# Advanced approaches to managing peri-implant mucositis: the role of chlorhexidine gel combined with ADS, PVP-VA, and sodium DNA

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## Abstract

**Peri-implant mucositis is an inflammatory and bacterial condition affecting dental implants' soft tissues. Including chlorhexidine (CHX) with polyvinylpyrrolidone-vinyl acetate (PVP-VA) in gel formulations enhances antibacterial properties by forming a protective film against microbial contamination and over-infection without directly impacting tissues or wounds. Sodium DNA promotes gingival tissue health. This study aimed to evaluate the effectiveness of a gel containing CHX (0.5%) with an anti-discoloration system (ADS), PVP-VA, and sodium DNA, compared to a placebo gel, for treating peri-implant mucositis. A single-center randomized controlled pilot trial included 24 patients with peri-implant mucositis. Participants were assigned to two groups: Group A (n = 12) received the test gel, while Group B (n = 12) used a placebo. The primary outcome was the Plaque Index (PI), with secondary outcomes including Bleeding on Probing (BOP) and Gingival Index (GI). Measurements were taken at baseline and two weeks post-treatment. At baseline, the mean PI scores were 2.4 ± 0.4 for Group A and 2.2 ± 0.5 for Group B ($p > 0.05$). After two weeks, Group A significantly reduced to 0.5 ± 0.4, compared to 1.7 ± 1.9 in Group B ($p < 0.05$). Similarly, mean BOP decreased from 57.1 ± 15.2% to 14.3 ± 6.6% in Group A, whereas Group B showed a smaller reduction from 55.3 ± 11.7% to 45.4 ± 9.8% ($p < 0.05$). After two weeks, the gel containing CHX, ADS, PVP-VA, and sodium DNA demonstrated significant improvements in gingival inflammation and biofilm reduction, outperforming the placebo. This treatment could provide an effective option for managing peri-implant mucositis**

**Keywords: Peri-implant mucositis, Dental implants, Chlorhexidine, Peri-implantitis prevention, Mucositis, Bacterial biofilms, Plaque**

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## Introduction

Human Papillomavirus (HPV) infections represent a significanPeri-implant mucositis is increasingly recognized as a significant complication associated with dental implants(1–8). It is characterized by inflammation of the soft tissues surrounding an implant and is primarily attributed to the accumulation of bacterial biofilm (9–18). If left untreated, this condition can progress to peri-implantitis (19–27), which involves irreversible bone loss and threatens implant stability (28–37). Thus, early intervention and effective management are critical to preserving implant longevity and oral health (38–47).

Chlorhexidine (CHX) stands out for its potent antimicrobial action (48–58)among the therapeutic options. However, its prolonged use can lead to adverse effects such as tooth discoloration and altered taste perception, potentially reducing patient adherence (59–68, 296). Recent innovations have focused on enhancing the benefits of CHX while mitigating its limitations (69–78). Incorporating anti-discoloration systems (ADS) has emerged as a promising strategy for preventing the staining commonly associated with CHX (79–87) . Additional compounds, such as Polyvinylpyrrolidone/Vinyl Acetate (PVP-VA) and Sodium DNA, contribute unique benefits: the former forms a protective biofilm barrier and supports cellular regeneration and tissue repair (88–97, 291).

This study evaluates the effectiveness of a novel gel formulation combining CHX, ADS, PVP-VA, and Sodium DNA in managing peri-implant mucositis compared to a placebo (98–108). By focusing on key clinical indicators such as the Plaque Index (PI), Bleeding on Probing (BOP), and Gingival Index (GI), the research aims to provide a comprehensive understanding of its therapeutic potential (109–119).

## Methods

### *Study Design*

A randomized, controlled, triple-blind pilot trial was conducted to ensure robust and bias-free results. This design minimized potential sources of distortion from participants and researchers alike, thereby enhancing the validity and reliability of the findings. Randomization ensured that confounding variables were evenly distributed between the groups, while control and blinding ensured that the outcomes could be attributed solely to the tested intervention.

