IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)
e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 25, Issue 9 Ser. 3 (September. 2026), PP 26-32
www.iosrjournals.org

Clinical evaluation of efficacy of Insulin-like Growth Factor (IGF) fibres as a local drug delivery agent in non-surgical management of chronic periodontitis: A split-mouth clinical study

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Abstract
Background*: Local drug delivery systems have emerged as valuable adjuncts to non-surgical periodontal therapy (NSPT) by enabling the targeted delivery of therapeutic agents directly into periodontal pockets. Presently, different local drug formulations such as fibers, gels, strips, films, irrigation systems, and microparticles are available. Fibres, being a reservoir-based device inserted circumferentially into the periodontal pocket are considered to ensure excellent retention and controlled and sustained drug release.*
Aim: *This study evaluated the clinical efficacy of locally delivered insulin-like growth factor 1(IGF-1) fibres as an adjunct to non-surgical periodontal therapy in subjects with chronic periodontitis.*
Materials and Methods: *This randomized controlled split-mouth trial was conducted in 25 sites per group affected with chronic periodontitis, with periodontal pockets present bilaterally. Test sites received scaling and root planing (SRP) with locally delivered IGF-1fibres, while control sites received SRP alone. Clinical parameters – plaque index (PI), gingival index (GI), probing pocket depth (PPD), and clinical attachment level (CAL) were recorded at baseline and 3 months. Intragroup changes across time points were analysed using the Mann-Whitney U test, and intergroup comparisons were performed using the Wilcoxon signed Rank test, with significance set at 0.05.*
Results: *Significant intragroup PPD reductions were observed in both groups at 3 months. Intergroup differences were non-significant at baseline (P > 0.05). At 3 months, the test group demonstrated significantly greater improvements in PPD and CAL indicating superior clinical outcomes.*
Conclusion: *Local delivery of IGF-1 fibres resulted in significant reductions in PPD and CAL, suggesting a promising adjunctive approach to periodontal therapy.*
Key words*: Insulin-like growth factor, Periodontitis, Local drug delivery, Non-surgical periodontal therapy*

Date of Submission: 09-09-2026 Date of Acceptance: 18-09-2026

I. Introduction

Periodontitis is a highly prevalent chronic inflammatory disease that poses a substantial global health burden owing to its detrimental effects and potential to cause tooth loss and systemic health complications. Non-surgical periodontal therapy (NSPT), serves as the cornerstone of treatment for controlling periodontal infection; however clinical response is often heterogeneous, with a proportion of population showing persistent disease activity. Therefore, improving the effectiveness of treatment outcomes continues to be an important objective in periodontal care. [1]

Local drug delivery systems have emerged as valuable adjuncts to NSPT by enabling the targeted delivery of therapeutic agents directly into periodontal pockets. These systems provide localized administration of antimicrobial or anti-inflammatory agents through either an immediate or controlled sustained release, while minimizing systemic exposure and adverse side effects. Currently, available local drug formulations include fibers, gels, strips, films, irrigation systems, and microparticles. [2,3]

Among these fibers, or thread-like, reservoir-type delivery systems, that are inserted circumferentially into the periodontal pockets using an applicator and secured with cyanoacrylate adhesive. The drug release from

these fibers is approximately 95% of the agent in the first two hours followed by first order release kinetics. [2,4] Despite the clinical benefits demonstrated by existing local drug delivery systems, their therapeutic efficacy remains variable.

The insulin-like growth factors (IGFs) are multifunctional peptide growth factors that play essential roles in the growth, development and function of almost every organ and tissue in the body. Their diverse biologic effects and their therapeutic potential across a wide range of clinical conditions, have made the IGFs an important focus of biomedical research. [5,6]

