RESEARCH PAPER

Local Aceclofenac Mucoadhesive Film Versus Systemic Aceclofenac for Postoperative Pain Control Following Periodontal Flap Surgery: A Pilot Randomized Clinical Study

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ABSTRACT

Background: Postoperative pain is a common consequence of periodontal flap surgery. Systemic non-steroidal anti-inflammatory drugs (NSAIDs) are effective but may produce systemic adverse effects. Local drug delivery may provide drug at the surgical site while potentially reducing systemic exposure.

Objective:

To compare postoperative pain intensity following periodontal flap surgery in patients receiving systemic aceclofenac with that in patients receiving a locally administered aceclofenac mucoadhesive film.

Materials and Methods:

This pilot randomized clinical study included 40 patients with localized chronic periodontitis requiring periodontal flap surgery. Participants were allocated to a systemic aceclofenac group (n=20) or an aceclofenac mucoadhesive film group (n=20) using a lottery method. The systemic group received oral aceclofenac 100 mg twice daily, whereas the test group received a locally adapted aceclofenac mucoadhesive film at the surgical site. Postoperative pain was assessed using a 10-cm Visual Analogue Scale (VAS) at baseline and at 1, 2, 4, 24, and 48 hours. The available study report describes between-group analysis using an unpaired t-test.

Results:

All 40 enrolled participants completed the study. In the systemic group, mean VAS scores were 5.28 ± 0.692 at baseline, 6.95 ± 0.655 at 1 hour, 5.76 ± 0.714 at 2 hours, 4.42 ± 0.826 at 4 hours, 0.84 ± 1.001 at 24 hours, and 0.32 ± 0.525 at 48 hours. Corresponding values in the mucoadhesive film group were 5.28 ± 0.692, 7.05 ± 0.695, 5.76 ± 0.714, 4.82 ± 1.062, 1.18 ± 0.865, and 0.32 ± 0.525. Exploratory Welch comparisons based on the reported summary statistics showed no statistically significant between-group difference at baseline (p=1.000), 1 hour (p=0.642), 2 hours (p=1.000), 4 hours (p=0.192), 24 hours (p=0.258), or 48 hours (p=1.000). No adverse reactions or treatment-related complications were reported.

Conclusion:

Within the limitations of this pilot study, postoperative pain decreased substantially in both treatment groups, and the reported mean VAS trajectories were broadly comparable. The findings support further adequately powered randomized clinical trials evaluating local aceclofenac delivery after periodontal surgery.

Keywords: Aceclofenac; mucoadhesive film; periodontal flap surgery; postoperative pain; local drug delivery; Visual Analogue Scale.

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INTRODUCTION

Postoperative pain, discomfort, and edema are common after periodontal surgical procedures and may affect patient comfort, treatment acceptance, and compliance during the early healing period. Pain is often most pronounced during the first postoperative day and is influenced by the extent of tissue manipulation and individual pain perception.

Non-steroidal anti-inflammatory drugs are commonly used for postoperative dental pain because of their analgesic and anti-inflammatory effects. However, systemic NSAID administration may be associated with gastrointestinal irritation, ulceration or bleeding, renal adverse effects, and drug interactions, particularly in susceptible patients.

Local drug delivery systems provide an alternative approach by placing the active agent close to the site of tissue injury. Mucoadhesive films are attractive because they can remain in contact with the mucosa and may permit sustained drug release. Aceclofenac is an NSAID with established analgesic and anti-inflammatory

activity and has been investigated in several topical and mucoadhesive formulations.

Although aceclofenac-containing topical and mucoadhesive formulations have been described, clinical evidence evaluating a locally applied aceclofenac mucoadhesive film specifically for postoperative pain following periodontal flap surgery remains limited. Therefore, this pilot randomized clinical study compared postoperative pain following systemic aceclofenac administration with pain following local application of an aceclofenac mucoadhesive film.

AIM

To compare the analgesic response to systemically administered aceclofenac and locally administered aceclofenac mucoadhesive film following periodontal flap surgery.

OBJECTIVES

To compare postoperative VAS pain scores between the two treatment groups.

To describe the temporal pattern of postoperative pain at baseline, 1, 2, 4, 24, and 48 hours.

To assess the short-term tolerability of the two treatment approaches during the 48-hour postoperative period.

