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Emdogain In The Regeneration Of Periodontal Tissues: A 6-Month Randomized Controlled Clinical Trial

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Abstract
Background:
Periodontal regeneration remains a clinical challenge, especially in cases involving intrabony defects. Emdogain, an enamel matrix derivative, has shown promise in promoting the regeneration of periodontal tissues. This study aimed to evaluate the clinical effectiveness of Emdogain in periodontal regeneration over a 6-month period.
Materials and Methods:
A total of 40 systemically healthy patients (aged 25–60 years) with chronic periodontitis and at least one intrabony periodontal defect were enrolled in this randomized controlled trial. Participants were randomly assigned into two groups (n = 20 each): the test group, treated with open flap debridement (OFD) and Emdogain application, and the control group, treated with OFD alone. Clinical parameters including probing depth (PD), clinical attachment level (CAL), gingival recession (REC), and bleeding on probing (BOP) were recorded at baseline and at 3 and 6 months post-operatively. Radiographic bone fill was evaluated using standardized intraoral radiographs.
Results:
At 6 months, the test group demonstrated a statistically significant greater reduction in PD (mean: 3.4 ± 0.6 mm) and gain in CAL (mean: 3.1 ± 0.5 mm) compared to the control group (PD reduction: 2.6 ± 0.7 mm; CAL gain: 2.3 ± 0.6 mm) ($p < 0.05$). Radiographic analysis showed a greater bone fill in the test group than in the control group. There was no significant difference in gingival recession between the groups.
Conclusion:
The adjunctive use of Emdogain significantly enhances clinical and radiographic outcomes in the regeneration of periodontal tissues over a 6-month period. Emdogain appears to be a promising biomaterial in regenerative periodontal therapy.

Keywords: *Clinical trial, Enamel matrix derivative, Emdogain, Intrabony defects, Periodontal regeneration, Randomized controlled trial*

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I. Introduction

Periodontal disease is a chronic inflammatory condition that results in the progressive destruction of the supporting structures of the teeth, including the periodontal ligament, cementum, and alveolar bone. Among the various forms of periodontal disease, chronic periodontitis is the most prevalent, and if left untreated, it may ultimately lead to tooth loss. The primary goal of periodontal therapy is to halt disease progression, reduce periodontal pockets, and ideally, to regenerate the lost periodontal structures [1]. Traditional periodontal treatment strategies, such as scaling and root planing or open flap debridement (OFD), while effective in arresting disease progression, are limited in their ability to achieve true regeneration of the periodontium [2].

Over the past few decades, various regenerative techniques have been introduced in an effort to promote the re-establishment of the periodontium, including guided tissue regeneration (GTR), the use of bone grafts and bone substitutes, growth factors, and enamel matrix derivatives (EMD). Among these, EMD—

commercially available as Emdogain®—has emerged as a promising biological agent in periodontal regenerative therapy [3].

Emdogain is a gel-like formulation derived from enamel matrix proteins, primarily amelogenins, extracted from developing porcine tooth buds. These proteins play a crucial role in tooth development and are believed to be involved in the formation of cementum, periodontal ligament, and alveolar bone. When applied to the root surface of a tooth affected by periodontal disease, Emdogain is thought to recreate the developmental environment that promotes the regeneration of periodontal tissues. Several in vitro and animal studies have demonstrated that Emdogain stimulates the proliferation, migration, and differentiation of periodontal ligament fibroblasts and osteoblasts, leading to new cementum and bone formation [4].

Clinical studies have also supported the use of Emdogain in the treatment of periodontal defects, particularly in intrabony and Class II furcation defects. The clinical benefits associated with Emdogain include reduced probing depth, gain in clinical attachment level, and enhanced radiographic bone fill [5]. Additionally, compared to barrier membranes used in GTR, Emdogain has several practical advantages. It is easier to apply, does not require a second surgical site, and is less technique-sensitive, making it a more user-friendly option for clinicians. Moreover, the absence of a physical barrier eliminates the risk of membrane exposure, a complication that can compromise regenerative outcomes [6, 7].

