

Efficacy and Safety of Zinc Citrate-Based Dental Gel in Subjects with Periodontitis and Gingivitis: A Multicenter, Randomized, Controlled, Open-Label Study

Henil Shah¹, Harsh Shah², Navita Budhiraja^{3*}, Preeti Kumbhar³, Arti Sanghavi³, Dr Syed Mujtaba Hussain Naqvi³, Simran Sethi⁴, Parth Joshi⁴, Priyanka Madiwale⁴

¹Tatva Dental Care, 31, Kajal-Kiran Complex, B/S Parthesh Appt., Navrangpura Jain Derasar, Navrangpura, Ahmedabad. Gujarat, India

²Vijay Dental Clinic, Shop#01, Shreeji Park, Bhavik School Road, Near Arbuda Nagar, Chandlodiya, Ahmedabad. Gujarat, India

³Dr. Reddy's Laboratories Ltd., 7-1-27, Ameerpet, Hyderabad, Telangana – 500016

⁴Cliantha Research, Sigma I Corporates, Sindhu Bhawan Road, Bodakdev, Ahmedabad – 380054, Gujarat, India

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*Corresponding author: Navita Budhiraja

Dr. Reddy's Laboratories Ltd., 7-1-27, Ameerpet, Hyderabad, Telangana – 500016

Abstract

Original Research Article

This study evaluated the clinical efficacy and safety of Stolin-R toothpaste, formulated with Zinc Citrate (2%), Alum (0.2%), Sodium Fluoride (990 ppm), and Xylitol (10%), in improving gingival health, plaque control, and halitosis in healthy individuals and patients with Type 2 Diabetes Mellitus (T2DM). A 30-day interventional study was conducted in healthy individuals and patients with Type 2 Diabetes Mellitus (T2DM), comparing Stolin-R toothpaste with a standard comparator. Gingival Index (GI), Plaque Index (PI), Bleeding on Probing (BOP), periodontal pocket depth, halitosis scores, and gum health characteristics (color, consistency, texture) assessments were performed at baseline, Day 15, Day 30, and post-discontinuation (Day 60). Safety was monitored through adverse event reporting. Stolin-R toothpaste showed markedly superior outcomes across all parameters. Gingival Index decreased by 64.42% with Stolin-R versus 16.93% with the comparator, reflecting significantly lower gingival inflammation. Plaque Index declined by 69.72% in healthy subjects and 62.50% in T2DM subjects, compared to modest improvements with the comparator. Bleeding gums resolved completely in healthy subjects and nearly resolved in T2DM subjects by Day 30. Periodontal pocket depth decreased by 24.76% in healthy individuals and 17.11% in T2DM subjects, while the comparator exhibited negligible changes. Halitosis scores improved by 97.5% in healthy subjects and 64.93% in T2DM subjects, reflecting strong anti-malodor activity. Gum health parameters color, consistency, texture, and bleeding normalized completely by Day 30 and sustained through Day 60 post-discontinuation. No local intolerance, adverse events, or serious safety concerns were reported throughout the study. Overall, Stolin-R toothpaste offers superior oral health benefits through a synergistic formulation combining antimicrobial, anti-inflammatory and astringent effects. It significantly improves gingival health, plaque control, and halitosis in both healthy individuals and T2DM patients, with sustained efficacy and excellent safety. Stolin-R represents a comprehensive approach for periodontal maintenance, particularly in high-risk populations such as those with diabetes.

Keywords: Toothpaste, Zinc Citrate, Periodontitis, Gingivitis, Oral Health, Dental Plaque, Gum Disease, Randomized Controlled Trial, Multicenter Study, Safety and Efficacy.

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1. INTRODUCTION

Periodontal diseases are chronic inflammatory conditions of the supporting structures of teeth and remain a major global health challenge. They encompass two primary forms: gingivitis, a reversible inflammation confined to the gingiva, and periodontitis, a progressive and destructive disease characterized by loss of periodontal ligament and alveolar bone, ultimately leading to tooth mobility and tooth loss. Epidemiological

data indicate that periodontal diseases affect billions worldwide, with severity increasing with age and systemic comorbidities [Rajhans *et al.*, 2011; Abdulkareem *et al.*, 2023].

The primary etiological factor for these conditions is dental plaque biofilm, a highly organized microbial community embedded in an extracellular polymeric matrix. Biofilm formation begins with

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salivary pellicle deposition on oral surfaces, followed by microbial adhesion and maturation. This structured ecosystem provides microorganisms with enhanced resistance to host immune responses and antimicrobial agents, making biofilms the cornerstone of oral pathogenesis [Bertolini *et al.*, 2022]. While *Streptococcus mutans* is strongly associated with dental caries, anaerobic species such as *Porphyromonas gingivalis*, *Fusobacterium nucleatum*, and *Tannerella forsythia* are key contributors to periodontal disease [Bertolini *et al.*, 2022; Kaur *et al.*, 2021].

The transition from gingivitis to periodontitis is not solely microbial but involves host susceptibility and systemic factors. Among these, diabetes mellitus (DM) is a well-documented risk factor, increasing periodontitis risk by two- to three-fold compared to non-diabetic individuals. Poor glycemic control exacerbates periodontal breakdown, leading to increased plaque accumulation, deeper periodontal pockets, and heightened gingival inflammation [Casanova *et al.*, 2015; Vijay Anand *et al.*, 2020]. Diabetic patients often exhibit higher indices of plaque and calculus and require more frequent periodontal interventions [Hasan *et al.*, 2021]. This bidirectional relationship between DM and periodontitis underscores the need for integrated oral care strategies.

Adjunctive therapies, such as antimicrobial, antiplaque, and astringent agents incorporated into dentifrices, have demonstrated efficacy in reducing plaque and gingival inflammation in general populations [Sanz *et al.*, 2020]. However, clinical evidence in diabetic cohorts remains scarce, representing a critical gap in periodontal research.

Recent *in vitro* studies on Stolin-R (Active Gum Care) toothpaste have shown promising results. The formulation exhibited potent antimicrobial activity against major periodontal pathogens, including *Porphyromonas gingivalis*, *Fusobacterium nucleatum*, and *Streptococcus mutans*, with low minimum inhibitory and bactericidal concentrations. Remarkably, >99.99% bacterial reduction was achieved within five minutes of exposure, suggesting strong potential for clinical application [Shukla *et al.*, 2024].

Building upon these findings, the present clinical study aims to evaluate the efficacy of Stolin-R toothpaste in improving gingival and periodontal health in both healthy individuals and subjects with type 2 diabetes mellitus (T2DM). Additionally, the study will assess the sustained effect of the product following discontinuation, thereby bridging the gap between laboratory evidence and real-world clinical outcomes.

2. MATERIAL & METHODS

2.1. Study Design and Participants

This clinical study was an open-label, prospective, multicenter, randomized, controlled, two-arm clinical study designed to evaluate the safety and efficacy of a zinc citrate-based dental gel in subjects with periodontitis / gingivitis. The study duration was 60 days, comprising a 30-day treatment period followed by a 30-day follow-up period, and included five scheduled visits (Figure 1). The visits were conducted as follows: Visit 1 (Day 1) for screening and enrollment, Visit 2 (Day 7), Visit 3 (Day 15), Visit 4 (Day 30) and Visit 5 (Day 60) for assessments.

Subjects were screened according to predefined inclusion and exclusion criteria after obtaining written informed consent. In addition to collecting demographic details, medical history, general wellbeing, physical and dental examination findings, and concomitant medications, all eligible subjects underwent comprehensive dental and subjective assessments. Safety was monitored throughout the study via adverse event reporting.

Subjects were categorized into two main groups (healthy individuals and those with type 2 diabetes mellitus [T2DM]) and further stratified into four subgroups (Figure 2). This stratification enabled comparison of the effectiveness of the test toothpaste versus a marketed comparator in improving gingival and periodontal health in both healthy and T2DM subjects, as well as evaluation of the sustained effect and recurrence of parameters following discontinuation of product use.

All subjects brushed twice daily using the assigned product following the modified Bass technique for two minutes with a pea-sized amount of toothpaste and a standard soft-bristle toothbrush, followed by rinsing with water. The modified Bass technique involved placing the toothbrush at a 45° angle to the gum line, brushing two to three teeth at a time with gentle circular motions, and flicking the brush away from the gum line. All tooth surfaces and the tongue were cleaned similarly. The test product was used twice daily for the treatment period. During scheduled visits, one brushing session was supervised at the clinical site; the second was performed at home. After the 30-day treatment period, subjects discontinued the study products but continued brushing twice daily with a standard toothpaste provided by the study team during the follow-up phase. The product was used twice daily during the follow-up period. Follow-up visit was conducted to assess the sustained effect and recurrence of periodontal parameters.

Subjects were instructed to adhere to all study guidelines and restrictions throughout the study.

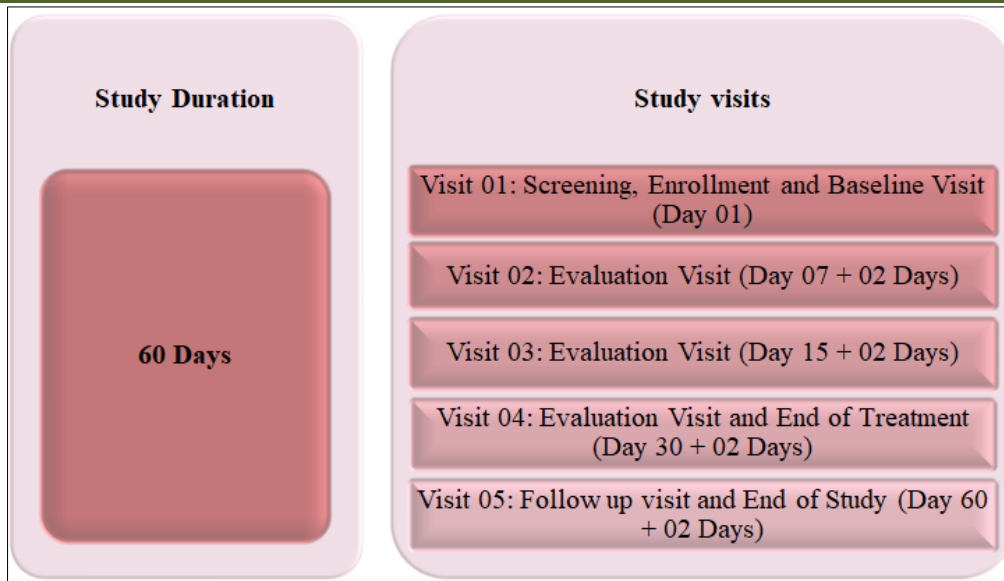


Figure 1: Schematic diagram of study visits

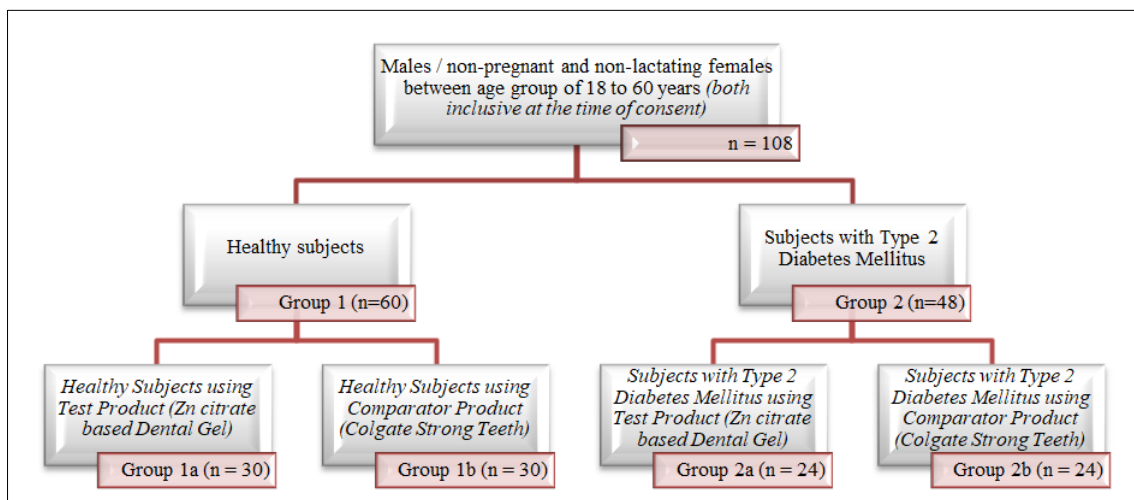


Figure 2: Schematic diagram of study population

Sample size estimation was performed using PASS 2022 software (Version 22.0.2). A total sample size of 108 subjects achieves 80% power to detect a difference of 0.13 between the test and reference groups, assuming a standard deviation of 0.23 for the test group and 0.19 for the reference group and with a two-sided

significance level (alpha) of 0.05. Anticipating a 20% attrition rate, 108 subjects (30 subjects in group 1a, 30 subjects in group 1b, 24 subjects in group 2a and 24 subjects in group 2b) were planned to be enrolled to ensure at least 86 evaluable subjects at study completion.

Table 1: Study participants

Disposition	Test (N = 54) n (%)	Comparator (N = 54) n (%)	Overall (N = 108) n (%)
Screened subjects	-	-	108 (100)
Screen fail subjects	-	-	0 (0)
Enrolled subjects	54 (100)	54 (100)	108 (100)
Study completed subjects	54 (100)	54 (100)	108 (100)
Discontinued/withdrawn subjects	0 (0)	0 (0)	0 (0)

Abbreviation(s): N = number of subjects in the specified group; n = number of subjects in the specified category

All 108 screened subjects were enrolled (54 in the test group and 54 in the comparator group), and all completed the study as per protocol (Table 1).

