

Clinical Efficacy of Aloe Vera Toothpaste on Periodontal Parameters of Patients with Gingivitis—A Randomized, Controlled, Single-masked Clinical Trial

Ferena Sayar¹, Amir H Farahmand², Maryam Rezazadeh³

ABSTRACT

Aim and objective: This study aims to assess the effects of aloe vera toothpaste on dental plaques and gingivitis.

Materials and methods: This single-center, single-blind, randomized, two-period crossover study was performed on 20 dental students with a mean age of 24.5 ± 4 years with gingivitis. Subjects were randomly assigned to two groups ($n = 10$). After 14 days of trial period, plaque index (PI) and gingival index (GI) were assessed for each group. The first group used aloe vera toothpaste for 30 days and then their PI and GI were recorded. A 2-week washout period was allowed and then the subjects used fluoride toothpaste for the next 30 days and underwent PI and GI assessment again. This order was reversed in group 2.

Results: Toothpaste-containing aloe vera showed no significant improvement in the GI and PI scores as compared with a fluoride-containing dentifrice. PI was 2.14 ± 1.3 at baseline and 1.84 ± 1.02 in 30 days ($p < 0.098$). GI was 0.62 ± 0.74 at baseline and 0.25 ± 0.46 at 30 days ($p < 0.068$). During the trial, no side effects were seen due to the use of aloe vera or fluoride toothpaste.

Conclusion: The effect of aloe vera toothpaste on PI and GI was similar to that of fluoride toothpaste and it seems that this toothpaste can be used as an alternative to a chemical toothpaste.

Clinical significance: The use of an aloe vera toothpaste in improving the progression of gingivitis can be evaluated.

Keywords: Aloe vera, Gingivitis, Oral hygiene, Toothpaste.

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INTRODUCTION

Periodontal diseases are chronic infectious diseases characterized by a bacterial challenge that can provoke a destructive host response, leading to a clinical attachment loss (AL) and ultimately possible tooth loss.^{1,2} Toothbrushing with toothpaste is the most common form of oral hygiene habit practiced by people in developed countries. Indeed, mechanical oral hygiene procedures are thought to be essential for proper plaque control and maintenance of periodontal health.³⁻⁷ Toothpaste is supposed to help in minimizing plaque accumulation, reinforcing teeth against caries, removing stains, removing food debris, and freshening the mouth.^{8,9} Toothpaste containing anti-plaque and anti-inflammatory agents would also improve plaque removal and help in overcoming the manual or mechanical shortcomings of brushing.¹⁰ Mechanical plaque removal by toothbrushing is the most commonly used technique for plaque control and prevention of periodontal diseases. However, for many people, optimal brushing is a challenge. Other oral hygiene measures, such as the use of toothpaste with different effective ingredients, have been suggested for these individuals to help them overcome the shortcomings of toothbrushing. In recent years, researchers have focused on the role of medicinal plants in decreasing gingival inflammation and assisting plaque removal with lower side effects.^{2,3,11} Aloe vera is a medicinal plant. Its use was first suggested by Hannibal in South Africa in 1750 BC.⁴ It belongs to the Liliaceae family and is a cactus plant. It is believed to have antimicrobial and anti-inflammatory properties and is used for the treatment of many inflammatory diseases like gingivitis.^{3,4,8,9,10,12-16} Sean et al. evaluated the antimicrobial effects of 14 herbal dentifrices and concluded that dental gels with various

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constituents, particularly aloe vera, had greater antimicrobial properties than other toothpastes. This property can explain the anti-inflammatory effects of a toothpaste containing aloe vera.¹⁷ Dental uses of aloe vera are added¹⁸; it is greatly helpful in the treatment of gum diseases, like gingivitis and periodontitis.¹⁹ It reduces bleeding, inflammation, and swelling of the gums. It is a potent antiseptic in pockets where normal cleaning is challenging, and its antifungal properties help greatly in the problem of denture stomatitis.²⁰ Some studies have investigated the effects of herbal toothpaste, particularly aloe vera (Foramen Herbal Aloe, Spain) on periodontal parameters, yielding controversial results.²¹⁻²⁹ The aim of the present study is to test whether the inhibiting effect of

commercially available aloe vera toothpaste was as effective as a chemical toothpaste in the management of gingivitis.

