Effects of Collagen Resorbable Membrane Placement After the Surgical Extraction of Impacted Lower Third Molars

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Purpose: The use of resorbable collagen membranes (RMs) in the treatment of intraosseous defects and deep periodontal pockets on the distal side of a lower second molar (L2M) after surgical extraction of an impacted lower third molar (L3M) has shown contradictory results. This study evaluated the effects of RM placement on the healing of a bone defect distal to an L2M after surgical extraction of a horizontal or mesioangular impacted L3M.

Patients and Methods: A parallel-group randomized controlled trial with 2 independent groups of 30 patients requiring surgical extraction of an L3M was carried out. After extraction, patients received an RM (Bio-Gide, Geistlich Pharma AG, Wolhusen, Switzerland) or only suture. At the initial checkup and during postoperative monitoring at 1, 3, and 6 months, the distal vestibular, distal, and distolingual probing depths and distal vestibular attachment level of the L2M were measured.

Results: Age (control group, 33.8 ± 6.9 yr; guided tissue regeneration group, 35.6 ± 6.3 yr; P = .322) and the number of women (control group, 15 of 29; guided tissue regeneration group, 14 of 27; P = .992) were similar in the 2 groups. The distal vestibular, distal, and distolingual probing depths of the L2M, distal vestibular attachment level, distance from the cementoenamel junction, and distance from the alveolar crest to the base of the defect showed greater improvement 6 months after surgical extraction in the RM group (P < .05).

Conclusions: The use of RMs after surgical extraction of mesioangular or horizontally impacted L3Ms stimulates bone regeneration, improving the attachment level and bone fill distal to the L2M. Likewise, it decreases the distal probing depth and results in faster recovery. RM placement after surgical extraction of an impacted L3M is recommended because it prevents periodontal defects after L3M surgery.

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Surgical extraction of impacted lower third molars (L3Ms) can cause a bone defect adjacent to the distal roots of the lower second molars (L2Ms). Several studies have shown that periodontal healing of the L2M after surgical extraction of the L3M is accompanied by intraosseous defects and deep periodontal pockets in patients older than 26 years and when the L3M is in a mesioangular or horizontal position.1-8

Over the years, different techniques have been developed for the prevention and treatment of intraosseous defects and deep periodontal pockets on the distal side of L2Ms after surgical extraction of an impacted L3M.9,19 Among those techniques is guided tissue regeneration, which consists of placing a biocompatible membrane (resorbable or nonresorbable) that acts as a physical barrier that prevents the migration of the periodontal epithelium toward the base of the intraosseous defect.20 During healing, epithelial tissue migrates quickly toward the wound, which makes bone regeneration more difficult. Guided tissue regeneration blocks this epithelial migration, with the objective of repairing periodontal tissues.

The concept of periodontal regeneration was defined by the American Academy of Periodontology21 as the process by which the architecture and function of periodontal tissues are completely restored. This includes the formation of new connective tissue, cementum, and supporting bone.22 Currently, it is still under debate whether periodontal treatment by guided tissue regeneration represents a restitutio ad integrum or simply a repair process.23

In recent years, various clinical studies have been carried out to evaluate the efficacy of guided tissue regeneration in the treatment of intraosseous defects and deep periodontal pockets on the distal aspect of L2Ms after surgical extraction of impacted L3Ms. Nonresorbable expanded tetrafluoroethylene membranes, resorbable polyactic acid and resorbable collagen membranes (RMs), bone graft substitutes, and platelet-rich plasma (PRP) have been used, with inconsistent results.10,11,13-17,24,25

With this background information in mind, the authors carried out a randomized, double-blinded clinical trial on guided tissue regeneration of intraosseous defects and deep periodontal pockets on the distal surface of L2Ms after surgical extraction of horizontal or mesioangular impacted L3Ms.

