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SOCKET PRESERVATION USING BIHYBRID COMPOSITE BONE GRAFT IN THE MAXILLARY ESTHETIC ZONE (RANDOMIZED CONTROLLED CLINICAL TRIAL)

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ABSTRACT

INTRODUCTION: Resorption of Alveolar ridge is a phenomenon noticed after the removal of teeth in a healthy patient. This condition tends to be progressive and irreversible, and the volume of alveolar ridge will commonly decrease and change morphologically. Alveolar ridge preservation techniques with an intra-socket osseous graft are broadly used in past & have been continuously evaluated. These methods have been done to counteract variations in soft & hard tissues that follow tooth extraction and showed reduced ridge alteration compared to extraction alone.

AIM OF THE STUDY : The aim of this study is compare clinical & radiographica effect of bi-hybrid composite bone graft in that would preserve the dimensions of tooth socket after extraction versus without it.

MATERIALS & METHODS: twenty cases with un-restorable teeth in the maxillary esthetic zone indicated for tooth extraction, and they were allocated randomly into two groups. The study group was treated by extraction using periotome followed by grafting the socket with bihybrid composite bone graft. While in control group, no bone graft had been placed in extraction socket. . After six months follow-up period, clinical inspection and radiographic evaluation was performed for both groups.

RESULTS: radiographic evaluation revealed a statistical significance between the groups and the study group showed better socket dimensional stability and bone density. the mean loss of height was 2,90mm in control group while 1.10 mm only for the study group ,and the decrease in width in study group was only 0.94mm while in control group it was 3.25mm.also, there was a significant difference in bone density between the two groups. Clinically, there was no significant difference regarding healing, infection or swelling for the both groups.

CONCLUSION: the use of bihybrid composite bone graft was effective in alveolar bone preservation.

KEYWORDS: Tooth extraction, Alveolar bone, Bihybrid composite bone graft, Ridge preservation, Periotome.

RUNNING TITLE: Socket preservation using bihybrid bone in esthetic zone.

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INTRODUCTION

Early bone loss following tooth extraction has been common complication encountered in field of implant & restorative dentistry. Furthermore, trauma & infection related to this invasive process causes alteration to underlying bone structure. Researches show up to one–three mm in alveolar ridge height & up to three–five mm in width can be resorbed throughout healing procedure (1).

Morjaria et al. found that ridge vertical dimension reduces, particularly in facial wall, & that resorption rate is maximal throughout first three months. As result, therapeutic decision is made prior to tooth extraction & includes three choices: alveolar ridge preservation, immediate implantation, & spontaneous alveolar socket healing. It is critical to consider both hard & soft tissues in order to achieve better clinical outcomes (2).

Use of resorbable bone substitutes decreases size of grafted defect & provides mechanical support till tissue has naturally regenerated & remodeled. Particulate bovine bone grafts have been one of most common types of bone substitutes used in dental applications between various types of bone substitutes available. These materials are used to fill, augment, & reconstruct periodontal or bony defects because of their dense packing into irregular & non-uniform defect places (3).

Noia et al it was significant to fill vestibulear gap with osteoconductive xenograft material because doing so was important factor in achieving long-

term stability of outcomes after dental implant placement (4).

Most common commercially available bone material substitutes are calcium phosphates, both synthetic & animal origin. Hydroxyapatite (HA), α-tricalcium phosphate, & β-tricalcium phosphate & combination mixture forming composite are examples of these. These materials have inherent porosity & may be tailored to form scaffolds to allow space for osteogenic cell recruitment & proliferation. Furthermore, degradation products & released ions increase cell activity & speed up bone repair (5).

Ideal bone graft material will be totally resorbed & replaced by new bone. To prevent losing augmentation volume & causing inflammation caused by foreign body response, capability to generate new bone should be balanced with resorption kinetics of bone graft material (6).