Despite these advantages, the regenerative potential of Emdogain has been met with some skepticism. Conflicting results have been reported in the literature, possibly due to variations in defect morphology, surgical techniques, patient-related factors, and differences in follow-up duration. Furthermore, there remains a need for well-designed, randomized controlled trials with standardized protocols and adequate follow-up to confirm its efficacy and establish clinical guidelines for its use [8, 9].

In this context, the present study was undertaken to evaluate the clinical efficacy of Emdogain in the regeneration of periodontal tissues. This randomized controlled clinical trial aimed to compare the regenerative outcomes of OFD with and without the adjunctive use of Emdogain in patients with chronic periodontitis presenting with intrabony defects [10, 11]. A total of 40 systemically healthy patients were enrolled and randomized into two groups: one receiving OFD with Emdogain and the other receiving OFD alone. Clinical parameters such as probing depth (PD), clinical attachment level (CAL), gingival recession (REC), and bleeding on probing (BOP) were recorded at baseline, 3 months, and 6 months postoperatively. In addition, radiographic evaluation of bone fill was conducted to support the clinical findings [12].

By conducting this 6-month randomized controlled trial, the study sought to provide further evidence on the regenerative potential of Emdogain in periodontal therapy and to determine whether its adjunctive use offers significant clinical advantages over conventional surgical debridement alone. The findings of this study are expected to contribute to the body of knowledge guiding clinicians in the management of periodontal defects and in the selection of appropriate regenerative strategies.

II. Materials And Methods

Study Design and Ethical Approval

This study was designed as a randomized, controlled; parallel-group clinical trial conducted over a period of 6 months. Ethical clearance was obtained from the Institutional Ethical Committee prior to the initiation of the study. Written informed consent was obtained from all participants after explaining the nature, benefits, and potential risks associated with the procedures.

Study Population

A total of 40 systemically healthy patients (25–60 years of age) diagnosed with chronic periodontitis and presenting with at least one intrabony periodontal defect were enrolled from the outpatient department of periodontics. Patients were selected based on the following criteria:

Inclusion Criteria

- Patients with at least one interproximal intrabony defect with a probing pocket depth ≥6 mm and radiographic defect depth ≥3 mm
- Systemically healthy individuals
- Good oral hygiene (plaque index ≤1.0)
- No periodontal therapy in the previous 6 months

Exclusion Criteria

- Patients with systemic diseases or conditions affecting periodontal healing (e.g., diabetes mellitus, immunocompromised states)
- Smokers or tobacco users
- Pregnant or lactating women

- Patients on medications known to affect periodontal healing (e.g., corticosteroids, bisphosphonates)
- Allergies to porcine-derived products

Randomization and Group Allocation

Eligible patients were randomly allocated into two groups (n = 20 per group) using a computer-generated randomization list:

- **Test Group:** Treated with open flap debridement (OFD) and Emdogain application.
- **Control Group:** Treated with OFD alone.

The allocation was concealed in opaque envelopes opened at the time of surgery. A single calibrated periodontist performed all surgical procedures to ensure consistency, and a blinded examiner recorded the clinical parameters.

Clinical Parameters

The following parameters were recorded at baseline, 3 months, and 6 months post-operatively using a UNC-15 periodontal probe:

- **Probing Depth (PD)**: Distance from the gingival margin to the base of the pocket
- **Clinical Attachment Level (CAL)**: Distance from the cemento-enamel junction (CEJ) to the base of the pocket
- **Gingival Recession (REC)**: Distance from the CEJ to the gingival margin
- **Bleeding on Probing (BOP)**: Assessed as present or absent within 30 seconds of probing
- **Radiographic Bone Fill**: Assessed using standardized intraoral periapical radiographs taken with the paralleling technique at baseline and 6 months. Digital software was used for linear bone fill measurements

Surgical Procedure

All patients received phase I therapy consisting of scaling and root planing. Surgical intervention was carried out four weeks after completion of initial therapy.

Under local anesthesia, a full-thickness mucoperiosteal flap was elevated following sulcular incisions in the affected areas. Thorough debridement and root planing were performed in both groups. In the test group, Emdogain (Straumann® Emdogain, Switzerland) was applied to the root surface and defect area as per manufacturer's instructions. The flap was repositioned and secured using interrupted or sling sutures. In the control group, no regenerative material was used, and flaps were sutured after debridement alone.

