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[Intervention Review]

# Enamel matrix derivative (Emdogain®) for periodontal tissue regeneration in intrabony defects

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## ABSTRACT

### Background

Periodontitis is a chronic infective disease of the gums caused by bacteria present in dental plaque. This condition induces the breakdown of the tooth supporting apparatus until teeth are lost. Surgery may be indicated to arrest disease progression and regenerate lost tissues. Several surgical techniques have been developed to regenerate periodontal tissues including guided tissue regeneration (GTR), bone grafting (BG) and the use of enamel matrix derivative (EMD). EMD is an extract of enamel matrix and contains amelogenins of various molecular weights. Amelogenins are involved in the formation of enamel and periodontal attachment formation during tooth development.

### Objectives

To test whether EMD is effective, and to compare EMD versus GTR, and various BG procedures for the treatment of intrabony defects.

### Search methods

We searched the Cochrane Oral Health Group Trials Register, CENTRAL, MEDLINE and EMBASE. Several journals were hand-searched. No language restrictions were applied. Authors of randomised controlled trials (RCTs) identified, personal contacts and the manufacturer were contacted to identify unpublished trials. Most recent search: February 2009.

### Selection criteria

RCTs on patients affected by periodontitis having intrabony defects of at least 3 mm treated with EMD compared with open flap debridement, GTR and various BG procedures with at least 1 year follow up. The outcome measures considered were: tooth loss, changes in probing attachment levels (PAL), pocket depths (PPD), gingival recessions (REC), bone levels from the bottom of the defects on intraoral radiographs, aesthetics and adverse events. The following time-points were to be evaluated: 1, 5 and 10 years.

### Data collection and analysis

Screening of eligible studies, assessment of the methodological quality of the trials and data extraction were conducted in duplicate and independently by two authors. Results were expressed as random-effects models using mean differences for continuous outcomes and risk ratios (RR) for dichotomous outcomes with 95% confidence intervals (CI). It was decided not to investigate heterogeneity, but a sensitivity analysis for the risk of bias of the trials was performed.

## Main results

Thirteen trials were included out of 35 potentially eligible trials. No included trial presented data after 5 years of follow up, therefore all data refer to the 1-year time point. A meta-analysis including nine trials showed that EMD treated sites displayed statistically significant PAL improvements (mean difference 1.1 mm, 95% CI 0.61 to 1.55) and PPD reduction (0.9 mm, 95% CI 0.44 to 1.31) when compared to placebo or control treated sites, though a high degree of heterogeneity was found. Significantly more sites had < 2 mm PAL gain in the control group, with RR 0.53 (95% CI 0.34 to 0.82). Approximately nine patients needed to be treated (NNT) to have one patient gaining 2 mm or more PAL over the control group, based on a prevalence in the control group of 25%. No differences in tooth loss or aesthetic appearance as judged by the patients were observed. When evaluating only trials at a low risk of bias in a sensitivity analysis (four trials), the effect size for PAL was 0.62 mm (95% CI 0.28 to 0.96), which was less than 1.1 mm for the overall result. Comparing EMD with GTR (five trials), GTR showed statistically significant more postoperative complications (three trials, RR 0.12, 95% CI 0.02 to 0.85) and more REC (0.4 mm 95% CI 0.15 to 0.66). The only trial comparing EMD with a bioactive ceramic filler found statistically significant more REC (-1.60 mm, 95% CI -2.74 to -0.46) at the EMG treated sites.

## Authors' conclusions

One year after its application, EMD significantly improved PAL levels (1.1 mm) and PPD reduction (0.9 mm) when compared to a placebo or control, however, the high degree of heterogeneity observed among trials suggests that results have to be interpreted with great caution. In addition, a sensitivity analysis indicated that the overall treatment effect might be overestimated. The actual clinical advantages of using EMD are unknown. With the exception of significantly more postoperative complications in the GTR group, there was no evidence of clinically important differences between GTR and EMD. Bone substitutes may be associated with less REC than EMD.

## PLAIN LANGUAGE SUMMARY

### Enamel matrix derivative (Emdogain®) for periodontal tissue regeneration in intrabony defects

Emdogain might have some advantages over other methods of regenerating the tissue supporting teeth lost by gum disease, such as less postoperative complications, but has not been shown to save more compromised teeth or that patients noticed any aesthetic improvement 1 year after its application.

Bacteria in plaque can cause gum disease (periodontitis) that breaks down tissue supporting teeth. Surgical cleaning tries to stop the disease to save loose teeth. Bone grafting, guided tissue regeneration and enamel matrix derivatives (such as Emdogain) aim to regenerate support tissues. Emdogain contains proteins (derived from developing pig teeth) believed to regenerate tooth attachment. The review found that adjunctive application of Emdogain regenerates about 1 mm more tissue than surgical cleaning alone, although it is unclear to which extent such improvement is noticeable since patients did not find any difference in the aesthetic results. Emdogain showed similar clinical results to guided tissue regeneration, but is simpler to use and determines less complications. Bone substitutes may induce less gum retraction than Emdogain. No serious adverse reactions to Emdogain were reported in trials.