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EVALUATION OF CLINICAL EFFICACY OF GREEN APPLE RIND EXTRACT GEL AS ADJUNCT TO NON-SURGICAL PERIODONTAL THERAPY: A RANDOMISED CONTROLLED CLINICAL TRIAL

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ABSTRACT

Background: While non-surgical periodontal therapy (NSPT) remains cornerstone of treatment, its effectiveness can be limited, especially in deeper pockets. Green apple (Malus domestica) rind extract, rich in antioxidants, may offer additional benefits as an adjunctive therapy. This study aimed to assess clinical effectiveness of green apple rind extract gel as an adjunctive treatment to NSPT in periodontitis patients. **Methods:** The present study was a prospective, double-blind, split-mouth randomized clinical trial including 30 systemically healthy individuals with bilateral periodontal pockets measuring 4–6 mm.. In each patient, one site received NSPT plus placebo gel (control), and contralateral site received NSPT plus green apple rind extract gel (test). Clinical parameters, including probing pocket depth (PPD), clinical attachment level (CAL), width of keratinized tissue (WKT), plaque index (PI), gingival index (GI), and sulcus bleeding index (SBI), were assessed at baseline, 3 months, and 6 months. **Results:** The test group demonstrated significantly greater improvement in PPD (3.57 ± 0.77 mm vs. 5.20 ± 0.71 mm; $p < 0.001$) and gain in CAL (4.40 ± 0.50 mm vs. 5.63 ± 0.61 mm; $p < 0.001$) compared to control. A significant increase in WKT was also noted (2.40 ± 0.50 mm vs. 1.97 ± 0.61 mm; $p = 0.02$). PI, GI, and SBI improved significantly in both groups, with more pronounced improvements in test group. **Conclusion:** The adjunctive use of green apple rind extract gel with NSPT demonstrated superior clinical outcomes, suggesting its potential as an effective, antioxidant-rich therapeutic option for periodontal regeneration.

KEYWORDS: Periodontitis, Non-Surgical Periodontal Therapy, Antioxidants, Phytotherapy, Local Drug Delivery.

INTRODUCTION

Periodontal disease (PD) is a persistent inflammatory disorder characterized by the gradual breakdown of supporting tissues around teeth, including the periodontal ligament and alveolar bone. This degradation is primarily driven by pathogenic microorganisms residing within the subgingival biofilm. Clinically, PD presents through the formation of periodontal pockets—abnormally deepened gingival sulci that occur due to the downward migration of the junctional epithelium and subsequent loss of connective tissue attachment.

Scaling and root planing (SRP), a key component of non-surgical periodontal therapy (NSPT) remains the gold standard for the initial management of periodontitis.[1] By mechanically debriding root surfaces, SRP effectively disrupts the subgingival biofilm and removes calculus, especially in shallow to moderate pockets. However, its efficacy diminishes significantly in deeper pockets (greater than 4.2 mm), where limited access hinders complete debridement.

In such cases, surgical intervention is often required to achieve optimal clinical outcomes. Unfortunately, surgical therapy may not be viable for all patients—especially those with systemic health issues, cognitive or physical impairments, or those living in resource-constrained settings.

To address these limitations, local drug delivery systems (LDDS) have been developed as adjuncts to SRP, allowing for the targeted and sustained release of antimicrobial and anti-inflammatory agents directly into periodontal pockets.

Various delivery systems—including gels, fibers, strips, and microparticles—have been investigated for their potential to improve clinical outcomes while minimizing systemic exposure and associated side effects.[2] Despite these advances, the need persists for more effective, bio-compatible therapeutic agents that offer both antimicrobial activity and regenerative potential. Numerous herbal extract-based gels have been investigated as adjunctive treatments for periodontitis, demonstrating varying degrees of clinical efficacy in reducing periodontal inflammation and improving clinical parameters.[3-5]

A promising herbal intervention in periodontal therapy is a gel formulation incorporating green apple (Malus domestica) rind extract, which contains high levels of antioxidant-rich polyphenols, such as phenolic acids and flavonoids.[6,7]