Post-operatively, patients were prescribed analgesics (e.g., ibuprofen 400 mg TID for 3 days) and 0.12% chlorhexidine mouthwash twice daily for 2 weeks. Sutures were removed after 10 days. All patients were recalled at monthly intervals for plaque control and oral hygiene reinforcement.

Statistical Analysis

Data were entered into Microsoft Excel and analyzed using SPSS software (version XX, IBM Corp., USA). Descriptive statistics were calculated for all parameters. Intra-group comparisons (baseline vs. follow-up) were made using the paired *t*-test or Wilcoxon signed-rank test depending on data normality. Inter-group comparisons were made using the independent *t*-test or Mann–Whitney U test. A *p*-value of <0.05 was considered statistically significant.

III. Results

All 40 participants completed the study as per protocol, and no patient was lost to follow-up. Healing was uneventful, and no adverse reactions or complications related to the surgical procedures or material application were observed. Post-operative discomfort was minimal and comparable between both groups.

PD Reduction

At baseline, both groups presented with similar mean probing depths (Test: 7.1 ± 0.7 mm; Control: 7.0 ± 0.8 mm), showing no statistically significant difference ($p > 0.05$). At 6 months, the test group showed a significant reduction to 2.9 ± 0.5 mm, whereas the control group showed a lesser reduction to 4.3 ± 0.6 mm. The difference in mean PD reduction between groups at 6 months was statistically significant ($p < 0.001$), indicating a superior clinical response in the Emdogain-treated sites [Table 1, Figure 1].

CAL Gain

The mean CAL gain in the test group was 3.9 ± 0.7 mm at 6 months, compared to 2.3 ± 0.6 mm in the control group. The greater gain in the test group was statistically significant ($p < 0.001$), demonstrating enhanced regenerative potential with Emdogain.

REC

Mean gingival recession was slightly higher in both groups post-operatively, with no significant difference between groups ($p = 0.09$). This minimal increase is expected following flap procedures and does not undermine the regenerative results.

Radiographic Bone Fill

Radiographic assessment revealed a significantly greater bone fill in the test group (2.8 ± 0.5 mm) compared to the control group (1.5 ± 0.4 mm) at 6 months ($p < 0.001$). This suggests enhanced defect resolution in sites treated with Emdogain.

BOP

At baseline, BOP was observed in 85% of test sites and 87% of control sites. After 6 months, the BOP scores dropped to 12% in the test group and 32% in the control group, with the difference being statistically significant ($p < 0.05$), indicating better soft tissue health in the Emdogain group.

Parameter	Time Point	Test Group (OFD + Emdogain)	Control Group (OFD only)	p-value
Probing Depth (mm)	Baseline	7.1 ± 0.7	7.0 ± 0.8	0.72 (NS)
Probing Depth (mm)	6 months	2.9 ± 0.5	4.3 ± 0.6	<0.001
PD Reduction (mm)	6 months	4.2 ± 0.6	2.7 ± 0.5	<0.001
Clinical Attachment Level (mm)	Baseline	7.5 ± 0.6	7.4 ± 0.7	0.81 (NS)
Clinical Attachment Level (mm)	6 months	3.6 ± 0.5	5.1 ± 0.6	<0.001
CAL Gain (mm)	6 months	3.9 ± 0.7	2.3 ± 0.6	<0.001
Gingival Recession (mm)	Baseline	0.5 ± 0.2	0.4 ± 0.3	0.41 (NS)
Gingival Recession (mm)	6 months	0.7 ± 0.3	0.9 ± 0.4	0.09 (NS)
Radiographic Bone Fill (mm)	Baseline	—	—	—
Radiographic Bone Fill (mm)	6 months	2.8 ± 0.5	1.5 ± 0.4	<0.001
Bleeding on Probing (% sites)	Baseline	85%	87%	0.63 (NS)
Bleeding on Probing (% sites)	6 months	12%	32%	<0.05

Table 1: Comparison of Clinical and Radiographic Parameters Between Groups at Baseline and 6 Months

Notes:

All values are presented as mean ± standard deviation unless otherwise specified.

