

EVALUATING THE EFFICACY OF HETAUFU DOLLIPOP AS NOVEL ADJUNCT FOR PLAQUE MANAGEMENT IN ORTHODONTIC PATIENTS- A PILOT STUDY

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Abstract:

Aim & Objective:

To evaluate the effectiveness of the Hetafu dollipop as an adjunct to conventional oral hygiene measures in reducing plaque accumulation in orthodontic patients.

Trial Design:

Parallel-group, pilot randomized controlled trial with a 1:1 allocation ratio.

Methods:

Hundred patients undergoing fixed orthodontic treatment were randomly allocated into control (n = 50; manual toothbrushing with interdental brushes) and experimental groups (n = 50; manual toothbrushing with interdental brush and two Hetafu dollipops daily for 7 days). Plaque accumulation was assessed using Plaque Index (PI) and Quigley–Hein Plaque Index (QHPI) at baseline, 3rd and 7th day. Repeated measures ANOVA was used for statistical analysis, with significance set at $p < 0.05$.

Results:

The experimental group showed a significantly greater reduction in PI and QHPI scores at 3rd and 7th day compared to the control group ($p < 0.05$).

Conclusion:

The Hetafu dollipop appears to be an effective adjunct for plaque control in orthodontic patients. Larger randomized controlled trials with longer follow-up are required to confirm these findings.

Keywords:

Orthodontic patients; Hetafu dollipop; Plaque Index; Quigley–Hein Index; Oral hygiene adjunct; Randomized controlled trial

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Introduction:

Fixed orthodontic appliances are widely used for the correction of malocclusion and improvement of dental esthetics and function. However, brackets, bands, elastomeric ligatures, and archwires create numerous plaque-retentive areas that interfere with effective self-cleansing and routine oral hygiene procedures. This leads to increased plaque accumulation and alteration of the oral microbiome, predisposing orthodontic patients to gingival inflammation, enamel demineralization, white spot lesions, and dental caries.(1,2) Studies have shown that plaque biofilm formation begins rapidly around orthodontic attachments, with significant increases in cariogenic microorganisms such as *Streptococcus mutans* and *Lactobacillus* species during fixed appliance therapy.(3) Although conventional oral hygiene measures such as manual toothbrushing, interdental brushing, fluoridated toothpaste, and professional prophylaxis are routinely recommended, maintaining adequate plaque control remains challenging, particularly among adolescents and young adults undergoing orthodontic treatment.(4)

In recent years, increasing attention has been directed toward adjunctive oral hygiene measures that target the microbial etiology of dental plaque and improve patient compliance. Functional foods and bioactive compounds have emerged as promising preventive approaches for maintaining oral health by reducing pathogenic microorganisms and supporting a balanced oral microbiome.(5) One such novel adjunct is the Hetafu dollipop, a confectionary-based oral hygiene aid containing bioactive ingredients such as xylitol, stevia, cinnamon, essential oils, ascorbic acid, *Bacillus coagulans*, and tocopherol. Essential oils including cinnamon, peppermint, and clove possess well-documented antimicrobial properties that disrupt bacterial cell membranes, inhibit biofilm formation, and reduce acidogenicity, thereby decreasing the cariogenic potential of oral microorganisms.(6) Xylitol has also been shown to reduce plaque adhesion and inhibit the growth of *Streptococcus mutans*, while probiotics contribute to maintenance of a healthy oral microbial environment.(7) In addition, the lollipop-based delivery system provides prolonged intraoral exposure to

active agents and stimulates salivary flow, which may enhance mechanical cleansing, buffering action, and plaque reduction around orthodontic appliances.(8)

Previous studies have demonstrated the effectiveness of Hetafu formulations in reducing pathogenic oral microorganisms through microbiological culture analysis.(9) Sowjanya et al. reported significant reductions in cariogenic bacterial counts with bioactive Hetafu candies, highlighting their potential role in oral health promotion.(10) However, despite evidence regarding reduction of pathogenic microorganisms, there is limited literature evaluating whether these antimicrobial effects translate into clinically visible plaque reduction in orthodontic patients. Most available studies have focused primarily on microbiological outcomes rather than clinically relevant plaque assessment indices. Therefore, the present pilot randomized controlled trial was undertaken to evaluate the effectiveness of the Hetafu dollipop as a novel adjunct to conventional oral hygiene measures in reducing plaque accumulation in orthodontic patients using the Plaque Index and Quigley–Hein Plaque Index.