Oxidative stress, which arises mainly due to the overproduction of reactive oxygen species (ROS) from hyperactive polymorphonuclear leukocytes (PMNs), plays a significant role in the pathogenesis of periodontitis by promoting inflammatory cascades and extracellular matrix degradation.[8,9] The antioxidant constituents of Malus domestica rind may scavenge ROS, attenuate oxidative stress-induced cellular damage, and modulate pro-inflammatory pathways, thereby contributing to the preservation of periodontal structures.[10] Preliminary in vitro studies also indicate that green apple extract may support fibroblast proliferation, enhance collagen synthesis, and facilitate tissue repair, suggesting its potential utility as a regenerative adjunct in periodontal treatment.[11-13] However, despite the promising biological attributes of green apple rind extract, there remains a notable lack of clinical studies evaluating its efficacy as a locally applied adjunct to SRP in treating periodontitis. This represents a significant gap in the literature, particularly given the urgent need for effective, minimally invasive treatment modalities in settings where surgical periodontal therapy is not readily accessible.

The present study aims to address this critical gap by evaluating the clinical effectiveness of a green apple rind extract-infused gel as an adjunct to NSPT. Despite the promising potential, no literature currently exists evaluating the effect of

locally delivered green apple rind extract gel as an adjunct to SRP in patients with periodontitis. The aim of this study was to fill this gap by assessing the clinical efficacy of this innovative gel in combination with nonsurgical periodontal therapy, potentially paving the way for a new standard in periodontal treatment.

MATERIALS AND METHODS

This research was structured as a prospective, randomized controlled clinical trial utilizing a double-blind, split-mouth design. The study adhered to the ethical principles outlined in the revised Declaration of Helsinki (2013) and obtained prior approval from the Institutional Ethics Committee. Furthermore, the trial was registered with the Clinical Trials Registry of India (CTRI/No:CTRI/2025/03/083051). Recruitment was carried out among patients visiting the Department of Periodontics and Implantology at the study institution, all of whom provided informed written consent before enrollment.

Sample size determination was based on the findings of a previous clinical trial by Pandya et al. (2021),[14] which reported an effect size of 2.27 for mean probing pocket depth (PPD). Using these parameters, a total of 60 sites (30 per group) were deemed adequate to achieve statistical significance difference at a 95% confidence level and 80% statistical power.

Participants included in the study were systemically healthy adults aged 18 to 65 years, with at least 14 natural teeth and no reported allergies. Eligible individuals had a clinical diagnosis of generalized Stage II or III periodontitis, in accordance with the 2017 classification from the World Workshop on Periodontal Diseases,[15] and exhibited bilateral periodontal pockets with probing depths ranging from 4 to 6 mm. Exclusion criteria included individuals who smoked, were pregnant or lactating, patients who had received radiotherapy, chemotherapy, immunosuppressive treatment, corticosteroids, or anticoagulants within the past 30 days, those currently taking non-steroidal anti-inflammatory drugs, antibiotics, or any medication that could influence the progression or treatment of periodontitis.

Eligible participants underwent full-mouth SRP under local anesthesia. In each patient, two comparable contralateral periodontal pockets (with PPD between 4–6 mm) were randomly allocated into the following groups:

Group 1 (Control): SRP followed by subgingival delivery of a placebo gel (sterile saline).
Group 2 (Test): SRP followed by subgingival delivery of a novel gel infused with green apple rind extract.

Randomization was carried out using a computer-generated sequence, and allocation concealment was ensured through opaque, sealed envelopes, opened just before the intervention. The study design was double-blind, with both participants and outcome assessors unaware of the group assignments.

Comprehensive clinical examinations were performed at baseline, followed by scheduled reviews at 3 and 6 months.

