

Original Research Article

Evaluation of Soft Tissue Healing after Periodontal Surgery Assisted with EPX® Biomolecule

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Article History

Received: 08.08.2026

Accepted: 24.09.2026

Published: 28.09.2026

Journal homepage:

<https://www.easpublisher.com>

Quick Response Code



Abstract: Periodontal surgery is widely used in dentistry to treat periodontal conditions and restore oral health. Biomolecules have been incorporated into periodontal procedures to promote healing and tissue regeneration. The EPX® Biomolecule is a nanostructure composed of chitosan, graphene, thymol, and metals, including colloidal silver nanoparticles, with potential regenerative, healing, and antiseptic properties. This study aimed to evaluate the quality of soft tissue healing following periodontal surgery assisted by EPX® Biomolecule in its pharmaceutical form as a surgical gel. An experimental Phase I clinical trial was conducted in 45 patients undergoing periodontal surgery at the University Polyclinic of the Mexicali School of Dentistry, Autonomous University of Baja California, Mexico, from February 2024 to May 2025. Following informed consent, EPX® Biomolecule surgical gel was applied intraoperatively. Healing was assessed using the Early Wound Healing Score (EHS) at 7, 14, and 28 days and compared with a control group of 45 patients treated with 0.12% chlorhexidine and selected based on procedural similarity. All patients demonstrated favorable postoperative soft tissue healing. At 7 days, the EPX® Biomolecule group showed significantly better re-epithelialization, inflammation, and overall EHS outcomes than the control group; at 14 days, a significant difference remained only for re-epithelialization, while no significant differences were observed at 28 days. No adverse reactions associated with the topical intraoperative application of EPX® Biomolecule were observed.

Keywords: Periodontics, Periodontal Surgery, Wound Healing, Nanoparticles, Chitosan, Surgical Antiseptic.

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INTRODUCTION

Periodontal surgery encompasses a group of procedures designed to treat periodontal diseases and restore oral health. The success of these treatments depends on proper soft-tissue healing, a process involving multiple cellular and molecular factors. Adequate restoration of periodontal tissues is crucial for patient recovery, as it impacts oral function, aesthetics, and oral health [1].

Despite advances in periodontal surgical techniques, one of the most significant challenges is

achieving predictable, high-quality healing. Factors such as inflammation, scar tissue formation, and the patient's individual response to surgery can positively or negatively impact outcomes. Therefore, there is a need to explore new strategies that optimize clinical outcomes and minimize postoperative complications [2].

In this context, the search for new methods to improve periodontal surgical procedures led to the use of biomolecules or nanomolecules. These substances are designed around a biologically derived molecule, reinforced with added nanoparticles, and have demonstrated great potential for regulating and

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stimulating the regeneration and healing processes of oral tissues [3].

A decade ago, MedicalTech Laboratorios S.A. de C.V., in collaboration with the Autonomous University of Baja California (UABC) and its Institute of Engineering, developed a biomolecule based on chitosan enriched with graphene nanoparticles, metals (colloidal silver and copper), and essential oils that provide specific properties, such as tissue regeneration and antiseptic action. This nanomedicine was registered as Biomolecule EPX® and is available in various pharmaceutical forms for dental use, such as surgical gel, post-surgical gel, mouthwash, and biodegradable strips for periodontal use [4, 5].

Biomolecule EPX® was evaluated in experimental *in vitro* and *in vivo* studies, as well as in preclinical trials, yielding very favorable and encouraging results due to its low incidence of adverse reactions. To continue the clinical studies, a general project was developed to evaluate various topical pharmaceutical forms in healthy individuals or those with mild conditions; from this, a specific project was derived to evaluate the efficacy of the surgical gel in periodontal procedures. For this reason, the Mexicali School of Dentistry, part of the UABC, specifically its University Postgraduate Polyclinic, was chosen as the site for the clinical trials because it possesses the material and human resources necessary for this type of research.