The purpose of this study was to evaluate the effects of RM placement on healing of a bone defect distal to an L2M after surgical extraction of a horizontal or mesioangular impacted L3M. The authors hypothesized that the use of RMs after surgical extraction of a mesioangular or horizontally impacted L3M would improve attachment level, probing depth, and bone fill of an L2M compared with controls. To this end, the distal vestibular attachment level (DVAL) was measured at the distal vestibular probing (DVPD), distal probing depth (DPD), and distolingual probing depth (DLPD) at the initial checkup and during postoperative monitoring visits at 1, 3, and 6 months, as was the bone defect distal to the L2M by determining the distance from the cementoenamel junction to the base of the defect (CEJBD) and the distance from the alveolar crest to the base of the defect (CRESTBD) on standardized periapical radiographs.

**Patients and Methods**

**STUDY DESIGN**

To address the research purpose, the authors designed and implemented a prospective randomized, double-blinded clinical trial. The study population was composed of consecutive patients who were referred to the Dental Clinic of the University of Barcelona (Barcelona, Spain) for the extraction of at least 1 L3M.

To be included in the study sample, patients had to be healthy (American Society of Anesthesiologists physical status I or II) men or women, at least 26 years of age, require surgical extraction of an L3M with a mesioangular or horizontal position with respect to the longitudinal axis of the L2M, and have total soft tissue coverage.

The following exclusion criteria were applied: absence of adjacent lower molars, active or advanced periodontal disease, pregnancy or breastfeeding, metal and ceramic crowns on the L2M, cavities or distal fillings on the L2M, serious systemic diseases that manifested during the study and could influence the maintenance of periodontal health, and treatment with agents associated with gingival hypertrophy or with immunosuppression.

Guidelines for reporting parallel-group randomized clinical trials from the Consolidated Standards of Reporting Trials (CONSORT) statement were followed.26 Approval was obtained from the ethical committee of clinical research from the Dental Clinic of the University of Barcelona. Likewise, recommendations for biomedical research in humans as outlined in the Declaration of Helsinki were followed.

Before inclusion in the study, all patients were informed about the purpose of the study and the benefits and dangers of participating in it. The sample size was calculated at 25 patients per group to detect differences in the bone level variable of 2 mm at 6 months (allocation ratio, 1:1; α = 0.05; power, 0.8; σ = 1.5 mm). Five additional patients per group were recruited to compensate for dropouts. Sixty patients gave their written consent and were included. Patients were randomly allocated to the control group or the RM group according to a computer-generated sequence.
PROCEDURES AND MONITORING

Each patient had an initial checkup, a surgical procedure, and 4 postoperative follow-up visits (at 10 days, 1 month, 3 months, and 6 months).

During the first session, the patient’s medical history was gathered and periapical radiography was performed to find the position of the L3M (angulation in relation to the longitudinal axis of the L2M) according to the classification systems outlined by Pell and Gregory and by Winter. The degree of coverage (completely mucosal, partly bony, or completely bony) was gathered and periapical radiography was performed under local anesthesia with 4% articaine and epinephrine 1:100,000 (Artinibsa; Inibsa, Lliça de Vall, Spain). The surgical field and all surgical material were sterile. The surgeon raised a full-thickness triangular flap, which was protected by a Minnesota retractor with a vertical releasing incision on the mesial vestibular aspect of the L2M. Sterile low-speed (20,000 rpm) handpieces and sterile saline solution were used for bone removal (required in all cases) and tooth sectioning (required for all but 2 L3Ms). Curettage and elimination of the remaining dental follicle and of the granulation tissue were performed. In the experimental group, an RM (Bio-Gide, Geistlich Pharma, Wolhusen, Switzerland) was placed so that it extended 3 mm beyond the margin of the bone defect and sutures were used to promote primary closure of the wound. In the control group, the surgical technique was exactly the same, but no membrane was placed.

After the procedure, all patients were prescribed amoxicillin 750 mg (Clamoxyl, GlaxoSmithKline, Madrid, Spain) every 8 hours for 10 days (or clindamycin 300 mg [Dalacin, Pfizer, Madrid, Spain] every 6 hours for 10 days, if the patient was allergic to penicillin), ibuprofen 600 mg (Espidifen, Zambon, Barcelona, Spain) every 8 hours for 7 days, and as a rescue medication metamizole 575 mg (Nolotil, Boehringer Ingelheim, Barcelona, Spain) in 2 capsules every 8 hours for 4 or 6 days. Twenty-four hours after the procedure, the patients rinsed with a 0.12% chlorhexidine solution (Perio-Kin, Laboratorios Kin, Barcelona, Spain) for 15 days. Ten days after the procedure, the suture was removed.