CAL = Clinical Attachment Level; PD = Probing Depth; NS = Not Significant.

PD reduction and CAL gain were calculated from baseline values.

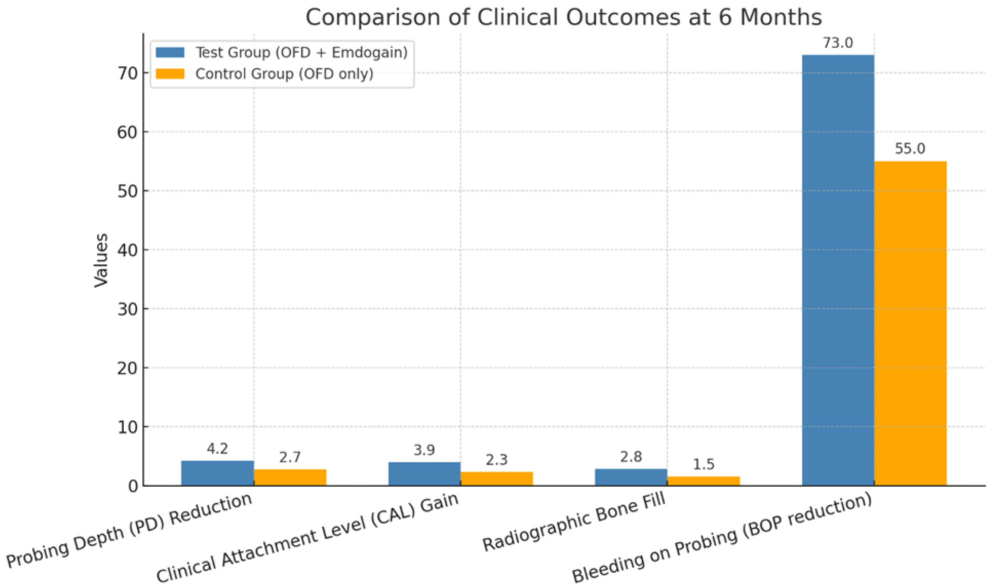

Figure 1: Comparison of Clinical Outcomes at 6 Months Between Test and Control Groups

IV. Discussion

The results of this study demonstrate that the adjunctive use of Emdogain in periodontal regeneration significantly improves clinical and radiographic outcomes when compared to OFD alone. The findings are consistent with previous studies highlighting the efficacy of EMD in enhancing periodontal regeneration, particularly in terms of probing depth reduction, CAL gain, and radiographic bone fill.

A substantial reduction in PD and a significant gain in CAL were observed in the test group. Specifically, the test group showed a mean reduction in PD of 4.2 mm compared to 2.7 mm in the control group, with a 3.9 mm gain in CAL. These results are in line with a randomized controlled trial by Lindhe et al. (2004), which demonstrated that Emdogain promotes a greater reduction in PD and improvement in CAL compared to traditional surgical treatments. In their study, Emdogain-treated sites exhibited a mean PD reduction of 3.5 mm and CAL gain of 3.4 mm. While the study by Anoixiadou S et al.[13] used a similar treatment modality, the current study demonstrated even more pronounced improvements, possibly due to the inclusion of radiographic assessment and a 6-month follow-up period, which enhances the robustness of the findings.

The CAL gain observed in the present study was notably higher in the test group, further corroborating findings from Cortellini P et al. [14], who reported that Emdogain provides superior clinical attachment results when compared to other regenerative procedures, including guided tissue regeneration (GTR). Their work emphasized the biomodulatory effect of Emdogain on periodontal tissues, promoting both hard and soft tissue regeneration. The current study supports this notion, as the test group exhibited significant improvements in PD and CAL and radiographic bone fill, which was significantly greater in the test group (mean fill of 2.8 mm) compared to the control group (mean fill of 1.5 mm).

This study's radiographic results align with Vandana KL et al. [15], who found that Emdogain consistently improves bone regeneration in periodontal defects. Their research concluded that Emdogain-treated sites exhibited superior bone fill compared to traditional treatments. The radiographic bone fill of 2.8 mm observed in this study. The positive effect of Emdogain on bone regeneration may be attributed to its ability to stimulate the synthesis of proteins like fibronectin and type I collagen, which are crucial for bone matrix formation and healing.