2.3 Ethics

The study adhered to the approved protocol and complied with the ethical principles outlined in the Indian Council of Medical Research (ICMR) guidelines, the International Council for Harmonisation (ICH) Good Clinical Practice (Step 5), and the Declaration of Helsinki. The Institutional Ethics committee, registered with Central Drugs Standard Control Organization (CDSCO), reviewed and approved the study Protocol (Version 01) on 27 November 2024. The trial was prospectively registered with the Clinical Trials Registry of India (CTRI) on 09 December 2024, prior to subject enrollment. Written informed consent was obtained from all subjects before participation. In accordance with the General Data Protection Regulation (GDPR), subject confidentiality was maintained, and all data was managed in compliance with applicable regulatory requirements.

2.4 Test Product(s)

The test product was a zinc citrate-based dental gel formulated as a toothpaste containing 2% zinc citrate, 0.2% alum, 990 ppm sodium fluoride, and 10% xylitol (Manufactured by: Dr. Reddy's Laboratories Ltd., India). This combination of active ingredients is intended to provide a comprehensive approach to oral care by offering anti-inflammatory, anti-plaque, and remineralization benefits.

2.5 Inclusion Criteria

Males and non-pregnant /non-lactating female subjects of age 18 to 60 years (both inclusive) at the time of consent were enrolled in the study. Healthy subjects (Group 1) were determined by the Investigator based on medical history and vital signs, while subjects in Group 2 had physician-diagnosed type 2 diabetes mellitus of

more than three months' duration, with HbA1c levels between 6.5 and 8 in the past three months and were under regular medical care for diabetes management. Key inclusion criteria included subjects with moderate to severe plaque (score 3–4 as per Plaque Index System), mild to moderate gingivitis/periodontitis (score 1–2), and slight to strong oral malodor (score 2–4 on the Organoleptic Scoring Scale) associated with periodontal disease.

2.6 Exclusion Criteria

Subjects who met any of the following criteria were excluded from the study: pregnant or breastfeeding or planning pregnancy and unwilling to use acceptable contraception; presence of orthodontic bands and partial removable dentures; oral tumor(s) or severe periodontal disease (purulent exudate, tooth mobility, or extensive attachment/bone loss); significant systemic conditions (e.g., HIV, hepatitis, uncontrolled hypertension, hyperthyroidism, acute cardiac or circulatory disease); chronic use of systemic corticosteroids, immunosuppressants, or antibiotics; dialysis; increased bleeding risk; need for essential dental care; heavy alcohol consumption (>2 drinks/day for women, >3 drinks/day for men); tobacco use; participation in a similar clinical study within the past 30 days; or any condition deemed unsuitable by the investigator.

2.7 Efficacy Endpoint(s)

2.7.1 Primary Endpoint(s)

The primary efficacy endpoint was the comparison of the test product and comparator in terms of reduction in gingivitis, assessed using the Gingival Index at Day 30 versus baseline. The response was evaluated by a qualified dental surgeon using a 4-point scale (Table 2).

Table 2: Scoring criteria for Gingival Index (GI)

Score	Criteria
0	No inflammation.
1	Mild inflammation, slight change in color, slight edema, no bleeding on Probing.
2	Moderate inflammation, moderate glazing, redness, bleeding on probing
3	Severe inflammation, marked redness and hypertrophy, ulceration tendency to spontaneous bleeding

2.7.2 Secondary Endpoint(s)

The secondary efficacy endpoints were to evaluate the effect of the test and comparator products on gingivitis, plaque, pocket depth/clinical attachment level, bleeding gums, halitosis, and overall gum health. Assessments were performed at baseline (Day 01), Day 07 (± 2 days), Day 15 (± 2 days), Day 30 (± 2 days), and recurrence at Day 60 (± 2 days).

- Plaque: assessed using Modified Quigley Hein Index (0–5 scale).
- Pocket depth/attachment: measured with a periodontal probe and graded as: 0–3 mm = No/Mild periodontitis; ≥ 4 mm and < 6 mm = Moderate; ≥ 6 mm = Severe.

- Bleeding gums: assessed using WHO probe; $< 30\%$ sites with BOP = localized bleeding, $\geq 30\%$ = generalized bleeding.
- Halitosis: evaluated using Organoleptic Scale (0–5).
- Overall gum health: assessed for color, consistency, texture, and bleeding.

Subjective evaluations included questionnaires on gum bleeding, oral malodor, teeth staining (Days 01, 07, 15, 30, 60), oral hygiene, gum health, and gum tightening effect (Days 07, 15, 30), and perception of taste, freshness, cooling sensation, and mouthfeel (Day 30). Safety was monitored throughout the study by recording adverse events (AEs) and serious adverse

events (SAEs) during scheduled visits and via subject self-reporting.

2.8 Statistical Analysis

The statistical analysis was done by using SAS® statistical software (Version: 9.4 or higher; SAS Institute Inc., USA). Demographic characteristics and results of the study were summarized with descriptive statistics (N, Mean, SD, Median, Minimum and Maximum) for continuous variable and frequency and percentages for categorical variable. The primary endpoint (reduction in gingival index) and secondary endpoints (gingivitis, plaque, pocket depth, bleeding gums, halitosis) were

analyzed using analysis of covariance (ANCOVA) with treatment as a fixed effect and baseline value as a covariate. Overall gum health was analyzed using Chi-square or Fisher's exact test. Subjective evaluation data were summarized as counts and percentages. Safety endpoints were listed only, with no statistical calculations performed. All statistical tests used a significance level of $\alpha \leq 0.05$, and two-tailed tests were applied for all analyses involving statistical testing.

3. RESULTS

3.1. Subject Demography

Table 3: Demography

Category/Statistics	Test (N = 54)	Comparator (N = 54)	Overall (N = 108)
Age (Completed Years)			
n	54	54	108
Mean ± SD	43.9 ± 9.57	44.9 ± 11.16	44.4 ± 10.36
Median	45.0	44.5	45.0
Min, Max	23, 59	19, 60	19, 60
p-value*	0.6054		
Gender [n (%)]			
Male	25 (46.30)	24 (44.44)	49 (45.37)
Female	29 (53.70)	30 (55.56)	59 (54.63)
p-value	0.8467		
Predominant Race [n (%)]			
Asian	54 (100)	54 (100)	108 (100)
Other	0 (0)	0 (0)	0 (0)
Subject's Condition [n (%)]			
Healthy	30 (55.56)	30 (55.56)	60 (55.56)
Type 2 diabetes mellitus	24 (44.44)	24 (44.44)	48 (44.44)
p-value	1.0000		
HbA1c			
n	24	24	48
Mean ± SD	6.82 ± 0.288	7.00 ± 0.291	6.91 ± 0.302
Median	6.70	7.10	6.80
Min, Max	6.6, 7.8	6.6, 7.4	6.6, 7.8
Abbreviation(s): Max = maximum; Min = minimum; N = number of subjects in the specified group; n = number of subjects in the specified category; SD = standard deviation.			
Note 1: The p-values are calculated using chi square or fisher exact test.			
Note 2: The p-value* is calculated using two sample t-test.			
Note 3: Percentages are based on the number of subjects in the specified treatment.			

A total of 108 Asian subjects were enrolled in the study, comprising 49 males and 59 females. Among these, 60 subjects were healthy, and 48 were diagnosed with type 2 diabetes mellitus (T2DM), with an overall mean HbA1c level of 6.91%. The age of participants ranged from 19 to 60 years, with a mean age of 44.4 years (Table 3).

Subjects were randomized equally into two groups: the test group and the comparator group, each

consisting of 54 individuals. The test group included 25 males and 29 females, with 30 healthy subjects and 24 subjects with T2DM (mean HbA1c: 6.82%). Their ages ranged from 23 to 59 years, with a mean age of 43.9 years. Similarly, the comparator group comprised 24 males and 30 females, also with 30 healthy subjects and 24 subjects with T2DM (mean HbA1c: 7.00%). The age range in this group was 19 to 60 years, with a mean age of 44.9 years.

3.2 Efficacy Assessments

3.2.1 Comparison of Reduction in Gingivitis Using Gingival Index

Table 4: Comparative Data

Visit	Statistics	Test (n = 54)	Comparator (n = 54)
Visit 01	Mean ± SD	2.00 ± 0.027	1.95 ± 0.146
	Median	2.00	2.00
Visit 04	Mean ± SD	0.71 ± 0.295	1.61 ± 0.186
	Median	0.65	1.60
	X times improvement	2.81*	1.21*
CFB to Visit 04	p-value*	<.0001	<.0001
	p-value#	<.0001#	
	% Difference	-281.87#	
	X times improvement	3.82#	
% CFB to Visit 04	Mean ± SD	-64.424 ± 14.9457	-16.925 ± 10.5801
	Median	-67.500	-20.000

Abbreviation(s): CFB = change from baseline; LS = least square; Max=maximum; min=minimum; N = number of subjects in specified treatment; n = number of subjects in specified category; SD=standard deviation; SE = standard error.

Note 1: CFB = Post Baseline –Baseline.

Note 2: p-value* will be calculated using analysis of covariance for within product.

Note 3: p-value will be calculated using analysis of covariance for between products.

Note 4: % CFB = ((Post Baseline –Baseline)/Baseline) *100.

Note 5:# indicates comparison between Test and Comparator product; * indicates % Difference and X time improvement within group.

Subjects in the Test Group (Stolin R Toothpaste) showed a 64.42% reduction in gingivitis over 30 days, with the mean Gingival Index score decreasing from 2.00 to 0.71 (*p value* <.0001). This indicates a shift from moderate to mild gingivitis, reflecting a 2.81-fold improvement in gingival health. In contrast, the Comparator Group (Colgate Strong Teeth) exhibited a 16.93% reduction in gingivitis, with the mean score decreasing from 1.95 to 1.61 (*p value* <.0001). Although statistically significant, the reduction

was less pronounced, and the severity of gingivitis remained within the moderate range, translating to a 1.21-fold improvement. On Day 30, the difference in gingival health between the two groups was statistically significant (*p value* <.0001). The Test Group (Stolin R Toothpaste), demonstrated a 3.82 times greater reduction in gingivitis compared to the Comparator Group (Colgate Strong Teeth), equating to over 100% greater improvement in gingival health (Table 4, Figure 3).

Figure 3: Assessment of Gingivitis using Gingival Index (Comparative)

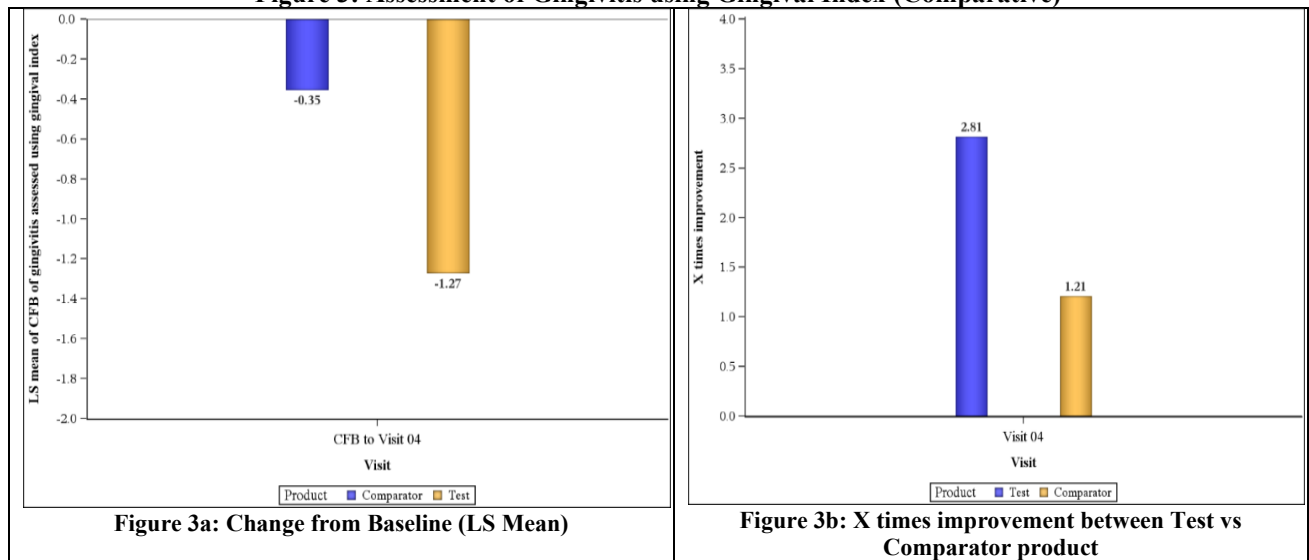


Figure 3a: Change from Baseline (LS Mean)

Figure 3b: X times improvement between Test vs Comparator product

3.2.2 Assessment of Gingivitis using Gingival Index For Healthy Subjects:

In the Test Group using Stolin R Toothpaste, the mean Gingival Index (GI) score decreased from 2.00 at baseline to 1.77 on Day 07, 0.94 on Day 15, and 0.49 on Day 30, indicating a transition from moderate to mild gingivitis. This represents reductions of 11.33%, 53.17%, and 75.33% (all $p < 0.0001$), corresponding to 1.13-, 2.14-, and 4.05-fold improvements. After discontinuation, the score slightly increased to 0.52 on Day 60, with no significant difference from Day 30, suggesting sustained benefit. In the Comparator Group (Colgate Strong Teeth), the mean GI score decreased from 2.00 to 1.90, 1.71, and 1.58 on Days 07, 15, and 30, respectively, remaining within the moderate range. Reductions were 5.00%, 14.50%, and 21.17% ($p \leq 0.0006$), corresponding to 1.05-, 1.17-, and 1.27-fold improvements. On Day 60 (i.e., after discontinuation), the score was 1.55, with no significant change from Day 30 (Table 5, Figure 4a).