Clinical assessments were conducted at six sites per tooth—mesio-buccal, mid-buccal, disto-buccal, mesio-lingual, mid-lingual, and disto-lingual—using a UNC-15 periodontal probe (PCPUNC 15; Hu Friedy, Chicago, IL) by single precaliberated examiner (VG). Recorded indices included the Plaque Index (PI) by Löe and Silness (1967),[16] Gingival Index (GI) by Löe and Silness (1963),[17] Sulcus Bleeding Index (SBI) by Muhlemann and Son (1971),[18] probing pocket depth (PPD), and clinical attachment level (CAL). All measurements were rounded to the nearest 0.5 mm and repeated by the same examiner (VG) to ensure intra-examiner reliability. In addition, a detailed gingival assessment was performed, noting the color, contour, consistency, surface texture, the position of the gingival margin, and the

width of keratinized tissue.

Preparation of Green Apple Rind Extract Gel

A hydroalcoholic extract of green apple rind was prepared using the maceration technique. Fresh green apples were procured from the local market, washed thoroughly, and manually peeled. The peels were then dried in a hot air oven at 52°C for 48 hours and finely ground into powder. A total of 20 g of peel powder was macerated in a hydroalcoholic solvent (1:1 ratio of ethanol and distilled water, 100 mL each) in a closed container, kept in a dark room for 7 days. The resulting mixture was filtered, and the filtrate was concentrated using an electric water bath to obtain a semi-solid gel-like extract for further formulation. The temperature-sensitive in situ gel was prepared by cold method using different polymers (poloxamers 407 and Carbopol-934) and 20% green apple rind extract.

Following SRP, the test sites received the green apple rind extract gel administered subgingivally using a sterile blunt-end cannula inserted gently into the depth of the periodontal pocket. The gel was delivered until the pocket was visibly filled. Similarly, the control sites received sterile saline as a placebo using an identical procedure. Care was taken to prevent mechanical trauma and ensure even distribution of the gel within the pocket. Post-operative instructions were given, and patients were given post-treatment guidelines, including refraining from eating, drinking, or rinsing for at least 30 minutes. Routine oral hygiene practices were continued under supervision throughout the study duration.

Continuous variables were described using mean, standard deviation, median, and range (minimum and maximum), whereas categorical variables were presented as counts and percentages. Given the split-mouth study design, comparisons between the two treatment groups were conducted using paired t-tests. To assess changes in parameters over time within each group, repeated measures analysis of variance (ANOVA) was employed. Paired comparisons between two specific time points were made without applying adjustments for multiple testing. For clinical parameters that did not meet parametric assumptions, the Friedman test—a non-parametric alternative to repeated measures ANOVA—was utilized. When required, the Wilcoxon signed-rank test was used for pairwise comparisons over time without correction for multiple comparisons. All statistical evaluations were conducted using IBM SPSS Statistics software version 26.0 (Armonk, NY, USA), with a significance threshold set at $p < 0.05$.

RESULTS

Table 1 summarizes the demographic characteristics of the study sample. The mean age was 38.7 years (median: 34; range: 19–73 years). The sample included 17 males (56.7%) and 13 females (43.3%). Table 2 compares periodontal parameters between the two groups at baseline, 3 months, and 6 months. At baseline, PPD was comparable between groups, while CAL and WKT showed significant differences. At 3 and 6 months, group 2 demonstrated significantly greater improvement than group 1, with lower PPD and CAL values and higher WKT, and all intergroup differences were statistically significant ($p < 0.05$). At 3 months, the mean PPD was 5.37 ± 0.72 mm in group 1, while it was 4.30 ± 0.60 mm in group 2. Similarly, the mean CAL in group 1 was 5.93 ± 0.78 mm, while it was 4.93±0.69 mm in group 2. The mean WKT in group 1 was 2.13 ± 0.57 mm, while that in group 2 was 2.40 ± 0.50 mm.

