RESEARCH PAPER

Local Delivery of Human Placental Extract Gel Using an Absorbable Gelatin Sponge During Periodontal Flap Surgery: A Randomized Split-Mouth Clinical Trial

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Abstract

Background: Periodontal flap surgery remains a cornerstone in the surgical management of periodontitis by facilitating effective root surface debridement and reducing periodontal pocket depth. Nevertheless, optimal postoperative wound healing and periodontal regeneration remain challenging. Human placental extract (HPE), a biologically active preparation rich in growth factors, peptides, amino acids, and cytokines, has demonstrated anti-inflammatory, angiogenic, and regenerative properties that may enhance periodontal tissue repair. This randomized split-mouth clinical trial evaluated the effectiveness of HPE gel as an adjunct to periodontal flap surgery in improving wound healing and clinical periodontal outcomes.

Methods: Fourteen systemically healthy patients diagnosed with Stage II or Stage III, Grade B periodontitis requiring periodontal flap surgery in at least two comparable quadrants were recruited. In each patient, one surgical site was randomly assigned to receive HPE gel (Placentrex®) incorporated into an absorbable gelatin sponge before flap closure (test site), while the contralateral site underwent conventional flap surgery without HPE application (control site). Clinical parameters, including Plaque Index (PI), Gingival Index (GI), Gingival Bleeding Index (GBI), Probing Pocket Depth (PPD), Clinical Attachment Level (CAL), and the Landry Wound Healing Index, were assessed at baseline and at 1 week, 1 month, and 3 months postoperatively. Statistical significance was established at $p < 0.05$.

Results: Both treatment groups exhibited significant improvements in periodontal clinical parameters throughout the study period. However, test sites treated with HPE demonstrated significantly superior early wound healing, greater reductions in gingival inflammation and bleeding, and more pronounced improvements in probing pocket depth and clinical attachment level than control sites ($p < 0.05$). No treatment-related adverse events or hypersensitivity reactions were observed.

Conclusion: Adjunctive application of human placental extract gel during periodontal flap surgery significantly enhanced early soft tissue healing and improved clinical periodontal outcomes compared with conventional flap surgery alone. These findings suggest that HPE gel is a safe and promising biologically active adjunct for enhancing periodontal surgical wound healing and may improve the predictability of postoperative clinical outcomes.

Keywords: Human placental extract; Placentrex®; Periodontal flap surgery; Periodontitis; Wound healing; Split-mouth clinical trial; Clinical attachment level; Periodontal regeneration.

How to cite this article: Shashank K, Kudva PB. Local Delivery of Human Placental Extract Gel Using an Absorbable Gelatin Sponge During Periodontal Flap Surgery: A Randomized Split-Mouth Clinical Trial. Int J Drug Deliv Technol. 2026;16(71s): 248-256. DOI: 10.25258/ijddt.16.71s.28

Introduction

Periodontitis is a chronic multifactorial inflammatory disease characterized by the progressive destruction of the periodontal supporting tissues, leading to clinical attachment loss, periodontal pocket formation, and eventual tooth loss if left untreated. The 2018 Classification of Periodontal and Peri-Implant Diseases and Conditions provides a comprehensive framework for diagnosis and treatment planning based on disease severity, complexity, and rate of progression. Although scaling and root planing (SRP) remains the cornerstone of periodontal therapy, non-surgical treatment alone may be insufficient in sites with persistent deep periodontal pockets and advanced periodontal destruction. In such cases, periodontal flap surgery is indicated to provide direct access for thorough root debridement, elimination of inflamed tissues, and improvement of periodontal health.

Successful periodontal flap surgery depends not only on effective debridement but also on rapid and predictable wound healing. Periodontal wound healing is a complex biological process involving inflammation, angiogenesis, fibroblast proliferation, collagen synthesis, extracellular matrix remodeling, and tissue maturation. However, delayed epithelialization, prolonged inflammatory responses, and the limited regenerative potential of periodontal tissues may compromise surgical outcomes. Consequently, there has been growing interest in biologically active adjunctive agents capable of enhancing tissue repair, accelerating wound healing, and improving clinical periodontal outcomes.