MATERIALS AND METHODS

Study design and ethical approval

This pilot randomized clinical study was conducted to compare postoperative pain following periodontal flap surgery in patients receiving systemic aceclofenac or a locally administered aceclofenac mucoadhesive film. The protocol was reviewed and approved by the Institutional Ethics Committee of Vivekanandha Dental College for Women, Tiruchengode (Ethics Committee Registration No. ECR/784/Inst/TN/2015). The study was conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from all participants before enrolment.

Participants

Forty patients diagnosed with localized chronic periodontitis and requiring periodontal flap surgery were recruited from the outpatient Department of Periodontology after completion of Phase I periodontal therapy and re-evaluation.

Eligibility criteria

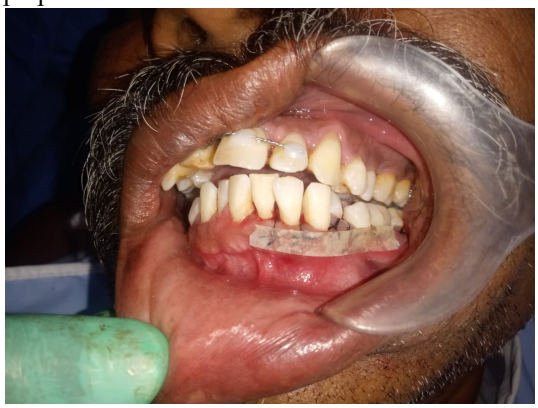
Inclusion criteria were age 35–50 years; localized chronic periodontitis requiring periodontal flap surgery; probing pocket depth ≥5 mm and clinical attachment loss >2 mm after Phase I therapy; radiographic evidence of alveolar bone loss; and absence of acute clinical inflammation at the time of surgery.

Exclusion criteria were a history of gastrointestinal ulceration or bleeding within the previous six months; pregnancy or lactation; use of analgesic, anti-inflammatory, or other medication that could influence pain perception within 48 hours before surgery; systemic disease or other conditions likely to interfere with wound healing; oral mucosal lesions; known hypersensitivity to aceclofenac; smoking; and alcohol dependency.

Preparation of the aceclofenac mucoadhesive film

The aceclofenac mucoadhesive film was prepared by the solvent-casting technique. The formulation contained aceclofenac (100 mg) incorporated into a polymeric matrix comprising hydroxypropyl methylcellulose, polyethylene glycol, and Carbopol. The available study report states that the prepared film was evaluated for drug-content uniformity, physical properties, and in-vitro drug-release characteristics before clinical application. The film was subsequently adapted to the periodontal surgical site.

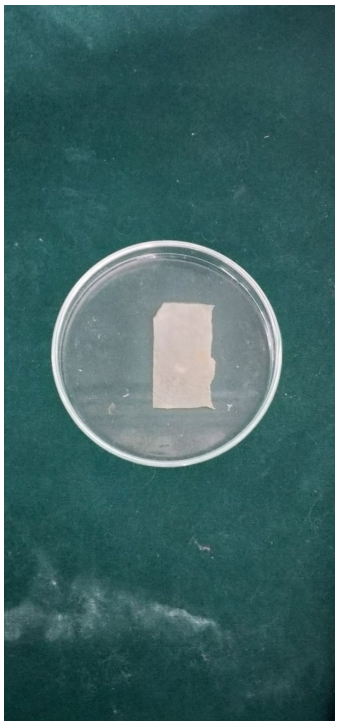
Figure 1. Aceclofenac mucoadhesive film prepared.



Randomization and intervention

Eligible participants were allocated to two groups of 20 participants each using a lottery method. The systemic aceclofenac group received oral aceclofenac 100 mg twice daily following surgery. The test group received an aceclofenac mucoadhesive film containing 100 mg aceclofenac; the film was trimmed and adapted to cover the surgical site immediately after completion of periodontal flap surgery.

Figure 2. Application of the aceclofenac adhesive film to the periodontal surgical site.



Surgical procedure

All periodontal flap surgeries were performed under local anesthesia using standard surgical protocols. Following completion of surgery and achievement of hemostasis, the allocated intervention was administered. Standard postoperative instructions were provided to all participants.

Outcome assessment

Postoperative pain intensity was assessed using a 10-cm VAS, with 0 representing no pain and 10 representing the worst imaginable pain. Scores were recorded at baseline, 1, 2, 4, 24, and 48 hours after surgery. The manuscript should clarify whether baseline VAS was recorded immediately before surgery, immediately after surgery, or at another predefined point, because this affects interpretation of the trajectory.

