Regenerative Surgery of Mandibular Class II Furcation Defects: A Comparison of Two Techniques in a Randomized Clinical Trial with 3D CBCT Measurements at 24 Months

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The aim of the present study was to evaluate, clinically and via CBCT, the long-term efficacy of a bioresorbable polylactic acid membrane combined with deproteinized bovine bone graft (DBBM) and compare it to enamel matrix derivative (EMD) combined with DBBM graft in the treatment of class II furcation defects. Sites were randomly assigned to the test group (Guidor Matrix Barrier + Bio-Oss) or the control group (Emdogain + Bio-Oss). Probing pocket depth (PPD), clinical attachment level (CAL), gingival recession (REC), and keratinized tissue (KT) width were assessed at 12 and 24 months, and radiographic bone gain was investigated at 24 months via CBCT. Both groups showed a significant radiographic bone fill and clinical gain. The combination of Emdogain + Bio-Oss showed better clinical outcomes and less complications, though this difference was not statistically significant. Int J Periodontics Restorative Dent 2023;43:29–37. doi: 10.11607/prd.6364

When periodontitis affects the furcation areas of multirooted teeth, difficulties frequently arise for the clinician concerning treatment and prognosis,1,2 mainly because of the anatomical features and posterior position3 which seriously restrict the access to perform accurate oral hygiene at home,4 professional debridement,5 and maintenance.6,7 Class I furcation defects can be treated successfully through non-surgical therapy,8 while class II furcation defects usually require surgical management through regenerative therapy, which the literature has demonstrated to be effective.9 Particularly, in the treatment of buccal mandibular class II furcation defects, it has been observed that the application of enamel matrix derivative (EMD) results in a considerably greater reduction in horizontal furcation depth and less recession and postoperative complications than standard membrane placement.10–12

The assessment of the therapeutic success is based on the radiographic analysis of bone fill at the furcation level and on the analysis of clinical variables, such as gain in clinical attachment level (CAL), class reduction according to the horizontal13 and vertical14 furcation classifications, and decrease in probing pocket depth (PPD). However, in regenerative furcation therapy, there are some critical issues to consider.

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that could improve success; one of these is blood clot stability in this delicate area. Guidor matrix barrier (Collagen Matrix) presents a special multilayered design that offers better stabilization of the wound site (due to its ability to maintain stability and function for a minimum of 6 weeks), aids in early integration of gingival connective tissue, and effectively impedes epithelial downgrowth.

Another critical issue that influences the evaluation of success is conventional 2D radiographic imaging, which has some limitations because of the inherent overlap of the nearby anatomic structures. CBCT provides 3D volumetric images, offers better diagnostic accuracy in detecting and measuring furcation defects than intraoral radiographs, and is also considerably more objective in highlighting bone level changes that occur following regenerative procedures. Lastly, in literature there are few clinical trials longer than 12 months, and this greatly limits the ability to evaluate the regenerative therapy’s stability over the years.

The present study aimed to evaluate the long-term efficacy of a bioresorbable polylactic acid membrane combined with heterologous bone graft and compare it to EMD combined with heterologous bone graft (which is considered the gold standard technique), in the treatment of class II furcation defects. These evaluations were performed to assess changes in areas of postsurgical newly formed bone before the surgical procedure (T0) and at 12 and 24 months via clinical measurements and intraoral radiographs and via CBCT scans at T0 and 24 months.

**Materials and Methods**

The study protocol was approved by the ethics committee of the University of Milan, and the investigation was conducted in accordance with the 1975 Declaration of Helsinki on experimentation involving human subjects. Patients were selected from the Dental Clinic of the University of Milan and from one private periodontal practice if they met the following inclusion criteria after receiving nonsurgical periodontal therapy: having a full-mouth plaque score (FMPS) and a full-mouth bleeding score (FMBS) ≤ 25%, buccal class II furcation involvement in mandibular molars, and proximal bone levels above the furcation fornx. Patients were excluded from the study if they met any of the following criteria: having a smoking habit, pregnancy or lactation, and any systemic condition (eg, diabetes or hypertension) or drug therapy that could interfere with patient’s health and the successful outcome of periodontal surgery. The desired benefits, surgical techniques, and purposes of the study were explained to the enrolled patients, and patients gave their informed and written consent. Patients were then randomly categorized into two groups using balanced random permuted blocks: the test group was treated by the combination of a polylactic acid barrier (Guidor) and heterologous bone (Bio-Oss, Geistlich) whereas the control group received the combination of EMD (Emdogain, Straumann) and heterologous bone (Bio-Oss).