MATERIALS AND METHODS

Eligible participants were all 20 dental students with a mean age of 24.5 ± 4 years without systemic diseases, no periodontal treatment at least 6 months prior to the study, no use of systemic antibiotic and anti-inflammatory drugs within the last 3 months with at least 20 natural teeth, nonsmokers, and not pregnant or lactating women. Subjects with orthodontic appliances, multiple bridges, partial dentures, and multiple caries and patients with known allergies to aloe vera or any of the components of the test product were excluded from the study. The study was registered at ClinicalTrials.gov as NCT02235532. The research was conducted according to the principles outlined in the Declaration of Helsinki on human medical experimentation. Written informed consent was obtained from all participants.

Inclusion Criteria

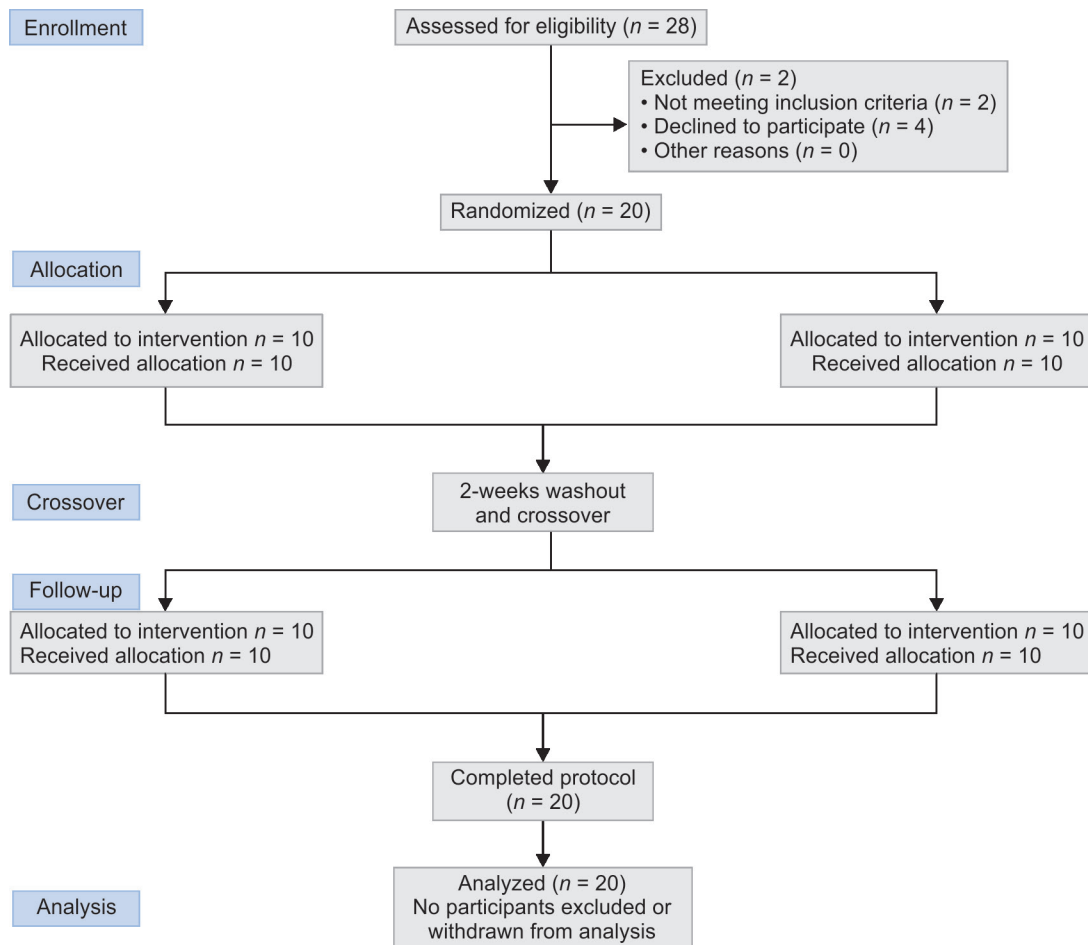
Gingivitis was defined in each patient as bleeding on probing (gentle) at $>30\%$ and a gingival index (GI)³⁰ of ≥ 1 at $>60\%$ of sites examined. All patients fulfilled the clinical criteria of having a pocket probing depth ≤ 3 mm, clinical AL < 1 , plaque index (PI) ≥ 2 as defined by Turesky et al., modification of Quigley–Hein PI^{31,32} with no evidence of radiographic bone loss.

