Alveolar Ridge Preservation Utilizing Composite (Bioceramics/Collagen) Graft: A Cone-Beam Computed Tomography Assessment in a Randomized Split-Mouth Controlled Trial

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ABSTRACT

Background: The vast percentage of the alveolar bone resorption process happens within the first 12 to 24 weeks post extraction; however, this phenomenon is chronic, and the alveolar ridge continues to resorb. In order to prevent this reduction or at least recompense the loss of bone dimensions, the alveolar ridge preservation (ARP) technique was developed. Objectives: This research studied the vertical and horizontal bone dimensional changes as a result of non-molar teeth extraction alone against extraction with alveolar ridge preservation utilizing composite (bioceramics/collagen) graft by cone-beam computed tomography radiographies analyses. Material and Methods: This research was a randomized split-mouth controlled trial. 12 patients need extraction of the maxillary non-molar teeth were enrolled and allocated into 2 groups. 12 sockets after atraumatic extraction were filled with a composite graft in the role of the test group, 12 sockets left to unassisted healing after atraumatic extraction without any graft materials in the role of the control group. Two CBCT radiographs were taken at baseline and at 4 months after extraction for comparison. Both vertical and horizontal resorptions of the alveolar ridge were analyzed between test and control group by CBCT radiographs. Results: 4 months after extraction, there was a mean of vertical alveolar bone resorption compared with the baseline (0.56 ± 0.15 mm) in the test group and (1.47 ± 0.30 mm) in the control group. Whereas it was a mean of horizontal alveolar bone resorption compared with the baseline (0.90 ± 0.16 mm) in the test group and (2.26 ± 0.30 mm) in the control group. Therefore, there was a significant difference between the two groups.
Within the limitations of this research, we demonstrated that the osteogen-plug technique significantly decreased the reduction of the bone dimensional in comparison to the tooth extraction alone, and showed that the dimensional change of the alveolar ridge after tooth extraction was minimized by using an osteogen-plug.

1. INTRODUCTION

Tooth extraction is indicated when tooth can’t restore or treatment will not serve the patient for a long period of time [1]. Also, tooth extraction usually releases many biological processes that cause resorption of the alveolar bone and a change in its dimensions [2]. Hence the necessity to maintain the alveolar ridge vertically and horizontally to obtain cosmetic results around fixed prostheses, and to facilitate the dental implant process and improve its results, especially in the aesthetic areas of the jaws. Therefore the idea of this research came to evaluate the technique of osteogen plug in preserving the alveolar ridge after extraction. Alveolar resorption after tooth extraction is described as irreversible, increases with time and continues for long periods and reducing the size of the alveolar in the vertical and horizontal dimensions [3]. Research has found that the resorption of the alveolar following extraction is greater in the lower jaw and thin buccal plates of both jaws. Thicker alveolar plate will increase resorption [4]. The largest proportion of alveolar resorption usually occurs within 3 - 6 months after extraction with continued resorption slower for up to 25 years [5]. In order to stop the alveolar resorption following the extraction or at least reduce it, what has been agreed upon is called the alveolar ridge preservation (ARP) techniques [6, 7]. ARP techniques have become an important practice in dental clinics to preparing for dental implants and even obtaining more aesthetic dental prostheses [8, 9]. The techniques for preserving the alveolar after extraction varied greatly, ranging from atraumatic extraction to the use of bone grafts, membranes, guided bone regeneration (GBR) techniques and alveolar seal techniques [10-13]. The principle that maintains the alveolar bone is to prevent the soft tissues from collapse into the socket of the extraction and the contribution of the materials used to induce the formation of new bone and thus reduce bone resorption or even increase the size of alveolar in some cases. For best outcomes, all bone grafts used must have a good blood perfusion, mechanical fixation and contain cells that are born or induced bone formation [14]. Graft materials must be some osteogenic, osteoconductive, or osteoinductive properties. Osteogen Plug is one of the industrial materials that have been used as one of the ARP techniques. The graft component is OsteoGen, a bioactive, non-ceramic calcium phosphate-based bone graft that is similar to human bone minerals and it helps to control migration of connective tissue. The OsteoGen® Bone Grafting Plug will be radiolucent on the X-ray at the time of application of the place of dental extraction and then turn to radiopaque on the X-ray within 3 - 5 months as a result of replacing them with bone and thus be ready for the dental implant procedure [15].