The overall objective of this study was to evaluate soft tissue healing after periodontal surgery assisted with the EPX® Biomolecule in its surgical gel formulation. Specifically, patients requiring periodontal surgical treatment were stratified according to clinical and therapeutic variables; to define postoperative healing parameters in periodontal surgery assisted with the EPX® Biomolecule in its surgical gel formulation; and to measure the therapeutic efficacy of the EPX® Biomolecule compared to a 0.12% chlorhexidine gluconate surgical solution.

METHODS

An experimental study was conducted—a Phase I, open-label, parallel-group clinical trial—to evaluate the pharmacodynamics and safety of the EPX® Biomolecule as an adjunct to periodontal surgery, through systematic monitoring of soft tissue healing and comparison with a 0.12% chlorhexidine gluconate solution.

The study population consisted of 168 patients requiring periodontal surgery who presented to the Periodontics Department at the University Polyclinic of the Mexicali Campus, Autonomous University of Baja California, Mexico, during the period from February 2024 to May 2025.

The study sample consisted of 90 patients, who were selected through controlled, non-randomized sampling and divided into two groups: a study group of 45 patients treated with the EPX® Biomolecule and a control group of 45 patients treated with 0.12% chlorhexidine gluconate. The selection method aimed to ensure the greatest possible parallelism between the two groups in terms of age groups, sex, and surgical procedure.

Inclusion Criteria:

- Adult patients (18 years of age or older) requiring periodontal surgery who provided valid informed consent to participate in the study.
- Patients with no history of medical conditions that would pose an uncontrolled surgical risk, no substance abuse, and no allergies to medications and/or foods.

Exclusion Criteria:

- Patients who did not meet any of the inclusion criteria.
- Patients with a history of previous periodontal treatments—both surgical and nonsurgical—within the last year.

Discharge Criteria:

- Patients who, after undergoing surgery, did not attend their scheduled postoperative follow-up appointments.

The Variables Studied Were:

- Clinical: Age (divided into age groups) and sex (biological condition at birth)
- Therapeutic: Types of surgical treatments on periodontal tissues.
- Intraoperative medication administered: EPX® Biomolecule (study group) and 0.12% chlorhexidine gluconate (control group)
- Clinical signs of healing: Re-epithelialization, hemostasis, and inflammation.

A Clinical Trial Protocol was developed and approved by the Ethics and Research and Graduate Studies Evaluation Committee in January 2024, with registration number FOM/UABC/CEEIP/2024-005-01-01. Its objective was to measure key parameters such as re-epithelialization, hemostasis, and reduction of inflammation, as well as to evaluate potential adverse effects. The study complied with the bioethical principles of autonomy, beneficence, non-maleficence, and justice, and was supported by the signing of a valid informed consent form prior to surgical treatment.

Techniques and Procedures for Gathering Information:

Initially, all patients participating in the study underwent some form of periodontal surgery.

During Surgery:

- Study group: The EPX® Biomolecule was applied as a surgical gel for 2 minutes and then rinsed off with normal saline.
- Control group: A 0.12% chlorhexidine gluconate surgical solution was applied for 2 minutes and then rinsed off with normal saline.

Subsequently, clinical follow-up with photographic documentation was conducted at three postoperative time points: 7 days, 14 days, and 28 days. During these follow-up visits, the Early Wound Healing Score (Early Wound Healing Score, EHS), published in 2018 and evaluated in 2019 by Marini L *et al.*, was used. It consists of three fundamental parameters: clinical signs of re-epithelialization (CSR), clinical signs of hemostasis (CSH), and clinical signs of inflammation (CSI) [6, 7].

Clinical Signs of Re-epithelialization (CSR): Measures the progress of new epithelium formation at the wound site and uses the following scoring system:

- 0 points: visible gap between the incision margins.
- 3 points: contact between the incision margins.
- 6 points: fused incision margins.

Clinical Signs of Hemostasis (CSH): Determines the quality of hemostasis in the surgical area; its scoring scale includes:

- 0 points: bleeding at the incision margins.
- 1 point: presence of fibrin at the incision margins.
- 2 points: absence of fibrin at the incision margins.