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Human placental extract (HPE) has emerged as a promising biologically active therapeutic agent owing to its rich composition of peptides, amino acids, nucleotides, enzymes, vitamins, cytokines, and growth factors. These bioactive constituents possess anti-inflammatory, antioxidant, angiogenic, and immunomodulatory properties that promote fibroblast proliferation, collagen synthesis, neovascularization, and epithelial regeneration. Collectively, these biological effects contribute to accelerated soft tissue healing and improved tissue remodeling, making HPE an attractive adjunct in regenerative periodontal therapy.

Several clinical studies have demonstrated the beneficial effects of HPE in periodontal treatment. Adjunctive use of HPE during scaling and root planing has been associated with greater reductions in probing pocket depth, improved clinical attachment gain, and enhanced resolution of gingival inflammation compared with conventional therapy alone. Histological studies have further reported improved epithelialization and connective tissue organization, while recent biomarker-based investigations have demonstrated increased periostin expression following periodontal flap surgery, supporting its role in enhancing periodontal wound healing and regeneration. These findings suggest that HPE may serve as a valuable biologically active adjunct in periodontal therapy.

Despite these encouraging findings, evidence regarding the adjunctive application of HPE during conventional periodontal flap surgery remains limited. Most available studies have primarily evaluated its role in non-surgical periodontal therapy or focused on isolated clinical and biomarker outcomes. Comprehensive assessment of postoperative wound healing together with clinical periodontal parameters in a randomized split-mouth clinical trial remains scarce. Therefore, the present study was undertaken to evaluate the effectiveness of human placental extract gel as an adjunct to periodontal flap surgery in enhancing wound healing and improving clinical periodontal outcomes. It was hypothesized that adjunctive application of HPE gel would result in superior postoperative healing and greater improvement in clinical periodontal parameters compared with periodontal flap surgery alone.

Study Population

Fourteen systemically healthy patients diagnosed with Stage II or Stage III, Grade B periodontitis according to the 2018 Classification of Periodontal and Peri-Implant Diseases and Conditions were recruited from the outpatient clinic of the Department of Periodontology and Implantology. Participants requiring periodontal flap surgery in at least two comparable quadrants were screened for eligibility.

Inclusion Criteria

- Patients aged 25–55 years.
- Stage II or Stage III, Grade B periodontitis.
- Presence of probing pocket depth (PPD) ≥5 mm in at least two comparable quadrants requiring periodontal flap surgery.
- Systemically healthy individuals.
- Patients willing to provide written informed consent.

Exclusion Criteria

- Presence of systemic diseases or conditions affecting periodontal wound healing.
- Antibiotic or anti-inflammatory therapy within the previous six months.
- Current smokers or tobacco users.
- Pregnant or lactating women.
- History of periodontal surgery at the selected sites within the previous six months.
- Known hypersensitivity to human placental extract or any study material.

Sample Size Estimation

Sample size estimation was performed using G*Power software (Version 3.1, Heinrich Heine University, Düsseldorf, Germany). Based on an effect size of 1.1 reported for probing pocket depth in a previous clinical study, with a significance level (α) of 0.05 and a statistical power of 85%, a total sample size of 28 surgical sites (14 patients in a split-mouth design) was determined to be sufficient for detecting clinically significant differences between the treatment groups.

Randomization

Eligible quadrants within each participant were randomly allocated to either the test or control group using a computer-generated randomization sequence. One quadrant received periodontal flap surgery with adjunctive human placental extract gel (test site), while the contralateral quadrant underwent conventional periodontal flap surgery alone (control site). The split-mouth design minimized patient-related confounding variables and enabled direct intra-individual comparison.

Clinical Parameters

The following clinical parameters were recorded at baseline and during follow-up:

- Plaque Index (PI)
- Gingival Index (GI)
- Gingival Bleeding Index (GBI)
- Probing Pocket Depth (PPD)
- Clinical Attachment Level (CAL)

Postoperative soft tissue healing was assessed using the Landry, Turnbull, and Howley Wound Healing Index, while postoperative pain and patient discomfort were evaluated using a Visual Analogue Scale (VAS) and a structured patient discomfort questionnaire. Any adverse events were documented and graded according to the Common Terminology Criteria for Adverse Events (CTCAE).