Not only chemical composition, as well as 3D-morphology, & particularly existence of open pores in bone graft substitutes, is demonstrated as critical prerequisite for repairing osseous deficiency, favouring osteoconduction through vascularization & osseous growth inside pores. Resorbable bone graft material must have enough open porosity to allow blood & cells to infiltrate. Micropores (<ten µm) aid in chemical degradation of material, while mesopores (>ten µm) & macropores (>one hundred µm) aid in stabilisation of initial blood coagulum as well as vascularization & integration of graft material in surrounding area (7).

One of the most commonly used xenografts in oral surgery is deproteinated bovine bone matrix (DBBM). This material has been used successfully in many periodontal and oral surgical procedures including ridge preservation, guided bone regeneration, sinus augmentation , and buccal contour augmentation. Despite the effectiveness of bovine xenograft in oral surgical procedures, alternative sources of xenograft material have been sought due either to concerns over potential bovine spongiform encephalopathy (BSE) transmission or possible patient objections for religious reasons (8).

Particulate bone fillers, on other hand, experience localised migration from defect site following implantation, which is caused by external compressive forces in oral cavity. To address this issue, barrier membrane is frequently used to cover defect & include particulate grafts, preventing defect from collapsing. This raises cost in addition to risk of infection, although also causing studied case inconvenience & discomfort (9).

Novel bihybrid composite bone graft (Smart bone) was developed in a special manner in order to regenerate bone reconstructive surgery. It is established by combining a bovine-derived cancellous bone mineral matrix with bioactive resorbable polymers and collagen fragments (in form of hydrolyzed gelatin). This recent concept of composite biomaterial induce a quick growth of the patient's cells into hybrid bioactive bone while its biopolymers degrade, providing perfect integration and osteogenesis (10).

Therefore, this study aimed to evaluate clinically, radiographically and the performance of the novel bihybrid composite bone graft substitute in preserving the dimension of alveolar bone after extraction.

MATERIALS & METODS

Research design: current research was randomized controlled clinical trial, 20 patients recruited from the Outpatient Clinics of Oral and Maxillofacial surgery department, Faculty of Dentistry, Alexandria University, Egypt. Parallel design with allocation ratio of 1:1 research had been approved by ethics committee at faculty of Dentistry Alexandria University. Approval number: 0377-01/2022 -16/1/2022.

Materials (Figure 1)

1- Periotome.
2- Smart bone.
3- Absorbable gelatin dental sponge .
4- Polypropylene 3/0 suture.

Eligibility criteria

Inclusion criteria

1) Patients having non restorable teeth in maxillary aesthetic zone.
2) Age 18-40 years.
3) Good oral hygiene.
4) Good compliance to the treatment.

Exclusion criteria

1) Patient with acute infection in the indicated tooth.
2) Patients with systemic diseases or disorders contraindicating the treatment.
3) Drug or alcohol abuse.
4) Heavy smoker patient (more than 10 cigarettes per day).

Pregnancy and lactation.

Pre-surgical procedure

- History of patients had been noted in full details containing name, years old, sex, occupation, address & general medical health.
- Clinical examination had been completed by inspection to detect any carious molar swelling, asymmetry, &malocclusion & by palpation to evaluate any tenderness or teeth mobility.
- Preoperative radiographic examination: Orthopantomogram for all patients for the purpose of diagnosis and treatment planning.
- Preoperative preparation: preoperative scaling and root planning for all patients and oral hygiene instructions.

Surgical procedure

- Local anesthesia was given to all patients

Local anesthesia by labial and buccal infiltration

- The needle was inserted with its bevel toward the bone and making an angle of forty-five degree with the buccal aspect.
  - The needle was pushed through the soft tissue until the bone is reached
  - The needle was held firmly and the solution is slowly deposited for buccal and labial injection.

Local anesthesia for palatal infiltration

- The needle was inserted from the opposite side making 90 degree with the palate mid way between gingival margine and mid line palatal ragh opposing of the tooth extraction until reaching the bone.
- The solution was slowly deposited.

5) **After anesthesia**

Figure (1): Materials (A) Periotome, (B) Smart bone.

