

Sustained Pain Relief Following Prolonged Use of Desensitizing Toothpaste in Dentinal Hypersensitivity: An Open-Label, Prospective, Randomized, Controlled Comparative Study

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DOI: <https://doi.org/10.36347/sjds.2026.v13i04.001>

Received: 14.02.2026 | Accepted: 26.03.2026 | Published: 03.04.2026

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Abstract

Original Research Article

This study evaluated the clinical efficacy and safety of hypersensitivity toothpaste containing 5% Calcium Sodium Phosphosilicate (CSPS) in reducing dentinal hypersensitivity (DH) and maintaining long-term relief across different treatment durations in Asian participants. An open-label, prospective, randomized, controlled study design was used over a 6-month period. Participants were randomized into two groups: Group A (1-month usage; 6-month follow-up; total 210 days) and Group B (3-month usage; 6-month follow-up; total 270 days). Participants brushed twice-daily using the modified Bass technique for their respective treatment periods. Afterward, they switched to a non-desensitizing toothpaste for a 6-month follow-up phase to evaluate the sustainability of pain relief. Assessments were performed at baseline, end-of-treatment (Day 30 for Group A; Day 90 for Group B), and at 3 and 6 months for both groups. Safety and compliance were monitored via clinical examinations and scheduled telephonic check-ins. Hypersensitivity toothpaste demonstrated significant improvements in all sensitivity parameters. At the end of treatment, Group B achieved an 86.39% reduction in air blast sensitivity, significantly outperforming Group A's 58.61% reduction. Self-perceived sensitivity (VAS) showed a 91.26% reduction (11.38-fold) in Group B versus 79.58% in Group A. Post-discontinuation, Group B exhibited superior durability with no recurrence reported at the 3-month follow-up, whereas Group A experienced significant recurrence by the 3-month time-point. By the end of 6 months, only 21.82% of Group B participants required re-treatment compared to 68.33% of Group A. Secondary benefits included 100% resolution of bad breath and significant improvements in perceived gingival strength. No local intolerance or adverse events (AEs/SAEs) were reported, confirming a favourable safety profile. Hypersensitivity toothpaste offers superior management of dentinal hypersensitivity through its bioactive, tubule-occluding formulation. While short-term use provides initial relief, a 3-month initial treatment regimen provides optimal and sustained relief, minimizes recurrence, and reduces the need for clinical re-intervention.

Keywords: Toothpaste, Calcium Sodium Phosphosilicate, Bioactive Glass, Dentinal Hypersensitivity, Schiff Scale, Visual Analogue Scale, Randomized Controlled Trial, Sustained Relief, Safety and Efficacy.

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1. INTRODUCTION

Dentinal Hypersensitivity (DH) is clinically defined as an acute, transient pain originating from exposed dentin when triggered by external stimuli—such as thermal, tactile, osmotic, chemical, or evaporative forces—that is not attributable to any other dental pathology [Canadian Advisory Board on Dentin Hypersensitivity, 2003]. As a diagnosis of exclusion,

clinicians must first rule out alternative etiologies of dental pain, including carious lesions, fractured or chipped teeth, cracked cusp syndrome, defective restorations, or developmental anomalies such as palatogingival grooves [Sharma *et al.*, 2012].

Global prevalence rates vary significantly, ranging from 3% to 57%, with peak incidence often

Citation: Henil Shah, Harsh Shah, Navita Budhiraja, Preeti Kumbhar, Arti Sanghavi, Syed Mujtaba Hussain Naqvi, Simran Sethi, Parth Joshi, Priyanka Madiwale. Sustained Pain Relief Following Prolonged Use of Desensitizing Toothpaste in Dentinal Hypersensitivity: An Open-Label, Prospective, Randomized, Controlled Comparative Study. Sch J Dent Sci, 2026 Apr 13(4): 68-86.

reported in adults aged 30–40 years. These disparities often stem from diverse study populations and varying diagnostic methodologies, such as subjective questionnaires versus objective clinical assessments [Sharma *et al.*, 2012, Dimitrios Dionysopoulos *et al.*, 2023]. While a higher incidence is frequently observed in females, this gender-based difference seldom reaches statistical significance. Any tooth can be affected; however, canines and premolars are the most frequently involved. Recent epidemiological data suggest a rising trend, potentially reaching up to 89% in specific populations, largely due to increased tooth retention and modern dietary habits [Dimitrios Dionysopoulos *et al.*, 2023, “Dentine Hypersensitivity: An Update,” 2025].

The onset of DH typically involves two distinct phases: lesion localization, involving the exposure of dentin via gingival recession or enamel loss, and lesion initiation, which involves the removal of the protective smear layer and the opening of dentinal tubules [Arora *et al.*, 2021, Sufyan Garoushi, 2015]. The most widely accepted explanation for the resulting pain is Brännström’s Hydrodynamic Theory [Arora *et al.*, 2021]. This theory posits that external stimuli cause rapid movement of fluid within patent dentinal tubules, which in turn triggers mechanoreceptors in the pulp-dentin complex, resulting in acute pain [Miglani *et al.*, 2010, Arora *et al.*, 2021]. Clinically, hypersensitive teeth have been shown to possess eight times more open tubules and twice the tubule diameter of non-sensitive teeth [Sufyan Garoushi, 2015].

Therapeutic strategies for managing dentinal hypersensitivity typically follow two primary mechanisms: the application of depolarising agents (e.g., potassium ions) to inhibit neural transmission of pain, or the use of tubule-occluding agents to physically obstruct exposed dentinal tubules. These occlusive materials—including strontium, oxalate, stannous salts, arginine, silicas, and bioactive glasses—serve to seal the dentinal surface, thereby arresting the fluid movement responsible for stimulating pulpal mechanoreceptors [Mason *et al.*, 2017].