For Subjects with T2DM:

For Stolin R, the mean GI score decreased from 1.99 at baseline to 1.63 on Day 07, 1.36 on Day 15, and 0.98 on Day 30, reflecting a shift from moderate to mild gingivitis. Reductions were 18.38%, 31.55%, and 50.79% (all $p < 0.0001$), corresponding to 1.23-, 1.46-, and 2.03-fold improvements. On Day 60 (i.e., after

discontinuation), the score was 1.01, with no significant difference from Day 30. For Colgate, the mean GI score decreased from 1.89 to 1.85, 1.75, and 1.66 on Days 07, 15, and 30, respectively, remaining moderate. Reductions were 6.88% and 11.62% at Days 15 and 30 ($p < 0.0001$), with no significant change on Day 07. On Day 60 (i.e., after discontinuation), the score was 1.67, indicating limited sustained benefit (Table 5, Figure 4b).

Between Group Comparisons:

Stolin R was significantly more effective than Colgate across all treatment points. Among healthy subjects, Stolin R achieved 2.27-fold greater reduction on Day 07 ($p = 0.0019$), increasing to 3.67-fold on Day 15 and 3.56-fold on Day 30 ($p < 0.0001$). Among T2DM subjects, Stolin R showed even greater superiority, with 8.00-fold greater reduction on Day 07 and sustained differences on Days 15 (4.58-fold) and 30 (4.42-fold; $p < 0.0001$). No significant differences persisted at Day 60 post-discontinuation. Within the Test Group, healthy subjects demonstrated better improvement than T2DM subjects at later time points (Day 15: 1.69-fold; Day 30: 1.49-fold; $p < 0.0001$), while T2DM subjects showed slightly better early response (Day 07: 0.62-fold; $p = 0.0042$). For the comparator, healthy subjects consistently showed greater improvement than T2DM subjects at Days 15 and 30 ($p \leq 0.0105$).

Figure 4: Assessment of Gingivitis using Gingival Index

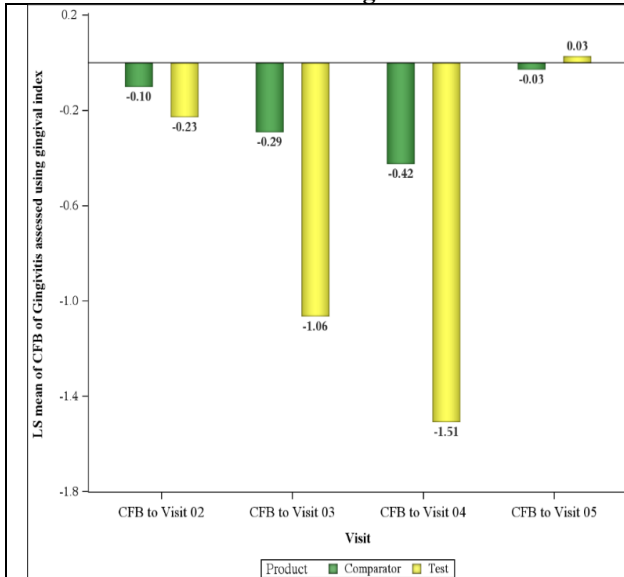


Figure 4a: Change from Baseline (LS Mean) – Healthy Subjects

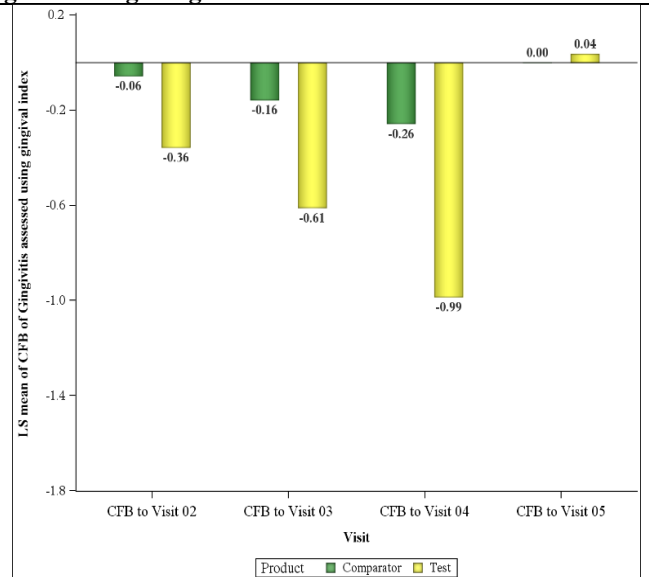


Figure 4b: Change from Baseline (LS Mean) –Subjects with T2DM

3.2.3 Assessment of Plaque Formation Using Plaque Index and Disclosing Agent For Healthy Subjects:

In the Test Group using Stolin R Toothpaste, the mean Plaque Index score decreased from 3.37 at baseline to 1.87 on Day 07, 1.03 on Day 15, and 1.00 on Day 30, indicating a substantial reduction in plaque levels. This corresponds to reductions of 44.72%,

68.89%, and 69.72% (all $p < 0.0001$), equating to 1.80-, 3.26-, and 3.37-fold improvements. On Day 60 (i.e., after discontinuation), the score slightly increased to 1.07, with no significant difference from Day 30, suggesting sustained benefit post-treatment. In the Comparator Group (Colgate Strong Teeth), the mean score decreased from 3.40 at baseline to 2.97, 2.50, and 2.27 on Days 07, 15, and 30, respectively, reflecting reductions of 12.78%,

26.67%, and 33.06% (all $p < 0.0001$), corresponding to 1.15-, 1.36-, and 1.50-fold improvements. On Day 60 (i.e., after discontinuation), the score was 2.20, with no significant change from Day 30 (Table 6, Figure 5a).

For Subjects with T2DM:

For Stolin R, the mean Plaque Index score decreased from 3.63 at baseline to 2.79 on Day 07, 2.17 on Day 15, and 1.33 on Day 30, representing reductions of 22.22%, 39.24%, and 62.50% (all $p < 0.0001$), equating to 1.30-, 1.67-, and 2.72-fold improvements. On Day 60 (i.e., after discontinuation), the score remained at 1.33, indicating sustained benefit. For Colgate, the mean score decreased from 3.63 to 3.54, 3.17, and 2.71 on Days 07, 15, and 30, respectively. Reductions were 12.50% and 25.00% at Days 15 and 30 ($p \leq 0.0003$), corresponding to 1.14- and 1.34-fold improvements, with no significant change on Day 07. On Day 60 (i.e., after discontinuation), the score was 2.63, with no significant difference from Day 30 (Table 6, Figure 5b).

Between Group Comparisons:

A statistically significant difference in plaque level reduction was observed between the Test Group (Stolin R Toothpaste) and the Comparator Group (Colgate Strong Teeth) across multiple time points. Among healthy subjects, Stolin R achieved 3.46-fold greater reduction on Day 07 ($p < 0.0001$), 2.59-fold on Day 15, and 2.09-fold on Day 30 ($p < 0.0001$). Among T2DM subjects, Stolin R showed 10.00-fold greater reduction on Day 07, 3.18-fold on Day 15, and 2.50-fold on Day 30 ($p < 0.0001$). No significant differences persisted at Day 60. Within the Test Group, healthy subjects demonstrated better improvement than T2DM subjects at all time points (Day 07: 1.80-fold; Day 15: 1.60-fold; Day 30: 1.03-fold; $p \leq 0.0031$). For the comparator, healthy subjects consistently showed greater improvement than T2DM subjects (Day 07: 5.20-fold; Day 15: 1.96-fold; Day 30: 1.24-fold; $p \leq 0.0182$).

Figure 5: Assessment of plaque formation using plaque index and disclosing agent

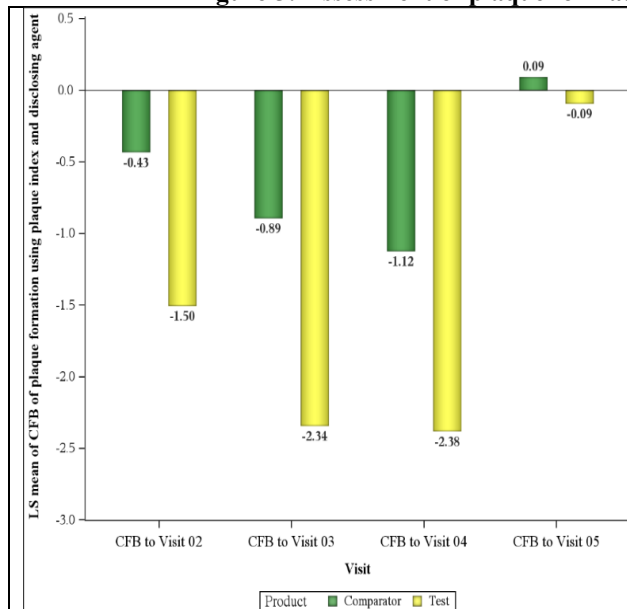


Figure 5a: Change from Baseline (LS Mean) – Healthy Subjects

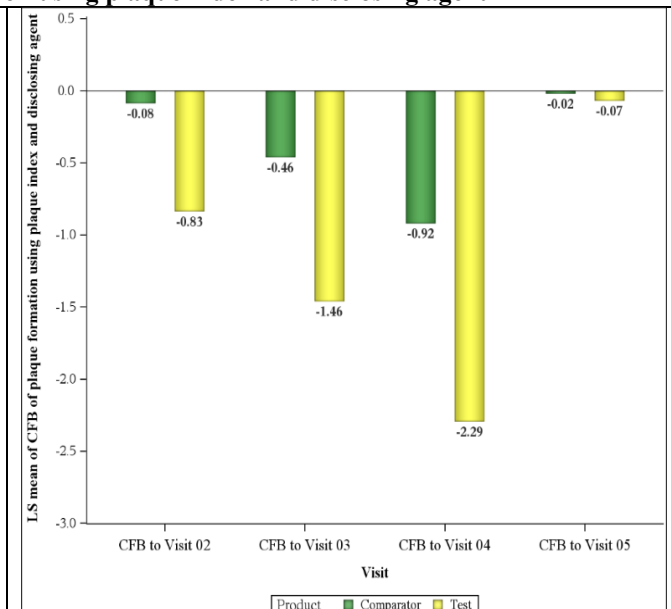


Figure 5b: Change from Baseline (LS Mean) –Subjects with T2DM

3.2.4 Assessment of Pocket Depth or Clinical Level Attachment Using a Periodontal Probe For Healthy Subjects:

In the Test Group using Stolin R Toothpaste, the mean pocket depth decreased from 3.342 mm at baseline to 3.325 mm on Day 07, 3.033 mm on Day 15, and 2.508 mm on Day 30, indicating progressive periodontal improvement. Reductions were 0.44%, 9.21%, and 24.76% at Days 07, 15, and 30, respectively ($p \leq 0.0321$), corresponding to 1.0-, 1.1-, and 1.3-fold improvements. On Day 60, the depth slightly increased to 2.542 mm, with no significant difference from Day 30, suggesting sustained benefit post-treatment. In the Comparator Group (Colgate Strong Teeth), the mean pocket depth remained largely unchanged (3.483 mm at

baseline, 3.400 mm on Day 30), with no significant improvement at any time point. On Day 60, the depth was 3.358 mm, indicating minimal change. (Table 7, Figure 6a).

For Subjects with T2DM:

For Stolin R, the mean pocket depth decreased from 3.604 mm at baseline to 3.396 mm on Day 15 and 2.990 mm on Day 30, reflecting reductions of 5.81% and 17.11% ($p < 0.0001$), corresponding to 1.1- and 1.2-fold improvements. No significant change was observed on Day 07. On Day 60, the depth was 2.979 mm, with no significant difference from Day 30, indicating sustained benefit. For Colgate, the mean pocket depth remained unchanged through Day 07 and Day 15 (3.552 mm and

3.542 mm) and slightly increased to 3.573 mm on Day 30, with no significant improvement at any time point. On Day 60, the depth was 3.583 mm, confirming lack of periodontal benefit.(Table 7, Figure 6b).

Between Group Comparisons:

No significant difference was observed between Test and Comparator groups on Day 07 for either healthy or T2DM subjects. By Day 15, the Test Group showed significantly greater reductions than the Comparator

(healthy: $p < 0.0001$; T2DM: 20-fold, $p < 0.0001$), and by Day 30, this difference was most pronounced (healthy: 10-fold; T2DM: 29.5-fold; both $p < 0.0001$). Within the Test Group, healthy subjects improved more than T2DM subjects at Days 15 and 30 ($p \leq 0.0311$), while for the Comparator, healthy subjects showed greater reductions only at Day 30 and Day 60 ($p \leq 0.0054$). No significant differences persisted post-discontinuation.