2. MATERIALS AND METHODS

This research was a randomized clinical study with split mouth technique. And it was done from June 2018 to February 2019 at the clinic of Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, University of Damascus Damascus, Syria.

12 patients (10 males, 2 females) requiring extraction of 24 non-molar maxillary teeth were included in this research (Table 1). The study teeth included 18 First premolars and 6 second premolars. The mean patient age was 30 years (Table 2). The reason for extraction was non-restorable tooth. The patients were given written information about the research, and their informed approval was obtained.

2.1. Inclusion Criteria

- Ages of patients from 18 to 45 years old.
- A non-molar maxillary tooth requiring extraction in each side with intact adjacent teeth.
- Remaining extraction sockets with intact wall.
Table 1. Gender information of the enrolled patients.

| Parameters | Male | Female | Total |
|------------|------|--------|-------|
| Frequency  | 10   | 2      | 12    |
| Percentage | 83.3%| 16.7%  | 100.0%|

Table 2. Age information of the enrolled patients.

| Parameters | Number | Mean   | Standard deviation |
|------------|--------|--------|--------------------|
| Age (yr)   | 12     | 30.17  | 5.98               |

2.2. Exclusion Criteria
- Untreated or uncontrolled periodontal disease.
- The presence of general diseases is a contraindication to oral surgery or local anesthesia.
- Allergy to a component of the bone graft used.
- Smoking patients.
- Lactation or pregnancy.

Sockets were randomized in a 1:1 ratio to either control or test group. Randomization was achieved with a quadric block randomization method with allocation concealed in opaque, sealed envelopes. 12 sockets were grafted with a composite graft as a test group, 12 sockets left to unassisted heal as a control group.

2.3. Surgical Procedure
After local anesthesia (2% lidocaine with 1/80,000 epinephrine), the target teeth were luxated with as little trauma as possible and gently atraumatic extracted with forceps. The atraumatic tooth extraction (ATE) is a comprehensive procedure to remove tooth or tooth root, while maintaining all the surrounding structures like bone, gingiva and other hard soft tissue structures [16]. The teeth were extracted without raising a flap. The flapless technique advantages include buccal keratinized gingiva and gingival contour protection [17]. The inside of the extraction sites was curetted, and soft tissue remnants were carefully removed. The sockets were irrigated with normal sterile saline. The presence of inflamed tissues in the socket of the extraction will lead to bone graft failure as a result of reduced Ph environment [18].

Group 1 (Composite graft; test group)
The sockets were filled with OsteoGen® Plug which combines OsteoGen® graft containing Bioactive Resorbable Calcium Apatite mix with a bovine Achilles tendon collagen and uncovered with membrane. Then the suture is done using the hidden x suture (and the suture needle is inserted from the buccal to the palatal from the mesial to the distal or vice versa, then the knot is made as in the normal x suture with the difference. The entire suture is hidden inside the alveolar socket. Suture in this way helps to hold the graft in place and prevents buccal tissue retract [19].

Group 2 (unassisted healing; control group)
The sockets were left to unassisted heal and It is followed by a hidden x suture.

Patients were asked to use an oral rinse (0.12% Chlorhexidine Gluconate) twice daily, and to receive (Ibuprofen 400) as an analgesic if there is pain. Patients were also asked to visit the clinic a week later to follow up and remove the suture. The patients agreed not to apply any prostheses during the 4-month healing period (Figure 1).

Clinical and radiographic evaluation of the extraction sites were administered by the same surgeon, at baseline (immediately after tooth extraction) and 4 months after the initial procedure for the measure-
ment. All sites healed with none complications. Horizontal and Vertical resorption of the alveolar socket were evaluated 4 months after the extraction within the test and control group using CBCT radiographs (Figure 2).