The objectives of the study were to evaluate the changes from baseline to 12 and 24 months in terms of PPD, CAL, gingival recession (REC), and keratinized tissue (KT) width, together with the radiographic bone gain assessed through CBCT 24 months after the surgical intervention. At T0, both test and control group patients received a full-mouth nonsurgical periodontal treatment to eliminate inflammation at the furcation level and underwent motivation sessions, during which oral hygiene instructions were given to ensure an adequate standard of supragingival plaque control. FMPS and FMBS were obtained at T0, 12 months, and 24 months. Furcation defects were classified according to Hamp et al using a Nabers probe. All measurements were taken with the same pressure-sensitive manual periodontal probe (PCP UNC15, Hu-Friedy) at 0.3 N and by a single examiner (E.L.), who was unaware of the treatment assignment. Moreover, gingival phenotype was classified through the Colorvue Biotype Probe System (Hu-Friedy) as thin, medium, or thick (Fig 1).

Orthogonal intraoral photographs of the buccal side of the tooth of interest and of the adjacent teeth were taken on a 1:1 scale in order to evaluate and compare the soft tissue changes before and after surgery. An intraoral radiograph was taken with an x-ray film holder by a standardized paralleling cone technique to assess the defect anatomy. A localized CBCT scan (GXDP-700, Gendex)
was also performed to measure, on a coronal plane, the area of bone radiolucency at the furcation defect level. The dose product area ranged from 365 to 484 mGy*cm². Measurements were performed using ImageJ (National Institutes of Health) and expressed in pixels. The baseline furcation defect area was compared with the area detected in a new CBCT scan 2 years after treatment (T24). The same T0 and T24 slices were overlapped, using bone and tooth anatomy as reference points. Thus, it was possible to calculate the percentage of radiographic CBCT bone gain.

Surgical Procedures

All surgical procedures were performed by the same clinician (E.L.). Following local anesthesia, a mucoperiosteal access flap (not involving the mesial and distal papillae) was raised on the buccal surface of the alveolar process (Fig 2a), and relieving incisions extending more than 2 mm beyond the mucogingival junction were made. The furcation area was carefully debrided with handheld mini-curettes and an ultrasonic device to remove granulation tissue and visible calculus and to expose the surface of the alveolar process. At this point, the horizontal furcation defect (HFD) was measured from the vestibular alveolar margin to the interradicular septum (using a periodontal probe in buccolingual direction); the vertical furcation defect (VFD) was measured from the furcation roof to the defect base (Figs 2b and 2c). The ratio between HFD and VFD was calculated in order to estimate the conformation of the defect: if HFD/VFD > 1, the defect was more wide than deep; if HFD/VFD < 1, the defect was more deep than wide. Vertical furcation subclassification was established using a periodontal probe according to a modification¹⁴ of the classification proposed by Tarnow and Fletcher.²⁰

At the test group sites (Fig 2), the furcation defect was filled with Bio-Oss and covered with a Guidor resorbable matrix barrier, which was secured to the tooth using the ligature integrated in the membrane. The flap was sutured to achieve tension-free primary closure and was repositioned coronally to reduce the possibility of membrane exposure. In test group cases, soft tissues were also partially reflected on the opposite side of the membrane in order to carefully place the integrated suture subgingivally. EDTA residue was removed by rinsing thoroughly with sterile saline solution. EMD was then applied in contact with the root surfaces and subsequently covered with Bio-Oss (previously hydrated with a physiologic solution) in order to fill the defect. Finally, the flap was replaced coronally and sutured with a classical sling suture.