Exclusion Criteria

Periodontal treatment (nonsurgical) within the previous 6 months; systemic diseases; hypersensitive to ibuprofen; systemic antibiotic or anti-inflammatory drugs within the 3 months preceding the beginning of the study; pregnant or nursing females; smoking; no acute periodontal conditions, such as necrotizing periodontal diseases or periodontal abscesses; mouth rinses during the entire period of the study orthodontic treatments; use of removable dentures; and extensive dental restorations.

Treatment Procedure and Clinical Evaluation

Twenty participants were randomly assigned to two treatment groups, and one arm per patient was treated with aloe vera dentifrice (T1) or fluoride toothpaste (Signal, India), (T2) (Flowchart 1). Patients were asked not to perform any oral hygiene (including chewing gum) for 8 hours before the baseline and follow-up examinations. Patients were assessed for plaque using the PI^{31,32} and gingival inflammation using the GI,³⁰ as well as for oral soft tissue status. Patients were instructed on proper toothbrushing technique and were given either the test or fluoride toothpaste along with a diary to record product usage and daily oral hygiene activities. Instructions for and demonstrations of modified Bass method of brushing were provided to the patients.³³ The dentifrices were dispensed to the



Flowchart 1: Flow diagram

patients by a dental assistant not involved in the study (Department of Periodontics); all tubes had a plain white covering, labeled only with lot numbers to ensure proper masking, and a soft-bristled toothbrush was given to the participants. Patients were asked to refrain from all other unassigned forms of oral hygiene, including nonstudy toothbrushes or toothpaste, dental floss, chewing gum, or oral rinses during the study. Patients were assessed in the same dental unit under identical conditions at baseline and follow-up examinations; the intraexaminer reproducibility was tested by examining five patients out of the study twice with an 1-hour interval. Measurements were made blindly and separately. Then, the participants underwent baseline registration of gingival inflammation and plaque accumulation. Probing with Williams periodontal probe was done on six sites around each tooth except the third molars.

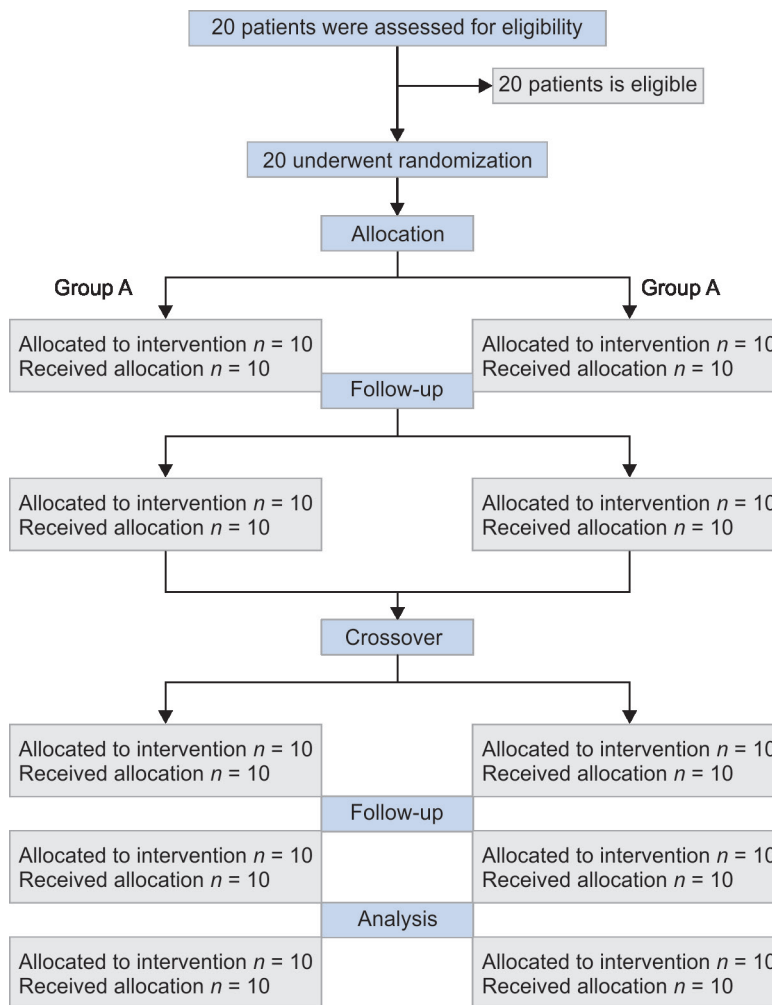
Postprocedural Instructions

All subjects had to undergo the assigned tooth cleaning regimens in a crossover manner for a treatment period of 30 days followed by a washout period of 14 days. Subjects were then told to brush with a toothpaste and toothbrush which they were using before the start of the study during the washout period. Clinical scores