Figure 6: Assessment of pocket depth or clinical level attachment using a periodontal probe

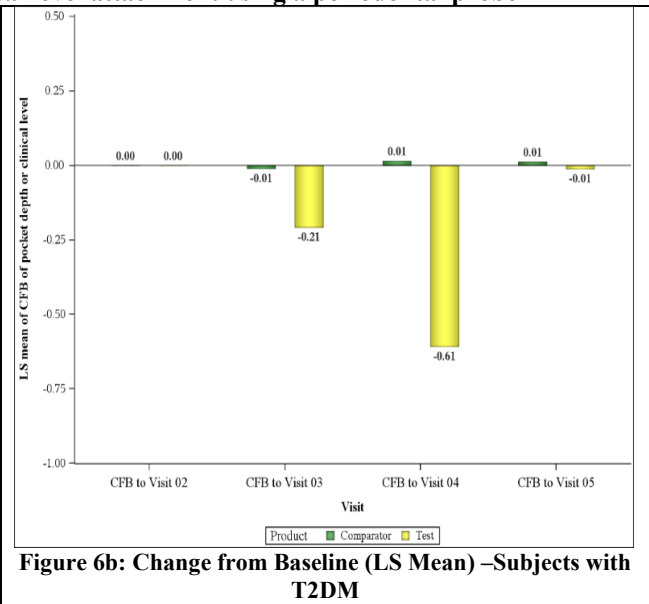
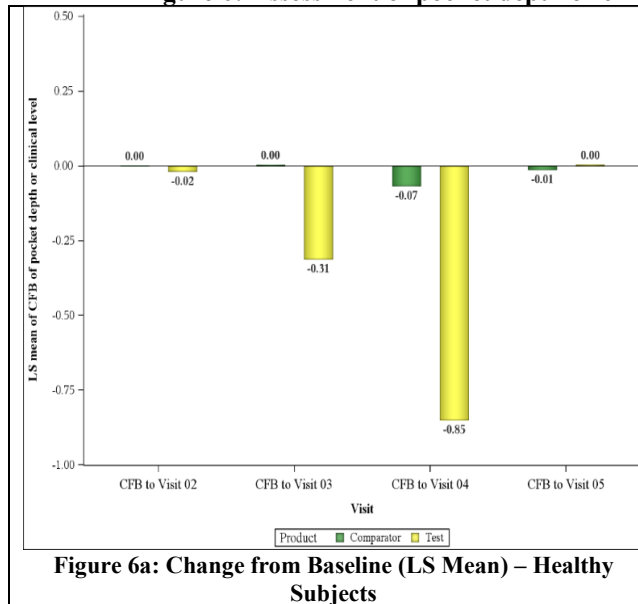


Figure 6a: Change from Baseline (LS Mean) – Healthy Subjects

Figure 6b: Change from Baseline (LS Mean) –Subjects with T2DM

3.2.5 Assessment of Bleeding Gums Using WHO Probe

For Healthy Subjects:

At baseline, 100% of subjects exhibited BOP > 30%, indicating severe gingival inflammation. With regular use of Stolin R Toothpaste, BOP improved markedly, with 56.67% achieving BOP < 30% by Day 07 (2.3-fold improvement). By Day 15, complete resolution was achieved, with 100% of subjects showing BOP < 30%, and this improvement was sustained through Day 30 and Day 60 post-discontinuation. In the comparator group using Colgate Strong Teeth, improvement was modest. On Day 07, Day 15, and Day 30, reductions were limited (1.1-fold (10.00%), 1.2-fold (16.67%), and 1.3-fold (20.00%), respectively). After discontinuation, 60% of subjects achieved BOP < 30% by Day 60, indicating partial improvement (Figure 7a).

For Subjects with T2DM:

In the test group, 100% of subjects exhibited BOP > 30% at baseline and Day 07. By Day 15, 50% of subjects achieved BOP < 30% (2-fold improvement),

and by Day 30, 95.83% achieved BOP < 30% (24-fold improvement). This improvement was sustained at Day 60. The comparator group showed minimal improvement. On Day 15 and Day 30, reductions were only 1-fold (4.17%) and 1.1-fold (12.50%), respectively. At Day 60, 87.5% of subjects still exhibited BOP > 30%, indicating negligible benefit (Figure 7b).

Between Group Comparisons:

Among healthy subjects, Stolin R demonstrated significantly greater reductions than the comparator: 5.7-fold on Day 07 ($p = 0.0003$), 6-fold on Day 15 ($p < 0.0001$), and 5-fold on Day 30 ($p = 0.0001$), with differences persisting at Day 60 ($p = 0.0001$). Among T2DM subjects, differences emerged by Day 15 (12-fold; $p = 0.0007$) and remained substantial on Day 30 (7.7-fold; $p < 0.0001$), also persisting at Day 60. Within the test group, healthy subjects improved faster than T2DM subjects at early time points (Day 07 and Day 15; $p < 0.0001$), while comparator groups showed no significant differences except at Day 60, where healthy subjects had better outcomes ($p = 0.0006$).

Figure 7: Assessment of bleeding gums using WHO probe

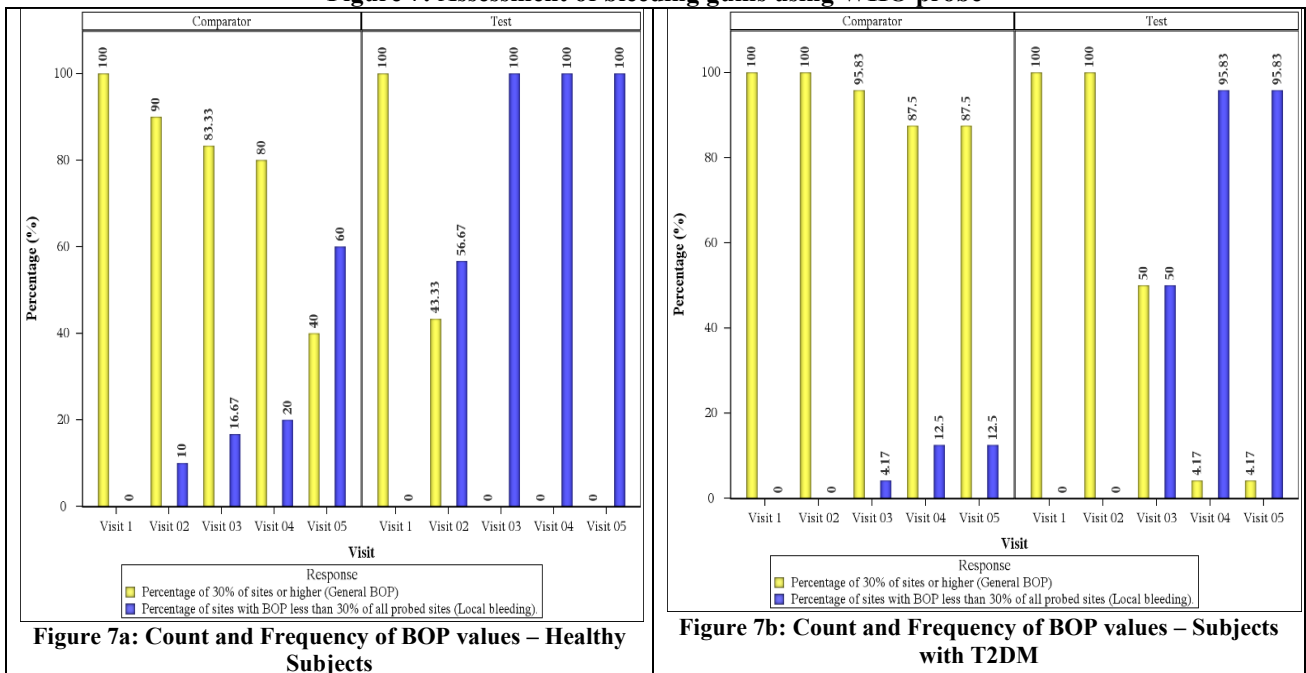


Figure 7a: Count and Frequency of BOP values – Healthy Subjects

Figure 7b: Count and Frequency of BOP values – Subjects with T2DM

3.2.6 Assessment of Halitosis by Qualified Dental Surgeon Using Organoleptic Scoring Scale For Healthy Subjects:

In the Test Group using Stolin R Toothpaste, the mean halitosis score was 3.4, indicating moderate oral malodour. With regular use of Stolin R Toothpaste, scores decreased to 1.6 on Day 07, 0.5 on Day 15, and 0.1 on Day 30, reflecting near-complete resolution of odour. Reductions were 53.61%, 86.11%, and 97.50% (all $p < 0.0001$), corresponding to 2.1-, 6.8-, and 34-fold improvements. On Day 60 (i.e., after discontinuation), the score slightly increased to 0.2 ($p = 0.0060$), but odour remained negligible. In the Comparator Group (Colgate Strong Teeth), the baseline score was 3.3, reducing to 2.9, 2.5, and 2.1 on Days 07, 15, and 30, respectively, indicating slight malodour. Reductions were 11.11%, 23.61%, and 34.72% ($p < 0.0001$), corresponding to 1.1-, 1.3-, and 1.5-fold improvements. On Day 60 (i.e., after discontinuation), the score remained at 2.1, with a minor but significant improvement (3.33%; $p = 0.0060$) (Figure 8a).

For Subjects with T2DM:

For Stolin R, the baseline score was 3.5, reducing to 2.6, 2.0, and 1.3 on Days 07, 15, and 30, indicating improvement from moderate to questionable odour. Reductions were 25.69%, 42.36%, and 64.93% ($p < 0.0001$), corresponding to 1.3-, 1.8-, and 2.8-fold improvements. On Day 60 (i.e., after discontinuation),

the score remained at 1.3, indicating sustained benefit. For Colgate, the baseline score was 3.5, reducing to 3.3, 2.8, and 2.4 on Days 07, 15, and 30, indicating slight malodour. Reductions were 4.86% ($p = 0.0344$), 20.14%, and 29.17% ($p < 0.0001$), corresponding to 1.1-, 1.3-, and 1.4-fold improvements. On Day 60 (i.e., after discontinuation), the score remained at 2.4, showing no further change (Figure 8b).

Between Group Comparisons:

Stolin R Toothpaste demonstrated significantly greater reductions in oral malodour compared to Colgate Strong Teeth across all treatment time points. Among healthy subjects, reductions were 4.5-fold greater on Day 07 ($p < 0.0001$), 3.8-fold on Day 15, and 2.8-fold on Day 30 ($p < 0.0001$). At Day 60, following discontinuation, the Test Group showed a slight recurrence, with oral malodour significantly higher than the Comparator Group ($p = 0.0032$). Among T2DM subjects, differences were also significant: 5.5-fold greater reduction on Day 07 ($p < 0.0001$), and 2.2-fold on Days 15 and 30 ($p < 0.0001$), with no difference at Day 60. Within the Test Group, healthy subjects consistently outperformed T2DM subjects, showing 2.0-, 1.9-, and 1.4-fold greater reductions on Days 07, 15, and 30 ($p < 0.0001$). For the Comparator Group, healthy subjects showed better improvement than T2DM subjects only on Day 07 (2.4-fold; $p = 0.0255$), with no significant differences thereafter.

Figure 8: Assessment of halitosis by qualified dental surgeon using Organoleptic Scoring Scale

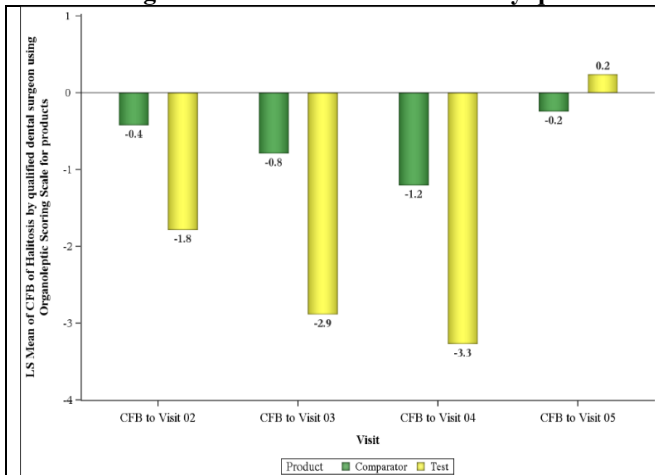


Figure 8a: Change from Baseline (LS Mean) – Healthy Subjects

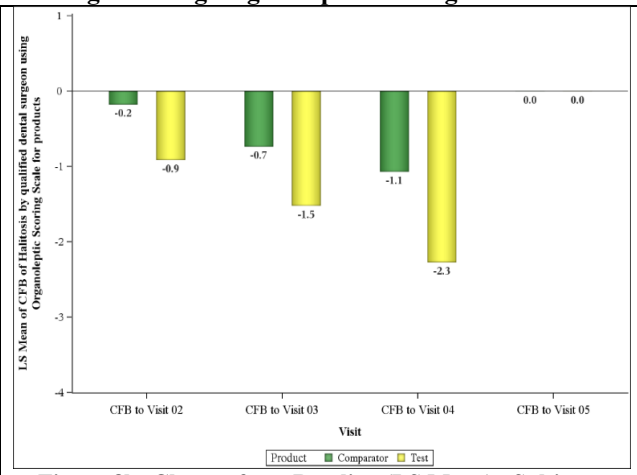


Figure 8b: Change from Baseline (LS Mean) –Subjects with T2DM

3.2.7 Assessment of Overall Gum Health (In Terms of Color, Consistency, Texture & Bleeding) By Dental Examination

For Healthy Subjects:

At baseline, all subjects (100%) exhibited abnormal gum health across colour, consistency, texture, and bleeding. With regular use of Stolin R Toothpaste, progressive improvements were observed: by Day 07, 23.33% showed normal colour, 36.67% normal consistency, 43.33% normal texture, and 26.67% showed no bleeding. By Day 15, improvements were substantial (83.33% normal colour, 96.67% normal consistency, 80.00% normal texture, and 100% showed no bleeding), and by Day 30, all subjects achieved normal gum health across all parameters. These results were sustained at Day 60 post-discontinuation. In the comparator group using Colgate Strong Teeth, no measurable improvement was observed by Day 07. By Day 15, only 3.33% showed normal consistency, with other parameters unchanged. On Day 30, 10% showed normal consistency and no bleeding, and 6.67% normal texture, while colour remained abnormal. At Day 60, partial improvements persisted (30% normal colour and consistency, 26.67% normal texture, 33.33% showed no bleeding), indicating limited benefit (Table 8, Figure 9a to 9d).