Systemic antibiotics and analgesics were prescribed after surgery. For biofilm control, patients were instructed to rinse with 0.12% chlorhexidine twice a day for 3 weeks. Brushing and interdental cleaning were suspended to avoid mechanical trauma at the surgical site.

Postsurgical Procedures

After 2 weeks, the sutures were removed. Any membrane exposure was recorded. If so, the exposed part of the membrane was removed with a blade, and chlorhexidine gel was applied until wound closure was achieved. All patients were included
in a maintenance program and received full-mouth professional oral hygiene care at 3, 6, 12, 18, and 24 months postoperative. At 12 and 24 months, clinical measurements of PPD, REC, CAL, and KT were recorded, as well as FMPS and FMBS indices. Intraoral radiographs were repeated at 12 months to make an initial assessment of bone augmentation. Finally, at 24 months, a localized CBCT scan was performed in order to compare it with the baseline scan.

Statistical Analyses

The PPD, CAL, REC, and KT values for each group were reported as mean ± SD. The parameters taken at different time points in each group were compared by performing repeated-measures analysis of variance. The mean changes in the parameters between test and control groups were compared.

Paired t test was used to compare the radiographic (CBCT) bone gain at 24 months between the two groups. Fisher exact test was used to compare gingival phenotype and regenerative success and to compare furcation defect morphology and regenerative success. P < .05 was considered statistically significant.

Results

A total of 15 patients (14 women, 1 man) were recruited and randomly assigned to the test group.
(8 patients) or control group (7 patients). Patient age ranged from 32 to 65 years. All patients reached the expected follow-up of 24 months.

**Clinical Outcomes**

Table 1 reports the clinical outcomes at baseline and at 12 and 24 months. Complete clinical furcation closure was achieved in 13 patients (6 in the test group, 7 in the control group). Partial clinical furcation closure was achieved in 1 patient in the test group. Reduction in the vertical component of the defects was also registered. However, 1 patient (test group) with an initial class II furcation defect displayed unchanged PPD and no furcation closure at the final 24-month examination.

Comparisons of PPD, CAL, REC, and KT from baseline to 12 months and 24 months between the two groups yielded statistically insignificant changes in both groups.

However, there was a statistically significant difference in PPD reduction at 24 months and in CAL gain at 12 months between both groups ($P < .05$). Additionally, there was a statistically significant difference in REC change and KT change at 12 and 24 months between both groups ($P < .05$).

There was no statistically significant association between gingival phenotype and regenerative success ($P = .33$; Table 2). The existence of an association between furcation defect morphology and regenerative success was also assessed, but there was no statistically significant association ($P = 1.0$; Table 3).

The mean percentage of radiographic CBCT bone gain was calculated by overlapping T0 and T24 slices and graphically highlighting the bone defect area changes (Fig 4). Bone gain at T24 was $68.78\% \pm 24.02\%$ for the test group and $67.26\% \pm 31.22\%$ for the control group ($P > .05$). There was no statistically significant difference in radiographic CBCT bone gain between both groups ($P = .47$).

**Discussion**

From the literature, one can identify an important change in the rational use of resorbable membranes. Today, resorbable membranes are used in periodontal regenerative surgery more for blood clot stabilization than for barrier function, as wound stability is one of the most
determining factors in periodontal regeneration success.\textsuperscript{23,24} The main innovation of the Guidor membrane used herein is the long resorption time. In fact, unlike conventional resorbable membranes that resorb in 20 to 30 days, the Guidor matrix barrier is designed to maintain a barrier function for a minimum of 6 weeks. Afterwards, the product resorbs within a predictable span of time and is gradually replaced by periodontal tissue. This results in a greater stability of the wound site and a more stable blood clot, and this could be a key factor in achieving a better regenerative result. Thus, the present study used a polylactic acid membrane with embedded suture (Guidor) in association with Bio-Oss (deproteinized bovine bone, which provided a scaffold material that could hold the space necessary for periodontal regeneration, preventing the collapse of the membrane into the defect) and compared it to the application of Bio-Oss and Emdogain (EMD) in the management of class II furcation defects in mandibular molars. The combination of xenogeneic bone graft and EMD is considered the gold standard technique nowadays, as some clinical studies and systematic reviews have shown a significantly greater reduction in