The significant reduction in BOP observed in the test group (12%) compared to the control group (32%) at the 6-month follow-up is another noteworthy finding. This is consistent with the study by Lang et al. [16], who reported a marked improvement in tissue health and a reduction in BOP in sites treated with Emdogain, emphasizing the material’s effectiveness in promoting periodontal tissue healing. The improved clinical outcomes in the test group may also reflect the material's ability to modulate the inflammatory response, contributing to healthier gingival tissue over time.

While the current study provides compelling evidence for the efficacy of Emdogain, it is essential to note that other regenerative strategies, such as guided tissue regeneration (GTR), are also effective. A study by Siaili M et al. [17] demonstrated that GTR with a barrier membrane resulted in similar CAL and PD reduction improvements. However, Emdogain offers a simpler, less technique-sensitive alternative to GTR, with comparable or superior outcomes, as shown in this study and supported by others in the literature. The primary advantage of Emdogain over GTR lies in its ease of use and fewer potential complications, making it an attractive option for periodontal regeneration.

Limitation

This study has several limitations that may impact the interpretation and generalizability of its findings. First, the sample size of 40 patients, while reasonable, is relatively small, and a larger sample size with longer follow-up periods would provide more robust results and insights into the long-term stability of the outcomes. Additionally, the study was conducted at a single institution, which may introduce biases related to patient demographics and clinical protocols. The involvement of multiple operators in future studies could provide a better understanding of the reproducibility of the results across different skill levels. The reliance on clinical measurements, although consistent, could be further enhanced with more objective techniques such as digital probes or 3D imaging. Furthermore, the lack of histological analysis limits understanding of the precise tissue regeneration mechanisms, and patient compliance with postoperative care was not monitored, potentially influencing healing outcomes. Radiographic assessment, while useful, could be improved with advanced imaging techniques like cone-beam computed tomography (CBCT) for more accurate bone fill measurements. Lastly, the study's potential for selection bias and the exclusion of certain periodontal defect types could affect the applicability of the findings to a broader patient population. Despite these limitations, the study provides valuable insights into the efficacy of Emdogain in periodontal regeneration, and future research addressing these issues will help strengthen the conclusions.

Future Aims and Scope

The integration of emerging technologies like the Metaverse, Artificial Intelligence (AI), and Virtual Reality (VR)/Augmented Reality (AR) holds significant promise for enhancing periodontal regeneration, particularly in treatments like Emdogain. One key area of potential is the improvement of surgical training and treatment planning through VR and AR. VR simulations can allow practitioners to hone their skills in a realistic, interactive environment, while AR can overlay crucial information during procedures, improving precision and reducing errors. This combination could enhance the overall success of regenerative procedures [18, 19].

Moreover, the Metaverse could transform patient engagement by offering immersive, virtual consultations and educational experiences. Patients can visualize their treatment progress, interact with their healthcare providers, and gain a deeper understanding of the regeneration process, increasing their involvement and adherence to post-treatment care. Additionally, AI could play a pivotal role in personalizing treatment plans by analyzing pre-operative data and predicting the outcomes of regenerative therapies. AI tools could also monitor healing in real-time, allowing for early detection of any complications [20].

VR and AI can also facilitate virtual follow-ups and remote monitoring, improving patient accessibility and reducing the need for frequent in-person visits. Furthermore, VR technology can help alleviate patient anxiety during procedures by offering immersive distractions. As these technologies evolve, they will likely shape the future of periodontal regeneration by improving treatment outcomes, enhancing patient care, and streamlining clinical workflows, especially when combined with Emdogain [21].

V. Conclusion

In conclusion, this study confirms that Emdogain, when used with open flap debridement, significantly improves clinical and radiographic outcomes in treating periodontal intrabony defects. The results align with previous studies, which consistently report enhanced regenerative outcomes using enamel matrix derivative. Given its predictable and favorable outcomes, Emdogain represents an effective and reliable adjunct to conventional periodontal therapy for regenerating periodontal tissues. Further long-term studies are needed to assess the stability of these results over time and explore the material's potential in more complex periodontal defects.

Conflict of Interest: Nil
Financial Support: Nil

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