.004*

*: Statistically significant at $p \leq 0.05$

DISCUSSION

The mean age in the present study was 34.90 ± 9.39 years for control group and 35.60 ± 8.96 years for study group. Females patients represented 45% and males 55% in the two groups, while females

represented 40% and males 60% in control group. at study group females 50% and males 50%. The effect of age and sex on healing was noticed but without significant difference. Changes between groups were detected without statistical significant differences.

Different materials is available for post-extraction ridge preservation. For optimal results, all grafts require an adequate blood supply, a form of mechanical support, and osteogenic cells supplied by the host, graft material, or both. Graft materials should have some osteogenic, osteoinductive, or osteoconductive properties. Osteoconductive grafts act as a scaffold or lattice for the surrounding cells to infiltrate and migrate through the graft⁽¹⁰⁾. Reinforced nano-hydroxyapatite bone graft and Poly-Lactide-co-Glycolide (PLG) polymer (Fisiograft) were used in the present study to enhance bone formation and bone height after tooth extraction. Our finding revealed to less decreasing in bone height and width in the study group more than the control group.

With agreement of our study, another study was done using resorbable bioscaffold poly lactic co-glycolic acid (PLGA) in post-extraction socket for maintaining the alveolar height. Results confirmed Reduction in alveolar bone height after placement of PLGA bioscaffold was significantly less in cases as compared to controls. No complications were observed throughout the follow-up period⁽¹¹⁾.

Another study was done for evaluation of Poly(Lactic-co-glycolic) Acid alone or in Combination with Hydroxyapatite after Sinus Lifting. Implant stability was achieved in all cases, after a six-months of healing period, the grafts were considered successful. In the PLGA/HA group, the mean of vertical bone height was increased more than in the PLGA -Fisiograft group. Also, PLGA-Fisiograft grafts appeared more radiolucent than PLGA/HA grafts⁽¹²⁾.

Histological study⁽¹³⁾, was done to determine the efficacy of nano-hydroxyapatite, polylactic acid and polyglycolic mixture, for socket and ridge

preservation. Homogeneous and integrated new bone formation.was detected at six months from surgery.

The first attempt of CBCT as a radiographic assessment, was done by Osburn in 1974⁽¹⁴⁾. This study was done to evaluate alveolar ridge dimensions after socket preservation. CBCT taken immediately and at 6 months after extraction to calculate the differences in width and height of the ridge and bone density in both groups. After this study, many studies supported using CBCT as a reliable and accurate diagnostic aid to measure ridge width and height⁽¹⁵⁾ and bone density⁽¹⁶⁾.

The efficacy and accuracy of different radiographic methods used for clinical applications of dentistry have been evaluated. Intraoral films, such as bite-wings and periapicals provide a two-dimensional image, while computed tomography produces a three-dimensional image⁽¹⁷⁾.

Regarding density, some researchers claim that CBCT grey values could be used as HU, where the linear attenuation coefficient for each material at the selected effective energy is converted to CT numbers Hounsfield units. While others point out that CBCT grey levels are subjected to variability for different reasons. These reasons may be due to variation in the devices, Image-acquisition settings, relationship between the object evaluated and FOV and Abrupt changes of density in the object⁽¹⁸⁾.

Alveolar ridge height and width can also be analyzed more accurately with CBCT than traditional dental films. Bolin et al⁽¹¹⁾, compared the mean bone heights of posterior edentulous areas in panoramic and tomographic radiographs; panoramic radiographs overestimated the available alveolar ridge height. In our study, At 6 months; there was a statistically significant difference between densities in the two groups. Study group showed the highest increase in density measurements.

CONCLUSION

In conclusion, the use of reinforced nano-hydroxyapatite bone graft and Poly-Lactide-co-Glycolide (PLG) polymer (Fisiograft) in the present study, were effective in socket preservation, in agreement with Hoda et al⁽¹¹⁾. Significantly minimized ridge resorption in all dimensions with increase the quality bone and was observed in the study group.

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