### Table 1 Clinical Outcomes at T0, 12 Months, and 24 Months

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Test group</th>
<th></th>
<th>Control group</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>T0</td>
<td>12 mo</td>
<td>24 mo</td>
<td>T0</td>
</tr>
<tr>
<td>PPD, mm</td>
<td>5.55 ± 1.13</td>
<td>3.05 ± 1.18</td>
<td>3 ± 1.58</td>
<td>5.67 ± 0.82</td>
</tr>
<tr>
<td>REC, mm</td>
<td>1.67 ± 0.9</td>
<td>1.33 ± 0.75</td>
<td>1.22 ± 0.67</td>
<td>1.25 ± 0.76</td>
</tr>
<tr>
<td>CAL, mm</td>
<td>7.33 ± 1.79</td>
<td>4.39 ± 1.62</td>
<td>4.22 ± 1.92</td>
<td>6.92 ± 0.92</td>
</tr>
<tr>
<td>KTW, mm</td>
<td>3.17 ± 1</td>
<td>3.17 ± 1.46</td>
<td>3.39 ± 1.41</td>
<td>3.25 ± 1.08</td>
</tr>
<tr>
<td>PPD reduction, mm</td>
<td>2.61 ± 1.54</td>
<td>2.67 ± 1.41*</td>
<td>3.25 ± 1.13</td>
<td>3.5 ± 0.55*</td>
</tr>
<tr>
<td>REC change, mm</td>
<td>−0.33 ± 1.12*</td>
<td>−0.44 ± 1.04*</td>
<td>0.5 ± 0.84*</td>
<td>0.25 ± 0.42*</td>
</tr>
<tr>
<td>CAL gain, mm</td>
<td>2.94 ± 2.44*</td>
<td>3.11 ± 2.16</td>
<td>2.75 ± 0.52*</td>
<td>3.25 ± 0.42</td>
</tr>
<tr>
<td>KTW change, mm</td>
<td>0 ± 0.90*</td>
<td>0.22 ± 0.79*</td>
<td>0 ± 1.38*</td>
<td>0.08 ± 1.32*</td>
</tr>
<tr>
<td>CBCT bone gain, %</td>
<td>68.78 ± 24.02</td>
<td>67.26 ± 31.22</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

CAL = clinical attachment level; KTW = keratinized tissue width; PPD = pocket probing depth; REC = gingival recession; T0 = before the surgical procedure.

Values are presented as mean ± SD. There was a statistically significant difference in PPD reduction, CAL gain, and REC and KT change at 12 and 24 months between both groups.

*Statistically significant (P < .05).

### Table 2 Phenotype

<table>
<thead>
<tr>
<th>Success</th>
<th>Very thick–Thick</th>
<th>Medium-Thin</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>10</td>
<td>4</td>
<td>14</td>
</tr>
<tr>
<td>No</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>10</td>
<td>5</td>
<td>15</td>
</tr>
</tbody>
</table>

There was no statistical association between phenotype and regeneration success nor between defect morphology and regeneration success.

### Table 3 Defect Morphology

<table>
<thead>
<tr>
<th>Success</th>
<th>More wide than deep</th>
<th>More deep than wide</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>7</td>
<td>7</td>
<td>14</td>
</tr>
<tr>
<td>No</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>7</td>
<td>8</td>
<td>15</td>
</tr>
</tbody>
</table>

There was no statistical association between phenotype and regeneration success nor between defect morphology and regeneration success.
horizontal furcation depth, less recession, and less postoperative complications after EMD application compared to treatment with resorbable membranes.\textsuperscript{12,25}

One negative aspect of using the Guidor membrane is its possible exposure. During the study, out of eight cases in the test group, there were three cases of membrane exposure about 2 weeks after surgery. In two of those three cases, no serious wound healing problems or inflammatory reactions were seen at the exposure sites, probably because the resorption process is affected by hydrolysis instead of enzyme activity.\textsuperscript{26} In accordance with literature, the wound sites were treated by topical application of 1\% chlorhexidine gel for 2 weeks.\textsuperscript{27} The wounds healed regularly.