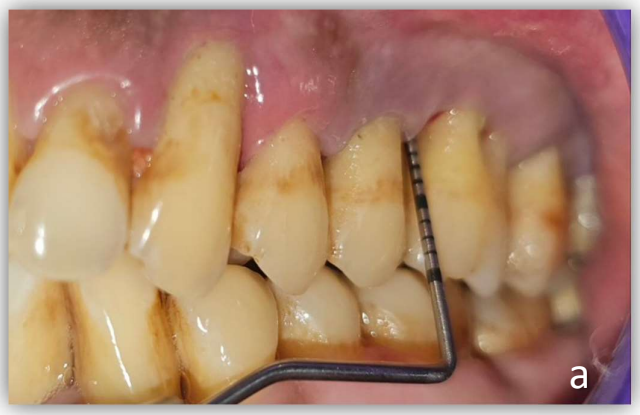
Surgical Procedure

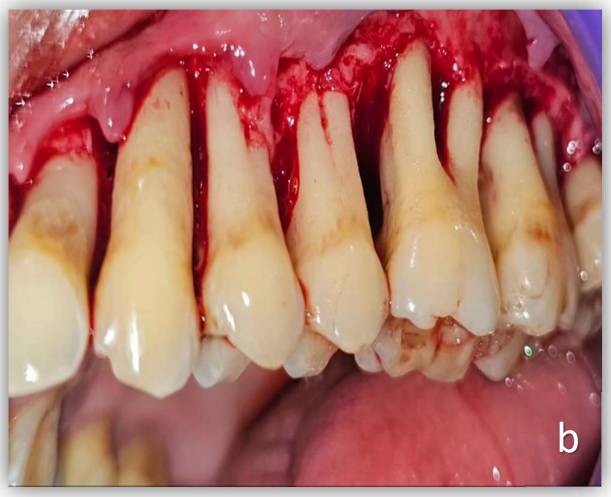
All participants initially underwent scaling and root planing followed by reinforcement of oral hygiene instructions. After completion of the initial phase of therapy, baseline clinical measurements were recorded prior to surgery.

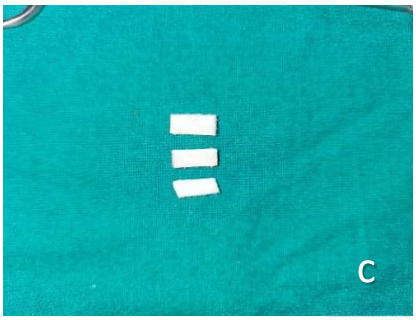
Following administration of local anesthesia using 2% lignocaine with 1:80,000 epinephrine, crevicular incisions

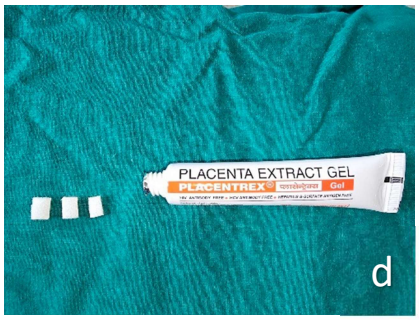
were made and full-thickness mucoperiosteal flaps were elevated to expose the root surfaces. Thorough debridement, root planing, and removal of granulation tissue were performed under direct vision, followed by irrigation with sterile normal saline.

At the test sites, approximately 1 mL of human placental extract gel (Placentrex®, Albert David Limited, India) was incorporated into small pieces of absorbable gelatin sponge (AbGel®, Sri Gopal Krishna Laboratories Pvt. Ltd., India) and placed within the surgical defect before flap repositioning. At the control sites, the surgical procedure was completed without the application of placental extract gel. In both groups, flaps were repositioned, secured with interrupted silk sutures.









