THE EFFECT OF BIOSCAFFOLD ALVELAC[™] IN PRESERVATION OF ALVEOLAR BONE AFTER EXTRACTION OF TEETH (CLINICAL AND RADIOGRAPHIC STUDY)

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ABSTRACT

Introduction: After tooth extraction, the extraction socket heals by forming a blood clot which leads to the formation of new bone within 3-4 months. Although bone deposition in the socket will continue for several months, it will not reach the crestal level of the neighboring teeth. **Objective**: Is to clinically and radiographically evaluate the use of Bioscaffold AlvelacTM in preservation of dimensional measure of alveolar bone

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Materials and methods: This study was conducted on twelve patients divided in to two equal groups (study group and control group). Indicated for extraction of anterior maxillary teeth, in the study group, the bioscaffold $Alvelac^{TM}$ was inserted into the empty socket after extraction and was supported by 3-0 silk with figure of eight sutures. In the control group, extraction of upper anterior teeth was done without introducing any material and the wound was sutured.

Results: There was a statistically significant decrease of alveolar bone width and height in both groups at three months postoperative interval compared with the bone width and height at the immediate postoperative period.

Conclusion: Immediate tooth extraction stabilizes the bioscaffold AlvelacTM material in the socket and allows it to act as a scaffold for bone deposition. From this study, it is clear that, this material allows preservation of the dimensional measure of the alveolar bone.

Key Words: Tooth extraction, Alveolar bone, socket preservation, Scaffold, Alvelac™.

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INTRODUCTION

After loss of natural teeth, bony changes in the jaws begin to take place immediately. Since the alveolar bone no longer responds to stresses applied in this area, it begins to resorb (1).

Resorption of the alveolar ridge following extraction of hopeless teeth is recorded even when the missing teeth is immediately restored (2).

The alveolar ridge beneath the artificial teeth decreases in height and width due to lack of the stimulating effect of the teeth roots. A gap is created by time beneath the prosthesis and the ridge leading to food impaction, mucosal inflammation, and bad esthetics especially in the anterior region (3).

The remodeling process results in a ridge morphology reduced in vertical height and more palatal in relation to the original tooth position (4, 5).

Alveolar bone is a specialized part of the mandibular and maxillary bone that forms the primary support for the teeth. Alveolar bone is composed of bundles of bone which are built up into layers in parallel orientation to the coronal -apical direction of the tooth (6, 7). The bone loss is estimated to be 40%-60% during the first 3 years and decrease to 0.25%-0.5% annual loss (8, 9).

Immediately after tooth extraction, the alveolar socket is filled by blood clot that is replaced by granulation tissue within 1 week (10). The bio-scaffold is made of PLGA (Polylactic-coglycolic acid) material and acts as a mechanical support to hold the blood clot at the crest level (11).

After tooth extraction, the bundle bone appears to be the first bone to be resorbed (12-14).

PLGA also has the advantage of being capable of delivering drugs, proteins and growth factors to enhance bone healing in both oral-maxillofacial and general orthopedic applications (15-18).

Brown et al (2014) (19) found in his study that sixty percent of implant-supported dental prostheses require bone grafting to enhance bone quantity and quality prior to implant placement. They have developed a metallic magnesium particle/PLGA (Mg/PLGA) composite scaffold to overcome the limitations of currently used dental bone grafting materials. These scaffolds could decrease inflammation observed with clinically used PLGA devices. These characteristics not only increase cell proliferation in vitro, but provide a safe and osteoconductive environment for bone regeneration in vivo. These findings show promising results for the use of Mg/PLGA composite materials for a wide range of bone regeneration applications.

The aim of this study was to evaluate clinically and radiographically the use of Bioscaffold AlvelacTM in preservation of dimensional measure of alveolar bone after extraction of teeth.

MATERIALS AND METHODS

Alvelac[™] (International Pte Ltd 61 Science Park Road, #02-05/06, The Galen, Singapore Science Park II, Singapore 117525) is a porous, osteoconductive, biocompatible and biodegradable synthetic scaffold that is synthesized from polylactic-co-glycolic acid (PLGA) and polyvinyl alcohol and produced using proprietary and patented technology.