Both clinical and radiologic parameters were considered for evaluating the effectiveness of treatment with the polylactic acid membrane. In the present study, both treatment modalities led to significant improvements in the primary outcome measure for 14 patients: CAL gain together with furcation closure or class I conversion between baseline and 24 months. Only one case showed no furcation closure and no CAL gain 2 years after surgery.

The control group showed better results for PPD and CAL than the test group, though both groups demonstrated statistically insignificant PPD reductions and CAL gain at 12 and 24 months. The difference in PPD reduction at 24 months and

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{Fig4.png}
\caption{Comparing the CBCT scans at (a to c) T0 and (d to f) T24 show formation of new bone in the furcation area. The yellow-outlined areas highlight the bone defect dimension.}
\end{figure}
in CAL gain at 12 months between the groups was statistically significant, indicating a better efficacy of combined EMD + demineralized bovine bone.

A greater increase in KT width and lower REC values were found at 12 months and 24 months postsurgery in the test group than in the control group, but it was not statistically significant. Both groups demonstrated statistically insignificant REC reductions and KT width gains at 12 and 24 months. There was a statistically significant difference in REC change and KT change at 12 and 24 months between both groups.

The relationship between phenotype and successful periodontal regeneration in furcation defects was analyzed. This site-related factor has a significant influence on the regenerative outcome. In fact, compared to a thick gingival phenotype, a thin gingival phenotype is often associated with a negative regenerative result and an increased risk of recession after guided tissue regeneration therapy. However, there was no statistically significant association between gingival phenotype and regenerative success.

The relationship between furcation defect morphology and success of periodontal regeneration in furcation defects after treatment was also assessed, and no statistically significant association was found.

No CAL worsening was seen in either group at the final examination visit (T24). This indicates that both surgical techniques could guarantee a stable regenerative result.

The percentage of radiologic bone gain at T24 was higher for the membrane (test) group than for the EMD (control) group, but it was not statistically significant. However, there was a high heterogeneity in the results obtained from the CBCT analysis, regardless of the technique employed. Some defects with a smaller area of radiolucency regenerated less than some defects with a larger area of radiolucency. This could be explained by the observation that a greater radiologic bone gain was recorded in furcation defects levels with a greater presence of bone marrow. In fact, bone marrow is present in the medullary cavities of the trabecular bone, which contains pluripotent mesenchymal stem cells that are involved in periodontal tissue regeneration, as they can differentiate into the phenotypes that form the mature tissues, including osteoblasts, cementoblasts, and fibroblasts. The radiologic investigation through CBCT allows a more thorough analysis of the defect's anatomical conformation and therefore of the regeneration predictability; the amount of regenerated tissue can also be objectively measured. CBCT is also superior to digital intraoral radiography and clinical probing when assessing regeneration outcomes in furcation defects after regenerative therapy, as it allows accurate measurement of the actual bone gain. Clinical probing has many limitations due to operator experience and technique, as well as tooth anatomy, position, and inclination. Intraoral 2D radiographs are limited by the intrinsic superimposition of anatomic structures that can underestimate bone gain detection.

This study was limited by the sample size. In order to obtain more statistically significant results with significant statistical value, future studies should include a larger sample of patients.

Conclusions

Both test and control regenerative techniques showed a statistically significant increase of clinical and radiographic success. Within the limitations of the present pilot study, the combination of xenogenic bone graft and EMDs showed superior clinical outcomes with less complications, although not statistically significant, compared to guided tissue regeneration with the polylactic acid membrane.

Acknowledgments

The authors would like to thank Sunstar (Schaumburg, IL, USA) for providing the Guidor membranes for this study. The study protocol was approved on October 31, 2017, by the ethics committee of the University of Milan, Italy (no. 41/17). The authors declare no conflicts of interest.

References