Clinical and Radiographic Evaluation of the Effect of Bovine-derived Hydroxyapatite (Bio-Oss®) and A Synthetic HA/β-TCP (Osteon®) in the Treatment of Class II Furcation Defects in Mandibular Molars

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Received: 2 April 2011; Accepted: 14 September 2011
This article is available from: http://dentistry.tbzmed.ac.ir/jpid
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Abstract

Background and aims. There are some studies comparing bone replacement grafts. The aim of this study was clinical evaluation of the effect of Osteon® (as a new bone material) and Bio-Oss® (Bovine-derived hydroxyapatite) in the treatment of mandibular molar class II furcation defects in humans.

Materials and methods. Eleven patients (10 females and 1 male, age range of 27-59 years ; mean age of 45.5±11.8 years) who had at least 22 mandibular class II buccal or lingual furcation defects were treated either with Osteon (as the case group) or Bio-Oss (as the control group). Each defect was randomly assigned to either the case group or the control group. Clinical parameters and the soft tissue and hard tissue measurements, including plaque index (PI), gingival index (GI), gingival recession of furcation area (GR), pocket depth (PD), clinical attachment level (CAL), horizontal defect depth (HDD), vertical defect depth (VDD) were recorded at baseline and six months after surgery. Data were analyzed using t-test or Wilcoxon's test.

Results. Similar healing results were observed for both treatments. The results showed significant probing depth reduction (case group: 0.77 mm and control group: 0.84 mm) and HDD reduction (case group: 0.51 mm and control group: 0.8 mm) and PI reduction. There was not statistically significant difference between the groups in all soft and hard tissue parameters.

Conclusion. The results of this study showed that the effect of using Osteon as a bone graft material is the same as that of Bio-Oss in the treatment of mandibular class II furcation defects.

Key words: Bio-OSS, furcation defects, Osteon, regeneration.
Introduction

Management of moderate-to-advanced furcation involvements is one of the major challenges in periodontal treatment. Molar teeth with furcation involvement are the most common teeth to be lost and Class II furcations present a common clinical problem, perplexing clinicians for many years. Several non-surgical and surgical therapies have been suggested and attempted to manage the problem. More recently, techniques using bone grafts and/or GTR have been evaluated in regeneration of furcation defects.

In this regard, Bio-Oss® (bovine anorganic natural bone mineral) has been reported to be biocompatible and appears to promote healing of bone defects due to its osteoconductive properties and its ability of remodeling. Osteon® is a new alloplastic bone material that can be mass-produced and no donor site is required. Bio-Oss and Osteon have a similar base of HA with different origins. Osteon consists of 70% HA, coated with 30% ß-TCP. Many studies have indicated that resorption of HA after implantation is too low to achieve optimal results. On the other hand, the resorption rate of ß-TCP ceramics is too fast for bone bonding. To achieve an optimum resorbability of the material, studies have mainly focused on the biphasic calcium phosphate ceramics composed of HA and TCP.

Nevertheless, clinical evaluation of the use of this material to enhance periodontal regeneration, especially in Class II furcation defects, is still necessary before its routine use is accepted. The aim of this study was to compare the clinical data of soft and hard tissue changes in vertical and horizontal defect fills in mandibular molar Class II furcation defects, treated with Bio-Oss® (Geistlich, Wolhusen, Switzerland) or Osteon® (Genoss Co, Korea).

Materials and Methods

Eleven patients (10 females and 1 male, age range of 27-59 years; mean age of 45.5±11.8 years) who had at least two comparable Class II furcation defects in lower molars and had referred to the Department of Periodontics, Tehran Azad University, Dental Branch, were included in this randomized, split-mouth study. The following criteria were considered for selecting the patients:

- **Inclusion Criteria:** furcation defects in mandibular molars with minimum of 4-5 mm of pocket depth and minimum of 3 mm horizontal probing depth
- **Exclusion Criteria:** patients with systemic diseases, pregnancy, lactation, any medications influencing periodontium, allergies to the materials used in the study, molar teeth with pulp involvement or root canal treatment

Informed consent was obtained after explaining the treatment procedures and its two stages.

All the patients received oral hygiene instructions, full-mouth scaling and root planing therapy, and if necessary, occlusal adjustments. After completion of the initial phase of therapy at baseline, all the subjects were required to achieve a minimum of 25% plaque control record (O’Leary Index) prior to the surgical phase of the therapy.