- 4-6minutes were left before starting extraction.
  - In order to minimize soft and hard tissue trauma,Atrumatic extraction by periotome with blade attachments was held in modified pen grasp and inserted at 20 degrees to the long axis of tooth into the gingival sulcus.
  - It was used to sever the cervical gingival attachment fibres first and then proceed several millimetres into periodontal ligament space and inclined first mesially and then distally tangential to root surface.
  - The instrument was gradually advanced into the PDL space repeating the same motion until two-thirds of the distance towards the apex of root was reached.
  - Tooth was extracted using extraction forceps exerting rotational force in a coronal direction.
  - After extraction, preparation of bone graft by mixing bone particles put on sterilized glass slap with normal saline .
  - In the Study group, Insertion of bihybrid composite bone grafting material into the socket using dental condenser was performed then covering the graft with absorbable gelatin sponge(Mascia Brunelli S.p.A,Italy) and placement of figure of eight polypropylene 3/0 suture (ghatwary medical GMS, Egypt).
  - In The control group, extraction of the tooth followed by the same steps performed in study group but without bone graft insersion. **(Figure 2)**

Figure (2): Clinical phases of socket preservation A) nonrestorable upper maxillary first premolar and maxillary left lateral incisor, B) lateral incisor, C) first premolar, D) sockets immediately after extraction, E)Smart bone graft inserted in lateral incisor socket, F)gelatin sponge covering the both sockets, G)suturing of both the sockets with polypropylene 3/0 suture.

Post-surgical phase

- Post-surgical medication: included the prescription of antibiotics-clindamycin (Dalacinc, pfizer, Egypt) 300 mg each twelve hours for 4 days, and non-steroidal anti-inflammatory drug Diclofenac-potassium (Cataflam, novartis, Egypt), 50 mg tablets every 8 hours for 5 days for all patients.
- Post-surgical instructions:
- Avoid mouthwash or gargle.
- Avoid hot food and drink.
- Apply cold fomentation to reduce anticipated postoperative swelling and pain in the first twenty four hours
- Warm mouthwash starting from following day, & oral hygiene instructions.

Radiographic evaluation

Follow-up phase

Clinical evaluation

Clinical evaluation for any sign of failure ,infection and for good healing was done by intra oral and extra oral inspection of all patients in both the groups , daily for the first week, and monthly during the first six months for any signs of complications.

Healing was assessed by the uninterrupted (adequate & proper) closure of the socket visually.

Radiographic evaluation

Cone Beam Computed Tomography (CBCT) was performed immediately after operation and after six months for the both groups.

Assessment of both vertical and horizontal dimensional changes of alveolar bone as well as and density of the newly-formed bone was performed in sagittal cut.

- Socket height measured from socket from socket crest to its apex while socket width measured from labial or bucall bone crest to palatal crest.
- Bone density measured using CBCT radiographs immediately after extraction and 6 months later,and a 12*12 mm² region of measurement used to assess the density in different points (Point A at the socket crest , Point B at the middle of the socket , Point C at the apex).**(Figure 3,4)**

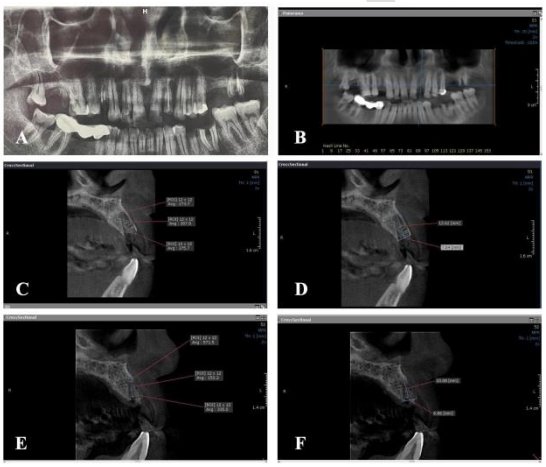

Figure (3): For the study group: A) Pre-operative panorama, B) postoperative panoramic evaluation, C) postoperative measurement of bone density, D) postoperative height and width of bone before grafting, E) bone density measurements after 6 months follow up, F) height and width of bone after 6 months follow up.