Clinical Signs of Inflammation (CSI): Assesses the presence of signs of inflammation as an indicator of wound healing and uses the following scores:

- 0 points: redness involving more than 50% of the incision's length and/or pronounced swelling.
- 1 point: redness involving less than 50% of the incision's length.
- 2 points: absence of redness along the entire length of the incision.

Early Wound Healing Score (EHS): A total score is obtained by summing the three parameters mentioned above.

- 0 to 5 points: favorable healing has not been achieved
- 6 to 10: the healing process has been favorable

Data Processing and Analysis Techniques

All information from the records and forms was entered into a database created using Microsoft Excel 2016. First, descriptive biostatistical methods were applied: frequencies and percentages; then, inferential biostatistics were used, including the calculation of the chi-square (χ^2) test for $p < 0.05$, with Yates' correction.

RESULTS

Table 1 shows the distribution of patients by age group and biological sex. It was determined that the study group consisted of 55.6% men and 44.4% women, while the control group consisted of 51.1% men and 48.9% women.

Table 1: Distribution of patients by age group and biological sex

Age groups (years)	Study group (nc=45)				Control group (nc=45)				Total	
	Female		Male		Female		Male			
	No.	%	No.	%	No	%	No.	%	No.	%
20 years or younger	1	2.2	3	6.7	2	4.4	2	4.4	8	8.9
21 to 30 years	3	6.7	2	4.4	3	6.7	2	4.4	10	11.1
31 to 40 years	2	4.4	5	11.1	3	6.7	4	8.9	14	15.6
41 to 50 years	5	11.1	3	6.7	4	8.9	4	8.9	16	17.7
51 to 60 years	4	8.9	5	11.1	4	8.9	5	11.1	18	20
61 years or older	5	11.1	7	15.6	6	13.3	6	13.3	24	26.7
Total	20	22.2	25	27.8	22	24.4	23	25.6	90	100

Source: The study's own database.

Table 2 shows the periodontal surgical procedures performed, and it was determined that the primary treatment needs were for aesthetic, functional,

prosthetic, and tissue preservation purposes. 63.3% of the treatments involved soft tissues, 21.1% involved hard tissues, and 15.6% involved both types of tissue.

Table 2: Types of surgical procedures performed during the study

Surgical procedures performed	Study group		Control group		Total	
	No.	%	No.	%	No.	%
Crown lengthening	14	31.1	16	35.6	30	33.3
Frenectomy	9	20	10	22.2	19	21.1
Guided tissue regeneration	9	20	7	15.6	16	17.8

Surgical procedures performed	Study group		Control group		Total	
	No.	%	No.	%	No	%
Implant placement	6	13.3	6	13.3	12	13.3
Distal wedge	3	6.7	3	6.7	6	6.7
Alveolar ridge contouring	2	4.4	2	4.4	4	4.4
Vestibuloplasty	2	4.4	1	2.2	3	3.3
Total	45	100	45	100	90	100

Source: The study's own database.

Table 3: Evaluation of clinical parameters for early wound healing at 7 days postoperatively

Clinical parameters	Ranges	Study group		Control group		Total	
		No.	%	No.	%	No	%
Clinical Signs of Re-epithelialization	< 3	18	20	29	32.2	47	52.2
	3 a 6	27	30	16	17.8	43	47.8
	Total	45	50	45	50	90	100
		X2 = 5.3884 p = 0.0203 Yates: X2 = 4.4532 p = 0.0348					
Clinical Signs of Hemostasis	0 a 1	13	14.5	19	21.1	32	35.6
	2	32	35.5	26	28.9	58	64.4
	Total	45	50	45	50	90	100
		X2 = 1.7457 p = 0.1864 Yates: X2 = 1.2123 p = 0.2709					
Clinical Signs of Inflammation	0 a 1	15	16.7	28	31.1	43	47.8
	2	30	33.3	17	18.9	47	52.2
	Total	45	50	45	50	90	100
		X2 = 7.526 p = 0.0061 Yates: X2 = 6.4127 p = 0.0113					
Early Wound Healing Score	0 a 5	16	17.8	27	30	43	47.8
	6 a 10	29	32.2	18	20	47	52.2
	Total	45	50	45	50	90	100
		X2 = 5.3884 p = 0.0203 Yates: X2 = 4.4532 p = 0.0348					

Source: The study's own database.

