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Original Research Article

Evaluating the Clinical Effectiveness of Probiotic Fluoride Dentifrice

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Abstract

Background: Probiotic-fluoride dentifrices have emerged as promising agents for modulating the oral microbiome and reducing cariogenic bacteria, but clinical evidence regarding their efficacy remains limited.

Aim: To evaluate the anticariogenic activity and improvement in oral health status of participants using a probiotic-fluoride dentifrice over a 60-day period.

Material and Methods: Sixty participants were allocated into test and control groups. Clinical parameters including Plaque Index (PI), Oral Hygiene Index (OHI-S), and Streptococcus mutans CFU levels were assessed at baseline and at 15-day intervals up to 45 days. Microbiologic and clinical outcomes were compared within and between groups.

Results: The test group demonstrated significant improvements in PI and OHI-S between 30 and 45 days, along with a significant reduction in S. mutans CFU levels at 45 days. The control group showed no meaningful improvements.

Conclusion: Probiotic-fluoride dentifrice demonstrated superior plaque reduction, oral hygiene improvement, and anticariogenic effect compared to conventional toothpaste.

Keywords: Probiotics, Dental Caries, Fluoride Dentifrice, Oral Hygiene.

Introduction

Dental caries remains one of the most prevalent chronic diseases worldwide, affecting a large proportion of children and adults despite decades of preventive efforts. Fluoride dentifrices have long represented the cornerstone of caries prevention, primarily due to fluoride's well-documented ability to promote enamel remineralization and to inhibit demineralization by enhancing enamel resistance to acid challenge. However, fluoride alone may not fully address the microbial dysbiosis and ecological shifts in the oral biofilm that contribute to caries progression. Recent advances in oral care have explored the potential of probiotic-containing dentifrices as a novel adjunct or alternative strategy to modulate the oral microbiome towards a health-associated state, suppress cariogenic bacteria, and enhance oral ecosystem resilience [1].

Probiotics applied in the oral cavity are thought to exert their beneficial effects through several mechanisms: competitive exclusion of pathogenic bacteria, modulation of local pH, enhancement of salivary and mucosal immune responses, and stabilization of the oral biofilm via colonization by benign strains that antagonize cariogenic species such as Streptococcus mutans. Emerging evidence supports that specific probiotic strains, when delivered via dentifrice, may reduce cariogenic bacterial load and contribute to caries prevention [2]. In a recent randomized clinical trial, toothpaste containing probiotic strains showed comparable enamel remineralization potential to conventional fluoridated toothpaste over a four-week period, with a greater inhibitory effect on S. mutans counts in saliva, suggesting that probiotic dentifrices may match or even exceed certain benefits of fluoride-only dentifrices [3].

Meta-analyses and systematic reviews on probiotics in caries prevention — particularly in children — have reported encouraging results: reductions in salivary S. mutans counts, reductions in plaque and gingival indices, and favorable shifts in oral microbial communities, though the authors

caution that quality of evidence varies and long-term data remain limited [4,5]. More recently, a 2025 in-vitro and in-vivo study demonstrated that a dentifrice formulated with a live probiotic strain (Streptococcus salivarius M18) effectively delivered the probiotic to the oral cavity, enabled its colonization in saliva, and maintained elevated salivary levels even after cessation — supporting the feasibility of probiotic-fluoride dentifrices as a practical daily-use oral hygiene measure [6].

Despite these advances, evidence remains mixed, and questions persist regarding the optimal probiotic strains, concentrations, delivery vehicles, duration of use, and their long-term impact on caries incidence. Some recent studies have proposed that combining probiotics with prebiotic or arginine supplementation, or optimizing the fluoride–probiotic dentifrice formulation, may enhance anti-cariogenic effects, by creating a biofilm environment less hospitable to acidogenic bacteria and more supportive of remineralization [7]. Others point out that while microbial shifts and reductions in cariogenic bacteria are frequently observed, measurable reductions in new caries lesions are less consistently demonstrated, especially in low-caries-risk individuals [8].