VARIABLES

In this study, type of treatment (control group and RM group) and time were the predictor variables and are described in the Procedures and Monitoring section. The outcome variables were probing depths and attachment level, which are described below. Other variables that could be related to outcome (age, number of women, smoking, tooth extracted, Pell and Gregory classification, Winter classification, type of retention) also were considered in the data analysis.

OUTCOME VARIABLES

The postoperative visits were handled by a blinded surgeon who did not participate in the surgical procedure and was unaware of the allocation sequence. At the initial checkup and during the postoperative monitoring visits at 1, 3, and 6 months, the DVAL was assessed and the DVDP, DPD, and DLPD of the L2M were measured. At these 4 sessions, the bone defect distal to the L2M also was evaluated using standardized periapical radiographs obtained with an intraoral positioner system and the distance from the CEJBD and the distance from the CRESTBD were determined using a ruler.

DATA ANALYSIS

The Shapiro-Wilk test was used to determine whether the data distribution was normal. Data are presented as mean ± standard deviation (SD) for variables with normal distribution or median (25th to 75th percentiles) for variables without normal distribution. To determine the effect of surgical procedure and recovery, values of the outcome variables were compared after 1, 3, and 6 months with the preoperative values using the Wilcoxon test. Data analysis was based on an intention to treat. To check for statistically significant differences in the variables analyzed between the control and RM groups, the Mann-Whitney U test was used for variables without normal distribution and the Student t test was used for independent measurements of variables with normal distribution. The χ² test was used to compare the number of women, smokers, and Pell and Gregory classification typologies between the control and RM groups. A 2-means clustering multivariate analysis was carried out to classify patients into 2 groups to track the evolution of the variables during the 6 months after the operation. Statistical analysis was performed using SPSS 21 (IBM Corporation, Armonk, NY). The results were considered statistically significant at a P value less than .05.

Results

Of the 60 patients recruited, 4 were excluded from the study for not presenting at the follow-up visits (3 from the control group and 1 from the RM group; Fig 1). All patients received the treatments to which they had been allocated. The patients’ ages were
similar in the 2 groups (control, 33.8 yr; SD, 6.9 yr; RM group, 35.6 yr; SD, 6.3 yr; \( P = .322 \)), as were the number of women (control group, 15 of 29; RM group, 14 of 29; \( \chi^2 = 0.000; P = .992 \)) and the prevalence of smoking (control group, 9 of 29; RM group, 5 of 29; \( \chi^2 = 1.168; P = .280 \)).

The extracted L3M was the left in 17 of the 27 patients in the control group and in 15 of the 29 patients in the RM group (\( \chi^2 = 0.721; P = .396 \)) and the right in the remaining patients.

Patients were classified according to the position of the L3M using the Pell and Gregory classification system, without finding any differences in the number of patients categorized as IIA (control group, 5 of 27; RM group, 5 of 29), IIB (control group, 14 of 27; RM group, 14 of 29), IIC (control group, 3 of 27; RM group, 5 of 29), IIIB (control group, 0 of 27; RM group, 2 of 29), or IIIC (control group, 5 of 27; RM group, 3 of 27) between the 2 groups (\( \chi^2 = 2.932; P = .569 \)). In addition, the Winter classification system was used, without finding significant differences (\( \chi^2 = 0.763; P = .382 \)) for the number of patients with horizontal (control group, 22 of 27; RM group, 26 of 29) versus mesioangular (control group, 5 of 27; RM group,
23 of 29) L3M positioning. The types of retention observed were partial bony retention (control group, 10 of 27; RM group, 12 of 29) and total bony retention (control group, 17 of 27; RM group, 17 of 29), without significant differences between groups (χ² = 0.111; P = .740). The depth of the L3M (control, 2.11 ± 0.69 mm; RM group, 2.10 ± 0.67 mm) and the distance from the L3M to the ramus of the mandible (control group, 1.18 ± 0.39 mm; RM group, 1.17 ± 0.38 mm) were not different between the 2 groups (P > .903). After the operation, no signs of infection were detected in any of the patients included in the study.