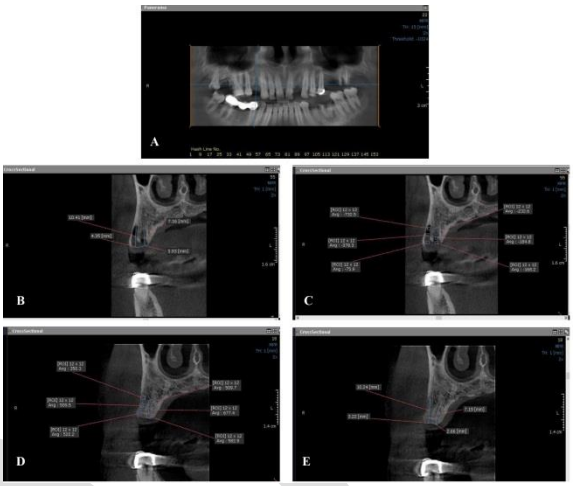

Figure (4): For the control group A) postoperative panoramic evaluation) postoperative measurements of height and width of bone, C) measurement of bone density immediately after extraction, D) bone density after 6 months evaluation, E) bone height and width after 6 months evaluation.

Statistical analysis

Statistical analysis of data

Data had been fed into computer & analysed with IBM SPSS software package version 20.0. IBM Corporation, Armonk, New York. Smirnov test had been used to confirm normality of distribution. Range, mean, standard deviation, & median had been used to define quantitative data. Significance of obtained outcomes was determined at five percent level.

Used tests were

1 - Student t-test

For generally distributed quantitative variables, to compare among 2 studied groups.

2 - Paired t-test

For normally distributed quantitative variables, to compare among 2durations.

RESULTS

A total of twenty patients (6 males, 14 females; average age of 38 years, range 24 to 62) was enrolled in this randomized controlled clinical trial and the follow up time was six months.no swelling, nor infection were recorded.

All extraction sockets were healed and the patients were visited daily for the first week, and monthly during the first six months for any signs of complications.

No patients experienced during the follow up period. In all cases no signs failures during the follow up period were observed.

Cone Beam Computed Tomography taken directly after extraction showed sound socket walls and good bone graft condensation, and another CBCT performed after six months suggested good healing of the sockets and remodeling of alveolar bone.

Analysis of outcomes revealed significant differences in dimensional changes and density of bone between ridge preservation with Smart bone graft and without this grafting material after six months of healing. For study group, the mean of decrease in bone width was 0.94 ± 0.40 while in control group was 3.25 ± 0.42. Also, the mean of the decrease in bone height was 1.10 ± 0.47 in the study group while it is 2.90 ± 1.22 in control group.

At the same time, there was remarkable change in bone density among the two groups. In study group, the mean of change in density was 230.8 ± 156.4 of increase for point A, 83.80 ± 134.1 for point B and 295.9 ± 37.59 for point C. while in control group, there was a huge increase the change of bone density, especially in point B and C which were 594.4 ± 173.9 and 710.4 ± 131.6 respectively, and 272.8 ± 76.20 in point A. **(Table 1, Figure 5,6)**

Table (1): Comparison between the two studied groups according to change of different parameters

	Control (n = 10)	Study (n = 10)	t	p
Decrease of socket width (mm)				
Min. – Max.	2.70 – 3.96	0.18 – 1.34		
Mean ± SD.	3.25 ± 0.42	0.94 ± 0.40	12.598*	<0.001*
Median	3.21	1.03		
Decrease of socket length (mm)				
Min. – Max.	-0.40 – 4.03	0.45 – 1.82		
Mean ± SD.	2.90 ± 1.22	1.10 ± 0.47	4.333*	<0.001*
Median	3.16	1.15		
Increase of point A				
Min. – Max.	195.9 – 414.0	-40.7 – 430.8		
Mean ± SD.	272.8 ± 76.20	230.8 ± 156.4	0.764	0.455
Median	232.5	253.0		
Increase of point B				
Min. – Max.	258.0 – 921.0	-234.6 – 231.6		
Mean ± SD.	594.4 ± 173.9	83.80 ± 134.1	7.353*	<0.001*
Median	569.0	94.50		
Increase of point C				
Min. – Max.	530.0 – 915.0	208.0 – 345.0		
Mean ± SD.	710.4 ± 131.6	295.9 ± 37.59	9.576*	<0.001*
Median	681.5	298.4		