2.4. Radiographies Analysis

The CBCT radiographs were done with a resolution of 1 mm (scan time of 5.9 seconds, exposure time of 9 seconds, 95 kV, 6 mA; PaX-i3D Green, VATECH, Korea). CBCT scans were performed immediately after applying the bone graft and four months after the alveolar preservation procedure. CBCT X-ray image information has been processed within the radiography analyzer program from the same company. Standardization of the two CBCT images is performed in time (immediately after extraction) and in time (after 4 months) before their study in order to avoid any changes that are caused by changes in the position of the patient’s head during imaging by stabilizing the horizontal and vertical axes of the image in fixed anatomical points (two fixed points in two levels). In the sagittal section the thickness of the section is determined by 0.5 mm, then we fix the horizontal axis of the CBCT image in a line that passes from the cementoenamel junction of the mesial tooth to the distal tooth. To stabilize the horizontal axis of the CBCT image in a line that passes from the mesial pulp canal to the distal pulp canal or roots bifurcation if the lateral tooth is molar (Figure 3). Thus, when the vertical and horizontal axes are placed in the center of the socket, according to these fixed points, the third coronal section will be fixed in the first and second images in the two time periods as in Figure 2.

2.4.1. Measure of the Alveolar Vertical Changes

The change within the alveolar height, on the coronal section, was calculated by measuring the quantity of change in the measured distance from the highest point of the alveolar bone to the reference line (a line that connects the adjacent teeth cementoenamel junction) in three areas (buccal, mid-Alveolar, palatal) within the two images (Figure 4).

The reference line is drawn and the horizontal axis is fixed to this reference line completely in the sagittal section first, and then the transition to the coronal section so the horizontal axis is representative of this same reference line. Next, we draw it and then we measure the vertical distance from the tip of the alveolar to this reference line is in three fixed areas: the tip of the buccal bone, the middle of the alveolar and the tip of the palatal bone. This is all recorded in the patient’s form.

2.4.2. Measure of the Alveolar Horizontal Changes

The maximum width of the alveolar within the buccopalatal direction was measured in the coronal plane in two fixed points according to the same reference line: (at a point 4 mm under the reference line, 6 mm under the reference line) within the two images (Figure 5).

Figure 1. The clinical process from baseline to 4 months after ARP. I: Test group, II: Control group. A: Clinical view before extraction, B: Extraction, C: Osteogen plug applied CII: Empty socket, D: Suture, E: Suture remove, F: 4 months follow up.
Figure 2. CBCT analysis. The horizontal and vertical dimensional changes were measured by comparing the CBCT images taken immediately after the graft (baseline) and after (4 months). I: Control group, II: Test group, A: Immediately after extraction, AII: Osteogen plug applied, B: Empty socket after 4 months, BII: Osteogen plug after 4 months.

Figure 3. Superimpose the two radiographs (two fixed points in two levels). A: a line that passes from the cementoenamel junction of the mesial tooth to the distal tooth. B: a line that passes from the mesial pulp canal to the distal pulp canal or roots bifurcation if the lateral tooth is molar.

Figure 4. An image showing how to measure change in the vertical dimension of the alveolar. 1: reference line, 2: the vertical distance from the tip of the buccal plate to the reference line 3: the vertical distance from the middle of the alveolar to the reference line, 4: the vertical distance from the tip of the palatal plate to the reference line.
Figure 5. An image showing how to measure the change in the horizontal dimension of the alveolar. 1: reference line, 2: the width of the socket at 4 mm under the reference line, 3: the width of the socket at 6 mm under the reference line, 4: distance of the measurement area under the reference line (4 and 6 mm).

The reference line was drawn in the coronal section in the same way as the previous method, then a column was drawn on it in the middle of the alveolar. The maximum buccopalatal width of the alveolar was measured at two points: under 4 mm, and under 6 mm in the two time periods and data was recorded on the patient’s form.