The variables DVPD, DPD, DLPD, DVAL, CEJBD, and CRESTBD showed a similar response to the surgical procedure in the 2 groups (Table 1). Nevertheless, the RM group had significantly lower values of DVPD, DVAL, and CEJBD after 3 months (P < .05; Table 1) and of DVPD, DPD, DLPD, DVAL, CEJBD, and CRESTBD after 6 months compared with the control group (P < .05).

To estimate the effect of the treatments on periodontal healing, the increase in value of the variables DVPD, DPD, DLPD, DVAL, CEJBD, and CRESTBD were calculated 6 months after the operation. Patients in the RM group showed greater improvement after 6 months than patients in the control group for variables DPD, CEJBD, and CRESTBD (Fig 2). In addition, the effect of the treatments was evaluated by classifying the patients into a fast recovery group or a slow recovery group through k-means multivariate analysis (Table 2). The number of patients with a faster recovery was significantly larger in the RM group (19 of 29; Table 2) than the control group (3 of 27; χ² = 17.352; P < .001).

### Discussion

The purpose of this study was to evaluate the effects of RM placement on the healing of a bone defect distal to the L2M after surgical extraction of a horizontal or mesioangular impacted L3M. The authors hypothesized that the use of RMs after surgical extraction of mesioangular or horizontally impacted L3Ms would improve attachment level, probing depth, and bone fill of the L2M compared with controls. The authors recommend RM placement after surgical extraction of impacted L3Ms because it prevents periodontal defects after L3M surgery.

The use of RMs after surgical extraction of impacted mesioangular or horizontal L3Ms improved the probing attachment level and bone fill at the L2M. Likewise, the probing attachment level decreased and exhibited faster progress compared with the control group. As far as the authors know, this is the first study to evaluate this hypothesis using this experimental model and with such a large number of patients. Therefore, because this was a pilot study and there are no similar previous studies, it is difficult to compare the present results with those of other studies.

In recent years, different techniques for bone regeneration have been proposed, such as membranes (resorbable or nonresorbable), demineralized bone powder, and PRP. There is some controversy about when bone regeneration techniques should be used. For example, Dodson recommended using osseous regeneration techniques before extraction of the L3M in patients with a distal periodontal defect, whereas others have recommended their use when the distal probing depth is greater than 7 mm and the distal probing attachment level of the L2M is greater than 6 mm. In their review, Aloy-Prosper et al concluded that the placement of membranes (resorbable and nonresorbable) could

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**Table 1. DVPD, DPD, AND DLPD OF LOWER SECOND MOLAR, DVAL, DISTANCE FROM THE CRESTBD BEFORE AND 1, 3, AND 6 MONTHS AFTER SURGERY**