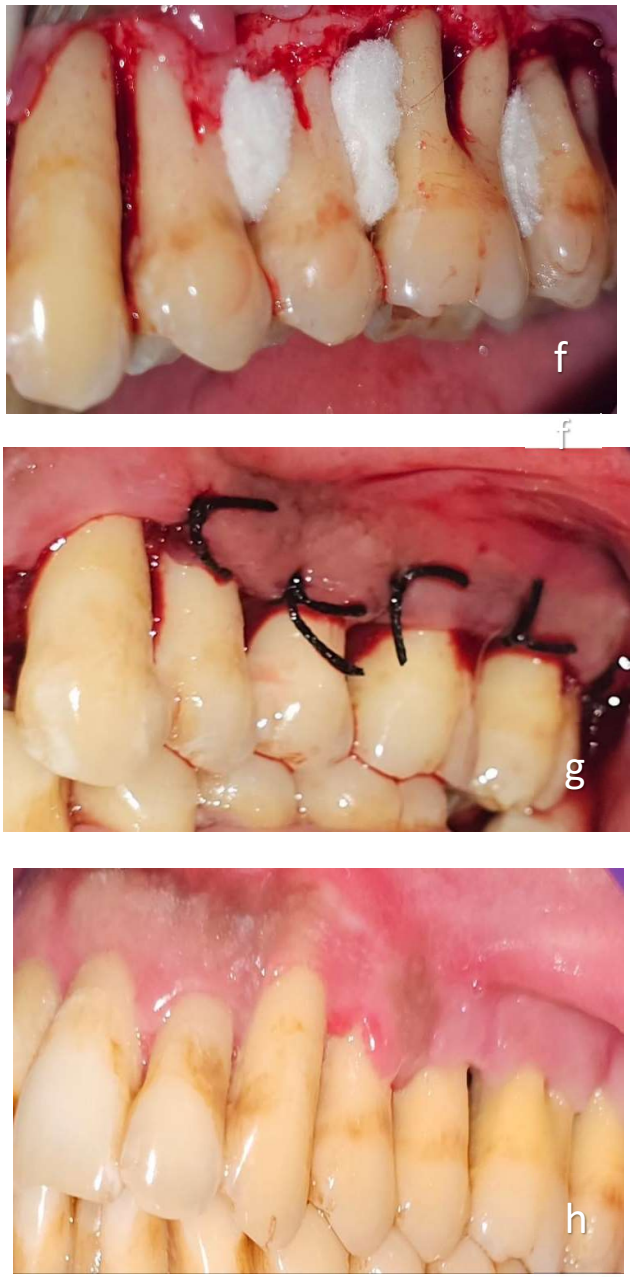


Figure 1: Test Site Surgical Workflow; a: Baseline clinical measurements recorded prior to surgery; **b:** Full-thickness mucoperiosteal flaps were elevated to expose the root surfaces. Thorough debridement, root planing, and removal of granulation tissue were performed; **c, d, e:** 1 mL of human placental extract gel (Placentrex®, Albert David Limited, India) was incorporated into small pieces of absorbable gelatin sponge (AbGel®, Sri Gopal Krishna Laboratories Pvt. Ltd., India); **f:** Local delivery of placental extract gel placed in the defect site; **g:** Flaps were repositioned, secured with interrupted silk sutures; **h:** Post-operative outcome after 3- months