## Participants

The trial included 24 adult patients aged 45–75 years recruited from a single dental clinic. Participants were selected based on strict inclusion and exclusion criteria to ensure sample homogeneity and reduce interference from external factors. Inclusion criteria required participants to be in good systemic health, have no history of aggressive periodontitis, and present with at least one dental implant exhibiting peri-implant mucositis. Peri-implant mucositis was defined as bleeding on probing (BOP) without radiographic evidence of bone loss. Exclusion criteria included smoking (more than 10 cigarettes per day), use of systemic antibiotics or anti-inflammatory drugs within the last three months, pregnancy, or breastfeeding.

## Intervention

All participants underwent professional oral hygiene procedures at the initial visit to standardize plaque levels across the groups. This included removing supra- and subgingival calculus using manual and ultrasonic instruments, followed by polishing with prophylaxis paste. This initial step ensured that the effects of the intervention were evaluated under controlled and uniform conditions.

Afterward, participants were randomly allocated to one of two groups:

- Group A (Test): Received a gel containing 0.5% chlorhexidine (CHX), Anti-Discoloration System (ADS), polyvinylpyrrolidone-vinyl acetate (PVP-VA), and sodium DNA.
- Group B (Control): A placebo gel was used, identical in appearance, consistency, and odor but devoid of active ingredients to maintain blinding.

Participants were instructed to apply their assigned gel twice daily, following toothbrushing, for two weeks. The application involved a syringe and nozzle to distribute evenly around the affected implant sites. Detailed instructions and a hands-on demonstration were provided to ensure compliance with the protocol. Patients were also instructed to maintain their usual mechanical oral hygiene practices throughout the study period, excluding the treated sites where the gel replaced other hygiene measures.

## Outcome Measures

To evaluate the intervention's efficacy, three primary clinical parameters were assessed at baseline (before treatment) and after two weeks of intervention:

1. Plaque Index (PI): This measure quantified the presence of bacterial biofilm along the gingival margin, serving as a proxy for patient hygiene and the effectiveness of biofilm control. A standardized scoring system recorded plaque quantity and distribution.
2. Bleeding on Probing (BOP): This indicator measured the inflammatory response of peri-implant tissues. A calibrated periodontal probe applied a light force (<25 g) to detect bleeding within 30 seconds, directly assessing tissue inflammation.
3. Gingival Index (GI): This parameter evaluates the severity of gingival inflammation through visual inspection and tactile assessment. Scores ranged from 0 (healthy gingiva) to 3 (severe inflammation with spontaneous bleeding).

Two calibrated operators, blinded to group assignments, performed the measurements. Each variable was recorded twice for each participant, and the average of the two readings was used for statistical analysis to ensure consistency.

## Statistical Analysis

Data were analyzed using paired t-tests to evaluate intra-group improvements between baseline and follow-up and independent t-tests to compare inter-group differences after two weeks. The Kolmogorov-Smirnov test assessed the normal distribution of variables, and a significance level of $p < 0.05$ was set. This analytical approach identified significant improvements in clinical parameters and evaluated the relative effectiveness of the test gel compared to the placebo.

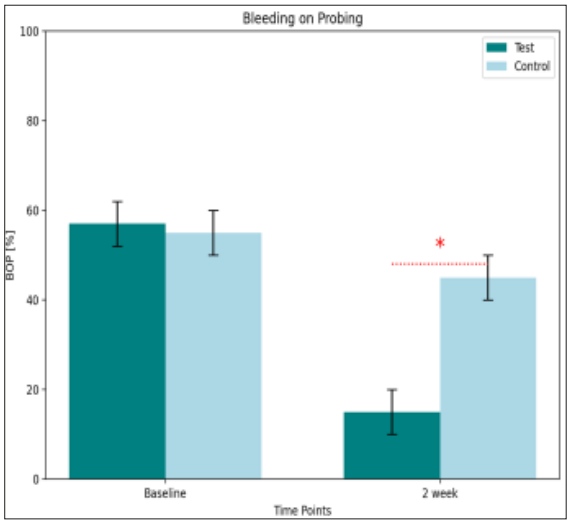
## Results

### *Participant Characteristics*

The study included an equal distribution of male and female participants, with a mean age of 64.2 years. Both groups exhibited comparable baseline characteristics, ensuring that observed differences could be attributed to the intervention rather than confounding factors.