SD: **Standard deviation t: Student t-test**

p: p value for comparing between the studied groups

*: Statistically significant at $p \leq 0.05$

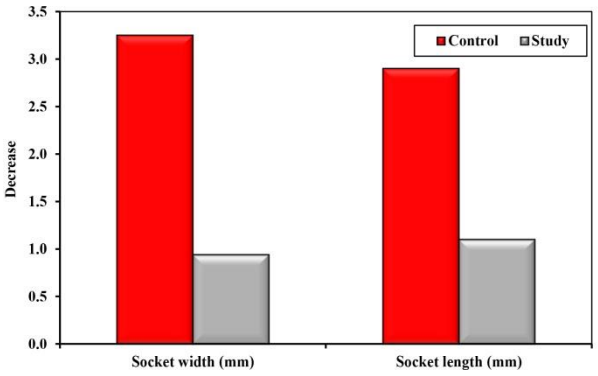

Figure (5): Comparing the difference between the two groups regarding the decrease in socket width and height after six months.

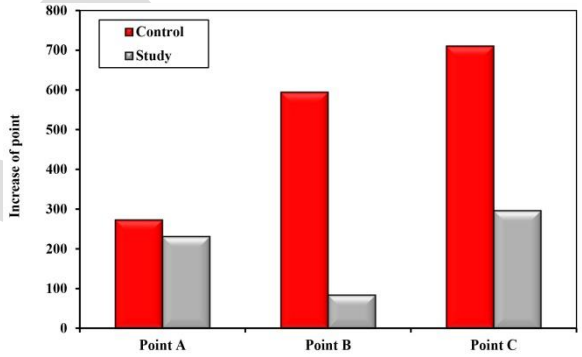

Figure (6): The difference between the two groups regarding the increase of bone density in point A,B and C after six months

DISCUSSION

Socket preservation has proven to show high level success in minimizing bone loss that naturally takes place following tooth extraction when compared to negative controls. For this reason, the procedure was employed in this research to clinically & radiographical assess performance of SmartBone®, a novel heterologous bone substitute enriched with collagen and biopolymers. The procedure provided better ridge dimensions for implant placement or prosthetic rehabilitation & decreased necessary for bone grafting or augmentation in future (11).

In this study, various methods for selecting cases were used. Smokers were excluded because smoking has unfavourable impacts on bone healing. It not only impairs host cell function & alters inflammatory response, however it decreases blood supply, resulting in decreased tissue perfusion & ischemia, which in turn impairs healing processes after tooth extraction. Smoking can rise post-extraction bone crest loss by 0.5 mm in clinical trials. To avoid teratogenic impact of great radiation exposure during CBCT scans, pregnant women were excluded (12).

From clinical point of view, in all grafted sockets, the healing occurred with no complications and soft and hard tissues after passing six months showen to

be more than satisfactory. Findings of Healthy Soft tissues and free of swelling or infection are interesting because the follow up time was only six months, shorter than many other research in the literature done using other biomaterials (13). Moreover, it should be noted that a second intention healing with a resorbable collagen membrane exposed did not in lead to infection, mucosal inflammation or to unsatisfactory healing.

Cone Beam Computed Tomography is highly accurate & valuable tool in dentistry; the ability to produce a three-dimensional image as well as obtaining linear measurements in axial, coronal or sagittal views has been utilized in the maxillofacial region for various purposes. CBCT is embraced due to the fact that it requires much less radiation dose compared to serial conventional tomography cuts and at the same time, provides better resolution and less distortion. CBCT was chosen to measure the primary outcome as it has shown its accuracy and reproducibility as voxel size accurately corresponds to the scanned physical dimensions (14).