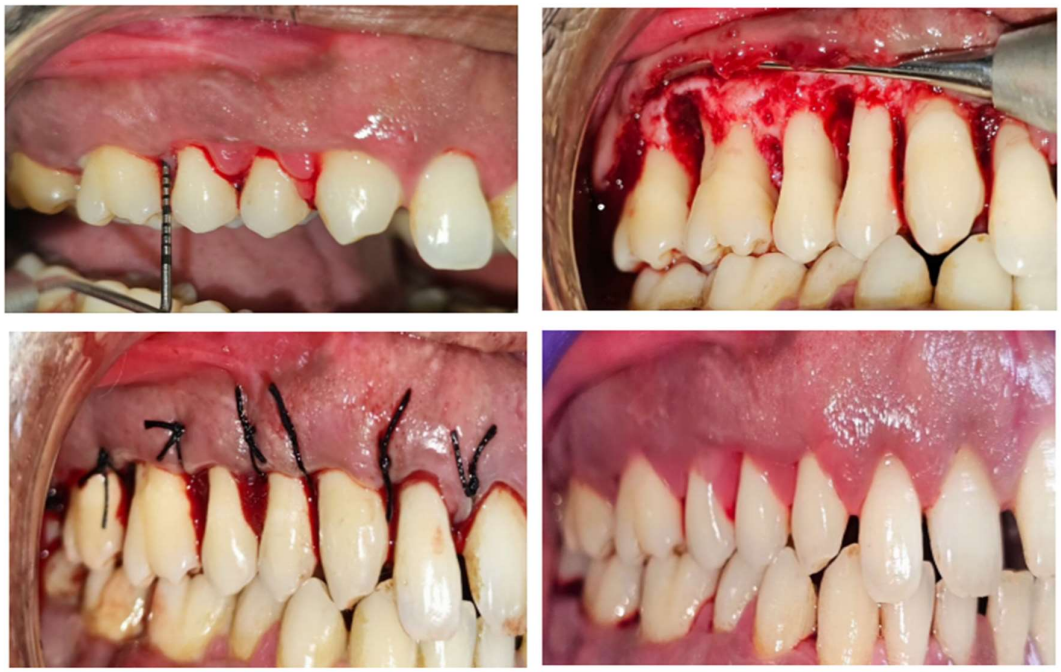


Figure 2: Control Site Surgical Workflow; Baseline clinical measurements recorded prior to surgery. Full-thickness mucoperiosteal flaps were elevated to expose the root surfaces. Thorough debridement, root planing, and removal of granulation tissue were performed. Flaps were repositioned, secured with interrupted silk sutures. Post-operative outcome after 3- months.

Postoperative Care

Participants received standardized postoperative instructions, including maintenance of oral hygiene and avoidance of mechanical trauma at the surgical sites. Analgesics were prescribed when required for postoperative pain management. Sutures and periodontal dressing were removed one week after surgery. Clinical evaluations were performed at 1 week, 1 month, and 3 months following the surgical procedure.

Outcome Measures

The primary outcome of the study was postoperative wound healing assessed using the Landry Wound Healing Index.

Secondary outcomes included changes in Plaque Index, Gingival Index, Gingival Bleeding Index, Probing Pocket Depth, Clinical Attachment Level, postoperative pain, patient discomfort, and incidence of adverse events throughout the follow-up period.

Statistical Analysis

Statistical analysis was performed using IBM SPSS Statistics software (Version 26.0; IBM Corp., Armonk, NY, USA). Data were expressed as mean ± standard deviation. Normality of data distribution was assessed using the Shapiro–Wilk test. Intergroup comparisons between test and control sites were performed using paired statistical tests appropriate for the split-mouth study design. Changes within each group over different follow-up intervals were analyzed using repeated-measures analysis. A p-value <0.05 was considered statistically significant.

Results

A total of 14 patients completed the study, with no dropouts during the three-month follow-up period. All participants attended the scheduled postoperative visits, and no protocol deviations were observed. Healing was uneventful in both groups, with no serious adverse events reported throughout the study period.

Early Wound Healing and Patient-Reported Outcomes

At the one-week postoperative evaluation, the test sites treated with human placental extract (HPE) gel demonstrated significantly superior wound healing compared with the control sites. The mean Landry Wound Healing Index score was 4.6 ± 0.3 in the test group compared with 3.8 ± 0.4 in the control group, indicating faster epithelialization and improved soft tissue maturation.

Postoperative pain, assessed using the Visual Analogue Scale (VAS), was consistently lower in the HPE-treated sites. At 24 hours, the mean VAS score was 2.1 ± 0.7 in

the test group compared with 3.4 ± 0.9 in the control group. Similarly, at one week, pain scores further decreased to 0.8 ± 0.4 in the test group, whereas the control group recorded a mean score of 1.6 ± 0.6, demonstrating a faster resolution of postoperative discomfort following adjunctive HPE application.

Patient-reported postoperative discomfort was also reduced in the test group, with a mean questionnaire score of 1.2 ± 0.5, compared with 2.4 ± 0.7 in the control group. Throughout the follow-up period, no major postoperative complications or adverse reactions were observed. According to the Common Terminology Criteria for Adverse Events (CTCAE), all participants remained within Grade 0–1, with fewer mild inflammatory reactions observed at HPE-treated sites.

Clinical Periodontal Outcomes

Both treatment groups demonstrated improvements in periodontal clinical parameters over the three-month follow-up period. However, the HPE-treated sites consistently exhibited greater clinical improvement than the control sites.