Materials and methodology:

This pilot study designed to be prospective clinical study was conducted in the Department of Orthodontics and Dentofacial Orthopedics of Adhiparasakthi Dental college and Hospital over a period of 7 days. Ethical approval was obtained from the Institutional Ethical Committee of Adhiparasakthi Dental College and Hospital, Melmaruvathur (ethical approval number: ECR/1742/APDCH/ORTHO/FM 05/TN2025), and the study was conducted after obtaining consent from the parents/guardians of the patients included in the study. This clinical trial was registered with the Clinical Trials Registry of India (REF/2026/03/126254).

This study was conducted as pilot study due to the differential composition of Hetafu dollipop and hence formal sample size calculation was not done. Based on recommendations for pilot studies, which suggest that approximately 10–12 participants per group are adequate for assessing feasibility and estimating outcome variability, a total sample size of 20 participants was selected(11).

The participants were recruited from patients undergoing fixed orthodontic treatment at Adhiparasakthi Dental College and Hospital who met the inclusion criteria.

Patients eligible for inclusion were those with full permanent dentition excluding third molars, clinically healthy periodontal tissues, and ongoing fixed orthodontic treatment. Individuals with evidence of periodontal breakdown, craniofacial deformities, severe skeletal discrepancies requiring surgical management, parafunctional oral habits,

previous maxillofacial surgery or trauma, systemic diseases influencing oral health, or allergy to any constituent of the Hetafu dollipop were excluded

Hetafu Dollipop is a novel probiotic-based oral healthcare confectionery developed by Lasarkaali Life Sciences Pvt. Ltd., a DPIIT-recognized startup focused on microbiome-centered oral healthcare solutions. The sugar-free formulation contains xylitol, stevia, *Bacillus coagulans* (probiotic), fructooligosaccharides (prebiotic), cinnamon, essential oils, ascorbic acid, and tocopherol. These bioactive ingredients are designed to promote oral health by supporting a balanced oral microbiome while reducing the proliferation of pathogenic microorganisms associated with dental plaque and caries.(10)

The proposed mechanism of action of Hetafu Dollipop involves a synergistic combination of probiotic, antimicrobial, and salivary stimulatory effects. *Bacillus coagulans* competitively inhibits pathogenic microorganisms and promotes microbial homeostasis, while cinnamon and essential oils exhibit antibacterial and anti-biofilm properties by interfering with bacterial adhesion, biofilm formation, and acid production(3). Furthermore, the lollipop-based delivery system provides prolonged intraoral exposure to active ingredients and stimulates salivary flow, thereby enhancing natural cleansing, buffering capacity, and clearance of food debris and microorganisms from tooth surfaces.(5,6)

These combined actions may contribute to a reduction in clinically visible plaque accumulation. By limiting bacterial colonization, inhibiting plaque biofilm maturation, and enhancing salivary-mediated plaque clearance, Hetafu Dollipop has the potential to improve oral hygiene in orthodontic patients, who are particularly susceptible to plaque retention around brackets and archwires(10).

All enrolled patients in experimental group are advised to practice conventional oral hygiene practices- manual toothbrush and interdental brush and adjunctive aid hetafu dollipops two per day one in morning and one in evening while in the control group only conventional measures of oral hygiene -manual toothbrushing and interdental brush are emphasised

Clinical visible plaque was measured by plaque scores with Plaque index and modified quigley hein index by turesky at three intervals-Baseline and 3rd day and 7th day. Informed consent was obtained from all patients, initially plaque scores was assessed based on Sillness and loe plaque index and type of oral hygiene was interpreted. Then, Two tone dye was dispensed in dappen dish and applicator tip is used to apply over all surfaces of the teeth and rinsed after 5-10 secs ,plaque scores was assessed using modified plaque index by Turesky et al and type of oral hygiene was interpreted

Statistical Analysis

Data were analyzed using IBM SPSS Statistics version 26.0. Descriptive statistics were expressed as mean $\pm$ standard deviation. Intergroup comparisons of Plaque Index (PI) and Quigley–Hein Plaque Index (QHPI) scores at baseline, day 1, and day 5 were performed using the Independent t-test. Intragroup changes over time were assessed using Repeated Measures Analysis of Variance (ANOVA), followed by Bonferroni post hoc analysis for pairwise comparisons. Categorical variables were analyzed using the Chi-square test. A p-value < 0.05 was considered statistically significant.