2.5. Statistical Analysis

The sample size was calculated according to (G Power 3.1.7) program, considering that the t-test used is: t-test for independent samples and significance level: 5%, study strength: 80%, and effect size: 1.39 mm after 4 months with maximum standard deviation: 7.68 mm, and then entered the information to the program was processed, so the required sample size was 12 cases per group, meaning that the full sample size is 24 cases. Statistical analysis of the variables of this research (horizontal and vertical changes) was done using a program Statistical Package for the Social Sciences (SPSS) version 20. Homogeneity of pretreatment values between the two groups was assessed using an independent t-test. The paired t-test was used to evaluate bone dimensional changes (vertical and horizontal). An independent t-test was performed to study the significance of the differences in the average amount of change in the width of the maximum socket (in mm) between the extraction group with the application of the osteogen plug and the extraction group without applying the bone graft in the research sample. (The p-value ≤ 0.05 was considered statistically significant).

3. RESULTS

This research evaluated the linear changes in vertical alveolar bone height (buccal, mid alveolar bone and palatal) (Table 3) and alveolar bone width (4 mm and 6 mm under referential line) (Table 4) and the total vertical and horizontal changes in the alveolar ridge (Table 5).

The research showed that the mean for vertical alveolar resorption was −0.56 mm in the test group and −1.47 mm in the control group. The difference between the two groups (0.91 mm) was found to be statistically significant (P < 0.05). The linear changes in alveolar bone width were −0.90 mm in the test group and −2.26 mm in the control group. The difference between the two groups (1.36 mm) was statistically significant (P < 0.05) (Table 6).

4. DISCUSSION

Alveolar resorption usually occurs after tooth extraction in varying degrees, as the decrease within the
height of the alveolar process of the mandible is greater than in the maxilla, and the decrease in the width of the alveolar process is greater in the buccal of both jaws, and the less thick buccal plates are subjected to greater resorption in both jaws [5].

Table 3. Descriptive statistics of the change in alveolar height after 4 months at 3 reference points within the two research groups.

| Parameters | Group  | Num. | Mean  | Standard deviation | Confidence Interval 95% |
|------------|--------|------|-------|-------------------|-------------------------|
|            |        |      | Lower limit | Upper limit |
| CHB        | Control | 12   | −2.14 | 0.50             | −2.46                   |
|            | Test    | 12   | −0.73 | 0.19             | −0.85                   |
| CHM        | Control | 12   | −1.33 | 0.37             | −1.56                   |
|            | Test    | 12   | −0.43 | 0.21             | −0.56                   |
| CHP        | Control | 12   | −0.93 | 0.51             | −1.26                   |
|            | Test    | 12   | −0.53 | 0.18             | −0.64                   |

CHB: change in ridge height at the buccal, CHM: change in ridge height at the mid-Alveolar, CHP: change in ridge height at the palatal.

Table 4. Descriptive statistics of the change in the width of the alveolar ridge with two reference points within the two research groups.

| Parameters | Group  | Num. | Mean  | Standard deviation | Confidence Interval 95% |
|------------|--------|------|-------|-------------------|-------------------------|
|            |        |      | Lower limit | Upper limit |
| CW4        | Control | 12   | −2.70 | 0.39             | −2.95                   |
|            | Test    | 12   | −1.18 | 0.30             | −1.37                   |
| CW6        | Control | 12   | −1.82 | 0.37             | −2.05                   |
|            | Test    | 12   | −0.63 | 0.20             | −0.75                   |

CW4: change in ridge width at a point 4 mm under the reference line, CW6: change in ridge width at a point 6 mm under the reference line.

Table 5. The change in total height and width of the alveolar ridge after 4 months in each of the two research groups.

| Parameters      | Group  | Num. | Mean  | Standard deviation | Confidence Interval 95% |
|-----------------|--------|------|-------|-------------------|-------------------------|
|                 |        |      | Lower limit | Upper limit |
| Vertical changes| Control | 12   | −1.47 | 0.30             | −1.65                   |
|                 | Test    | 12   | −0.56 | 0.15             | −0.65                   |
| Horizontal changes| Control | 12   | −2.26 | 0.30             | −2.45                   |
|                 | Test    | 12   | −0.90 | 0.16             | −1.00                   |
Table 6. T test for independent samples to study the change in the height and width of the alveolar process after 4 months of extraction between the control group and the test group.