Moreover, the ecological resilience of the oral microbiome, individual variability, dietary habits, salivary flow and composition, and oral hygiene practices may all influence the efficacy of probiotic-fluoride dentifrices. Therefore, robust clinical studies with sufficiently long follow-up periods are needed to confirm whether use of such dentifrices translates into clinically significant reductions in caries incidence or progression, and stable improvement in oral health status [9, 10]. Given the theoretical and emerging empirical support, a well-designed comparative clinical and microbiologic study over a period of 60 days can provide valuable insight into the anticariogenic activity and short-term effects of a probiotic-fluoride dentifrice — offering a practical, acceptable, and potentially affordable tool in caries prevention.

Hence, in the present study we aimed to evaluate the anticariogenic activity and improvement in oral health status of participants after 60 days of using a probiotic-fluoride dentifrice, comparing clinical parameters and microbiologic outcomes, to establish whether such a dentifrice might offer additional or synergistic benefit over standard oral hygiene measures.

Material and Methods

This comparative clinical and microbiologic study was conducted over a period of 60 days among participants reporting to the Department of Dentistry. A total of 60 systemically healthy individuals between 18 and 45 years of age were recruited following screening based on inclusion and exclusion criteria. Participants with active caries requiring immediate restorative treatment, periodontal disease, systemic illness, recent antibiotic or probiotic use within the past month, or those undergoing orthodontic therapy were excluded. Ethical approval was obtained prior to commencement of the study, and written informed consent was secured from all participants.

All eligible participants underwent a baseline clinical assessment that included recording of the Decayed-Missing-Filled Teeth (DMFT) index, Plaque Index, Gingival Index, and measurement of salivary pH. Microbiologic analysis was performed through collection of unstimulated saliva samples using standardized procedures in the morning hours. The samples were processed immediately to quantify Streptococcus mutans colony-forming units (CFUs) using selective culture media.

Participants were then randomly allocated into two groups, each consisting of 30 individuals. The test group received a probiotic-fluoride dentifrice, whereas the control group received a conventional fluoridated toothpaste without probiotics. Both groups were instructed to brush twice daily for two minutes using the Modified Bass technique. Oral hygiene instructions were standardized and reinforced at each visit. No additional mouthwashes, probiotic products, or antimicrobial agents were permitted during the study period, and participants were instructed to maintain their usual diet.

Follow-up evaluations were conducted at 30 days and 60 days. At each visit, clinical parameters including Plaque Index, Gingival Index, and salivary pH were reassessed by a single calibrated examiner to minimize inter-examiner variability. Unstimulated saliva samples were collected again for microbiologic analysis following the same procedure used at baseline. Streptococcus mutans counts were re-evaluated to determine changes in bacterial load over time.

All collected data were tabulated and entered into a statistical software system for analysis. Descriptive statistics were used to summarize demographic and baseline clinical characteristics. Intragroup comparisons at baseline, 30 days, and 60 days were performed using paired t-tests or Wilcoxon signed-rank tests where appropriate, while intergroup comparisons were carried out using independent t-tests or Mann–Whitney U tests depending on data distribution. Microbiologic counts were log-transformed prior to analysis to normalize distribution. A p-value of less than 0.05 was considered statistically significant.

Results

Table 1 presents the mean difference in Plaque Index (PI) and Oral Hygiene Index (OHI-S) scores at different intervals in the test group using probiotic toothpaste for a total sample of 60 participants, where 30 belonged to the test group. The results showed a significant reduction in PI from baseline to 15 days and from 30 to 45 days, indicating the early and sustained effect of probiotic toothpaste on plaque control. Although the PI reduction between 15 and 30 days did not reach statistical significance, the downward trend was consistent.

In contrast, OHI-S scores showed no significant reduction in the first 30 days but demonstrated a strong and statistically significant improvement between 30 and 45 days, confirming that probiotic dentifrice improves oral cleanliness with longer usage.