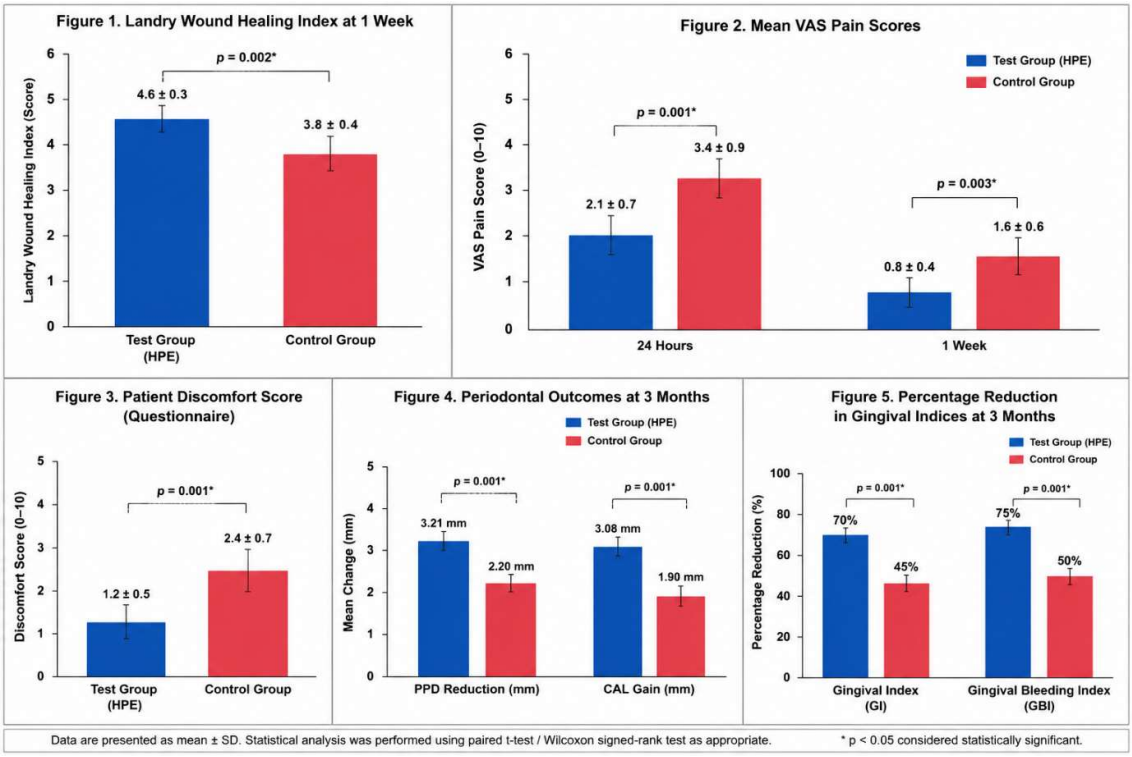
At three months, the mean reduction in probing pocket depth (PPD) was 3.21 mm in the test group compared with 2.20 mm in the control group. Similarly, the mean clinical attachment level (CAL) gain was greater at the test sites (3.08 mm) than at the control sites (1.90 mm).

Improvements in gingival health were also more pronounced in the HPE group. The Gingival Index (GI) showed a 70% reduction in the test group compared with 45% in the control group, representing approximately 54% greater improvement following adjunctive HPE therapy. Likewise, the Gingival Bleeding Index (GBI) decreased by 75% in the test group compared with 50% in the control group, indicating substantially greater resolution of gingival inflammation.

Overall, adjunctive application of human placental extract gel resulted in enhanced early wound healing, reduced postoperative pain and discomfort, greater improvement in clinical periodontal parameters, and excellent postoperative safety compared with conventional periodontal flap surgery alone.