<table>
<thead>
<tr>
<th></th>
<th>Before Surgery</th>
<th>1 mo After Surgery</th>
<th>3 mo After Surgery</th>
<th>6 mo After Surgery</th>
</tr>
</thead>
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<tr>
<td><strong>DVPD</strong></td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>Control</td>
<td>5 (3-7)</td>
<td>6 (3-8)</td>
<td>5 (3-6)</td>
<td>4 (3-6)</td>
</tr>
<tr>
<td>RM</td>
<td>4 (3-5)</td>
<td>5 (3-7)</td>
<td>3 (3-4)</td>
<td>3 (2-4)</td>
</tr>
<tr>
<td><strong>DPD</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>5 (2-8)</td>
<td>7 (5-8)</td>
<td>5 (4-6)</td>
<td>4 (3-6)</td>
</tr>
<tr>
<td>RM</td>
<td>5 (3-6)</td>
<td>6 (6-8)</td>
<td>4 (3-6)</td>
<td>3 (3-4)</td>
</tr>
<tr>
<td><strong>DLPD</strong></td>
<td></td>
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</tr>
<tr>
<td>Control</td>
<td>4 (3-7)</td>
<td>3 (3-4)</td>
<td>3 (3-4)</td>
<td>3 (3-3)</td>
</tr>
<tr>
<td>RM</td>
<td>3 (3-5)</td>
<td>3 (3-3)</td>
<td>3 (3-3)</td>
<td>3 (2-3)</td>
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<tr>
<td><strong>DVAL</strong></td>
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<tr>
<td>Control</td>
<td>6 (3-7)</td>
<td>6 (5-9)</td>
<td>5 (4-7)</td>
<td>5 (4-6)</td>
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<tr>
<td>RM</td>
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<td>5 (4-7)</td>
<td>4 (3-5)</td>
<td>3 (3-5)</td>
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<tr>
<td><strong>CEJBD</strong></td>
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</tr>
<tr>
<td>Control</td>
<td>10 (8-11)</td>
<td>9 (8-11)</td>
<td>6 (6-8)</td>
<td>6 (5-6)</td>
</tr>
<tr>
<td>RM</td>
<td>10 (9-12)</td>
<td>9 (8-11)</td>
<td>6 (4-7)</td>
<td>3 (2-4)</td>
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<tr>
<td><strong>CRESTBD</strong></td>
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<tr>
<td>Control</td>
<td>7 (5-8)</td>
<td>7 (5-8)</td>
<td>4 (3-6)</td>
<td>4 (3-5)</td>
</tr>
<tr>
<td>RM</td>
<td>8 (7-9)</td>
<td>7 (6-8)</td>
<td>4 (2-5)</td>
<td>2 (1-2)</td>
</tr>
</tbody>
</table>

*Note: Data are presented as median (25th to 75th percentiles).

Abbreviations: CEJBD, cementoenamel junction to base of defect; CRESTBD, alveolar crest to base of defect; DLPD, distolingual probing depth; DPD, distal probing depth; DVAL, distal vestibular attachment level; DVPD, distal vestibular probing depth; RM, resorbable collagen membrane.

* P < .05 versus before surgery.
† P < .01 versus before surgery.
‡ P < .001 versus before surgery.
§ P < .05 versus control group.
¶ P < .01 versus control group.
‖ P < .001 versus control group.

not be justified, but that the use of demineralized bone powder or PRP decreased the distal probing depth and attachment level of the L2M. Differences in the methodology of the present study and previous studies could account for these discrepancies.17,19,24 Dodson19 evaluated the effect of placing demineralized bone powder or resorbable membrane in 24 patients whose L3M was extracted bilaterally, and he compared it with the opposite side (where no surgery was carried out), without finding any statistical differences between the 2 techniques. A clear disadvantage of the study performed by Dodson is the smaller sample. However, in patients with a previous distal periodontal defect of the L2M, Dodson17 found a statistical decrease in the distal attachment level from 7.6 ± 3.5 to 1.4 ± 0.5 mm after 26 weeks in the group with grafted bone compared with the control group. Nevertheless, there were no statistical differences between the control group and the group with the resorbable membrane, although Dodson17 emphasized that patients older than 26 years with a previous periodontal defect and a mesioangular or horizontally impacted L3M could benefit from osseous regeneration techniques. Similarly, Karapataki et al.24 after placing resorbable or nonresorbable membranes in 19 patients with distal intraosseous defects of at least 4 mm in the L2M, did not find statistical differences in the postoperative distal attachment level and probing depth. A weak point in this study was the small number of participants.

However, in line with the present findings, Aimetti et al.15 evaluated recovery after guided osseous regeneration by placing membranes at the distal surface of L2Ms after surgical extraction of mesioangular L3Ms. Twelve months after the surgery, they observed statistical differences in distal attachment level and bone gain. Likewise, Aimetti and Romano16 compared the effect of radicular scraping and smoothing of the L2M distal surface alone or in association with the application of a resorbable membrane and concluded that although the 2 methods of treatment yielded improvements in clinical parameters, application of a resorbable membrane was statistically more efficient than only radicular smoothing in decreasing the distal probing depth and in improving the distal attachment level.