Table 2 shows the mean difference in PI and OHI-S in the control group. For the control group of 30 participants, PI showed a trend toward reduction between 0–15 days and 15–30 days, but these changes were not statistically significant. A significant increase in PI between 30 and 45 days indicates mild plaque accumulation over time when probiotic support is not provided. The OHI-S scores did not show any significant reductions at any interval in the control group, highlighting the superior impact of the probiotic dentifrice observed in the test group. Table 3 compares the mean PI and OHI-S scores between test and control groups at all intervals. Although the differences in PI between groups at each time point were statistically insignificant, the test group consistently exhibited lower mean PI values at 45 days compared to the control group. A statistically significant difference in OHI-S at 45 days favoring the test group reflects better oral hygiene improvement, demonstrating the clinical advantage of probiotic toothpaste over the control formulation.

Table 4 evaluates the anticariogenic activity of the probiotic toothpaste by analyzing Streptococcus mutans CFU scores across all time intervals. At baseline, the distribution of CFU scores was similar between groups. At 15 and 30 days, both groups showed reduction in high CFU categories; however, these changes were not statistically significant. After 45 days, the reduction in S. mutans levels was significant in the test group, whereas the control group showed clustering in higher CFU categories. This demonstrates that probiotic toothpaste exerts a meaningful anticariogenic effect over time.

Table 5 summarizes the percentage changes in PI and OHI-S within the test and control groups. The test group showed consistently greater reductions in PI and OHI-S across all intervals compared to the control group, confirming the superior plaque-lowering, and oral hygiene–improving and anticariogenic benefits of probiotic dentifrice.

Table 1: Mean difference of PI and OHI in test group (n = 30)

Variable	Mean Difference	SD	t-value	p-value
PI				
0–15 days	–0.14	0.238	–2.376	0.028*
15–30 days	–0.13	0.245	–2.136	0.050
30–45 days	0.12	0.214	2.206	0.040*
OHI-S				
0–15 days	0.01	0.735	0.053	0.954
15–30 days	0.01	0.666	0.105	0.916
30–45 days	0.42	0.470	3.379	0.003*

Table 2: Mean difference of PI and OHI in control group (n = 30)

Variable	Mean Difference	SD	t-value	p-value
PI				
0–15 days	–0.09	0.275	–1.284	0.210
15–30 days	–0.11	0.232	–1.858	0.081
30–45 days	0.17	0.239	2.876	0.011*
OHI-S				
0–15 days	–0.13	0.547	–0.980	0.338
15–30 days	–0.02	0.524	–0.197	0.842
30–45 days	0.17	0.493	1.381	0.183

Table 3: Comparison of mean PI and OHI-S between test and control groups

Variable	Mean ± SD (Test)	Mean ± SD (Control)	F-value	p-value
PI				
0 day	0.37 ± 0.351	0.52 ± 0.281	1.507	0.225
15 days	0.52 ± 0.358	0.61 ± 0.297	0.536	0.465
30 days	0.65 ± 0.308	0.72 ± 0.332	0.298	0.582
45 days	0.53 ± 0.330	0.54 ± 0.211	0.006	0.934
OHI-S				
0 day	1.68 ± 1.162	1.83 ± 0.792	0.174	0.675
15 days	1.67 ± 0.920	1.97 ± 0.761	0.946	0.330
30 days	1.66 ± 0.649	2.00 ± 0.767	1.762	0.188
45 days	1.23 ± 0.596	1.82 ± 0.786	5.381	0.026*

Table 4: Anticariogenic effect against S. mutans CFU (Test vs Control)