Customized acrylic occlusal stents were fabricated on the study casts (Figure 1). The stents were made prominent in the buccal or lingual areas. One vertical groove was prepared in the stent with a fissure bur in the middle of furcation site to serve as a fixed reference point to take measurement and to reproduce probing site and angulation. Furthermore, in order to standardize and reproduce the geometry of radiographs, two processes were produced in the acrylic stents.

The clinical measurements were obtained by one examiner after calibration of repeatability using a William's probe and digital calipers to the nearest 0.01 mm. The examiner and the patients were not aware of the distribution of the type of treatment. In order to carry out measurement procedures, an endodontic rubber stopper was adapted to the probe and fitted to the margin of the stent.

The following parameters were obtained at baseline and 6 months after surgeries:

- Plaque index (PI) (Silness & Loe)
- Gingival index (GI) (Loe & Silness)
- Gingival recession (GR): from CEJ to gingival margin
- Pocket depth (PD)
- Clinical attachment level (CAL): from the inferior margin of surgical stent to the base of the pocket

Figure 1. Acrylic stent with groove.
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Figure 2. Horizontal defect depth (HDD).

Figure 3. Vertical defect depth (VDD).

- Horizontal defect depth (HDD): horizontal penetration of periodontal probe from furcation entrance which was marked by adjusting the rubber stopper to another probe that was tangent on the buccal or lingual surfaces of the roots (Figure 2)
- Vertical defect depth (VDD): distance from the inferior margin of the stent to the base of the osseous defect (Figure 3)
- In addition, to be sure of seating the stent like the baseline measurements, the distance of the inferior margin of the stent to cementoenamel junction (CEJ) at the test sites was recorded.

The surgeries on the experimental teeth consisted of local anesthesia with lidocaine (1:80000 Epinephrine), intrasulcular incisions, full-thickness flaps and removal of granulation tissues.

The root surfaces were scaled and planed with manual and ultrasonic instruments. A solution of 250 mg of tetracycline in 2 mL of normal saline was used for root surface conditioning for 1 minute (Figure 4).¹⁰

Then the defects were randomly assigned to one of the treatment groups by a flip of a coin: 1: Bio-Oss as the control group; 2: Osteon as the case group.

Bone grafts were mixed with normal saline and placed in the furcation area (Figure 5). The flap was coronally displaced and sutured carefully with silk 4-0 using sling suture technique to ensure that no furcation entrance was left exposed (Figure 6). Amoxicillin 500 mg tid for 1 week and 0.2% chlorhexidine mouthwash twice a day for 7 to 10 days were prescribed. The flap sutures were removed after 7 days.

Figure 4. Root conditioning with tetracycline.

Figure 5. Preparation and placing of biomaterial in furcation defect.
Additional sites (if presented) were treated with the same modality.

Patients returned at 1- and 3-month intervals for plaque control and presence of any adverse tissue reactions. All the parameters were repeated on the same person after 6 months of treatment calibration. Radiographs were taken with paralleling technique before surgery and 6 months post-operatively.

Statistical analysis was carried out to compare the results between baseline and 6-month values in each group and between Osteon and Bio-Oss groups using a statistical software program (SPSS version 12.0). After determining normal and non-normal parameters by one-sample Kolmogorov-Smirnov test, independent sample t-test was used for inter-group comparison of normal parameters and paired sample t-test was used for intra-group analysis. For non-normal parameters Wilcoxon’s signed ranks test was used for intra-group analysis and Mann-Whitney test was used for inter-groups analysis.

**Results**

All the patients showed good compliance and the healing period was uneventful for both treatment groups without infections or complications. Baseline analysis showed no significant differences between the groups for any of the variables assessed.

For all the patients, plaque indexes decreased from baseline to six months post-operatively. However, gingival index decrease was not statistically significant in the control and case groups (Table 1).

Comparison of probing bone level measurements (bone sounding measurements) and bone level measurements (surgical entry measurements) at baseline (Figures 7 and 8) revealed a statistically significant regression between horizontal and vertical depths of furcation defects through bone sounding and through surgical entry with $\beta=0.75$ in the Bio-Oss group and $\beta=0.85$ in the Osteon group in VDD and $\beta=0.65$ in HDD (Table 2).

Changes in soft and hard tissue parameters at six-month interval post-operatively for Bio-oss and Osteon groups are presented in Table 3.

Comparison between the two groups at six-month post-operative interval showed no statistically significant differences (Table 4).