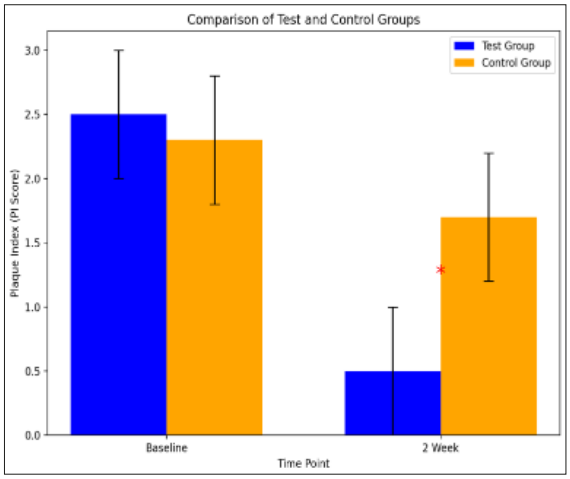
## Plaque index

At baseline, both groups demonstrated similar PI scores, indicating comparable levels of biofilm accumulation. After two weeks, Group A experienced a significant reduction in PI (0.5 ± 0.4), while Group B showed a modest decrease (1.7 ± 0.9). The difference between groups was statistically significant ($p < 0.05$), underscoring the enhanced efficacy of the test gel in biofilm control.




## Bleeding on Probing

BOP scores at baseline revealed moderate inflammation in both groups (Group A: 57.1%, Group B: 55.3%). By the end of the study, Group A exhibited a dramatic reduction in BOP (14.3%), compared to a more minor improvement in Group B (45.4%). This finding highlights the test gel's superior anti-inflammatory properties.




## Gingival Index

The GI outcomes paralleled those of BOP, with Group A showing more pronounced improvements in gingival health. These results further validate the combined efficacy of CHX, ADS, PVP-VA, and Sodium DNA in managing peri-implant mucositis.

## Discussion

The findings of this study highlight the efficacy and potential advantages of the tested gel formulation (97,112–117,120–127) as an advanced therapeutic tool for managing peri-implant mucositis (118,119,122–126,128–130). The gel's ability to address the condition's microbial and inflammatory aspects through a multifaceted mechanism positions it as a promising adjunct in peri-implant care(131–142). This approach is beneficial in controlling early inflammatory changes around implants, preventing progression to more severe peri-implant diseases such as peri-implantitis (143–153).

## Mechanisms of Action

The unique combination of active ingredients in the tested gel contributes to its comprehensive efficacy:

- **Chlorhexidine (CHX)**: As the primary antimicrobial agent, CHX effectively disrupts bacterial membranes and inhibits biofilm matrix formation (154–167). Its proven antiplaque and antibacterial properties reduce microbial load while preventing recolonization

bop score table

| BOP score (mean, SD) | Group A (Test) | Group B (Control) | p value |
|---|---|---|---|
| Baseline | 57.1% ± 15.2% [95% CI: -136.0/250.2] | 55.3% ± 11.7% [95% CI: -93.36/204.0] | $p > 0.05$ |
| 2 weeks | 14.3% ± 6.6% [95% CI: -69.56/98.16] | 45.4% ± 9.8% [95% CI: -79.12/169.9] | $p < 0.05$ |

plaque index table

| Plaque index (mean, SD) | Group A (Test) | Group A (Test) | p value |
|---|---|---|---|
| Baseline | 2.4 ± 0.4 [95% CI: -2.682/7.482] | 2.2 ± 0.5 [95% CI: -4.153/8.553] | $p > 0.05$ |
| 2 weeks | 0.5 ± 0.4 [95% CI: -4.582/5.582] | 1.7 ± 0.9 [95% CI: -9.736/13.14] | $p < 0.05$ |

of treated areas. CHX remains the gold standard in chemical plaque control, particularly in peri-implant and periodontal care (168–177, 292).

- **Anti-Discoloration System (ADS)**: A critical component, ADS enhances patient adherence to treatment by addressing aesthetic concerns such as staining of teeth, prostheses, or restorations (178–188). This addition ensures that the therapeutic benefits of CHX are retained without compromising the aesthetic and sensory experience of the patient, thus improving compliance (189–195).
- **Polyvinylpyrrolidone-Vinyl Acetate (PVP-VA)**: As a film-forming agent, PVP-VA creates a protective barrier over the gingival and peri-implant tissues (196–207). This barrier impedes microbial adhesion, slows biofilm formation, and facilitates the sustained release of CHX for prolonged antimicrobial activity (208–219). This mechanical obstruction enhances the gel's effectiveness by reducing bacterial colonization over time (220–223).
- **Sodium DNA**: This ingredient regenerates by promoting cellular turnover and supporting tissue repair mechanisms (224–226). Sodium DNA has been shown to mitigate oxidative stress, a common feature in inflamed peri-implant tissues, thus contributing to the resolution of inflammation (227–232, 293). Additionally, it enhances fibroblast activity, which supports connective tissue repair and the overall health of peri-implant soft tissues (233–241, 294).