Results

A total of 40 orthodontic patients were included and equally allocated to the experimental and control groups (n = 20 each). No statistically significant differences were observed between the groups at baseline for either Plaque Index (p = 0.705) or Quigley–Hein Plaque Index (p = 0.868), indicating comparable baseline oral hygiene status. By day 3, the experimental group exhibited a significantly lower Plaque Index score than the control group (p = 0.007). This reduction became more pronounced by day 7, where the mean Plaque Index score decreased to 0.79 in the experimental group while increasing to 1.78 in the control group (p = 0.001). (Table 1 and Graph 1)

Similar results observed from Quigley-Hein index also. No statistically significant difference was observed between groups at baseline (p = 0.868). Following intervention, the experimental group demonstrated significantly lower Quigley–Hein scores at both day 3 (p = 0.005) and day 7 (p = 0.002) compared with the control group. The reduction in plaque

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scores observed in the experimental group indicates improved plaque control following Hetafu Dollipop use.(Table 2 and Graph 2)

Repeated Measures ANOVA revealed a statistically significant reduction in Plaque Index scores within the experimental group over time ($p = 0.001$). Conversely, the control group showed a significant increase in plaque accumulation during the study period ($p = 0.006$). These findings indicate that Hetafu Dollipop effectively prevented plaque accumulation and improved oral hygiene status over the 7-day period(Table 3 and Graph 3)

Bonferroni-adjusted post hoc analysis demonstrated statistically significant reductions in Plaque Index scores between all assessment intervals. Significant reductions were observed from baseline to the 3rd day, baseline to the 7th day, and from the 3rd day to the 7th day. The greatest reduction occurred between baseline and the 7th day, indicating a cumulative plaque-control effect of Hetafu Dollipop with continued use.(Table 4)

Repeated Measures ANOVA showed a statistically significant reduction in Quigley–Hein Plaque Index scores within the experimental group over time ($p = 0.001$). The reduction observed on the 3rd day continued through the 7th day, demonstrating sustained effectiveness of the intervention. The control group did not show comparable improvement, further supporting the beneficial role of Hetafu Dollipop in plaque control.(Table 5 Graph 4)

Post hoc analysis showed statistically significant reductions in Quigley–Hein scores from baseline to day 1, baseline to day 7, and day 3 to day 7. This indicates that the beneficial effect of Hetafu Dollipop was evident within 72 hours and continued to improve throughout the study period. The greatest reduction was observed between baseline and day 7, suggesting cumulative plaque-control benefits following repeated use(Table 6)



Figure 1- **Materials** -1-Hetafu dollipop,2-Mouth mirror&Curved

explorer,3.Alphaplac(Two tone disclosing solution)4.Dapen dish(To dispense the disclosing solution),5.Applicator tip(to apply over tooth surfaces)

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EXPERIMENTAL Group

PATIENT NAME : _____ AGE/SEX : _____

Baseline scores

16	12	24
44	32	36

UR							
UL							
	1	2	3	4	5	6	7
LR							
LL							

Sum of scores of all teeth = _____ = _____ ORAL HYGIENE

6 x 4 = 24

3rd day scores

16	12	24
44	32	36

UR							
UL							
	1	2	3	4	5	6	7
LR							
LL							

Sum of scores of all teeth = _____ = _____ ORAL HYGIENE

6 x 4 = 24

7th day scores

16	12	24
44	32	36

UR							
UL							
	1	2	3	4	5	6	7
LR							
LL							

Sum of scores of all teeth = _____ = _____ ORAL HYGIENE

6 x 4 = 24

Figure 2- Plaque scores evaluation sheet



Figure 3- At 3rd day, Visible plaque after using disclosing agent

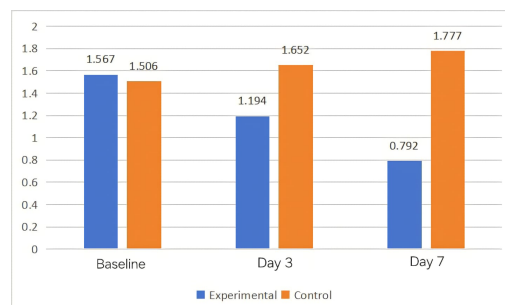
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Figure 4- At 7th day, Visible plaque after using disclosing agent

	Group	N	Mean	Std. Deviation	p-value
Baseline PLAQUE INDEX	Experimental	20	1.5670	0.43653	0.705
	Control	20	1.5060	0.24798	
3 rd day PLAQUE INDEX	Experimental	20	1.1940	0.43625	0.007
	Control	20	1.6520	0.18737	
7 th day PLAQUE INDEX	Experimental	20	0.7920	0.48942	0.001
	Control	20	1.7770	0.15056	

Table 1: Comparison of Plaque Index Scores Across Study Groups at Different Time Points using Independent t test