For Subjects with T2DM:

Among subjects with T2DM using Stolin R Toothpaste, all exhibited abnormal gum health at baseline and Day 07. By Day 15, improvements began (20.83% normal colour, 29.17% normal consistency, 20.83% normal texture, and 37.50% showed no

bleeding). By Day 30, 75% showed normal colour, 91.67% normal consistency, 83.33% normal texture, and 100% showed no bleeding. These improvements were sustained at Day 60. In the T2DM comparator group, all subjects exhibited abnormal gum health at baseline and Day 07. By Day 15, only 4.17% showed normal consistency, texture, and no bleeding. On Day 30, 12.50% showed normal colour and no bleeding, and 4.17% normal consistency and texture. At Day 60, improvements remained minimal (16.67% normal colour, 4.17% normal consistency and texture, 12.50% showed no bleeding) (Table 8, Figure 9e to 9h).

Between Group Comparisons:

A statistically significant difference in improvement of gum health parameters was observed between the Test Group and Comparator Group across all time points in healthy subjects ($p < 0.05$), with differences persisting at Day 60 ($p < 0.001$). Among T2DM subjects, no difference was noted on Day 07, but by Day 15, the Test Group showed significantly greater improvement in colour, consistency, and bleeding ($p < 0.05$), and by Day 30, across all parameters ($p < 0.001$), sustained at Day 60. Within the Test Group, healthy subjects improved faster than T2DM subjects at Days 07 and 15 ($p < 0.05$), while differences diminished by Day 30 and were absent at Day 60. For the Comparator Group, no significant differences were observed between healthy and T2DM subjects at Days 07–30; however, by Day 60, healthy subjects showed better consistency and texture ($p < 0.05$).

Figure 9: Assessment of overall gum health (in terms of Color, Consistency, Texture & Bleeding)

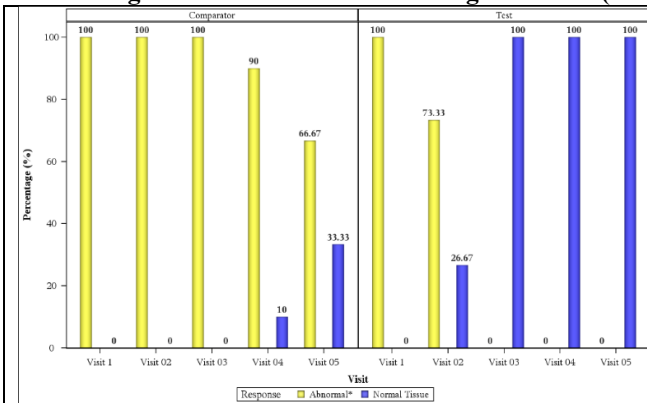


Figure 9a: Change in gum health in terms of Bleeding – Healthy Subjects

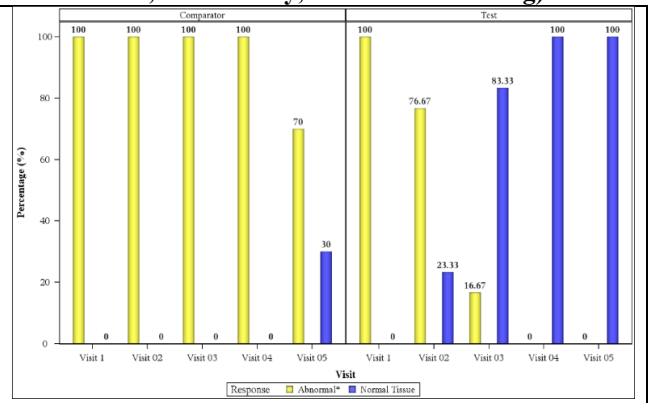


Figure 9b: Change in gum health in terms of Color – Healthy Subjects

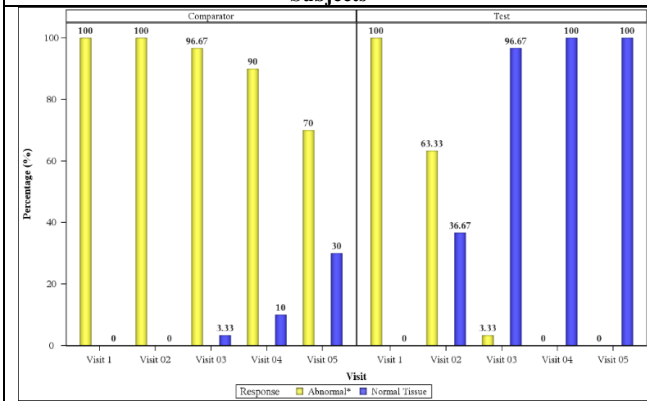


Figure 9c: Change in gum health in terms of Consistency – Healthy Subjects

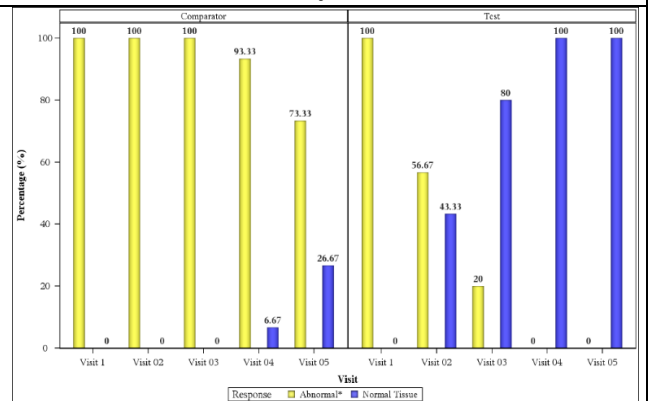


Figure 9d: Change in gum health in terms of Texture – Healthy Subjects

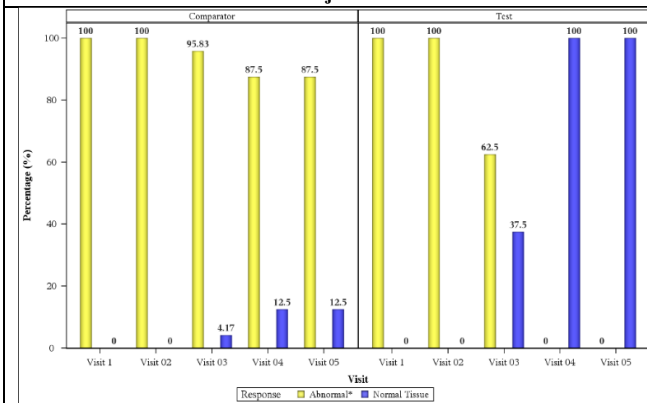


Figure 9e: Change in gum health in terms of Bleeding – Subjects with T2DM

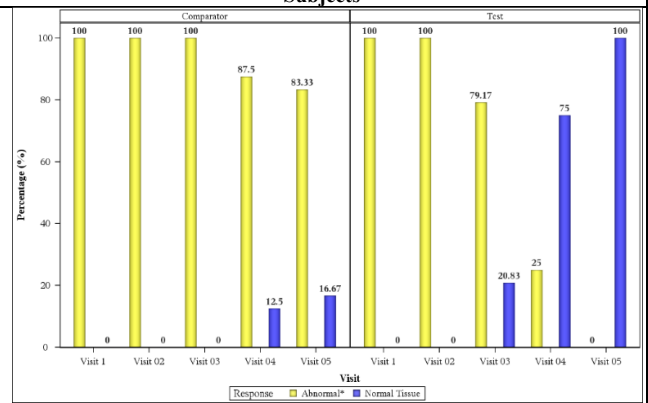


Figure 9f: Change in gum health in terms of Color – Subjects with T2DM

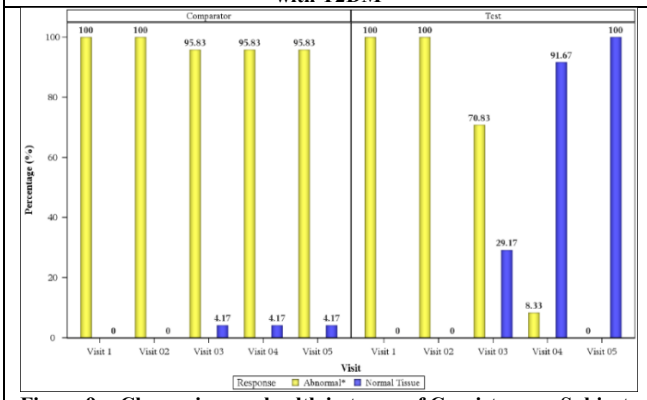


Figure 9g: Change in gum health in terms of Consistency – Subjects with T2DM

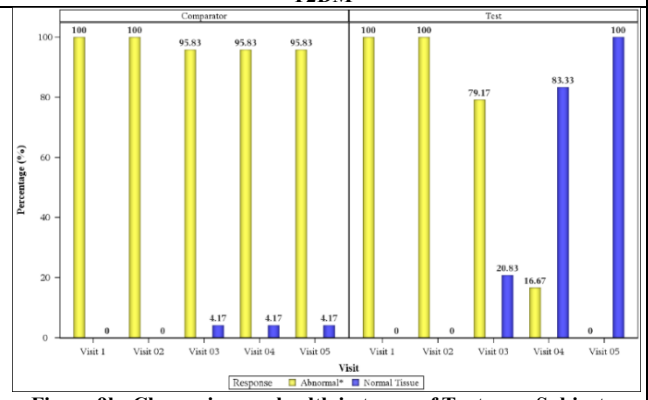


Figure 9h: Change in gum health in terms of Texture – Subjects with T2DM

3.2.8 Assessment of Subjective evaluation questionnaires

For reduction in bleeding gums, all subjects (100%) in both groups reported bleeding gums at baseline. In the Test Group (Stolin R Toothpaste), progressive improvement was observed with regular use: 72.23% reported reduction by Day 7, 98.15% by Day 15, and complete resolution (100%) by Day 30. After discontinuation, no recurrence of gum bleeding was reported. In contrast, the Comparator Group (Colgate Strong Teeth) showed only marginal improvement: 1.85% by Day 7, 7.41% by Day 15, and 18.52% by Day 30, with recurrence after discontinuation (Table 9, Figure 10a, 10b, 10g).

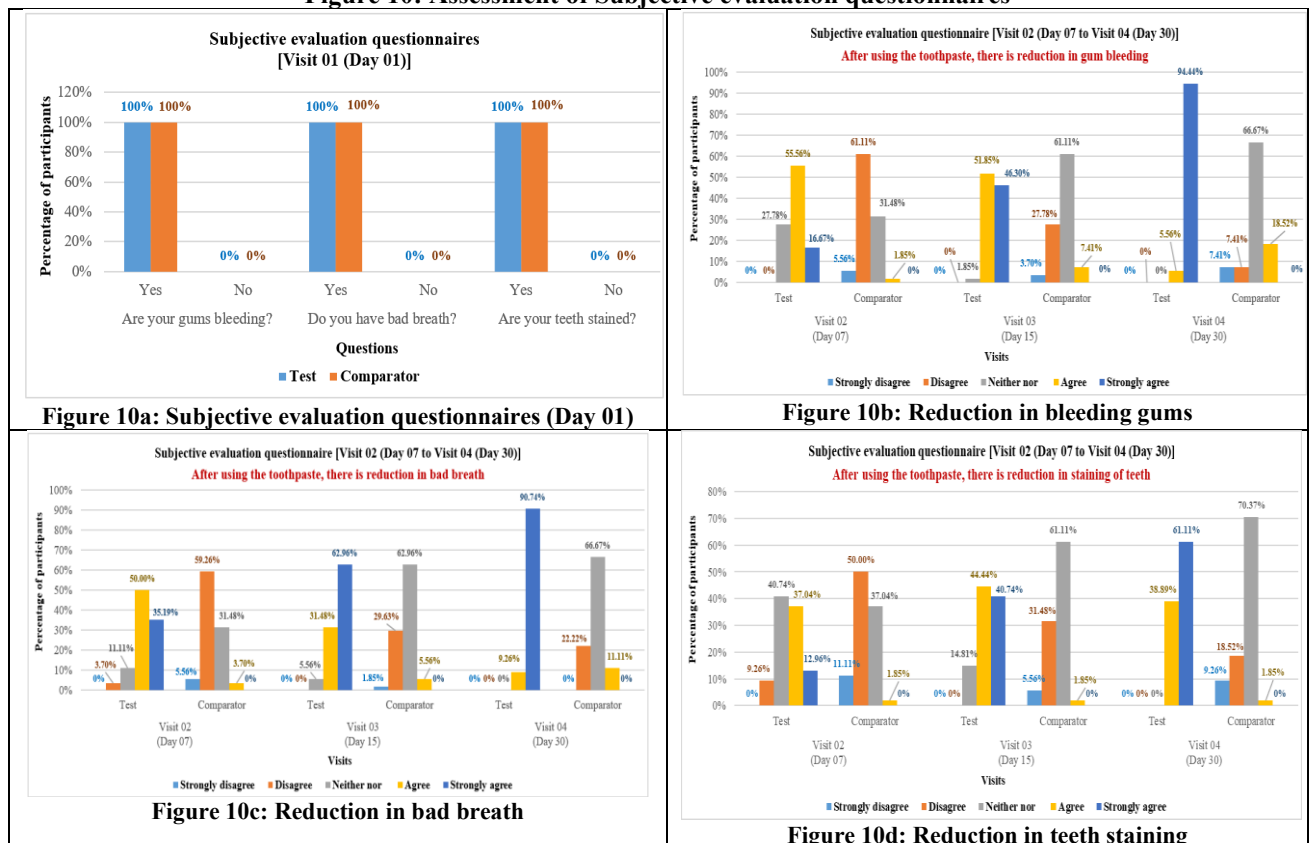
For reduction in bad breath, all subjects (100%) had bad breath at baseline. In the Test Group, improvement was noted in 85.19% by Day 7, 94.44% by Day 15, and 100% by Day 30. The Comparator Group demonstrated minimal improvement, with 3.70% by Day 7, 5.56% by Day 15, and 11.11% by Day 30 (Table 9, Figure 10a, 10c).