Among the family, insulin-like growth factor-1 (IGF-1) has attracted particular interest because of its biologic effects and its actions on different tissues. As a principal mediator of many of the physiological actions of growth hormone, IGF-1 promotes osteogenesis, enhance protein synthesis, glucose uptake by skeletal muscle, and support neuronal survival and myelin formation. In addition, IGF-1 help preserve lean body mass by reducing muscle protein degradation and improving nitrogen balance during periods of nutritional deficiency. IGF-I has been investigated as a potential therapeutic agent for conditions such as osteoporosis, diabetes mellitus, obesity, insulin resistance, neuromuscular disorders, growth hormone resistance and other catabolic disease. Although its broad biological activity offers considerable therapeutic promise, the same diversity of actions may also increase the risk of off-target effects and adverse events, underscoring the need for careful evaluation of its clinical use. [5,7]

Additionally, the actions of IGF include the following:

- Promotion of regeneration of approximately 50% of the lost periodontal attachment apparatus within 4 weeks highlights its potential as a biologic mediator. [8]
- Recombinant human platelet-derived growth factor and IGF has resulted in regeneration of cementum, periodontal ligament, bone and connective tissue in experimental animals demonstrating a synergistic effect on periodontal regeneration.[7]
- Acceleration of soft tissue wound healing by stimulating cellular proliferation and regulating DNA and protein synthesis. [9]
- Promotion of osteogenic differentiation of periodontal ligament fibroblasts by activating periodontal ligament stem cells. [10]

Although SRP remains the cornerstone of non-surgical periodontal therapy, several factors limit its effectiveness. Complex anatomy of the tooth, tissue-invasive organisms, deep periodontal pockets, bacterial penetration into dentinal tubules and recolonization of pathogenic bacteria. To address these limitations, antimicrobial agents administered either systemically and local drug delivery are used as adjuncts to mechanical therapy. [2,4]

Research findings on IGF insulin like growth factor could significantly contribute to the development of enhanced treatment protocols and improve the overall management of periodontitis. However, its application as a local drug delivery agent has not been studied yet. Therefore, the aim of the present study was to evaluate the effect of IGF fibres as a local drug delivery agent in non-surgical management of chronic periodontitis.

II. Objectives

1. To evaluate the adjunctive effect of IGF fibres as a local drug delivery agent within the periodontal pockets.
2. To evaluate the change in clinical parameters following application of IGF fibres within the periodontal pockets.
3. To evaluate and compare the effect of SRP alone to that of adjunctive use of IGF fibres to SRP on the depth of periodontal pockets.

III. Materials and Methods

This prospective split-mouth, randomized clinical trial was conducted to evaluate the effect of locally delivered IGF fibres in subjects with periodontitis from August to November 2025 at the Department of Periodontics of our institute. The study protocol which, adhered to the guidelines of the Declaration of Helsinki was approved by the Institutional Ethical Committee (GDCH/ IEC /VII- 225) and was aregistered under Clinical Trial Registry of India. A written informed consent was obtained from each of the subjects before participation in the study.

Study population

The sample size was determined based on the results from a previous study. [11] A power analysis was established by G*Power version. Total minimum calculated sample size of 10 per group would yield 95% power to detect significant differences and significance level at 0.05. The sample size was rounded off to 25 per group to anticipate for the loss to follow up.

Inclusion criteria

- Age 20-55 years
- Male and female subjects with chronic periodontitis
- Presence of at least two contralateral sites with PPD of 5-6 mm
- Systemically healthy subjects

Exclusion criteria

- Pregnancy and lactation
- Smokers and tobacco users
- Hypertension
- Diabetes mellitus
- Any other systemic disorders which may affect the outcome of the treatment
- Subjects who are unwilling to participate in the study
- Subjects with chronic periodontitis showing radiographic evidence of angular bone defects

IV. Methodology

Following the recording of case history, clinical periodontal parameters such as PI, GI, PPD and CAL were assessed at baseline and at the end of 3 months. For each subject, equal number of sites from contralateral quadrants were selected with a maximum of three sites per quadrant were included. Following SRP, all subjects were recalled after 1 week for evaluation. All sites within a particular quadrant were randomly assigned using a lottery method, to one of the following groups:

Control Group (Group A): SRP alone

Test Group (Group B): SRP + IGF

Subjects from Group A were followed up every month for up to 3months to monitor the maintenance of oral hygiene and clinical periodontal parameters were evaluated at the end of 3 months.