Graph:1 Comparison of Plaque Index Scores Across Study Groups at Different Time Points using Independent t test

Timepoint	Group	N	Mean	Std. Deviation	p-value
Baseline QUIGLEY HEIN INDEX	Experimental	20	1.3770	0.62936	0.868
	Control	20	1.4120	0.19269	
3 rd day QUIGLEY HEIN INDEX	Experimental	20	1.0680	0.44439	0.005
	Control	20	1.5680	0.22523	
7 th day QUIGLEY HEIN INDEX	Experimental	20	0.7730	0.44522	0.002
	Control	20	1.5310	0.49418	

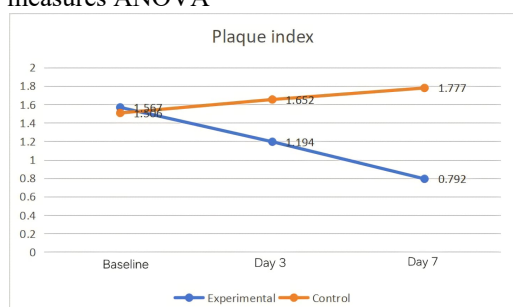
Table 2: Comparison of Quigley Hein Index Scores Across Study Groups at Different Time Points using independent t test

Group		Mean	Std. Deviation	p-value
Experimental	Baseline PLAQUE INDEX	1.5670	0.43653	0.001
	3 rd day PLAQUE INDEX	1.1940	0.43625	

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	7 th day PLAQ UE INDEX	0.79 20	0.4894 2	
Control	Baseline PLAQ UE INDEX	1.50 60	0.2479 8	0.006
	3 rd day PLAQ UE INDEX	1.65 20	0.1873 7	
	7 th day PLAQ UE INDEX	1.77 70	0.1505 6	

Table 3: Comparison of plaque index scores within groups at various timepoints by repeated measures ANOVA



Graph 3: Comparison of plaque index Scores Across Study Groups at various Time Points using Repeated measures ANOVA

Group			Mean Difference (I-J)	p-value	95% Confidence Interval for Difference	
Experimental	Baseline	Day 3	.373*	0.003	0.142	0.604
		Day 7	.775*	0.000	0.567	0.983
	Day 3	Day 7	.402*	0.001	0.187	0.617
Control	Baseline	Day 3	-	0.0	-	-

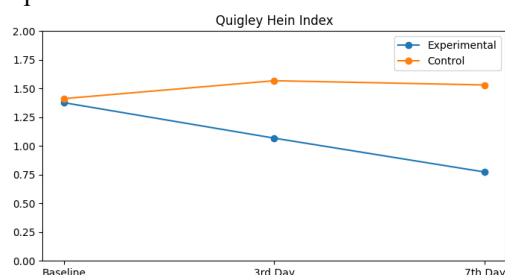
1	line	y 3	.146*	18	0.266	0.026
		Day 7	.271*	03	0.438	0.104
	Day 3	Day 7	.125*	0.035	-0.241	-0.009

Table 4 :Bonferroni Post Hoc Analysis – Pairwise comparison of Plaque Index scores

Group		Mean	Std. Deviation	p-value
Experimental	Baseline QUIGE LY HEIN INDEX	1.3770	0.62936	0.001
	3 rd day QUIGE LY HEIN INDEX	1.0680	0.44439	
	7 th day QUIGE LY HEIN INDEX	0.7730	0.44522	
Control	Baseline QUIGE LY HEIN INDEX	1.4120	0.19269	0.001
	3 rd day QUIGE LY HEIN INDEX	1.5680	0.22523	
	7 th day QUIGE	1.5310	0.49418	

	LY			
	HEIN			
	INDEX			

Table 5: Comparison of Quigely hein index scores within groups at various timepoints by repetaed measures ANOVA



Graph 4: Comparison of Quigely index Scores Across Study Groups at various Time Points using Repeated measures ANOVA

Discussion:

Maintaining adequate oral hygiene during fixed orthodontic treatment remains a significant challenge because brackets, bands, and archwires create plaque-retentive areas that facilitate biofilm accumulation and increase the risk of enamel demineralization, gingival inflammation, and dental caries. Consequently, there is growing interest in adjunctive approaches that not only suppress pathogenic microorganisms but also promote a balanced oral microbiome. Hetafu products have recently emerged as novel microbiome-modulating oral healthcare formulations containing probiotics, prebiotics, essential oils, and bioactive compounds designed to support oral health. (1)The present pilot randomized controlled trial evaluated the effectiveness of Hetafu Dollipop on clinically visible plaque accumulation in orthodontic patients using Plaque Index and Quigley–Hein Plaque Index scores. (3)