Table 1. Comparison of Postoperative Clinical Outcomes Between Test and Control Groups

Parameter	Test Group (HPE)	Control Group
Landry Wound Healing Index (1 week)	4.6 ± 0.3	3.8 ± 0.4
VAS Pain Score (24 hours)	2.1 ± 0.7	3.4 ± 0.9
VAS Pain Score (1 week)	0.8 ± 0.4	1.6 ± 0.6
Patient Discomfort Score	1.2 ± 0.5	2.4 ± 0.7
CTCAE Adverse Events	Grade 0–1	Grade 1
PPD Reduction (3 months)	3.21 mm	2.20 mm
CAL Gain (3 months)	3.08 mm	1.90 mm
Gingival Index Reduction	70%	45%
Gingival Bleeding Index Reduction	75%	50%



Discussion

The present randomized split-mouth clinical trial evaluated the clinical effectiveness of locally delivered human placental extract (HPE) gel incorporated into an absorbable gelatin sponge as an adjunct to conventional periodontal flap surgery. The study was designed to determine whether localized delivery of HPE could improve postoperative wound healing, enhance periodontal clinical outcomes, reduce postoperative discomfort, and demonstrate acceptable clinical safety. The overall observations indicate that adjunctive HPE application may provide additional therapeutic benefits beyond conventional flap surgery by promoting a more favorable healing environment during the early postoperative period.

Periodontal wound healing is a dynamic biological process involving sequential phases of inflammation, cell migration, angiogenesis, extracellular matrix deposition, and tissue remodeling. Although periodontal flap surgery provides adequate access for debridement and elimination of local etiologic factors, the quality and rate of healing are influenced by the biological response of the host. Therefore, strategies capable of modulating the local healing environment have gained considerable attention. Local drug delivery systems are particularly attractive in periodontal therapy because they permit delivery of therapeutic agents directly to the surgical site, maintain higher local drug concentrations than systemic administration, reduce systemic exposure, and potentially improve therapeutic efficacy.

A distinguishing feature of the present study was the use of an absorbable gelatin sponge as a local carrier for HPE. In addition to facilitating placement of the gel within the periodontal defect, the carrier may help retain the bioactive preparation at the surgical site during the initial healing phase. Such localized retention could enhance tissue exposure to the active constituents of HPE while minimizing premature displacement after flap repositioning. Although the release kinetics of HPE from the gelatin sponge were not evaluated, the carrier represents a practical biodegradable platform that may improve local bioavailability of regenerative molecules during the critical stages of wound repair. From a drug delivery perspective, this approach combines ease of clinical application with targeted therapy, both of which are desirable characteristics of an adjunctive periodontal delivery system.

The enhanced wound healing observed following adjunctive HPE application may be explained by the diverse biological constituents present within placental extract. HPE contains peptides, amino acids, nucleotides, enzymes, vitamins, cytokines, and growth factors that collectively influence several stages of tissue repair. Experimental evidence suggests that these bioactive molecules stimulate fibroblast proliferation, promote collagen synthesis, enhance angiogenesis, regulate inflammatory mediators, and accelerate epithelial regeneration. The combined effect of these mechanisms contributes to improved extracellular matrix organization and maturation of healing tissues, thereby supporting favorable postoperative wound healing.

The biological rationale described above is consistent with previously published investigations evaluating placental extract in periodontal therapy. Sharma et al. reported improved clinical periodontal parameters following adjunctive HPE use during non-surgical periodontal

therapy, while Bhadauriya et al. demonstrated enhanced clinical outcomes with placental extract used in conjunction with scaling and root planing. Garapati et al. further reported improved epithelial organization and reduced inflammatory cell infiltration following HPE application, providing histological support for its regenerative potential. More recently, Rathana et al. demonstrated increased periostin expression after adjunctive HPE therapy during periodontal flap surgery, suggesting enhanced extracellular matrix remodeling and connective tissue maturation. Although the methodologies and outcome measures differed among these studies, the available evidence consistently supports the regenerative potential of HPE in periodontal wound healing.

An additional observation of the present study was the improvement in periodontal clinical parameters following local HPE application. Improved probing pocket depth reduction and clinical attachment gain may be attributed to rapid resolution of postoperative inflammation combined with enhanced connective tissue repair. Control of inflammation is essential during the early healing phase because excessive inflammatory activity may impair fibroblast function, delay collagen deposition, and compromise tissue maturation. By promoting a favorable healing environment, HPE may indirectly contribute to improved periodontal stability during postoperative remodeling. Although clinical attachment gain cannot be interpreted as direct evidence of true periodontal regeneration, the observed improvements suggest enhanced healing compared with conventional flap surgery alone.