In Group B, subjects underwent the procedure of local drug delivery. The required number of IGF fibres were cut to match the depth of the pocket and gently inserted into the base of the pocket with the help of tweezer or a curette. The fibres were carefully looped or layered within the pocket as an attempt to avoid trauma to the soft tissue. Care was taken to avoid overpacking so as to maintain blood supply and tissue integrity. Non-eugenol periodontal dressing was placed to stabilize the fibers and prevent dislodgment. After a period of 7 to 10 days, the periodontal dressing was gently removed. Subjects were followed up every month for up to 3 months to monitor the maintenance of oral hygiene and clinical periodontal parameters were recorded at 3 months follow up.

V. Statistical Analysis

Descriptive statistics were represented as mean and standard deviation for quantitative data, while frequency distribution was used for qualitative data. Intra-group comparisons of clinical parameters for two groups across two time points (baseline and 3 months) were conducted using the Mann-Whitney U test. Inter-group comparisons between the test and control groups at these time points were analysed with Wilcoxon signed Rank test. In addition, paired t-tests were utilized for intra-group comparisons between two time points. Statistical analyses were performed with a significance threshold of 0.05, where P values below this threshold were considered statistically significant. Data analysis was carried out using the SPSS software version 26.0 to ensure accuracy and reliability.

VI. Results

A total of 15 subjects completed the study. In all, 25 sites per group were treated comprising an equal distribution in each group - Control Group (Group A) and Test Group (Group B).

No statistically significant variations in PI and GI scores were observed between the two groups at any time point, indicating that the two treatment modalities produced similar gingival health and plaque control outcomes.

Table 1 presents the inter-group comparison of PPD between different time points (baseline and 3 months). When comparing baseline, control group and test group showed no statistically significant changes in the parameter with P = 0.309. While at 3 months, statistically significant change was noted in the parameter with P = 0.041. (Graph 1)

	Groups	Median (IQR)	Z value	p Value
Baseline	Control (A)	5(5-5)	-1.018	0.309
	Test (B)	5(5-5)		
3 Months	Control (A)	3(3-3)	-2.039	0.041

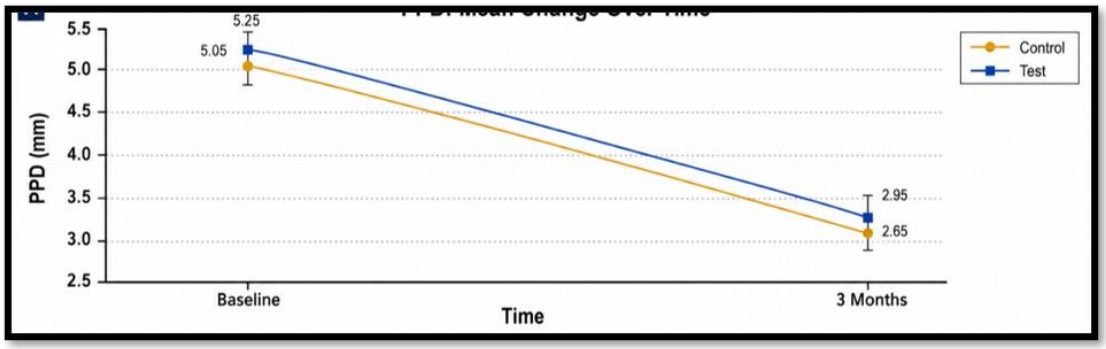
	Test (B)	3(2-3)		

Table 1: Comparison of PPD (mm)between control and test group at baseline and 3 months by using Mann-Whitney U test

Table 2 presents the intra-group comparison of PPD between different time points. When comparing baseline and 3 months, control group showed statistically significant changes in all parameters with P < 0.001. Similarly, in test group, PPD was statistically significant with P < 0.001. (Graph 1)

Groups	**Duration**	**Median (IQR)**	**Z value**	**p Value**
Control (A)	**Baseline**	5(5-5)	-4.165	<0.001
	3 Months	3(3-3)		
Test (B)	**Baseline**	3(3-3)	-4.137	<0.001
	3 Months	3(2-3)		