| Parameters          | T     | p-value | Mean Difference | Confidence Interval 95% |
|---------------------|-------|---------|-----------------|-------------------------|
|                     |       |         |                 | Lower limit  | Upper limit  |
| Vertical changes    | −9.508| 0.000   | −0.91mm         | −1.11        | −0.71        |
| Horizontal changes  | −13.908| 0.000   | −1.36 mm        | −1.56        | −1.16        |

Preserving the alveolar ridge using bone grafts and absorbing membranes showed an improvement in the dimensions of the alveolar after extraction in both the horizontal and vertical dimensions rather than extraction without using any procedure [20]. Modern studies mostly assess the changes in the alveolar bone after using ARP techniques by taking horizontal and/or vertical measurements and comparing them [21, 22].

Several authors specified a higher horizontal loss of alveolar crest than its vertical component [2, 10, 11, 23], horizontal and vertical bone loss of the maxilla mainly substantiates at first three months after extraction [3].

Evian et al. [24] indicated that in untreated sockets, dense bone formation takes about four months. Bone grafts are utilized effectively in clinical practice to preserve the alveolar. And among the different materials utilized in the bone grafts, the autogenous graft is considered the gold standard, but the autologous grafts are still suffering from many issues, such as high pathogenicity, the possibility of resorption, high cost, limited amount and a secondary defect in the donor place [25].

To avoid these deficiencies, we need efforts to develop an ideal graft.

Here we will show an innovative technique to graft the extraction socket to get results that are expected to be good for preparing dental implants and even improving the performance of fixed compensation. We use OsteoGen Plug, which is a homogeneous mixture of bovine collagen and the bone part (hydroxyapatite absorbent). It is considered a malleable product, easy to use, effective in maintaining the alveolar bone and less complicated to use by a general practitioner.

It was initially presented in cases of preserving the alveolar to prepare for implantation [26], and in addition to that, it had been used with cases of immediate implantation to fill the gap formed between the surface of the implant and the alveolar socket walls [27].

Osteogen plug is one of the compound grafts (hydroxyapatite/collagen), which is used to preserve the socket in one step and without the need to use any membrane for coverage.

In this research, the linear changes in vertical alveolar bone height (buccal, mid alveolar bone and palatal) and alveolar bone width were evaluated (4 mm and 6 mm under referential line). We found that the mean change in vertical bone height was −0.56 mm in the test group and −1.47 mm in the control group. The difference between the two groups (0.91 mm) was found to be statistically significant (P < 0.05). We can explain this result by the role of osteogen-plug in reducing bone resorption. These results agree with Iasella et al. 2003; Aimetti et al. 2009; Barone et al. 2013a; Jung et al. 2013; Cardaropoli et al. 2014 who found the standardized mean difference in vertical mid-buccal bone height was 0.739 mm.

According to this research the linear changes in alveolar bone width were −0.90 mm in the test group and −2.26 mm in the control group. The difference between the two groups (1.36 mm) was found to be statistically significant (P < 0.05). These results agree with Iasella et al. 2003; Aimetti et al. 2009; Barone et al. 2013a; Jung et al. 2013 who found the standardized mean difference in the horizontal bone width was 1.198 mm.

However, this research was not without limits, and we faced some challenges, such as the difficulty of obtaining a tissue biopsy from the preserved alveolar because our research did not include performing dental implants after preserving the socket.

Also, one of the limitations of this research is our inability to assess the survival rate, stability, and
success of dental implants placed within the alveolar grafted with this type of graft. Therefore, we need long-term clinical studies to accurately assess this point.

5. CONCLUSIONS

Within this research, we find that the use of the osteogen plug has reduced the resorption of the alveolar bone in the horizontal and vertical dimensions at 4 months post-extraction significantly compared to the normal healing of alveolar after extraction.

However, it was not able to completely prevent it from occurring and was not able to achieve any increase in the dimensions of the socket.

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The Institutional Review Board and Ethical Committee of Damascus University (Damascus-Syria) No. 1816 approved this research.

CONFLICTS OF INTEREST

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

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