Safety assessment

Participants were monitored during the study period for adverse events, allergic reactions, or treatment-related complications. Clinical observations and patient-reported symptoms were recorded during follow-up. No adverse reactions, allergic manifestations, or treatment-related complications were reported during the 48-hour observation period.

Statistical analysis

The original analysis was performed using SPSS version 20.0. Descriptive data were summarized as mean ± standard deviation, and the original report states that an unpaired t-test was used for intergroup comparisons with statistical significance set at $p<0.05$.

VAS scores were expressed as mean ± standard deviation. Intergroup comparisons at each predefined postoperative time point were performed using an independent-samples t-test. Mean differences with 95% confidence intervals and Cohen's d effect sizes were calculated. A two-sided p-value <0.05 was considered statistically significant.

The analysis was based on the reported group-level outcome data at each predefined time point; therefore, the findings should be interpreted as time-specific intergroup comparisons.

RESULTS

A total of 40 participants completed the study and were included in the final analysis. No adverse reactions, allergic manifestations, or treatment-related complications were observed during the study period.

The control group receiving systemic aceclofenac demonstrated a mean VAS score of 5.28 ± 0.692 at baseline. Pain intensity increased to 6.95 ± 0.655 at 1 hour postoperatively and subsequently decreased to 5.76 ± 0.714 at 2 hours, 4.42 ± 0.826 at 4 hours, 0.84 ± 1.001 at 24 hours, and 0.32 ± 0.525 at 48 hours. Detailed postoperative pain scores for the systemic aceclofenac group are presented in Table 1.

Table 1. Mean VAS Scores in the Systemic Aceclofenac Group.

Time Interval	Mean ± SD	Minimum	Maximum
Baseline	5.28 ± 0.692	5	7
1 Hour	6.95 ± 0.655	6	8
2 Hours	5.76 ± 0.714	5	7
4 Hours	4.42 ± 0.826	2	6
24 Hours	0.84 ± 1.001	0	3
48 Hours	0.32 ± 0.525	0	2

Similarly, the test group receiving aceclofenac mucoadhesive film demonstrated a mean VAS score of 5.28 ± 0.692 at baseline. The mean VAS score increased to 7.05 ± 0.695 at 1 hour and subsequently decreased to 5.76 ± 0.714 at 2 hours, 4.82 ± 1.062 at 4 hours, 1.18 ± 0.865 at 24 hours, and 0.32 ± 0.525 at 48 hours. Detailed

postoperative pain scores for the aceclofenac mucoadhesive film group are presented in Table 2.

Table 2. Mean VAS Scores in the Aceclofenac Mucoadhesive Film Group.

Time Interval	Mean ± SD	Minimum	Maximum
Baseline	5.28 ± 0.692	5	7
1 Hour	7.05 ± 0.695	6	8
2 Hours	5.76 ± 0.714	5	7
4 Hours	4.82 ± 1.062	2	6
24 Hours	1.18 ± 0.865	0	3
48 Hours	0.32 ± 0.525	0	2

Both treatment groups exhibited a progressive reduction in pain intensity over the 48-hour postoperative period. The greatest pain intensity was observed during the first postoperative hour, followed by a steady decline in pain scores. By 48 hours, both groups demonstrated minimal pain levels, indicating effective postoperative pain control.

Intergroup comparison revealed comparable pain scores between the two treatment modalities throughout the observation period. These findings suggest that locally administered aceclofenac mucoadhesive film provides analgesic efficacy comparable to systemic aceclofenac administration following periodontal flap surgery. The comparative analysis of postoperative pain scores between the two treatment groups is summarized in Table 3.

Table 3. Intergroup Comparison of Mean VAS Scores.

Time	Mean difference	95% CI	t	df	p-value	Cohen's d	Interpretation
Baseline	0.00	−0.44 to 0.44	0.000	38.0	1.000	0.00	Not significant
1 hour	−0.10	−0.5 to 0.31	−0.46	37.4	0.649	−0.15	Not significant
2 hours	0.00	−0.46 to 0.46	0.000	38.0	1.000	0.00	Not significant
4 hours	−0.40	−0.99 to 0.19	−1.360	36.8	0.182	−0.42	Not significant
24 hours	−0.34	−0.90 to 0.22	−1.211	37.0	0.233	−0.36	Not significant
48 hours	0.00	−0.34 to 0.34	0.000	38.0	1.000	0.00	Not significant

Values were calculated from the reported group-level means and standard deviations using an independent-samples t-test (n=20 per group). Mean difference represents systemic aceclofenac minus mucoadhesive film. A two-sided p-value <0.05 was considered statistically significant.