The findings of the present study demonstrated a significant reduction in both Plaque Index and Quigley–Hein Plaque Index scores in the experimental group compared with the control group. These findings suggest that adjunctive use of Hetafu Dollipop enhances plaque control beyond that achieved by conventional oral hygiene measures alone. The observed reduction may be attributed to the combined action of probiotics, essential oils, xylitol, and prolonged salivary stimulation provided by the lollipop delivery system, which may interfere with bacterial adhesion, inhibit biofilm maturation, and enhance natural oral cleansing mechanisms. (3,5–7)

The results of the present study are consistent with the findings reported by Lakkoju et al., who evaluated HETAFU candies and demonstrated significant reductions in cariogenic microorganisms, particularly *Streptococcus mutans*, following regular consumption of the candies.(10)The authors reported a dose-dependent reduction in microbial load, with greater improvements observed among participants consuming higher quantities of HETAFU candies. Although their study focused on microbiological outcomes rather than clinical plaque measurements, both studies indicate that Hetafu formulations positively influence oral health and may reduce factors associated with plaque formation and caries development. (10)

Similarly, Vijaykumar et al. evaluated Hetafu mouthwash in orthodontic patients and reported a significant reduction in cariogenic microorganisms, including *Streptococcus mutans* and *Streptococcus oralis*, along with an increase in beneficial commensal bacteria such as *Streptococcus salivarius*. (9)Their findings suggested that Hetafu exerts a microbiome-modulating effect rather than acting solely as an antimicrobial agent. The present study complements these findings by demonstrating that such microbiological changes may translate into clinically measurable reductions in plaque accumulation. Unlike the mouthwash study, which assessed bacterial colony counts over an extended period, the present investigation evaluated short-term clinical plaque outcomes using validated plaque indices. (9)

A notable strength and novelty of the present study is that it assessed visible plaque accumulation rather than microbial counts alone. Previous Hetafu studies primarily relied on microbiological culture techniques to quantify bacterial changes.(10)While reduction in pathogenic microorganisms is important, clinicians are ultimately concerned with whether these microbial changes result in improved oral hygiene and reduced plaque accumulation. By using the Plaque Index and Quigley–Hein Plaque Index, the present study provides clinically relevant evidence that Hetafu Dollipop may contribute to improved plaque control in orthodontic patients. (9)

The findings are also supported by broader evidence regarding probiotic-based oral healthcare products. Previous studies and systematic reviews have reported that probiotics can reduce plaque accumulation, decrease *Streptococcus mutans* levels, and

improve gingival health by modulating the oral microbiome and suppressing pathogenic bacteria.(5) These mechanisms may explain the significant reduction in plaque scores observed in the experimental group. Furthermore, the presence of essential oils and xylitol in Hetafu Dollipop may enhance its anti-biofilm effect by reducing bacterial adhesion and acidogenicity. (7,12)

Despite the promising results, the present study was a pilot trial with a relatively small sample size and short follow-up duration. Therefore, caution should be exercised when generalizing the findings. Larger randomized controlled trials with longer observation periods and additional outcomes such as gingival indices, white spot lesion assessment, salivary parameters, and microbiological evaluation are required to establish the long-term effectiveness of Hetafu Dollipop.

Within the limitations of the present study, the findings suggest that Hetafu Dollipop may be considered a promising adjunctive oral hygiene aid for orthodontic patients. The significant reduction in Plaque Index and Quigley–Hein Plaque Index scores, together with previous evidence demonstrating reductions in pathogenic microorganisms and improvements in oral microbial balance, supports its potential role as an adjunct rather than a replacement for conventional mechanical plaque control measures. (9,10)Further high-quality randomized controlled trials are needed before definitive clinical recommendations can be made. (7,12)

Conclusion :

Within the limitations of this pilot randomized controlled trial, Hetafu Dollipop demonstrated a significant reduction in Plaque Index and Quigley–Hein Plaque Index scores among orthodontic patients when used as an adjunct to conventional oral hygiene measures. The findings suggest that its probiotic, antimicrobial, and salivary stimulatory properties may contribute to improved plaque control around fixed orthodontic appliances. Furthermore, unlike previous studies that primarily focused on microbiological outcomes, the present study provides preliminary clinical evidence of visible plaque reduction. Therefore, Hetafu Dollipop shows promise as a novel adjunctive oral hygiene aid in orthodontic patients; however, larger studies with longer follow-up periods are required to confirm its long-term effectiveness.

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