for each parameter were obtained by a single examiner. After the 30-day trial period, each subject returned for scoring of clinical parameters, baseline registration, and instruction for another (of the two) tooth cleaning regimen. The study continued in this manner for a period of 2.5 months, allowing each group to follow each of the two regimens for 30 days followed by a washout period of 14 days to avoid a carryover effect. The difference between the study groups was the sequence of using toothpaste; group A used the aloe vera toothpaste for the first 30-day period followed by the fluoride-containing toothpaste while group B used the fluoride toothpaste for the first 30-day period. The clinical examiner had no knowledge as to which study group patients were assigned at any time during the study period. At every visit, the occurrence of any undesirable side effects or adverse events that could be related to the treatment was recorded (Flowchart 2).

Statistically Methods

The sample size was determined on the basis of a previous study comparing scaling and root planing (SRP) with adjunctive aloe vera and fluoride toothpaste, where the difference in the number of residual pockets may decrease after crossover because everyone will have been treated with the toothpaste.



Flowchart 2: Study design



The sample size was calculated using $\alpha = 0.05$ and the power $(1 - \beta) = 80\%$. For variability ($\sigma = SD$), the value of 0.5 mm was used, considering the reduction in PI of 0.79 from baseline to 1 month as the main outcome variable. Based on these data, the number of patients required to be enrolled to conduct this study was calculated as 10 patients per arm. However, considering the possibility of having a certain amount of dropout patients (10%), the total number of requested patients was 12 per treatment group. Statistical software was used to analyze the data. The values of different parameters collected were expressed as means \pm standard deviation. Repeated measures two-way analysis of variance was used for the comparison of quantitative indices while Wilcoxon signed-rank test with p value adjustment was applied for the comparison of qualitative variables. A p value <0.05 was considered statistically significant. A p value <0.001 was considered statistically significant.

RESULT

Twenty patients (10 males and 10 females) with a mean age of 24.5 ± 4 years completed the study and were included in the analysis. No patients abandoned the study after the treatment; group sample sizes were decided by power analysis with 90% power and a significance level of 0.05. There was no significant difference between groups 1 and 2 with respect to the PI and GI scores at baseline. There was a gradual decrease in the PI and GI scores by the 1-week and 2-week-time intervals, respectively, in all two groups (Tables 1 and 2). The finding that showed the mean PI and GI at different time points was based on the toothpaste used. PI and GI did not significantly change after the use of aloe vera toothpaste. PI was 2.14 ± 1.3 at baseline and 1.84 ± 1.02 in 30 days ($p < 0.098$); also GI was 0.62 ± 0.74 at baseline and 0.25 ± 0.46 at 30 days ($p < 0.068$). No significant difference was found between the case and control groups at any time interval ($p < 0.07$ for PI and $p < 0.308$ for GI). During the experiment, no side effects were seen due to the use of aloe vera or fluoride toothpaste (Tables 1 and 2).

DISCUSSION

The purpose of this study is to estimate the clinical effects of an herbal dentifrice containing aloe vera on plaque and gingivitis compared to a fluoride-containing dentifrice over a period of 30 days. There was no significant variance between the aloe vera-containing toothpaste and the toothpaste containing fluoride in the reduction of PI and GI. The outcomes of this current study are in agreement with those of De Oliveira et al. who found that