Table 2: Comparison of PPD (mm) from baseline to 3 months for control and test group by using Wilcoxon signed Rank test



Graph 1: PPD - Mean change over time

Table 3 presents the inter-group comparison of CAL between different time points (baseline and 3 months). When comparing baseline, control group and test group showed no statistically significant changes in the parameter with P = 0.309. At 3 months, no statistically significant change was observed in the parameter with P = 0.138. (Graph 2)

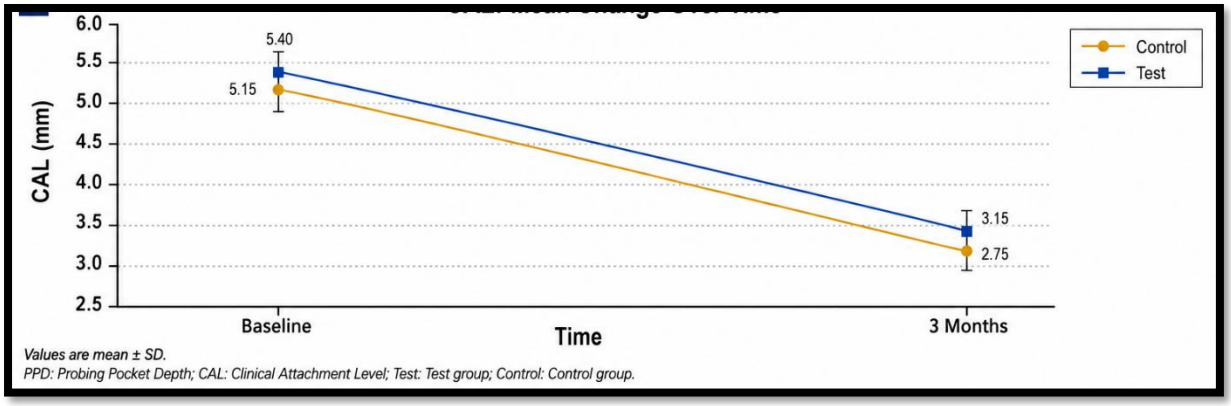
	Groups	**Median (IQR)**	**Z value**	**p Value**
Baseline	**Control (A)**	5(5-5)	-0.855	0.309
	Test (B)	5(5-6)		
3 Months	**Control (A)**	5(5-6)	-1.483	0.138
	Test (B)	5(5-6)		

Table 3: Comparison of CAL (mm)between control and test group at baseline and 3 months by using Mann-Whitney U test

Table 4 presents the intra-group comparison of CAL between different time points. When comparing baseline and 3 months, control group showed significant changes in all parameters with P < 0.001. Similarly, in test group, PPD was significant with P < 0.001. (Graph 2)

Groups	**Duration**	**Median(IQR)**	**Z value**	**p Value**
Control (A)	**Baseline**	5(5-6)	-4.097	<0.001
	3 Months	3(3-3)		
Test (B)	**Bseline**	5(5-6)	-4.11	<0.001
	3 Months	3(2-3)		

Table 4: Comparison of CAL (mm) from baseline to 3 months for control and test group by using Wilcoxon signed Rank test



Graph 2: CAL - Mean change over time

VII. Discussion

In periodontitis, the accumulation of pathogenic bacterial biofilm initiates a host immune response aimed to eliminate microbial challenge. Activated neutrophils and macrophages generate large quantities of reactive oxygen species (ROS) as an innate defense mechanism. [12] However excessive ROS production overwhelms the endogenous antioxidant defense system and results in oxidative stress, leading to damage of cellular DNA, proteins and lipids.[13] Oxidative stress activates key signaling pathways, including nuclear factor (NF)-κB signalling pathway and Mitogen- Activated Protein Kinase (MAPK) signalling pathway, thereby enhancing inflammatory mediators and accelerating the destruction of tooth-supporting structures, with potential systemic impact. [14]

To improve the limitations of conventional mechanical therapy, various local drug delivery systems (LDDSs) have been developed to achieve sustained delivery of therapeutic agents directly into periodontal pockets. Fibres, being a reservoir-based device inserted circumferentially into the periodontal pocket are considered to ensure excellent retention and controlled and sustained drug release. However, some cases have been found to cause localized tissue irritation in some subjects. Fiber placement is technic sensitive, labor intensive and time-consuming, making routine clinical use challenging even for experienced clinicians. These practical drawbacks have limited the widespread adoption of fibre-based DDSs in periodontal practice. [15-18]. In the present study, the placement of IGF fibers was uneventful and none of the cases treated with IGF experienced localized tissue irritation.