The radiographic density was included as the primary outcome as it can indirectly be correlated to anatomical and histological bone quality which is advantageous for successful dental implant (15).

Some researches compared socket preservation with biomaterials versus clots after extraction & concluded that in all cases, using socket preservation with bone grafts resulted in better crest width maintenance than healing socket with blood clots (16).

Same result had been evident in this research, where we got variations among research group and control group in the important parameters for evaluation of socket after extraction with or without bone graft; that is, height, width of socket & middle & cervical thirds-crucial regions beside the density of bone in the extraction site.

Analysis of outcomes revealed high significant differences in median of dimensional changes and density of bone between ridge preservation with Smart bone graft and without this grafting material after six months of healing. For study group, the median of decrease in bone width was 1.03 while in control group was 3.21. Also, the median of the decrease in bone height was 1.15 in the study group while it is 3.16 in control group.

At the same time, there was remarkable change in bone density among the two groups. In study group, the change in density was 253.0 for point A, 94.50 for point B and 298.4 for pint C. while in control group, there was a huge increase the change of bone density, especially in point B and C which were 569.0 and 681.5 respectively, and 232.5 in point A.

For graft materials used in the oral cavity, there is a plethora of literature providing evidence concerning the use of allografts, xenografts or alloplasts; each with its own benefits and limitations. Some authors proposed filling alveolus with only clot, followed by coating with smart bone graft membrane to restore alveolar ridge/bone architecture & promote bone formation.4 months after surgery, bone regeneration & alveolar architecture maintenance were noted, allowing for placement of dental implant (17).

Januário et al. Cone beam computed tomography was used to measure thickness of facial bone wall in anterior maxillary region & discovered that after dental extraction in anterior region, alveolar buccal bone will be resorbed, particularly in more coronal site (18).

Various researches have shown that ridge resorption will continue even with immediate implant placement. Numerous socket preservation methods are defined for decreasing bone volume loss at extracted site while maintaining soft tissue dimensions. For socket preservation methods, various biomaterials like autogenous grafts, allografts, & xenografts had been used (19).

As it is previously clearly found that if nothing is prepared at time of tooth extraction, studied case would be subject to average absorption of fifty percent of socket volume. Therefore, we chose to use natural clotting, however covered alveoli with bihybrid composite bone graft, advantages of which are well documented, when used appropriately in socket preservation processes (20).

Fotek et al (21) performed histomorphometric analysis to show more vital bone on smart bone grafted group than on AlloDerm group, nonetheless without statistical significance. **Ronda et al** (22), found no change among quality of newly bone formed under either dense & expanded graft material for guided bone regeneration. However **Iasella et al**, total amount of vital bone in group left to heal with only blood clots was greater than in group with allograft, despite fact that this group had better result on volume after ridge preservation (23).

These results may be described by existence of bone substitute, which remains in area for longer period of time until resorption & incorporation, whichever occurs. However, only natural new bone is expected to form at sites where there is only blood clot, albeit with smaller volume because of contraction. Same is expected of research, despite fact that histomorphometric analysis was not result.

As limitation of our research, we chose to contain teeth with different root anatomies, ranging from lateral incisors to second premolars, for testing viability of biomaterials in all typical situations; however, it is uncommon to use different materials based on tooth position in mouth or arch. As result, we did not differentiate among outcomes of mandible & maxillae, despite fact that they have different patternsof resorption, which can have resulted in bias in outcomes.

CONCLUSION

Within limitations of this research, we concluded that use of the tested biomaterial (bihybrid

composite bone graft) was effective in preserving alveolar bone socket height and width. In addition, better bone density were found in grafted sockets when compared to those left without graft.

We recommend additional researches with longer follow-ups to verify stability of these findings.

CONFLICT OF INTEREST

Authors announce that they have no conflicts of interest.

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