The reduction in postoperative pain and patient discomfort observed in the HPE-treated sites may also be explained by its biological activity. Previous investigations have suggested that placental extract exhibits anti-inflammatory and antioxidant properties capable of modulating local inflammatory mediators and reducing oxidative tissue injury. Enhanced angiogenesis and accelerated epithelial repair may further contribute to reduced tissue sensitivity during the early postoperative period. From a clinical perspective, improved patient comfort may encourage better compliance with postoperative instructions and improve the overall acceptance of periodontal surgical treatment.

The safety profile observed following local HPE administration was encouraging. No clinically significant adverse reactions or hypersensitivity responses were encountered during the follow-up period, supporting the biocompatibility of the therapeutic approach. Local administration offers an additional advantage by concentrating the therapeutic agent at the target site while minimizing systemic exposure. This characteristic is particularly relevant in periodontal therapy, where localized disease can often be managed effectively using site-specific delivery systems rather than systemic medication.

The findings of the present study have important clinical implications for periodontal drug delivery. Successful regenerative therapy requires not only effective elimination of infection but also maintenance of an environment that supports tissue repair. The combination of HPE with a biodegradable gelatin sponge represents a simple and clinically feasible local delivery strategy that integrates biological stimulation with targeted placement of the therapeutic agent. Compared with repeated topical application, incorporation of HPE into a carrier may improve retention within the surgical site and enhance contact between the bioactive preparation and healing tissues. Such characteristics make this delivery approach attractive for routine periodontal surgical practice.

Several strengths of the present investigation should be acknowledged. The randomized split-mouth design minimized inter-patient variability by allowing each participant to serve as their own control. Standardized surgical procedures and postoperative protocols reduced procedural variability, while assessment of both clinical and patient-reported outcomes provided a comprehensive evaluation of treatment response. Nevertheless, certain limitations should be considered when interpreting the findings. The relatively small sample size and short follow-up period may limit generalization of the results. In addition, pharmacokinetic behavior, release characteristics of HPE from the gelatin sponge, biomarker expression, and histological evidence of periodontal regeneration were not investigated. Future studies should incorporate controlled drug-release analysis, molecular biomarkers, advanced imaging techniques, and longer follow-up periods to further characterize the therapeutic potential of this localized delivery system.

Overall, the present investigation supports the concept that localized delivery of human placental extract using an absorbable gelatin sponge may represent a promising adjunctive strategy in periodontal flap surgery. By combining a biodegradable carrier with a biologically active regenerative agent, this approach has the potential to improve the local healing environment, enhance postoperative recovery, and support favorable periodontal clinical outcomes. Further well-designed randomized clinical trials with comprehensive pharmacodynamic and controlled-release evaluations are warranted to establish the long-term clinical effectiveness of this drug delivery approach.

Conclusion

Within the limitations of the present randomized split-mouth clinical trial, adjunctive application of human placental extract (HPE) gel using an absorbable gelatin sponge as a local drug delivery system demonstrated favorable clinical outcomes following periodontal flap surgery. The localized delivery approach may enhance retention of the bioactive agent at the surgical site, thereby supporting early wound healing, reducing postoperative pain and discomfort, and improving clinical periodontal parameters. The biodegradable gelatin sponge provided a simple and clinically feasible carrier for HPE, highlighting its potential as an effective adjunct in periodontal surgical therapy. Although the findings indicate that localized HPE delivery may improve postoperative healing and periodontal outcomes, further multicenter randomized controlled trials with larger sample sizes, longer follow-up periods, and evaluation of pharmacokinetic, biomarker, and histological outcomes are required to confirm these

observations and establish its long-term clinical efficacy. Within the scope of the present study, HPE gel delivered through an absorbable gelatin sponge appears to be a promising adjunctive local drug delivery strategy for enhancing periodontal wound healing following flap surgery.

Acknowledgements
The authors express their sincere gratitude to the Department of Periodontology and Implantology, Sri Siddhartha Dental College and Hospital, Tumakuru, Karnataka, for providing the necessary facilities and institutional support to conduct this study. The authors also thank all the participants for their cooperation and willingness to participate.

Funding
Funding
The authors received no external financial support for the conduct of this study.

Conflict of Interest
The authors declare that there are no conflicts of interest regarding the publication of this manuscript.

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