## Clinical Implications

The results demonstrate that within two weeks, the tested gel formulation significantly reduced plaque levels and inflammatory markers, such as bleeding on probing (BOP) (242–249). These improvements reflect the gel's efficacy in controlling the biofilm and indicate its potential to mitigate early inflammatory changes (250–256). This dual action underscores the gel's utility as a valuable adjunct in routine peri-implant maintenance protocols (111,257–262).

Unlike conventional CHX formulations, integrating ADS minimizes side effects like staining and taste alteration, negatively impacting patient compliance (263–269, 295). The additional presence of PVP-VA and sodium DNA enhances the gel's therapeutic performance, creating a synergistic effect that extends beyond antimicrobial action to include protective and reparative properties (270–280). This combination is especially advantageous in cases where patients may have difficulty maintaining optimal oral hygiene or are at an elevated risk of peri-implant inflammation (281–290).

## Limitations and Future Directions

Although the results of this study are encouraging, its status as a pilot trial introduces limitations, primarily the small sample size. While the findings provide valuable preliminary insights, larger-scale, multicenter clinical trials are necessary to validate these results and confirm their applicability across diverse populations.

Additionally, the short follow-up period limits the ability to assess the long-term outcomes of the tested gel, such as its effectiveness in preventing the progression of mucositis to peri-implantitis. Future research should explore the gel's sustained benefits over extended periods and its performance in high-risk groups, including smokers or patients with systemic conditions like diabetes. Further investigation into its role in managing established peri-implantitis would also be valuable, potentially broadening its indications and confirming its utility in more advanced peri-implant diseases.

Finally, studies examining the cost-effectiveness of this gel compared to conventional treatments could provide insights into its practical application in routine clinical settings, particularly in large-scale peri-implant maintenance programs.

## Conclusions

This study demonstrates that a CHX-based gel enriched with ADS, PVP-VA, and Sodium DNA offers significant advantages over placebo in managing peri-implant mucositis. Its ability to reduce plaque, inflammation, and bleeding without compromising patient comfort highlights its potential as an integral component of peri-implant care protocols. Further research will solidify its role in preventing implant-related complications and promoting long-term oral health.

## Abbreviations

| | |
|---|---|
| CHX | Chlorhexidine |
| ADS | Anti-Discoloration System |
| PVP-VA | Polyvinylpyrrolidone-Vinyl Acetate |
| DNA | Sodium Deoxyribonucleic Acid |
| PI | Plaque Index |
| BOP | Bleeding on Probing |
| GI | Gingival Index |
| RCT | Randomized Controlled Trial |
| SPT | Supportive Periodontal Therapy |

| General characteristics | |
|---|---|
| Total simple size | n= 24 12 subjects (Group A); 12 subjects (Group B) |
| Average age of subjects | 64.2 ± 8.3 years |
| Age range | 41-74 years |
| Gender | Male/Female ratio 0.92/1 (Group A); 0.95/1 (Group B) |
| Total of rated implant with mucositis | N= 62 implants 32 implants (Group A); 26 implants (Group B) |
| Incisal/canine region implants | 82.26 % (51 implants) |
| Molar/ premolar region implants | 17.74% (11 implants) |
| Mean pocket depth (DS) | Group A: 2.2 ± 0.6 mm [ median: 1.6 mm]; Group B 2.4 ± 0.5 [median: 1.7 mm] |

## Ethics Approval and Consent to Participate

Ethical Committee for Biomedical Research of Polytechnic University of Marche (Prot. N. 1776/5.12.2019).

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## Conflict of Interest

The authors declare no conflict of interest. LM is serving as a member of this journal's Editorial Board and Guest editor. We declare that LM was not involved in the peer review of this article and has no access to information regarding its peer review. LM was delegated full responsibility for the editorial process for this article

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