### Table 1. Means of plaque index (PI) and gingival index (GI) values at baseline and 6 months postoperatively in Bio-Oss and Osteon groups

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Baseline</th>
<th>6 Month</th>
<th>Difference</th>
<th>P-value</th>
<th>Baseline</th>
<th>6 Month</th>
<th>Difference</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plaque index</td>
<td>1.18 ± 0.6</td>
<td>0.36 ± 0.5</td>
<td>0.82 ± 0.60</td>
<td>&lt; 0.05</td>
<td>0.91 ± 0.8</td>
<td>0.46 ± 0.5</td>
<td>0.46 ± 0.69</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td>Gingival index</td>
<td>0.64 ± 0.5</td>
<td>0.45 ± 0.52</td>
<td>0.19 ± 0.60</td>
<td>NS</td>
<td>0.64 ± 0.67</td>
<td>0.36 ± 0.5</td>
<td>0.28 ± 0.79</td>
<td>NS</td>
</tr>
</tbody>
</table>

### Table 2. Comparison of bone sounding and bone level measurements at baseline

<table>
<thead>
<tr>
<th></th>
<th>HDD in the control group</th>
<th>VDD in the control group</th>
<th>HDD in the case group</th>
<th>VDD in the case group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bone sounding</td>
<td>4.71 ± 0.96</td>
<td>7.76 ± 1.41</td>
<td>4.59 ± 0.79</td>
<td>8.40 ± 1.38</td>
</tr>
<tr>
<td>Open bone level</td>
<td>5.03 ± 1.08</td>
<td>8.53 ± 1.39</td>
<td>4.90 ± 0.94</td>
<td>8.93 ± 0.98</td>
</tr>
<tr>
<td>Difference of Means</td>
<td>0.32 ± 0.88</td>
<td>0.77 ± 0.98</td>
<td>0.31 ± 0.73</td>
<td>0.53 ± 0.75</td>
</tr>
<tr>
<td>Regression ($\beta$)</td>
<td>0.63</td>
<td>0.75</td>
<td>0.64</td>
<td>0.85</td>
</tr>
</tbody>
</table>

### Table 3. Comparison of soft and hard tissue results of Osteon and Bio-Oss groups at six-month interval postoperatively

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Baseline</th>
<th>6 Month</th>
<th>Difference</th>
<th>P-value</th>
<th>Baseline</th>
<th>6 Month</th>
<th>Difference</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PD</td>
<td>4.26 ± 0.66</td>
<td>3.49 ± 0.58</td>
<td>0.77 ± 0.75</td>
<td>&lt; 0.001</td>
<td>4.31 ± 0.93</td>
<td>3.47 ± 0.69</td>
<td>0.85 ± 0.43</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>CAL</td>
<td>7.73 ± 1.32</td>
<td>7.49 ± 1.18</td>
<td>0.24 ± 0.72</td>
<td>NS</td>
<td>7.30 ± 1.37</td>
<td>7.19 ± 1.23</td>
<td>0.11 ± 0.64</td>
<td>NS</td>
</tr>
<tr>
<td>GR</td>
<td>1.27 ± 1.42</td>
<td>1.18 ± 1.40</td>
<td>0.09 ± 0.54</td>
<td>NS</td>
<td>1.55 ± 1.51</td>
<td>1.27 ± 1.10</td>
<td>0.28 ± 0.90</td>
<td>NS</td>
</tr>
<tr>
<td>HDD</td>
<td>4.59 ± 0.79</td>
<td>4.08 ± 0.87</td>
<td>0.51 ± 0.50</td>
<td>&lt; 0.05</td>
<td>4.71 ± 0.96</td>
<td>3.91 ± 1.02</td>
<td>0.8 ± 0.89</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td>VDD</td>
<td>8.40 ± 1.38</td>
<td>8.00 ± 1.36</td>
<td>0.40 ± 0.94</td>
<td>NS</td>
<td>7.76 ± 1.41</td>
<td>7.67 ± 1.43</td>
<td>0.09 ± 1.08</td>
<td>NS</td>
</tr>
</tbody>
</table>
Discussion

The results of the present study showed that applying only Osteon® or Bio-Oss® in the treatment of mandibular molars Class II furcation defects has some positive effects which are limited to pocket depth and HDD reduction. In addition, post-operative assessments in both treatment groups suggested significant reduction in PI, with no significant differences between the groups. This result might be attributed to oral hygiene instruction and good compliance of patients. Changes of gingival recession were not significant in both groups due to the attempt for coronally positioning of flaps and covering the furcation entrance. However, it seems that the unfavorable result of CAL gain was caused by releasing the periodontium and lifting it.