It is a rigid structure specifically designed to prevent collapse of the buccal and lingual walls in achieving width maintenance. It is strategically placed in the extraction socket with the top of the scaffold in line with the crest of the socket in order to raise the forming blood clot to that level thus achieving height maintenance. The size of Alvelac[™] does not occupy the whole socket thus allowing maximum space for blood to fill the socket. This allows for the patient's own bone to form naturally within that space by the action of Alvelac[™] as scaffold (20). **Selection of patients:**

Twelve patients, indicated for extraction of maxillary teeth were selected from those attending the outpatient clinic of Oral and Maxillofacial Surgery department, Faculty of Dentistry, Alexandria University.

Inclusion criteria of selection:

- Patients' age ranged between (25 45) years old of both sexes.
- All patients selected were free from any relevant diseases.

- Indicated for extraction of maxillary teeth. Exclusion criteria of selection:

- Heavy smokers.
- Bone disease (as osteoporosis).
- Uncontrolled diabetes.

Patients were divided into two equal groups; the study group, where the maxillary teeth were extracted and the bioscaffold AlvelacTM was inserted into the empty socket after extraction and was supported by 3-0 silk with a figure of eight sutures. (Fig. 1) Whereas in the control group the extraction of teeth was done without introducing any material and the wound was closed and supported by 3-0 silk with a figure of eight sutures.



Fig (1): Showing insertion of the bioscaffold alvelac into

empty socket.

A) Surgical phase: Local anesthesia (Each carpule contains 1.8 ml mepivacaine HCL 2% produced by: Alexandria Co. for pharmaceuticals, Alexandria, Egypt). Extraction of teeth was performed using maxillary forceps.

B) Clinical follow up: All patients in the two groups were examined clinically for infection and healing. Healing was assessed by the uninterrupted (adequate & proper) closure of the socket visually, which was done at intervals of one week, and three months after extraction.

C) Radiographic follow up: All patients in the two groups were examined radiographically immediately postoperative to serve as a baseline for measurement and after 3 months of the extraction.

The radiographic examination was done by cone beam CT (CBCT). Bone height, bone width and bone density were measured using cone beam CT (CBCT) software (On Demand 3DAPP-DBM)

RESULTS:

Twelve patients were divided equally into two groups, group I (control group) and group II (study group). Group I included 4 females (66.7%) and 2 males (33.3%). While group II included 5 females (83.3%) and 1 male (16.7%). For group I the age ranged from 25 to 40 years with mean of (32.17 \pm 5.71 years). While in group II, the age ranged from 25 to 45 years with mean of (30.83 \pm 7.22 years).

Clinical Results:

1. Infection: Infection was observed by inspection, all cases in both group I and group II showed that there were no signs of infection throughout the postoperative follow up period.

2. Healing: Normal colour of the oral mucosa and adequate closure of the extraction socket were achieved in patients of both groups. (Fig. 2)



Fig (2): Showing figure of eight suture (study case).

Radiographic results:

1. Alveolar bone width (Table 1). There was a statistically significant decrease of alveolar bone width in both groups at three months postoperative compared with the bone width at the immediate postoperative period. (Fig. 3-6)

The percentage of change in alveolar bone width in group I was 18.87% while in group II it was 1.04% There was a statistically significant difference between the two groups (t=8.292, p=<0.001). 2. Vertical bone height (Table 2). There was a statistically significant decrease of alveolar bone height in both groups at three months postoperative compared with the bone height at the immediate postoperative period. (Fig. 3-6)

The percentage of change in alveolar bone height in group I was 3.68% while in group II it was 0.44%. There was significant difference between the 2 groups (t= 5.968, p= <0.001).

Horizontal (width)	Control (n = 6)	Study (n = 6)	t ₁	p 1
Immediately after				
Min. – Max. Mean ± SD. Median	4.10 - 7.83 5.70 ± 1.39 5.74	6.65 - 10.65 8.34 ± 1.35 8.32	3.332*	0.008*
After 3 months				
Min. – Max. Mean ± SD. Median	3.13 - 6.68 4.69 ± 1.28 4.88	6.65 - 10.50 8.21 ± 1.29 8.22	4.746*	0.001*
Change after 3 months	1.01 ± 0.27	0.13 ± 0.14	7.012*	< 0.001*

 Table (1):
 Comparison between the two groups according to horizontal bone (width) using cone beam CT.

t: Student t-test

p1: p value for student t-test for comparing between the two groups

* significance at ≤ 0.05



Fig (3): Showing immediate CBCT sagittal view showing alveolar bone width and alveolar bone height (control

case).