Safety

No adverse reactions, allergic manifestations, or treatment-related complications were observed or reported during the 48-hour observation period.

DISCUSSION

Postoperative pain management remains an important component of periodontal therapy because discomfort following surgical procedures may negatively affect patient compliance and overall treatment acceptance. NSAIDs continue to be widely used for postoperative pain control; however, their systemic administration may be associated with gastrointestinal irritation, ulceration, and other adverse effects. Consequently, localized drug delivery systems have attracted increasing attention as alternatives capable of providing effective analgesia while minimizing systemic exposure. (1,5,7)

The present pilot clinical study evaluated the effectiveness of a locally administered aceclofenac mucoadhesive film compared with

conventional systemic aceclofenac administration following periodontal flap surgery. The findings demonstrated a progressive reduction in pain intensity in both treatment groups throughout the postoperative observation period. Pain scores reached their maximum during the first postoperative hour, which is consistent with the inflammatory response associated with surgical tissue manipulation. Thereafter, pain intensity gradually decreased in both groups and reached minimal levels by 48 hours. (7,8)

In the systemic aceclofenac group, mean VAS scores decreased from 5.28 ± 0.692 at baseline to 0.32 ± 0.525 at 48 hours. Similarly, the aceclofenac mucoadhesive film group demonstrated a reduction from 5.28 ± 0.692 at baseline to 0.32 ± 0.525 at 48 hours. These findings indicate that local delivery of aceclofenac through a mucoadhesive film achieved pain control comparable to that obtained with systemic administration. (8-10) .This observation is supported by the comparable VAS scores presented in Table 3.

The favorable performance of the mucoadhesive film may be attributed to its ability to maintain prolonged contact with the surgical site, thereby facilitating sustained drug release and direct delivery of the active agent to the affected tissues. This targeted approach may enhance local drug availability while reducing systemic drug exposure and associated adverse effects. (9,10,15,16)

Previous studies evaluating topical and mucoadhesive NSAID formulations have reported effective postoperative pain reduction and improved patient acceptance. The present findings are consistent with these reports and further support the potential role of aceclofenac mucoadhesive films as an alternative postoperative analgesic strategy in periodontal therapy. (9,10,15,19-24)

No adverse reactions or allergic manifestations were observed in either treatment group during the study period, indicating that both treatment modalities were well tolerated. This observation supports the clinical safety of locally administered aceclofenac mucoadhesive films when used for short-term postoperative pain management. (5,9,15)

The limitations of the present study include the relatively small sample size and short follow-up duration of 48 hours. Future studies with larger sample sizes, extended follow-up periods, and multicenter designs are recommended to further validate the clinical effectiveness of aceclofenac mucoadhesive films and to evaluate their long-term therapeutic benefits. (21-25)

Within the limitations of this pilot study, aceclofenac mucoadhesive film demonstrated postoperative analgesic efficacy comparable to systemic aceclofenac administration and may represent a promising localized drug delivery approach for pain management following periodontal flap surgery.

CLINICAL SIGNIFICANCE

A locally applied aceclofenac mucoadhesive film represents a potentially useful approach for postoperative pain management after periodontal flap surgery. In this pilot study, the reported pain trajectories were broadly similar to those observed with systemic aceclofenac. However, larger and methodologically rigorous clinical trials are required before local aceclofenac delivery can be considered an established alternative to systemic therapy.

CONCLUSION

Within the limitations of this pilot randomized clinical study, postoperative VAS scores decreased substantially in both the systemic aceclofenac and aceclofenac mucoadhesive film groups over 48 hours. The reported mean pain scores were broadly comparable between groups. These findings support further investigation of local aceclofenac mucoadhesive delivery as a postoperative analgesic strategy following periodontal flap surgery, but do not establish therapeutic equivalence or reduced systemic exposure.

DECLARATIONS

Ethics approval and consent to participate: Approved by the Institutional Ethics Committee of Vivekanandha Dental College for Women, Tiruchengode (ECR/784/Inst/TN/2015). Written informed consent was obtained from all participants.

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