Table 4: Evaluation of clinical parameters for early wound healing at 14 days postoperatively

Clinical parameters	Ranges	Study group		Control group		Total	
		No.	%	No.	%	No	%
Clinical Signs of Re-epithelialization	< 3	6	6.7	15	16.6	21	23.3
	3 a 6	39	43.4	30	33.3	69	76.7
	Total	45	50	45	50	90	100
		X2 = 5.0311 p = 0.0249 Yates: X2 = 3.9752 p = 0.0461					
Clinical Signs of Hemostasis	0 a 1	16	17.8	20	22.2	36	40
	2	29	32.2	25	27.8	54	60
	Total	45	50	45	50	90	100
		X2 = 0.7407 p = 0.3894 Yates: X2 = 0.4167 p = 0.5186					
Clinical Signs of Inflammation	0 a 1	13	14.4	21	23.3	34	37.7
	2	32	35.6	24	26.7	56	62.3
	Total	45	50	45	50	90	100
		X2 = 3.0252 p = 0.0820 Yates: X2 = 2.3162 p = 0.1280					
Early Wound Healing Score	0 a 5	8	8.9	14	15.6	22	24.4
	6 a 10	37	41.1	31	34.4	68	75.6
	Total	45	50	45	50	90	100
		X2 = 2.1658 p = 0.1411 Yates: X2 = 1.504 p = 0.2201					

Source: The study's own database.

Table 3 shows that, 7 days post-surgery, the application of the EPX® Biomolecule yielded better results in terms of re-epithelialization and inflammation compared to patients treated with 0.12% chlorhexidine. This had an impact on the Early Wound Healing Score score, with significant chi-square (X²) values and p < 0.05, even after applying the Yates correction.

Table 4 shows the data 14 days after surgery; the only significant values (chi-square and p < 0.05, even after applying Yates' correction) were observed in the re-epithelialization rate. The remaining parameters were not significant when comparing the EPX® Biomolecule with 0.12% chlorhexidine.

Table 5: Evaluation of clinical parameters for early wound healing at 28 days

Clinical parameters	Ranges	Study group		Control group		Total	
		No.	%	No.	%	No	%
Clinical Signs of Re-epithelialization	< 3	2	4.4	4	8.9	6	6.7
	3 a 6	43	95.6	41	91.1	84	93.3
	Total	45	50	45	50	90	100
	X2 = 0.7143 p = 0.3980 Yates: X2 = 0.1786 p = 0.6726						
Clinical Signs of Hemostasis	0 a 1	0	0	0	0	0	0
	2	45	100	45	100	90	100
	Total	45	50	45	50	90	100
	Statistical testing was not applicable						
Clinical Signs of Inflammation	0 a 1	0	0	0	0	0	0
	2	45	50	45	50	90	100
	Total	45	50	45	50	90	100
	Statistical testing was not applicable						
Early Wound Healing Score	0 a 5	0	0	0	0	0	0
	6 a 10	45	50	45	50	90	100
	Total	45	50	45	50	90	100
	Statistical testing was not applicable						

Source: The study's own database.

Table 5 shows the clinical data on healing 28 days after periodontal surgery, and it was found that, at 4 weeks, there were no significant differences between patients treated with the EPX® Biomolecule and those treated with 0.12% chlorhexidine.

DISCUSSION

In this clinical trial, the majority of participants were patients over 60 years of age, a finding consistent with what has been described in the literature regarding the higher prevalence of advanced periodontitis in this age group, as noted by Dolińska [8], and Hasan [9], and their colleagues. Regarding gender, men were overrepresented in the study population. However, these findings should be interpreted as descriptive characteristics of the sample, since the present study did not directly evaluate immunological, behavioral, or dental care access factors that might explain these differences, as reported by Natarajan [10], and Herrera [11], and their colleagues.