At 6 months, the mean PPD was 5.20 ± 0.71 mm in group 1, while it was 3.57 ± 0.77 mm in group 2. Similarly, the mean CAL in group 1 was 5.63 ± 0.61 mm, while it was 4.40 ± 0.50 mm in group 2. The mean WKT in group 1 was 1.97 ± 0.61 mm, while that in group 2 was 2.40±0.50 mm.

Table 3 shows the intragroup comparison of periodontal parameters over time. In group 1, mean PPD reduced significantly from baseline (5.63 mm) to 3 months (5.37 mm) and 6 months (5.20 mm) ($p = 0.01$), while CAL and WKT showed no significant changes. In group 2, mean PPD reduced significantly from baseline (5.90 mm) to 3 months (4.30 mm) and 6 months (3.57 mm) ($p < 0.001$). Similarly, CAL showed a significant reduction from baseline (6.63 mm) to 3 months (4.93 mm) and 6 months (4.40 mm), and WKT increased significantly from baseline (1.83 mm) to 3 months (2.40 mm) and 6 months (2.40 mm) ($p < 0.001$)

Table 4 provides the comparison of clinical parameters across time. The plaque index showed statistically significant reduction from baseline to 3 months and 6 months with a p-value < 0.001. Similarly, GI showed a significant reduction from baseline to 3 months and 6 months with a p-value < 0.001. Further, SBI also showed significant reduction from baseline to 3 months and 6 months with a p-value < 0.001.

Table 1: Descriptive statistics for demographic parameters of patients.

Parameter	Gender	Statistic
Age in years [Mean ± SD; Median; (Min, Max)]		38.7 ± 16.08; 34.0, (19, 73)
Sex [n (%)]	Male	17 (56.7%)
	Female	13 (43.3%)

Table 2: Comparison of three periodontal parameters between two treatment groups according to time (N=30).

Time	Parameter	Group I					Group 2					P-value
		Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	
Baseline	Pocket Probing Depth (mm)	5.63	0.85	5.00	5.00	8.00	5.90	0.80	6.00	5.00	8.00	0.088
	Clinical Attachment Level (mm)	6.00	1.02	6.00	4.00	8.00	6.63	0.93	6.50	5.00	9.00	**0.002**
	Width of Keratinized tissue (mm)	2.03	0.61	2.00	1.00	3.00	1.83	0.59	2.00	1.00	3.00	**0.012**
3 months	Pocket Probing Depth (mm)	5.37	0.72	5.00	4.00	7.00	4.30	0.60	4.00	3.00	5.00	**< 0.001**
	Clinical Attachment Level (mm)	5.93	0.78	6.00	5.00	7.00	4.93	0.69	5.00	4.00	6.00	**< 0.001**
	Width of Keratinized tissue (mm)	2.13	0.57	2.00	1.00	3.00	2.40	0.50	2.00	2.00	3.00	**0.01**
6 months	Pocket Probing Depth (mm)	5.20	0.71	5.00	4.00	6.00	3.57	0.77	3.00	3.00	5.00	**< 0.001**
	Clinical Attachment Level (mm)	5.63	0.61	6.00	5.00	7.00	4.40	0.50	4.00	4.00	5.00	**< 0.001**
	Width of Keratinized tissue (mm)	1.97	0.61	2.00	1.00	3.00	2.40	0.50	2.00	2.00	3.00	**0.002**

P value obtained using paired t-test; Bold p-values indicate statistically significant difference.

Table 3: Comparison of each periodontal parameter across time in each treatment group (N=30).