For reduction in teeth staining, all subjects (100%) reported stained teeth at baseline. In the Test Group, improvement was observed in 50% by Day 7, 85.18% by Day 15, and 100% by Day 30, with no staining reported after discontinuation. The Comparator Group showed negligible improvement, with only 1.85% of subjects reporting improvement at all time points, and staining persisted after discontinuation (Table 9, Figure 10a, 10d, 10g).

Regarding gums feeling tight/strong, the Test Group showed progressive improvement: 55.55% by Day 7, 88.89% by Day 15, and 100% by Day 30. The Comparator Group exhibited minimal improvement, with only 1.85% reporting improvement at each time point (Table 9, Figure 10e).

For visible improvement in the appearance of teeth, the Test Group reported improvement in 59.26% of subjects by Day 7, 92.59% by Day 15, and 100% by Day 30. The Comparator Group showed marginal improvement, with 3.70% by Day 7, 9.26% by Day 15, and 12.96% by Day 30 (Table 9, Figure 10f).

Figure 10: Assessment of Subjective evaluation questionnaires



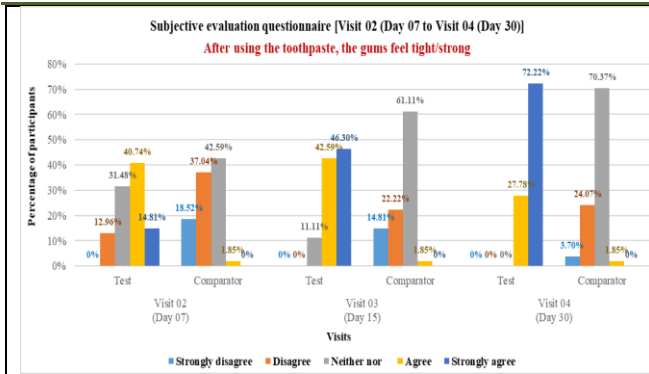


Figure 10: Gums feeling tight/strong

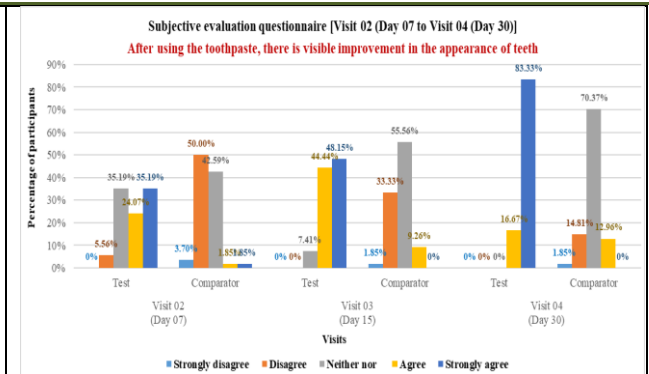


Figure 10f: Visible improvement in the appearance of teeth

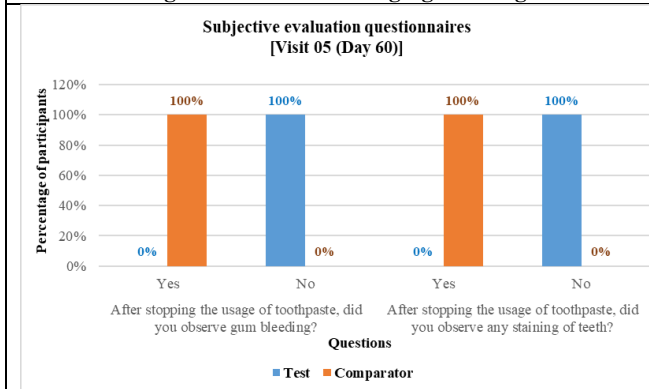


Figure 10g: Subjective evaluation questionnaires (Day 60)

3.2.9 Assessment of Subjects' Perception Questionnaires

For the Test Group (Stolin R Toothpaste), all subjects (100%) reported a highly positive sensory experience. Specifically, the taste of the toothpaste was found to be appealing, the freshness felt in the mouth was described as long-lasting, and the product provided a noticeable cooling effect after brushing. Additionally, the overall mouthfeel after using the test product was considered better than their current toothpaste, and subjects expressed that they overall liked the test product (Table 10, Figure 11).

In contrast, for the Comparator Group (Colgate Strong Teeth), 77.78% of subjects reported that the taste was not appealing, and 22.22% were neutral. Furthermore, 94.45% of subjects felt that the freshness was not long-lasting, and 5.56% were neutral. A majority (92.59%) reported no noticeable cooling effect after brushing, and 7.41% were neutral. Regarding mouthfeel, 94.44% felt that the comparator toothpaste was not as good as their current toothpaste, while only 5.56% found it better. Overall, 98.15% of subjects reported that they did not like comparator toothpaste, with only 1.85% expressing a positive opinion (Table 10, Figure 11).

Figure 11: Assessment of Subjects' Perception questionnaires

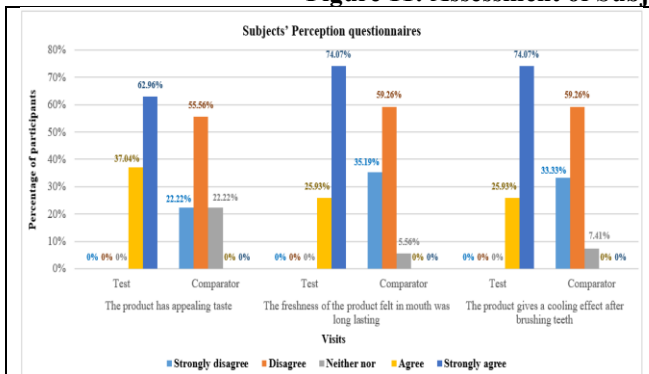


Figure 11a: Appealing Taste, Freshness, Cooling Effect

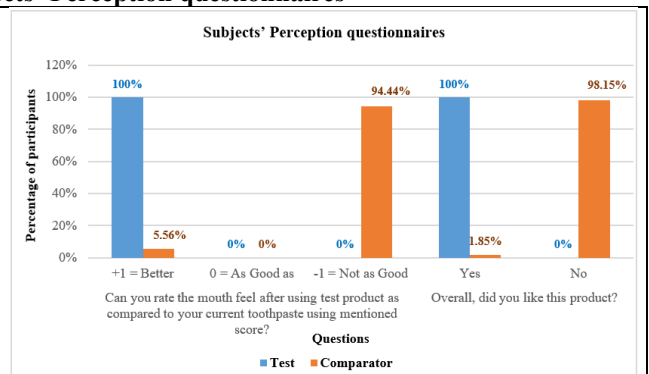


Figure 11b: Mouth Feel and Overall Likeability

3.3 Safety Assessments

The study recorded no instances of local intolerance in any participant, supporting the favorable

safety profile of the test product. Additionally, during 30 days of continuous use and up to the end of the study, no

adverse events (AEs) or serious adverse events (SAEs) occurred.

Supplementary Data

Table 5: Assessment of Gingivitis using Gingival Index

Visit	Statistics	Healthy		T2DM	
		Test (n=30)	Comparator (n=30)	Test (n=24)	Comparator (n=24)
Visit 01	Mean ± SD	2.00 ± 0.000	2.00 ± 0.000	1.99 ± 0.041	1.89 ± 0.206
	Median	2.00	2.00	2.00	2.00
Visit 02	Mean ± SD	1.77 ± 0.162	1.90 ± 0.139	1.63 ± 0.192	1.85 ± 0.184
	Median	1.80	1.90	1.60	1.90
	X times improvement	1.13*	1.05*	1.23*	1.02*
CFB to Visit 02	LS Mean	-0.23	-0.10	-0.36	-0.06
	SE of LS Mean	0.028	0.028	0.031	0.031
	p-value*	<.0001	0.0006	<.0001	0.0775
% CFB to Visit 02	Mean ± SD	-11.333 ± 8.0872	-5.000 ± 6.9481	-18.380 ± 9.7043	-2.222 ± 4.0428
	Median	-10.000	-5.000	-17.500	0.000
Visit 03	Mean ± SD	0.94 ± 0.243	1.71 ± 0.149	1.36 ± 0.150	1.75 ± 0.191
	Median	0.90	1.75	1.40	1.80
	X times improvement	2.14*	1.17*	1.46*	1.08*
CFB to Visit 03	LS Mean	-1.06	-0.29	-0.61	-0.16
	SE of LS Mean	0.037	0.037	0.031	0.031
	p-value*	<.0001	<.0001	<.0001	<.0001
% CFB to Visit 03	Mean ± SD	-53.17 ± 12.140	-14.50 ± 7.468	-31.55 ± 7.740	-6.88 ± 7.932
	Median	-55.00	-12.50	-30.00	-7.50
Visit 04	Mean ± SD	0.49 ± 0.162	1.58 ± 0.122	0.98 ± 0.177	1.66 ± 0.237
	Median	0.40	1.60	0.95	1.70
	X times improvement	4.05*	1.27*	2.03*	1.14*
CFB to Visit 04	LS Mean	-1.51	-0.42	-0.99	-0.26
	SE of LS Mean	0.026	0.026	0.042	0.042
	p-value*	<.0001	<.0001	<.0001	<.0001
% CFB to Visit 04	Mean ± SD	-75.33 ± 8.087	-21.17 ± 6.114	-50.79 ± 9.109	-11.62 ± 12.570
	Median	-80.00	-20.00	-52.50	-11.44
Visit 05	Mean ± SD	0.52 ± 0.162	1.55 ± 0.159	1.01 ± 0.229	1.67 ± 0.257
	Median	0.50	1.60	1.00	1.70
	X times improvement	0.95*	1.02*	0.97*	1.00*
CFB to Visit 05	LS Mean	0.03	-0.03	0.04	0.00
	SE of LS Mean	0.038	0.038	0.038	0.038
	p-value*	0.4728	0.4728	0.3418	0.9854
% CFB* to Visit 05	Mean ± SD	5.97 ± 15.845	-1.56 ± 5.485	3.58 ± 15.961	0.17 ± 3.935
	Median	0.00	0.00	0.00	0.00

Treatment Specification: Test= Test product (Stolin R Toothpaste); Comparator= Comparator Product (Colgate Strong Teeth).

Abbreviation(s): CFB = change from baseline; LS = least square; N = number of subjects in specified treatment; n = number of subjects in specified category; SD=standard deviation; SE = standard error; T2DM = type 2 diabetes mellitus.

Note 1: CFB = Post Baseline – Baseline; CFB = Visit 05 – Visit 04.*

Note 2: X times improvement = Baseline/Post Baseline; X times improvement# = A/B; % Difference = ((A-B)/B)*100.*

*Note 3: % CFB = ((Post Baseline – Baseline)/Baseline) *100; % CFB* = ((Post Baseline – Visit 04)/Visit 04) *100.*

*Note 4: * indicates X time improvement within group.*

Note 5: Visit 01 - Screening, Enrollment and Baseline Visit (Day 01); Visit 02 - Evaluation Visit (Day 07 + 02 days); Visit 03 - Evaluation Visit (Day 15 + 02 days); Visit 04 - Evaluation Visit and End of Treatment (Day 30 + 02 days); Visit 05 - Follow up visit and End of Study (Day 60 + 02 days).

Table 6: Assessment of plaque formation using plaque index and disclosing agent

Visit	Statistics	Healthy		T2DM	
		Test (n=30)	Comparator (n=30)	Test (n=24)	Comparator (n=24)
Visit 01	Mean ± SD	3.37 ± 0.490	3.40 ± 0.498	3.63 ± 0.495	3.63 ± 0.495
	Median	3.00	3.00	4.00	4.00
Visit 02	Mean ± SD	1.87 ± 0.571	2.97 ± 0.669	2.79 ± 0.658	3.54 ± 0.509
	Median	2.00	3.00	3.00	4.00
	X times improvement	1.80*	1.15*	1.30*	1.02*
CFB to Visit 02	LS Mean	-1.50	-0.43	-0.83	-0.08
	SE of LS Mean	0.091	0.091	0.103	0.103
	p-value*	<.0001	<.0001	<.0001	0.4248
% CFB to Visit 02	Mean ± SD	-44.722 ± 14.759	-12.778 ± 15.119	-22.222 ± 18.169	-2.083 ± 7.0582
	Median	-41.667	0.000	-25.000	0.000
Visit 03	Mean ± SD	1.03 ± 0.183	2.50 ± 0.509	2.17 ± 0.482	3.17 ± 0.702
	Median	1.00	2.50	2.00	3.00
	X times improvement	3.26*	1.36*	1.67*	1.14*
CFB to Visit 03	LS Mean	-2.34	-0.89	-1.46	-0.46
	SE of LS Mean	0.056	0.056	0.116	0.116
	p-value*	<.0001	<.0001	<.0001	0.0003
% CFB to Visit 03	Mean ± SD	-68.89 ± 5.331	-26.67 ± 9.884	-39.24 ± 16.204	-12.50 ± 15.926
	Median	-66.67	-29.17	-50.00	0.00
Visit 04	Mean ± SD	1.00 ± 0.000	2.27 ± 0.450	1.33 ± 0.565	2.71 ± 0.624
	Median	1.00	2.00	1.00	3.00
	X times improvement	3.37*	1.50*	2.72*	1.34*
CFB to Visit 04	LS Mean	-2.38	-1.12	-2.29	-0.92
	SE of LS Mean	0.053	0.053	0.119	0.119
	p-value*	<.0001	<.0001	<.0001	<.0001
% CFB to Visit 04	Mean ± SD	-69.72 ± 4.084	-33.06 ± 10.143	-62.50 ± 16.485	-25.00 ± 15.346
	Median	-66.67	-33.33	-66.67	-25.00
Visit 05	Mean ± SD	1.07 ± 0.254	2.20 ± 0.407	1.33 ± 0.565	2.63 ± 0.576
	Median	1.00	2.00	1.00	3.00
	X times improvement	0.94*	1.03*	1.00*	1.03*
CFB to Visit 05	LS Mean	-0.09	0.09	-0.07	-0.02
	SE of LS Mean	0.078	0.078	0.051	0.051
	p-value*	0.2418	0.2418	0.1999	0.7492
% CFB* to Visit 05	Mean ± SD	6.67 ± 25.371	-2.22 ± 8.457	0.00 ± 0.000	-2.43 ± 8.326
	Median	0.00	0.00	0.00	0.00

Treatment Specification: Test= Test product (Stolin R Toothpaste); Comparator= Comparator Product (Colgate Strong Teeth).