The use of PRP also has been proposed as a good technique for bone regeneration after extraction of the L3M.30-32 Sammartino et al.13 researched the clinical effects of an RM of porcine origin in combination with PRP compared with PRP alone on osseous regeneration after surgical removal of L3Ms in 18 young patients and concluded that although the clinical results of PRP alone compared with PRP and the RM can be considered similar (without differences in the amount of osseous regeneration), from a histologic point of view, the association of the membrane to PRP showed preliminary signs of bone maturation.

| Table 2. MULTIVARIATE ANALYSIS FOR CLASSIFICATION OF PATIENTS INTO 2 CLUSTERS TO TRACK THE PROGRESS OF VARIABLES ANALYZED IN THE POSTOPERATIVE PERIOD |
|-----------------------------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|
| Fast Recovery Group (n = 22)           | Slow Recovery Group (n = 34) | F<sub>1,54</sub>     | P Value              |
| ∆pre-6 mo DVPD (mm)                   | 2.09                 | 0.47                 | 10.165               | .002                 |
| ∆pre-6 mo DPD (mm)                    | 2.45                 | −0.24                | 16.128               | <.001                |
| ∆pre-6 mo DLPD (mm)                   | 2.32                 | 1.15                 | 3.849                | .055                 |
| ∆pre-6 mo DVAL (mm)                   | 2.00                 | −0.12                | 13.504               | <.001                |
| ∆pre-6 mo CEJBD (mm)                  | 7.73                 | 3.50                 | 74.563               | <.001                |
| ∆pre-6 mo CRESTBD (mm)                | 6.95                 | 2.88                 | 71.844               | <.001                |

Abbreviations: CEJBD, cementoenamel junction to base of defect; CRESTBD, alveolar crest to base of defect; ∆pre-6 mo, change from before to 6 months after surgery; DLPD, distolingual probing depth; DPD, distal probing depth; DVAL, distal vestibular attachment level; DVPD, distal vestibular probing depth.

With an experimental design similar to the present one, Corinaldesi et al.\(^{33}\) evaluated the effect of guided tissue regeneration using RMs compared with nonresorbable membranes in 11 patients with L2M bilateral distal probing depths of at least 6 mm and intraosseous defects of at least 3 mm. They concluded that RMs have the same effect on the decrease in distal probing depth and on the improvement of the distal attachment level as the nonresorbable membranes, with the 2 methods yielding successful results 9 months after surgery.\(^{33}\)

In 28 patients 30 to 35 years old, Hassan et al.\(^{34}\) investigated the effect of the use of a xenograft and a membrane as graft material in periodontal defects distal to the L2M compared with extraction sites not grafted after extraction of the L3M and observed a statistical decrease in distal probing depth and an improvement in the distal attachment level and of bone fill when the xenograft was used in conjunction with a membrane, which suggests that periodontal disease could be prevented.\(^{34}\)

This study was a randomized controlled trial with a lower risk of bias compared with nonrandomized experimental or observational studies. The sample was quite homogeneous (mesioangular L3M and age, among others), thus improving internal validity. Moreover, horizontal and mesioangular L3Ms seemed to be more prone to resorb the distal bone of the L2M. The benefit of guided tissue regeneration in this group should be maximal compared with other situations. However, blinding could have been comprised because the patient could have realized whether a membrane had been placed. The observer also could have discerned whether the patient had received a membrane because swelling was more severe. However, to avoid these biases, the postoperative visits were handled by a blinded surgeon who did not participate in the surgical procedure. The starting probing depth could have been underestimated because the probe stopped at the crown of the L3M, although randomization minimizes this possible error. The conclusions cannot be applied to younger or older patients or to other positions of the L3M.

In conclusion, according to the present data, and coinciding with various studies previously referenced, the use of RMs after surgical extraction of mesioangular or horizontally impacted L3Ms stimulates bone regeneration, improving the attachment level and bone fill distal to L2M. Likewise, it decreases distal probing depth and results in faster recovery. Therefore, RM placement after surgical extraction of an impacted L3M prevents periodontal defects after L3M surgery. Future studies should investigate the long-term effects (ie, 1-year follow-up) of RM placement after surgical extraction of an impacted L3M.

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