Parameter	Time	Group I					Group 2				
		Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max
Pocket Probing Depth (mm)	Baseline	5.63	0.85	5.00	5.00	8.00	5.90	0.80	6.00	5.00	8.00
	3 months	5.37	0.72	5.00	4.00	7.00	4.30	0.60	4.00	3.00	5.00
	6 months	5.20	0.71	5.00	4.00	6.00	3.57	0.77	3.00	3.00	5.00
	P-value	**0.010**					**< 0.001**				
Clinical Attachment Level (mm)	Baseline	6.00	1.02	6.00	4.00	8.00	6.63	0.93	6.50	5.00	9.00
	3 months	5.93	0.78	6.00	5.00	7.00	4.93[b]	0.69	5.00	4.00	6.00
	6 months	5.63	0.61	6.00	5.00	7.00	4.40	0.50	4.00	4.00	5.00
	P-value	0.051					**< 0.001**				
Width of Keratinized tissue (mm)	Baseline	2.03	0.61	2.00	1.00	3.00	1.83	0.59	2.00	1.00	3.00
	3 months	2.13	0.57	2.00	1.00	3.00	2.40	0.50	2.00	2.00	3.00
	6 months	1.97	0.61	2.00	1.00	3.00	2.40	0.50	2.00	2.00	3.00
	P-value	0.179					**< 0.001**				

Bold p-values indicate statistical significance; Different superscripts indicate statistical significance between two time points in pair wise comparison.

Table 4: Comparison of clinical parameters across time.

Parameter	Time	Statistics				
		Mean	SD	Median	Min	Max
Plaque index	Baseline	2.28	0.28	2.30	1.80	2.77
	3 months	1.62	0.29	1.70	1.00	2.00
	6 months	0.83	0.47	1.00	0.00	1.20
	P-value	**< 0.001**				
Gingival index	Baseline	2.36	0.26	2.30	2.00	2.90
	3 months	1.64	0.27	1.65	1.00	2.00
	6 months	0.96	0.53	1.05	0.00	1.80
	P-value	**< 0.001**				
Sulcus bleeding index	Baseline	2.10	0.31	2.00	2.00	3.00
	3 months	1.53	0.57	1.50	1.00	3.00
	6 months	0.47	0.51	0.00	0.00	1.00
	P-value	**< 0.001**				

P value Obtained using Friedman analysis of variance; Bold p-values indicate statistical significance; Different superscripts indicate statistical significance between two time points in pair wise comparison.

DISCUSSION

This clinical investigation was designed to assess the therapeutic value of green apple rind extract gel when used alongside non-surgical periodontal therapy (NSPT) in managing periodontitis. By incorporating this novel, antioxidant-rich formulation into nonsurgical therapy, our research investigated a potentially transformative approach that unites microbial control, oxidative stress reduction, and tissue regeneration within a single, patient-friendly treatment. The study demonstrated significant improvements in all measured clinical indicators—most notably in probing pocket depth (PPD), clinical attachment level (CAL), and width of keratinized tissue (WKT)—in the test group that received the adjunctive herbal formulation.

While both groups had similar baseline PPD values, CAL and WKT differed slightly, though not detracting from the observed clinical gains in the test group over the 6-month period. The improvements in PI, GI, and SBI, although present in both groups, were more pronounced in the sites treated with the green apple rind gel, reflecting better inflammation control and oral hygiene outcomes.

The findings of this study are consistent with existing literature emphasizing the role of local drug delivery systems as effective adjuncts to SRP. Numerous investigations have confirmed that locally delivered anti-inflammatory and antimicrobial agents can significantly boost clinical outcomes.[19,20]

The beneficial role of antioxidants in periodontal therapy has been increasingly acknowledged. According to Chapple and Matthews (2007),[9] oxidative stress is a major contributor to the pathogenesis of periodontitis, and antioxidant therapy may help restore redox balance and limit tissue damage. The green apple rind extract used in the present study is known to be rich in polyphenolic compounds and quercetin, both of which possess potent free radical-scavenging properties.[12]

Furthermore, recent in vitro studies have demonstrated that apple extracts can promote fibroblast proliferation and support collagen synthesis,[21] which may explain the observed improvements in CAL and WKT in our study. The present findings are also supported by the study conducted by Pushparani et al. (2020),[22] which demonstrated the effectiveness of plant-derived antioxidant gels in reducing oxidative stress markers in gingival crevicular fluid, leading to enhanced periodontal healing.