Abbreviation(s): CFB = change from baseline; LS = least square; N = number of subjects in specified treatment; n = number of subjects in specified category; SD=standard deviation; SE = standard error; T2DM = type 2 diabetes mellitus.

Note 1: CFB = Post Baseline –Baseline; CFB = Visit 05 – Visit 04.*

Note 2: X times improvement = Baseline/Post Baseline; X times improvement# = A/B; % Difference = ((A-B)/B)*100.*

*Note 3: % CFB = ((Post Baseline –Baseline)/Baseline) *100; % CFB* = ((Post Baseline – Visit 04)/Visit 04) *100.*

*Note 4: * indicates X time improvement within group.*

Note 5: Visit 01 - Screening, Enrollment and Baseline Visit (Day 01); Visit 02 - Evaluation Visit (Day 07 + 02 days); Visit 03 - Evaluation Visit (Day 15 + 02 days); Visit 04 - Evaluation Visit and End of Treatment (Day 30 + 02 days); Visit 05 - Follow up visit and End of Study (Day 60 + 02 days).

Table 7: Assessment of pocket depth or clinical level attachment using a periodontal probe

Visit	Statistics	Healthy		T2DM	
		Test	Comparator	Test	Comparator
Visit 01	Mean ± SD	3.342 ± 0.4329	3.483 ± 0.4401	3.604 ± 0.2201	3.552 ± 0.3295
	Median	3.500	3.500	3.625	3.500
Visit 02	Mean ± SD	3.325 ± 0.4212	3.483 ± 0.4401	3.604 ± 0.2201	3.552 ± 0.3295
	Median	3.500	3.500	3.625	3.500
	X times improvement	1.0*	1.0*	1.0*	1.0*
CFB to Visit 02	LS Mean	-0.018	0.001	0.000	0.000
	SE of LS Mean	0.0082	0.0082	NE	NE
	p-value*	0.0321*	0.8735*	NE	NE
% CFB to Visit 02	Mean ± SD	-0.444 ± 1.6914	0.000 ± 0.0000	0.000 ± 0.0000	0.000 ± 0.0000
	Median	0.000	0.000	0.000	0.000
Visit 03	Mean ± SD	3.033 ± 0.4536	3.483 ± 0.4401	3.396 ± 0.2436	3.542 ± 0.3269
	Median	3.000	3.500	3.500	3.500
	X times improvement	1.1*	1.0*	1.1*	1.0*
CFB to Visit 03	LS Mean	-0.312	0.003	-0.208	-0.011
	SE of LS Mean	0.0304	0.0304	0.0158	0.0158
	p-value*	<.0001*	0.9119*	<.0001*	0.5045*
% CFB to Visit 03	Mean ± SD	-9.209 ± 6.7023	0.000 ± 0.0000	-5.811 ± 2.6874	-0.278 ± 1.3608
	Median	-7.143	0.000	-6.667	0.000
Visit 04	Mean ± SD	2.508 ± 0.3742	3.400 ± 0.4026	2.990 ± 0.2993	3.573 ± 0.2707
	Median	2.500	3.500	3.000	3.500
	X times improvement	1.3*	1.0*	1.2*	1.0*
CFB to Visit 04	LS Mean	-0.850	-0.067	-0.608	0.015
	SE of LS Mean	0.0372	0.0372	0.0392	0.0392
	p-value*	<.0001*	0.0791*	<.0001*	0.7116*
% CFB to Visit 04	Mean ± SD	-24.757 ± 7.0215	-2.249 ± 3.5893	-17.106 ± 5.9832	0.883 ± 5.4636
	Median	-23.077	0.000	-16.518	0.000
Visit 05	Mean ± SD	2.542 ± 0.3833	3.358 ± 0.3753	2.979 ± 0.3032	3.583 ± 0.2725
	Median	2.500	3.250	3.000	3.625
	X times improvement	1.0*	1.0*	1.0*	1.0*
CFB* to Visit 05	LS Mean	0.004	-0.013	-0.012	0.012
	SE of LS Mean	0.0260	0.0260	0.0131	0.0131
	p-value*	0.8699*	0.6299*	0.3624*	0.3624*
% CFB* to Visit 05	Mean ± SD	1.407 ± 5.3640	-1.117 ± 2.5469	-0.347 ± 1.7010	0.298 ± 1.4580
	Median	0.000	0.000	0.000	0.000

Treatment Specification: Test= Test product (Stolin R Toothpaste); Comparator= Comparator Product (Colgate Strong Teeth).

Abbreviation(s): CFB = change from baseline; LS = least square; N = number of subjects in specified treatment; n = number of subjects in specified category; SD=standard deviation; SE = standard error; T2DM = type 2 diabetes mellitus.

Note 1: CFB = Post Baseline –Baseline; CFB = Visit 05 – Visit 04.*

Note 2: X times improvement = Baseline/Post Baseline; X times improvement# = A/B; % Difference = ((A-B)/B)*100.*

*Note 3: % CFB = ((Post Baseline –Baseline)/Baseline) *100; % CFB* = ((Post Baseline – Visit 04)/Visit 04) *100.*

*Note 4: * indicates X time improvement within group.*

Note 5: Visit 01 - Screening, Enrollment and Baseline Visit (Day 01); Visit 02 - Evaluation Visit (Day 07 + 02 days); Visit 03 - Evaluation Visit (Day 15 + 02 days); Visit 04 - Evaluation Visit and End of Treatment (Day 30 + 02 days); Visit 05 - Follow up visit and End of Study (Day 60 + 02 days).

Table 8: Assessment of overall gum health (in terms of Color, Consistency, Texture & Bleeding) by dental examination (Count and Frequency Within Groups)

Parameters	Visit	Response	Statistics	Healthy		T2DM	
				Test	Comparator	Test	Comparator
Color	Visit 01	Normal Tissue	n (%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
		Abnormal	n (%)	30 (100%)	30 (100%)	24 (100%)	24 (100%)
	Visit 02	Normal Tissue	n (%)	7 (23.33%)	0 (0%)	0 (0%)	0 (0%)
		Abnormal	n (%)	23 (76.67%)	30 (100%)	24 (100%)	24 (100%)
	Visit 03	Normal Tissue	n (%)	25 (83.33%)	0 (0%)	5 (20.83%)	0 (0%)
		Abnormal	n (%)	5 (16.67%)	30 (100%)	19 (79.17%)	24 (100%)
	Visit 04	Normal Tissue	n (%)	30 (100%)	0 (0%)	18 (75.00%)	3 (12.50%)
		Abnormal	n (%)	0 (0%)	30 (100%)	6 (25.00%)	21 (87.50%)
	Visit 05	Normal Tissue	n (%)	30 (100%)	9 (30.00%)	24 (100%)	4 (16.67%)
		Abnormal	n (%)	0 (0%)	21 (70.00%)	0 (0%)	20 (83.33%)
Consistency	Visit 01	Normal Tissue	n (%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
		Abnormal	n (%)	30 (100%)	30 (100%)	24 (100%)	24 (100%)
	Visit 02	Normal Tissue	n (%)	11 (36.67%)	0 (0%)	0 (0%)	0 (0%)
		Abnormal	n (%)	19 (63.33%)	30 (100%)	24 (100%)	24 (100%)
	Visit 03	Normal Tissue	n (%)	29 (96.67%)	1 (3.33%)	7 (29.17%)	1 (4.17%)
		Abnormal	n (%)	1 (3.33%)	29 (96.67%)	17 (70.83%)	23 (95.83%)
	Visit 04	Normal Tissue	n (%)	30 (100%)	3 (10.00%)	22 (91.67%)	1 (4.17%)
		Abnormal	n (%)	0 (0%)	27 (90.00%)	2 (8.33%)	23 (95.83%)
	Visit 05	Normal Tissue	n (%)	30 (100%)	9 (30.00%)	24 (100%)	1 (4.17%)
		Abnormal	n (%)	0 (0%)	21 (70.00%)	0 (0%)	23 (95.83%)
Texture	Visit 01	Normal Tissue	n (%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
		Abnormal	n (%)	30 (100%)	30 (100%)	24 (100%)	24 (100%)
	Visit 02	Normal Tissue	n (%)	13 (43.33%)	0 (0%)	0 (0%)	0 (0%)
		Abnormal	n (%)	17 (56.67%)	30 (100%)	24 (100%)	24 (100%)
	Visit 03	Normal Tissue	n (%)	24 (80.00%)	0 (0%)	5 (20.83%)	1 (4.17%)
		Abnormal	n (%)	6 (20.00%)	30 (100%)	19 (79.17%)	23 (95.83%)
	Visit 04	Normal Tissue	n (%)	30 (100%)	2 (6.67%)	20 (83.33%)	1 (4.17%)
		Abnormal	n (%)	0 (0%)	28 (93.33%)	4 (16.67%)	23 (95.83%)
	Visit 05	Normal Tissue	n (%)	30 (100%)	8 (26.67%)	24 (100%)	1 (4.17%)
		Abnormal	n (%)	0 (0%)	22 (73.33%)	0 (0%)	23 (95.83%)
Bleeding	Visit 01	Normal Tissue	n (%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
		Abnormal	n (%)	30 (100%)	30 (100%)	24 (100%)	24 (100%)
	Visit 02	Normal Tissue	n (%)	8 (26.67%)	0 (0%)	0 (0%)	0 (0%)
		Abnormal	n (%)	22 (73.33%)	30 (100%)	24 (100%)	24 (100%)
	Visit 03	Normal Tissue	n (%)	30 (100%)	0 (0%)	9 (37.50%)	1 (4.17%)
		Abnormal	n (%)	0 (0%)	30 (100%)	15 (62.50%)	23 (95.83%)
	Visit 04	Normal Tissue	n (%)	30 (100%)	3 (10.00%)	24 (100%)	3 (12.50%)
		Abnormal	n (%)	0 (0%)	27 (90.00%)	0 (0%)	21 (87.50%)
	Visit 05	Normal Tissue	n (%)	30 (100%)	10 (33.33%)	24 (100%)	3 (12.50%)
		Abnormal	n (%)	0 (0%)	20 (66.67%)	0 (0%)	21 (87.50%)

Treatment Specification: Test= Test product (Stolin R Toothpaste); Comparator= Comparator Product (Colgate Strong Teeth).

Abbreviation(s): T2DM = type 2 diabetes mellitus.

Note 1: Visit 01 - Screening, Enrollment and Baseline Visit (Day 01); Visit 02 - Evaluation Visit (Day 07 + 02 days);

Visit 03 - Evaluation Visit (Day 15 + 02 days); Visit 04 - Evaluation Visit and End of Treatment (Day 30 + 02 days);

Visit 05 - Follow up visit and End of Study (Day 60 + 02 days).