both a toothpaste containing aloe vera and a dentifrice containing fluoride resulted in a significant reduction of plaque and gingivitis, but no statistically significant difference was observed between them.¹⁴ Manual control of dental plaque has been clearly shown to retard the advancement of gingivitis and periodontal diseases.^{34,35} Axelsson and Lindhe described that noncompliant patients showed marks of persistent disease processes; due to the variation of simple mechanical control of plaque accumulation, several chemotherapeutic factors have been combined into home-use products to control plaque and gingivitis.³⁵ Pradeep exhibited the influence of aloe vera toothpaste on GI and PI improvement as well as microbiological counts were identical to a toothpaste containing triclosan, while on evaluation of placebo toothpaste a noteworthy improvement was achieved by aloe vera toothpaste. It was demanded that acetylated mannans, gel polysaccharides from aloe vera, had the main role in inflammation control.²² As a consequence of problems with proper mechanical control of plaques among the population, altered ingredients have been merged in mouthwashes and dentifrices to better control the oral microorganisms. Aloe vera has about 75 possibly active components, in which polysaccharides are considered to have anti-inflammation and immunomodulation effects.¹³ Also, antioxidant properties have been shown in aloe vera gel which could be important to control and for the treatment of periodontal diseases.¹⁴ Abdulwahab stated that regular application of herbal extract toothpaste through 42 days provided a significant decline of dental plaque buildup and a lot of gingival inflammation signs, such as gingival bleeding, and these agents have a bactericidal response against most of the periodontal pathogens without a negative effect on the normal microflora.³⁷ Because of the inconsistency of simple mechanical control of plaque accumulation, a number of chemotherapeutic agents have been merged into home-use products to control plaques and gingivitis. These agents have mostly been incorporated into either mouth rinses or toothpaste. The main action of these agents has been focused on their antimicrobial action. There have been a number of active ingredients incorporated into various dentifrices.³⁵ The importance of plaque control is documented in the literature.^{36,38} The use of the correct method to do oral hygiene seems the best way to control the composition of subgingival bacteria.^{39,40} Karim et al. showed that aloe vera mouth rinse is equally effective in reducing periodontal indices as chlorhexidine, and also indicated that aloe vera may prove to be an efficient mouthwash owing to its ability in reducing periodontal indices.⁴¹ Saito et al.⁴² proposed that a glycoprotein, aloctin A, which was isolated from *Aloe arborescens* Miller, markedly prevents arthritis in rats and carrageenan-induced edema in rats. Hutter et al.⁴³ identified an anti-inflammatory agent C-glucosyl chromone from *Aloe barbadensis*. Aloe vera is known to contain several active ingredients, including a carboxypeptidase that inactivates bradykinin *in vitro*, salicylates, and a substance that inhibits thromboxane (TX) synthesis.⁴⁴ Yagi et al. in a study found that three aloesin derivatives from aloe (namely isorabaichromione, feruloylaloetin, and p-coumaroylaloetin) have potent free radical and superoxide anion scavenging possessions.⁴⁵ Heggers and Robson demonstrated that barbolin and aloe emodin in aloe vera block prostaglandin synthesis. The decrease in the GI can be assigned to the presence of sterols as anti-inflammatory agents and lupeol as an antiseptic analgesic.⁴⁶ It was found that aloesin compounds inhibited cyclooxygenase-2 and TXA2 synthase, which clarifies the healing effects of aloe vera.^{45,47} The creation of reactive oxygen kinds is an essential protective mechanism against diseases associated with phagocytic infiltration and is the

Table 1: The mean PI at baseline and 1 month time points in the two groups

Group/time point	Mean \pm SD at day zero	Mean \pm SD at 1 month	p value	p value
Control	2.31 ± 1.02	1.94 ± 0.52	<0.19	0.07
Test	2.14 ± 1.3	1.84 ± 1.02	<0.098	

Table 2: The mean GI at baseline and 1 month time points in the two groups

Group/time point	Mean \pm SD at baseline	Mean \pm SD at 1 month	p value	p value
Control	0.47 ± 0.63	0.31 ± 0.48	<0.17	0.308
Test	0.62 ± 0.74	0.25 ± 0.46	<0.068	

host defense mechanism against bacterial pathogens⁴⁸; however, Moghaddam et al. exhibited that as there was no significant difference in PI in three phases between control and experimental groups, topical usage of aloe vera gel could be considered an adjunctive medication with SRP for chronic periodontitis⁴⁹. Therefore, Hudwekar et al. revealed that the use of aloe vera extract was effective in significantly improving the healing scores after periodontal flap surgery in the 1st week,⁵⁰ and also Elsadek et al.⁵¹ mentioned that the use of antimicrobial photodynamic therapy plus aloe vera gel resulted in decreasing periodontal inflammation; in addition, the aloe vera gel provided added advantage in decreasing the bleeding index. Our study was conducted on dental students and the obtained results highlighted the important role of correct toothbrushing technique. The correct technique of toothbrushing attenuates the role of the type of toothpaste used. Future trials are necessary to be implemented on a larger sample size selected from the general population and for a longtime study.

CONCLUSION

The use of natural herbal preparations in oral health care continues to be popular, and aloe vera dentifrice may be a useful addition; therefore, it could be used for the improvement of plaque and gingival status. Additional long-term prospective studies are needed to confirm the results achieved in this study.

CLINICAL SIGNIFICANCE

The use of an aloe vera toothpaste in improving the progression of gingivitis can be evaluated.

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