Hard tissue evaluations in horizontal defect fills were significant in both groups, with no significant differences between the two groups, which is consistent with the results reported by Cury et al on the greater improvement in the horizontal component of furcation defect, which can be considered the ideal outcome after regenerative therapy.

In the present study, in the Bio-Oss® group, pocket depth reduction was 0.84 mm and HDD reduction was 0.8 mm, which is consistent with the Bio-Oss® group in a previous study comparing Bio-Oss® and Bio-Oss®/Bio-Guide® but less than that with 2.10 mm of pocket depth reduction and 2.20 mm of HDD reduction. This finding might be attributed to baseline differences between the parameters in the two studies. Furthermore, this is consistent with the results of another study comparing open flap debridement and MBA (mineralized human allograft) and MBA+GTR in which HDD parameter of the bone graft group and GTR + bone graft group showed 1.1 mm of reduction which is better than OFD group results with 0.2 mm. However, the latter was not a split-mouth study.

Similarly, in the Osteon® group, pocket depth reduction was 0.77 mm and HDD reduction was 0.51 mm, which were statistically significant.

On the other hand, in the vertical defect fill, the results of the present study are less favorable than that reported previously. In conclusion, differences in osseous defects type (horizontal vs. vertical) may mediate and alter repair response.

In the present study, there was less post-surgical gingival recession, with no statistically significant differences, which is consistent with the results of Reddy et al, and in contrast with the results of Simonpietri-C et al, who compared GTR+ABB (Bovine-Derived Anorganic Bone) and GTR alone. They showed recession, especially in combination group, which might be attributed to the use of membrane and exposure of it, which can increase microbial retention and consequently may jeopardize the regenerative response. Furthermore, it might help explain the non-significant gain of vertical clinical attachment level and the small loss of bone height for the GTR group. However, the better result in HDD reduction in the study carried out by Simonpietri-C et al, especially in GTR+ABB group, can be attributed to the positive effect of the membrane.

Comparison of the outcome of the present study with those reported by Meyel et al in application of enamel matrix derivative (EMD) or membrane in the treatment of buccal Class II furcation involvements shows a better result in pocket depth reduction. It seems that using only bone grafts is more effective

Table 4. Comparison of treatment results in the case and control groups at six-month post-operative interval

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Case Group</th>
<th>Control Group</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI</td>
<td>0.82 ± 0.60</td>
<td>0.46 ± 0.69</td>
<td>NS</td>
</tr>
<tr>
<td>GI</td>
<td>0.19 ± 0.60</td>
<td>0.28 ± 0.79</td>
<td>NS</td>
</tr>
<tr>
<td>PD</td>
<td>0.77 ± 0.75</td>
<td>0.85 ± 0.43</td>
<td>NS</td>
</tr>
<tr>
<td>CAL</td>
<td>0.24 ± 0.72</td>
<td>0.11 ± 0.64</td>
<td>NS</td>
</tr>
<tr>
<td>GR</td>
<td>0.09 ± 0.54</td>
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than EMD or GTR alone in some parameters.

Although surgical entry is the most accurate method to assess hard tissue changes, it may cause discomfort for the patient and possibly some damage to the regenerated tissue. Therefore, probing bone level measurements have been introduced and found to be reliable to evaluate hard tissue changes.\(^\text{16}\) In the present study, comparison between probing bone level measurements (bone sounding measurements) and open bone level measurements (surgical entry) at baseline showed a statistically significant regression between two measurements with $\beta=0.75$ in the Bio-Oss group and $\beta=0.85$ in the Osteon group in VDD and $\beta=0.65$ in HDD.

Although in the present study both buccal and lingual defects were treated, no differences were observed in PI and GI and also in the location of defects in the first and second molars, which is in contrast with the results of Mardam-Bey et al\(^{17}\) and similar to those of Bowers et al\(^{18}\) and Tsao et al.$^2$

In the present study only three patients were smokers. Their good oral hygiene, however, might have prevented smoking from exerting an effect on the treatment outcome.

Conclusions

In summary, this study demonstrated similar clinical results when treatment with Osteon\(^\text{®}\) was compared with Bio-Oss\(^\text{®}\) in treating mandibular Class II furcation defects. Evaluation of clinical and osseous changes associated with this study indicated that treatment with Osteon\(^\text{®}\) leads to similar regenerative outcomes as treatment by Bio-Oss\(^\text{®}\).

References