Table 9: Subjective evaluation questionnaire

Test (N = 54) n (%)						Comparator (N = 54) n (%)					
Question 1						Are your gums bleeding?					
Response	Yes	No				Response	Yes	No			
Visit 01 (Day 01)	54 (100%)	0 (0%)				Visit 01 (Day 01)	54 (100%)	0 (0%)			
Question 1A						After using the toothpaste, there is reduction in gum bleeding.					
Response	Strongly disagree	Disagree	Neither nor	Agree	Strongly agree	Response	Strongly disagree	Disagree	Neither nor	Agree	Strongly agree
Visit 02 (Day 7)	0 (0%)	0 (0%)	15 (27.78%)	30 (55.56%)	9 (16.67%)	Visit 02 (Day 7)	3 (5.56%)	33 (61.11%)	17 (31.48%)	1 (1.85%)	0 (0%)
Visit 03 (Day 15)	0 (0%)	0 (0%)	1 (1.85%)	28 (51.85%)	25 (46.30%)	Visit 03 (Day 15)	2 (3.70%)	15 (27.78%)	33 (61.11%)	4 (7.41%)	0 (0%)
Visit 04 (Day 30)	0 (0%)	0 (0%)	0 (0%)	3 (5.56%)	51 (94.44%)	Visit 04 (Day 30)	4 (7.41%)	4 (7.41%)	36 (66.67%)	10 (18.52%)	0 (0%)
Question 1B						After stopping the usage of toothpaste, did you observe gum bleeding?					
Response	Yes	No				Response	Yes	No			
Visit 05 (Day 60)	0 (0%)	54 (100%)				Visit 05 (Day 60)	54 (100%)	0 (0%)			
Question 2						Do you have bad breath?					
Response	Yes	No				Response	Yes	No			
Visit 01 (Day 01)	54 (100%)	0 (0%)				Visit 01 (Day 01)	54 (100%)	0 (0%)			
Question 2A						After using the toothpaste, there is reduction in bad breath.					
Response	Strongly disagree	Disagree	Neither nor	Agree	Strongly agree	Response	Strongly disagree	Disagree	Neither nor	Agree	Strongly agree
Visit 02 (Day 7)	0 (0%)	2 (3.70%)	6 (11.11%)	27 (50.00%)	19 (35.19%)	Visit 02 (Day 7)	3 (5.56%)	32 (59.26%)	17 (31.48%)	2 (3.70%)	0 (0%)
Visit 03 (Day 15)	0 (0%)	0 (0%)	3 (5.56%)	17 (31.48%)	34 (62.96%)	Visit 03 (Day 15)	1 (1.85%)	16 (29.63%)	34 (62.96%)	3 (5.56%)	0 (0%)
Visit 04 (Day 30)	0 (0%)	0 (0%)	0 (0%)	5 (9.26%)	49 (90.74%)	Visit 04 (Day 30)	0 (0%)	12 (22.22%)	36 (66.67%)	6 (11.11%)	0 (0%)
Question 3						Are your teeth stained?					
Response	Yes	No				Response	Yes	No			
Visit 01 (Day 01)	54 (100%)	0 (0%)				Visit 01 (Day 01)	54 (100%)	0 (0%)			
Question 3A						After using the toothpaste, there is reduction in staining of teeth					
Response	Strongly disagree	Disagree	Neither nor	Agree	Strongly agree	Response	Strongly disagree	Disagree	Neither nor	Agree	Strongly agree
Visit 02 (Day 7)	0 (0%)	5 (9.26%)	22 (40.74%)	20 (37.04%)	7 (12.96%)	Visit 02 (Day 7)	6 (11.11%)	27 (50.00%)	20 (37.04%)	1 (1.85%)	0 (0%)
Visit 03 (Day 15)	0 (0%)	0 (0%)	8 (14.81%)	24 (44.44%)	22 (40.74%)	Visit 03 (Day 15)	3 (5.56%)	17 (31.48%)	33 (61.11%)	1 (1.85%)	0 (0%)
Visit 04 (Day 30)	0 (0%)	0 (0%)	0 (0%)	21 (38.89%)	33 (61.11%)	Visit 04 (Day 30)	5 (9.26%)	10 (18.52%)	38 (70.37%)	1 (1.85%)	0 (0%)
Test (N = 54) n (%)						Comparator (N = 54) n (%)					
Question 3B						After stopping the usage of toothpaste, did you observe any staining of teeth?					
Response	Yes	No				Response	Yes	No			
Visit 05 (Day 60)	0 (0%)	54 (100%)				Visit 05 (Day 60)	54 (100%)	0 (0%)			
Question 4						After using the toothpaste, the gums feel tight/strong					
Response	Strongly disagree	Disagree	Neither nor	Agree	Strongly agree	Response	Strongly disagree	Disagree	Neither nor	Agree	Strongly agree

Visit 02 (Day 7)	0 (0%)	7 (12.96%)	17 (31.48%)	22 (40.74%)	8 (14.81%)	Visit 02 (Day 7)	10 (18.52%)	20 (37.04%)	23 (42.59%)	1 (1.85%)	0 (0%)
Visit 03 (Day 15)	0 (0%)	0 (0%)	6 (11.11%)	23 (42.59%)	25 (46.30%)	Visit 03 (Day 15)	8 (14.81%)	12 (22.22%)	33 (61.11%)	1 (1.85%)	0 (0%)
Visit 04 (Day 30)	0 (0%)	0 (0%)	0 (0%)	15 (27.78%)	39 (72.22%)	Visit 04 (Day 30)	2 (3.70%)	13 (24.07%)	38 (70.37%)	1 (1.85%)	0 (0%)
Question 5											
After using the toothpaste, there is visible improvement in the appearance of teeth											
Response	Strongly disagree	Disagree	Neither nor	Agree	Strongly agree	Response	Strongly disagree	Disagree	Neither nor	Agree	Strongly agree
Visit 02 (Day 7)	0 (0%)	3 (5.56%)	19 (35.19%)	13 (24.07%)	19 (35.19%)	Visit 02 (Day 7)	2 (3.70%)	27 (50.00%)	23 (42.59%)	1 (1.85%)	1 (1.85%)
Visit 03 (Day 15)	0 (0%)	0 (0%)	4 (7.41%)	24 (44.44%)	26 (48.15%)	Visit 03 (Day 15)	1 (1.85%)	18 (33.33%)	30 (55.56%)	5 (9.26%)	0 (0%)
Visit 04 (Day 30)	0 (0%)	0 (0%)	0 (0%)	9 (16.67%)	45 (83.33%)	Visit 04 (Day 30)	1 (1.85%)	8 (14.81%)	38 (70.37%)	7 (12.96%)	0 (0%)

Abbreviation(s): N = number of subjects in the specified group; n = number of subjects in the specified category.

Table 10: Subjects' Perception questionnaires

Response	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
Question 1	The product has appealing taste.				
Test (N = 54) n (%)	0 (0%)	0 (0%)	0 (0%)	20 (37.04%)	34 (62.96%)
Comparator (N = 54) n (%)	12 (22.22%)	30 (55.56%)	12 (22.22%)	0 (0%)	0 (0%)
Question 2	The freshness of the product felt in mouth was long lasting.				
Test (N = 54) n (%)	0 (0%)	0 (0%)	0 (0%)	14 (25.93%)	40 (74.07%)
Comparator (N = 54) n (%)	19 (35.19%)	32 (59.26%)	3 (5.56%)	0 (0%)	0 (0%)
Question 3	The product gives a cooling effect after brushing teeth.				
Test (N = 54) n (%)	0 (0%)	0 (0%)	0 (0%)	14 (25.93%)	40 (74.07%)
Comparator (N = 54) n (%)	18 (33.33%)	32 (59.26%)	4 (7.41%)	0 (0%)	0 (0%)
Response	+1 = Better	0 = As Good as	-1 = Not as Good		
Question 4	Can you rate the mouth feel after using test product as compared to your current toothpaste using mentioned score?				
Test (N = 54) n (%)	54 (100%)	0 (0%)	0 (0%)		
Comparator (N = 54) n (%)	3 (5.56%)	0 (0%)	51 (94.44%)		
Response	Yes	No			
Question 5	Overall, did you like this product?				
Test (N = 54) n (%)	54 (100%)	0 (0%)			
Comparator (N = 54) n (%)	1 (1.85%)	53 (98.15%)			

Abbreviation(s): N = number of subjects in the specified group; n = number of subjects in the specified category.

4. DISCUSSION

Gingival and periodontal diseases represent some of the most prevalent oral health conditions globally, affecting individuals across all age groups and increasing in severity with age [Rajhans *et al.*, 2011]. Gingivitis, the initial stage, is characterized by inflammation confined to the gingiva and is reversible with proper oral hygiene. If untreated, it can progress to periodontitis a chronic, destructive condition involving the periodontal ligament, cementum, and alveolar bone, ultimately leading to tooth loss [Abdulkareem *et al.*, 2023; Casanova *et al.*, 2015]. Periodontal disease is primarily initiated by dental plaque biofilm, a complex microbial community that adheres to tooth surfaces and gingival margins [Kaur *et al.*, 2021]. These biofilms provide a protective environment for pathogenic

bacteria, making them resistant to host defenses and antimicrobial agents [Bertolini *et al.*, 2022].

The pathogenesis of periodontal disease is multifactorial, involving microbial dysbiosis and an exaggerated host immune response that results in tissue destruction rather than protection [Assessment of Effective Oral Health 2020]. While gingivitis is reversible, periodontitis is irreversible and associated with systemic implications, including diabetes, cardiovascular disease, and adverse pregnancy outcomes, due to chronic low-grade inflammation and bacteremia [Sanz *et al.*, 2020, Hasan *et al.*, 2021]. Diabetes mellitus, in particular, is a major risk factor, increasing susceptibility to periodontitis by two- to three-fold, especially in cases of poor glycemic control [Shukla

et al., 2024]. Individuals with diabetes exhibit higher plaque indices, deeper periodontal pockets, and greater gingival inflammation, necessitating more intensive periodontal care [Sreenivasan *et al.*, 2024].

In this context, adjunctive agents such as antimicrobials, astringents, and anti-plaque compounds delivered via dentifrices have been proposed to enhance periodontal maintenance [Zhou *et al.*, 2024]. Zinc citrate-based formulations have gained attention due to their antimicrobial, anti-inflammatory, and anti-halitosis properties. Previous studies have demonstrated that zinc-containing toothpastes significantly reduce gingivitis, plaque accumulation, and gingival bleeding compared to fluoride-only formulations [Adams *et al.*, 2025]. Multiple randomized controlled trials have shown that zinc-containing toothpastes significantly reduce gingival index and bleeding scores compared to fluoride-only formulations. For example, a 6-week study reported 13.4% reduction in gingivitis and 55.3% reduction in gingival bleeding with zinc toothpaste versus control ($p < 0.001$). Zinc inhibits plaque biofilm formation by reducing bacterial adhesion and metabolic activity. Studies have demonstrated up to 17% reduction in plaque scores compared to non-zinc formulations. [Sreenivasan *et al.*, 2024]. Zinc also neutralizes volatile sulfur compounds, effectively controlling halitosis and inhibiting pathogenic bacteria such as *Porphyromonas gingivalis* and *Tannerella forsythia* [Ziyati *et al.*, 2024]. Zinc enhances fluoride's remineralization effect by stabilizing enamel and reducing demineralization, offering dual protection against caries and periodontal disease [Caruso *et al.*, 2024]. Zinc's anti-inflammatory and antimicrobial properties are particularly beneficial for individuals with diabetes, who exhibit heightened periodontal risk. Evidence suggests zinc formulations help reduce gingival inflammation and improve periodontal parameters even in compromised systemic conditions [José Carlos Alarcón-Moreno *et al.*, 2024]. Zinc citrate is considered safe for daily use in dentifrices. It does not cause mucosal irritation and is well tolerated across populations, including those with systemic conditions like diabetes.

Our study findings align with these observations. Stolin-R Toothpaste, containing 2% zinc citrate along with alum, fluoride, and xylitol, achieved a 64.42% reduction in gingival index over 30 days compared to 16.93% with the comparator. Bleeding gums resolved completely in healthy subjects and nearly completely in T2DM subjects by Day 30, with sustained benefits post-discontinuation. Plaque index reductions were substantial 69.72% in healthy subjects and 62.50% in T2DM subjects versus modest improvements with the comparator. Periodontal pocket depth decreased significantly (24.76% in healthy subjects; 17.11% in T2DM subjects), while the comparator showed negligible changes. Halitosis scores dropped by 97.5% in healthy subjects and 64.93% in T2DM subjects, reflecting strong anti-malodour activity. Complete

normalization of gum health parameters color, consistency, texture, and bleeding was achieved by Day 30 and sustained through Day 60.

The superior outcomes observed with Stolin-R can be attributed to the synergistic action of its carefully selected ingredients. Zinc Citrate (2%) provides antimicrobial and anti-inflammatory benefits, effectively reducing plaque accumulation and gingival bleeding, as supported by studies from Adams *et al.*, 2025 and Ziyati *et al.*, 2024. Alum (0.2%) acts as an astringent, tightening gingival tissues and further minimizing bleeding, as noted by Zhou *et al.*, 2024. Additionally, Sodium Fluoride (990 ppm) plays a crucial role in promoting enamel remineralization and preventing dental caries, while Xylitol (10%) inhibits the growth of cariogenic bacteria and reduces plaque adherence. Together, these components create a comprehensive formulation that enhances oral health through multiple mechanisms [Adams *et al.*, 2025; Ziyati *et al.*, 2024; Zhou *et al.*, 2024].

Importantly, while healthy subjects exhibited faster initial responses, diabetic participants achieved comparable improvements by Day 30, confirming Stolin-R's efficacy across both groups. This is clinically significant given the heightened periodontal risk in diabetes due to systemic inflammation and impaired healing. Sustained benefits post-discontinuation further highlight Stolin-R's potential for long-term periodontal health maintenance.

No local intolerance, adverse events (AEs), or serious adverse events (SAEs) were reported, confirming Stolin-R's favorable safety profile for routine use.

5. CONCLUSION

The findings highlight that Stolin-R delivers superior oral health benefits in both healthy individuals and patients with Type 2 Diabetes Mellitus (T2DM). Its synergistic formulation combining Zinc Citrate and Alum for antimicrobial, anti-inflammatory, and astringent effects significantly reduces plaque accumulation and gingival bleeding across both populations. Sodium Fluoride supports enamel remineralization and caries prevention, while Xylitol inhibits cariogenic bacteria and minimizes plaque adherence. Importantly, these effects are particularly relevant for T2DM patients, who are predisposed to periodontal complications due to impaired immune response and altered oral microbiota. Thus, Stolin-R offers a comprehensive, multi-mechanistic approach to improving oral health outcomes in diverse patient groups.

Limitations:

The authors acknowledge few limitations of the study, including an small sample size, short duration and absence of microbiological analysis warranting larger, long-term trials for validation.

Conflict of Interest

This study was sponsored by Dr. Reddy's Laboratories Ltd. Preeti Kumbhar, Arti Sanghavi, Navita Budhiraja and Dr Syed Mujtaba Hussain Naqvi are employees of the sponsor. The remaining authors report no conflicts of interest. All authors agree with the content and conclusions of this article.

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Data Availability Statement

The data supporting the findings of this study are available from the corresponding author upon reasonable request and subject to prior approval and consent.

Ethics Statement

This study was conducted in compliance with applicable ethical standards and regulatory requirements. All necessary ethical approvals were obtained prior to trial initiation. Ethical approval for this study was granted by the OM Institutional Ethics Committee (registered with CDSCO). All subjects provided written informed consent before participation. The study was registered with the Clinical Trials Registry of India (CTRI) under reference number CTRI/2024/12/077856 prior to subject enrollment.

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