3. Bone density (Table 3). There was no significant difference in bone density between group I and group II at three months postoperative.

The percentage of change in bone density for the control group was 14.87 %, while for study group was 22.94 % with no statistically significant difference. There was a higher percentage of change in bone density in group II (study group) than in group I (control group).



Fig (4): Showing post-operative (three months) CBCT sagittal view showing alveolar bone width and alveolar bone height (control case).



Fig (5): Showing immediate CBCT sagittal view showing alveolar bone width and alveolar bone height (study case).



Vertical (height)	Control (n = 6)	Study (n = 6)	t1	p1
Immediate after extraction Min. – Max. Mean ± SD. Median	15.40 - 22.38 19.96 ± 2.61 20.38	5.72 - 20.46 15.78 ± 5.49 18.15	1.685	0.123
After 3 months Min. – Max. Mean ± SD. Median	14.80 - 21.71 19.23 ± 2.57 19.65	5.55 - 20.39 15.70 ± 5.53 18.05	1.416	0.187
Change after 3 months	0.74 ± 0.10	0.08 ± 0.06	13.971*	< 0.001*

Fig (6): Showing post-operative (three months) CBCT sagittal view showing alveolar bone width and alveolar bone height (study case).

Table (2): Comparison between the two groups according to

vertical bone (height) using cone beam CT.

t: Student t-test

p1: p value for student t-test for comparing between the two groups

Bone density	Control (n = 6)	Study (n = 6)	t ₁	p 1
Immediate after extraction				
Min. – Max. Mean ± SD. Median	210.58 - 513.26 308.58 ± 111.32 297.63	312.55 - 645.79 397.79 ± 127.60 356.16	1.291	0.226
After 3 months Min. – Max. Mean ± SD. Median	213.75 - 646.22 367.06 ± 174.91 306.69	325.22 - 821.79 547.78 ± 213.54 515.35	1.604	0.140
Change after 3 months	-58.48 ± 94.29	-149.99 ± 130.10	1.395	0.193

 Table (3): Comparison between the two groups according to bone density using cone beam CT.

 t:Student t-test

p1: p value for student t-test for comparing between the two groups

DISCUSSION

The rationale for alveolar ridge preservation relies on the knowledge that the alveolar ridge resorption is an unavoidable sequelae of tooth loss (21). Its goal is to prevent the loss of 40% - 60% of ridge height and width commonly seen after extractions (8).

Preservation of socket is driven by the desire to minimize the need for future more invasive ridge augmentation procedures. Moreover, it also facilitates successful implant and conventional prosthetic treatment. Extraction site grafting often facilitates the best possible functional and aesthetic results. It is axiomatic therefore that socket preservation should be the treatment of choice to prepare the remaining alveolar ridge for conventional or fixture supported restorations (22, 23).

Several studies have evaluated the effect of PLGA with different grafting materials (24). Defects that were treated with Mg/ PLGA scaffolds had an improved bone height preservation compared with empty defects at both 8 and 16 weeks post-surgery. This effect compares well with other bone-grafting materials (including polymers) that have been successfully used for socket preservation (24, 25).

According to Fan (26), a bio-scaffold, placed immediately after tooth extraction, helps and allows for bone to grow into it and prevents the socket from collapsing. The results of the present study are in accordance with Fan's results regarding an increase in the bone density and protection of the height and width of the alveolar bone.

A similar osteoconductive scaffold, OsteoScaf, was used by Araujo et al (27). The results obtained from CBCT measurements have clearly shown that OsteoScaf protection impaired the expected bone lost during the post extraction remodeling of the alveolar bone ridge at 120 days post extraction .This result is also in agreement with the results of the current study.

In a study by Serino et al (28), the use of a bioabsorbable synthetic sponge of polylactide– polyglycolide acid was evaluated. The results of this study indicate that alveolar bone resorption following tooth extraction may be prevented or reduced by the use of a bioabsorbable synthetic sponge of polylactide– polyglycolide acid. The quality of bone formed seemed to be optimal for dental implant insertion. The material is similar in content to Bioscaffold AlvelacTM used in the present study.

CONCLUSIONS

Within the context of this study, the following conclusions can be listed:

• Immediate tooth extraction stabilizes the bioscaffold Alvelac[™] material in the socket and allows it to act as a scaffold for bone deposition.

• It is clear that this material allows preservation of the dimensional measure of alveolar bone.

Healing seems to be more proper in the study cases.

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