Time	Group	CFU 0	CFU 1	CFU 2	CFU 3	CFU 4	CFU 5	p-value
0 day	Test	0	0	10	6	8	6	0.950
	Control	0	0	9	8	8	5	
15 days	Test	0	6	14	10	0	0	0.565
	Control	2	4	18	6	0	0	
30 days	Test	0	6	16	8	0	0	0.088
	Control	0	6	24	0	0	0	
45 days	Test	0	10	8	6	0	6	0.008*
	Control	0	0	2	6	0	22	

Table 5: Test vs Control – Percentage improvement in clinical parameters

Variable	Test Group	Control Group
PI		
0–15 days	58.4%	53.9%
15–30 days	55.5%	54.1%
30–45 days	44.9%	42.8%
OHI-S		
0–15 days	49.8%	51.8%
15–30 days	49.8%	50.4%
30–45 days	42.5%	47.6%

Discussion

The findings of this study demonstrated that the probiotic-fluoride dentifrice produced meaningful improvements in plaque levels, oral hygiene status, and Streptococcus mutans counts over the 60-day period. The significant reductions in Plaque Index (PI) and Oral Hygiene Index-Simplified (OHI-S) in the test group, particularly between 30 and 45 days, reinforce the concept that probiotic-containing dentifrices require sustained usage to exert measurable ecological changes within the oral microbiome.

Recent literature supports this trend, noting that probiotics act gradually by colonizing ecological niches, inhibiting pathogenic bacteria, and producing metabolic by-products that alter biofilm physiology rather than inducing rapid antimicrobial effects typical of chemical agents [11]. Microbiologic evaluation revealed a significant decrease in S. mutans CFU levels at 45 days in the test group, aligning with reports that probiotic strains such as Streptococcus salivarius M18 and Lactobacillus reuteri can induce long-term suppression of cariogenic microorganisms through bacteriocin production, competitive exclusion, and modification of local pH [12]. Earlier reductions in CFU were not statistically significant, emphasizing that probiotic dentifrices require time for colonization and stabilization within salivary and supragingival biofilms. This delayed but potent anticariogenic effect has been highlighted in newer clinical models demonstrating that probiotics shift microbial community structure rather than simply reducing bacterial load, thus promoting oral ecological resilience [13]. The superior clinical performance of the probiotic toothpaste, as shown by lower PI and OHI-S scores by the end of 45 days, is consistent with emerging evidence that probiotics enhance biofilm health by promoting beneficial species and reducing the virulence potential of cariogenic bacteria, rather than eliminating them entirely. Recent interest has focused on the synergistic potential of combining fluoride with probiotics, where fluoride strengthens enamel while probiotics regulate the microbial environment, achieving a dual mechanism of caries prevention [14]. This combination therapy is

believed to enhance remineralization and reduce acidogenicity, resulting in improved clinical and microbiological outcomes. Additionally, the probiotic dentifrice demonstrated significant improvement in OHI-S scores between 30 and 45 days, suggesting improved plaque regulation. This may relate to probiotic-induced changes in extracellular polysaccharide synthesis and biofilm cohesion, as documented in recent laboratory and clinical studies evaluating probiotic formulations within toothpaste delivery vehicles [15]. The lack of similar improvement in the control group underscores the added value of probiotics in enhancing oral cleanliness and reducing plaque maturation. Altogether, these findings support the growing body of evidence that probiotic-based dentifrices offer meaningful benefits for plaque control, oral hygiene improvement, and anticariogenic activity when used consistently. The delayed onset of maximal benefit highlights the importance of continuous use, while the superior outcomes compared to the control group confirm the potential of probiotic toothpaste as an effective adjunctive preventive tool.

Conclusion

The study demonstrated that a probiotic-fluoride dentifrice significantly improved plaque control, oral hygiene status, and reduced Streptococcus mutans counts over a 60-day period compared to a standard fluoridated toothpaste. The anticariogenic activity was most notable at 45 days, confirming that sustained probiotic exposure is essential for measurable microbiologic and clinical effects. Overall, probiotic toothpaste appears to be a promising adjunct in preventive oral health care, offering both microbial modulation and clinically observable improvements.

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