Rubido et al. (2018)[23] investigated the immediate effects of apple consumption on oral microbial load in a cohort of 20 individuals. Their study demonstrated a notable reduction in salivary bacterial viability immediately following apple mastication, suggesting a potential cleansing effect linked to enhanced salivary flow and a transient increase in salivary pH. This alkalinisation may promote a natural lavage action, thereby diluting and flushing out oral microorganisms.

Interestingly, while this study highlights the mechanical and biochemical benefits of apple chewing, there remains a paucity of literature evaluating bacterial viability as a direct parameter for assessing the antibacterial potential of apple derivatives on salivary flora.

Over the past two decades, growing interest has emerged in exploring plant-derived polyphenols for their anti-cariogenic and antimicrobial properties.[24-26] Polyphenols have been shown to disrupt bacterial colonization mechanisms by inhibiting glucosyltransferase activity, which is critical for biofilm formation, and by reducing bacterial adherence to tooth surfaces.[27] Several types of polyphenols, including flavonoids and catechins found in apples, have demonstrated broad-spectrum antimicrobial activity against key oral pathogens such as Streptococcus mutans, Porphyromonas gingivalis, and Aggregatibacter actinomycetemcomitans.[28]

The rind of green apple is particularly rich in such bioactive constituents, including quercetin, chlorogenic acid, and catechins, all of which possess documented anti-inflammatory and antioxidant activities.[29] These phytochemicals may contribute to modulation of the subgingival biofilm and attenuation of inflammatory responses, both of which are central to periodontal disease progression.

The previous literature indirectly support the hypothesis of your current clinical study, which seeks to assess the efficacy of a green apple rind extract-based gel as an adjunct to non-surgical periodontal therapy. By leveraging the antioxidant and antimicrobial attributes of green apple rind, this formulation may enhance clinical outcomes by reducing microbial load and promoting gingival healing. Moreover, our study fills a significant gap in current literature by evaluating the topical application of green apple bioactives in a periodontal setting, a novel approach that extends beyond traditional mechanical or dietary interventions.

The results suggest that incorporating green apple rind extract into LDDS formulations offers a promising, minimally invasive approach to enhance periodontal healing, especially in non-surgical settings. This is particularly relevant for patients with systemic comorbidities, those averse to surgical intervention, or those in underserved populations with limited access to advanced care. The observed improvements in WKT are of clinical significance, as adequate keratinized tissue plays a critical role in maintaining gingival health and resisting mechanical trauma. The significant increase in WKT in the test group may indicate that the green apple rind extract not only reduces inflammation but also supports gingival tissue regeneration.

Despite the encouraging outcomes, several limitations must be acknowledged. While statistically powered, the study had a modest sample size, which may limit generalizability. The follow-up period of 6 months, although sufficient to evaluate short-term healing, does not provide insights into the long-term stability of the results.Being conducted at a single institution may introduce site-specific biases and limit the external validity of the findings. Further studies with larger, multi-center populations and longer follow-up durations are warranted to validate the long-term efficacy and safety of green apple rind extract gel. Moreover, incorporation of molecular and biochemical analyses (e.g., levels of malondialdehyde, interleukin-1β, and matrix metalloproteinases) could provide mechanistic insights into its therapeutic

potential. Future research may also explore synergistic effects with other natural bioactive compounds and assess different delivery vehicles such as nanoparticles or hydrogels for enhanced bioavailability and sustained release.

CONCLUSION

The adjunctive use of green apple rind extract gel with non-surgical periodontal therapy demonstrated statistically and clinically significant improvements in periodontal outcomes, including reduction in probing pocket depth, gain in clinical attachment level, and an increase in the width of keratinized tissue. These results indicate that this novel antioxidant formulation may serve as an effective adjunct in non-surgical periodontal management. The findings support its potential role in enhancing therapeutic outcomes through modulation of oxidative stress, while offering a patient-friendly, plant-based alternative. Overall, this study adds to the growing body of evidence supporting the use of phytotherapeutic agents in contemporary periodontal regenerative and adjunctive treatment strategies.

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