With recent advances in biomaterials and nanotechnology, the potential of LDDS exists not only for effective infection control, but also for promoting alveolar bone regeneration has significantly broadened. Furthermore, in the context of antimicrobial resistance, LDDSs offer the advantage of reduced antibiotic dosages and enable the use of alternative antimicrobial agents. [2,16,18]

In the present study, intragroup analysis revealed significant reductions in PI, GI, PPD, and CAL from baseline to the 3-month postoperative period. SRP effectively reduced the bacterial load and disrupted the bacterial biofilm. There were no statistically significant variations in PI and GI scores observed between the two groups at any time point, indicating that the two treatment modalities produced similar gingival health and plaque control outcomes. Test group also demonstrated slightly lower PPD at three months compared to control group, indicating reductions in PPD with the adjunctive use of placental extract gel. There was slight difference between the two groups at three months in CAL. These findings are consistent with previous studies that reported short-term clinical improvements in PI, GI, and PPD following phase I therapy.[19]

Vijayalashmi et al. [20] investigated tetracyclines-loaded collagen fibers in both aqueous media and in a stimulated periodontal pocket environment containing serum to evaluate the drug release kinetics of the drug and the antimicrobial efficacy against Porphyromonas gingivalis. The collagen membrane exhibited controlled release for up to 10 days, maintaining therapeutic concentrations and effectively inhibiting the growth of P. gingivalis under simulated periodontal pathological environment.

Ze He et al. [21] developed PLGA nanofibers loaded with tea polyphenols (TP), bioactive compounds rich in catechins and their derivatives, that possess potent antioxidant and anti-inflammatory properties. [22,23]. The sustained release of TPs from PLGA nanofibers reduced the expression of major pro-inflammatory cytokines, including interleukin-1(IL-1) and tumor necrosis factor (TNF-α), which are the major pro-inflammatory cytokines that attenuate periodontal inflammation.

Pratap et al. [24] assessed the effectiveness of 1% (w/v) melatonin gel as an adjunct to NSPT in in subjects with Stage II periodontitis. Adjunctive melatonin therapy resulted in significant improvements in clinical

periodontal parameters, and increasing superoxide dismutase (SOD) levels in gingival crevicular fluid and reducing antimicrobial activity against Aggregatibacter actinomycetemcomitans and Prevotella intermedia. These findings suggest that locally delivered melatonin gel may improve periodontal healing by combining antioxidant, anti-inflammatory, and antimicrobial effects. [24]

The findings of the present study suggest that the incorporation of IGF insulin like growth factor fibres as a local drug delivery agent as an adjunct to SRP can result in enhanced periodontal treatment outcomes. The improvements in PPD and CAL reduction incidence highlight the potential clinical benefits of this adjunctive therapy.

Despite the positive outcomes, limitations of the present study were that only chronic localized periodontitis was addressed, and the results may not be directly applicable to other types of periodontal diseases or generalized periodontitis. Furthermore, the study was conducted with a smaller population and shorter duration, which limited the external validity and generalizability of the findings. Hence, more research with a diverse population is needed to elaborately determine the benefits and drawbacks of using IGF fibers in the treatment of periodontal diseases.

VIII. Conclusion

The present study demonstrated that adjunctive treatment with IGF fibres alongside SRP led to significant improvements in periodontal clinical parameters such as pocket probing depth and clinical attachment level compared to SRP alone. These findings suggest the potential efficacy of IGF fibres as a local drug delivery agent in the management of chronic localized periodontitis. The amalgamation of conventional techniques with innovative approaches, such as local drug delivery with IGF, may open avenues for more tailored and efficacious periodontal treatment.

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