In the study population, crown lengthening was the most common periodontal surgical procedure, followed by frenectomy and guided tissue regeneration, in accordance with the patients' individual treatment and rehabilitation needs. The selection of these procedures depends on the clinical characteristics of each case, particularly when nonsurgical treatment proves insufficient, as noted by Herrera [11], and colleagues. In the present study, all patients showed a favorable postoperative course and adequate soft-tissue healing.

The available evidence suggests that the use of biomolecules in periodontal surgery may contribute to favorable healing outcomes. Atia [12], Torres-Rosas [13], Zhou [14], and Jøraholmen [15], and their colleagues have described antimicrobial effects and beneficial effects on re-epithelialization associated with

formulations containing chitosan, chlorhexidine, and metal nanoparticles. In the present study, the EPX® Biomolecule, formulated with these components, showed more favorable postoperative recovery than 0.12% chlorhexidine, particularly during the initial phases of healing.

Seven days after the procedure, patients treated with the EPX® Biomolecule showed more favorable healing outcomes, according to the Early Wound Healing Score. These results are consistent with those reported by Yuan [16], Sethiya [17], and Soto [18], and their collaborators, who described favorable outcomes in parameters related to wound healing. Furthermore, Atia [12], de Jesus [19], and Espinoza [20], have documented the antimicrobial properties and potential beneficial effects of chitosan and metal nanoparticles; however, the mechanisms related to cell proliferation and angiogenesis were not directly evaluated in the present study. Taken together, the findings suggest a potential benefit of the EPX® Biomolecule as an adjuvant in postoperative wound healing, although clinical trials with larger sample sizes are needed.

At 14 days, patients treated with the EPX® Biomolecule showed a modest but significant improvement in re-epithelialization, while the other parameters were similar to those observed with 0.12% chlorhexidine. At 28 days, no clinical differences were identified between the two groups. These results are consistent with those reported by Soto [18], and colleagues, who note that the combination of chitosan and nanoparticles enhances antimicrobial activity and healing, supporting the potential of the EPX® Biomolecule as an adjunct in periodontal surgery.

The therapeutic efficacy of the EPX® Biomolecule, compared with 0.12% chlorhexidine

gluconate, was favorable during the first 7 postoperative days; however, at 14 and 28 days, the clinical signs of healing were similar in both groups. These results are consistent with those of de Jesus [19], and Espinoza [20], who note that, although chlorhexidine is an effective antiseptic, it does not necessarily accelerate soft tissue healing, highlighting the importance of exploring biomolecular alternatives to optimize post-surgical recovery.

The findings support the potential use of the EPX® Biomolecule as an adjunct, based on the observed clinical outcomes and the absence of reported adverse reactions. Postoperative follow-up showed adequate recovery of epithelial and subcutaneous tissues, suggesting that the EPX® Biomolecule is not only safe but also effective in promoting healing.

CONCLUSION

In conclusion, the results of this study support the hypothesis that the EPX® Biomolecule has a positive impact on soft tissue healing when applied during periodontal surgery in its surgical gel formulation. Crown lengthening, frenectomy, and guided tissue regeneration were the most common surgical procedures in a population predominantly consisting of men over 50 years of age. Compared with the 0.12% chlorhexidine gluconate surgical solution, the EPX® Biomolecule showed better clinical results 7 days postoperatively, and there were no significant differences between the two groups at 14 and 28 days post-surgery. Further research is recommended in larger randomized groups to compare other pharmacological parameters of the EPX® Biomolecule in periodontal surgery.

Conflict of Interest:

Roberto Luis Ibarra Wiley declares his affiliation with MedicalTech Laboratorios S.A. de C.V., the company responsible for the development, manufacture, supply, financing, and intellectual property rights of the EPX® Biomolecule. The other authors declare that they have no conflicts of interest and that they participated in the research as part of their academic, clinical, and research activities at UABC.

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Cite This Article: Moreno-Solorio, M. A., Hermida-Rojas, M., Ibarra-Wiley, R. L., & Gómez-Flores, M. (2026). Evaluation of Soft Tissue Healing after Periodontal Surgery Assisted with EPX® Biomolecule. *EAS J Dent Oral Med*, 8(5), 164-170. <https://doi.org/10.36349/easjdom.2026.v08i05.003>