Calcium sodium phosphosilicate (CSPS) is a bioactive particulate material specifically formulated to treat hypersensitivity. Upon contact with an aqueous medium-like saliva, CSPS undergoes a rapid cation exchange, releasing sodium ions and inducing a localised pH elevation. This environment facilitates the subsequent release of calcium and phosphate ions, which precipitate to form a resilient, hydroxycarbonate apatite-like layer over the exposed dentin [Greenspan, 2010, Efflandt *et al.*, 2002, LaTorre & Greenspan, 2010, Earl *et al.*, 2011a, Earl *et al.*, 2011b]. The efficacy of dentifrices containing 5% CSPS in reducing dentinal hypersensitivity has been demonstrated in randomised controlled clinical studies of up to 8 weeks’ duration [Mason *et al.*, 2017]. Clinical trials have confirmed that 5% CSPS dentifrices significantly reduce sensitivity

within 2 to 4 weeks of twice-daily use, with cumulative benefits observed over longer durations. Furthermore, *in vitro* evidence suggests that the occlusive mineral layer formed by CSPS remains stable even when subjected to dietary acid challenges [Mason *et al.*, 2017].

This desensitising toothpaste (Group Pharmaceuticals Ltd., India) formulated with 5% calcium sodium phosphosilicate (CSPS), designed to alleviate the acute discomfort associated with thermal and tactile stimuli. The product utilizes a rapid-acting mechanism that precipitates a mineralized, hydroxyapatite-like layer over the dentinal surface, mimicking natural enamel to provide a physical barrier against external triggers. Studies indicate that CSPS offers more significant and rapid reduction in DH compared to traditional agents like potassium nitrate [Satyapal *et al.*, 2014, Shetty *et al.*, 2012].

Despite established evidence of the immediate efficacy of occluding dentifrices, there remains a paucity of clinical data regarding the optimum duration of usage required to maintain these benefits. Specifically, the relationship between treatment length and the recurrence of dentinal hypersensitivity (DH) following product discontinuation has not been extensively investigated. Also, despite the documented efficacy of CSPS-based formulations, clinical evidence regarding the durability of its effect after treatment discontinuation remains limited [Acharya *et al.*, 2013]. Most studies focus on immediate or short-term relief, leaving a gap in understanding the potential “rebound effect” or recurrence of symptoms once regular application ceases. Therefore, this study aimed to evaluate the efficacy of Hypersensitivity Toothpaste in reducing DH over different treatment durations (1 month vs. 3 months) and to assess the sustained therapeutic benefit and recurrence rates during a long-term post-discontinuation follow-up period.

Consequently, this study was designed to evaluate the impact of different treatment durations—1 month versus 3 months—on the reduction and subsequent recurrence of DH symptoms. By assessing the sustained therapeutic effect post-discontinuation, this research aims to identify the most effective clinical regimen for preventing the relapse of hypersensitivity and ensuring long-term patient comfort.

2. MATERIAL & METHODS

2.1. Study Design and Participants

This clinical investigation was an open-label, prospective, randomized, controlled, comparative study designed to evaluate sustained pain relief following prolonged use of a desensitizing toothpaste in participants with dentinal hypersensitivity. Eligible participants were screened and enrolled only after obtaining written informed consent. Screening was performed in accordance with predefined inclusion and exclusion criteria.

The total study duration was 270 days. Participants were randomized into two groups based on the duration of study product usage (Figure 1). Group A received the desensitizing toothpaste for 1 month, followed by a 6-month follow-up period, resulting in a total participation duration of 210 days. Group B received the same toothpaste for 3 months, followed by a 6-month follow-up period, resulting in a total participation duration of 270 days. Each group completed four scheduled study visits.

For Group A, study visits were conducted as follows: Visit 1 (Day 00) for screening, enrollment, and baseline assessment; Visit 2 (Day 30) for evaluation and end of treatment; Visit 3 (Day 120/3 months); and Visit 4 (Day 210/6 months) for follow-up assessments. For Group B, visits were conducted as follows: Visit 1 (Day 00) for screening, enrollment, and baseline assessment; Visit 2 (Day 90) for evaluation and end of treatment; Visit 3 (Day 180/3 months); and Visit 4 (Day 270/6 months) for follow-up assessments. In addition, telephonic check-ins were conducted on Day 30 and Day 60 for Group B to monitor participant safety and ensure compliance with study product usage (Figure 2).

At screening and baseline, demographic data, vital signs, medical history, general wellbeing, physical and dental examination findings, and concomitant medication use were recorded. All eligible participants underwent comprehensive dental and subjective assessments related to dentinal hypersensitivity.

Participant safety was monitored throughout the study by continuous adverse event reporting.

All participants were instructed to brush their teeth twice daily using the assigned toothpaste, following the modified Bass brushing technique. Brushing was performed for two minutes using a pea-sized amount of toothpaste and a soft-bristle toothbrush, followed by rinsing with water. Participants in Group A used the study toothpaste twice daily for 1 month, while participants in Group B used the toothpaste twice daily for 3 months, corresponding to their respective treatment periods. After completion of the assigned treatment period, participants in both groups discontinued use of the study toothpaste and were provided with an additional toothpaste for use during the remainder of the study. During the follow-up phase, participants continued brushing twice daily using the same brushing technique until the end of the study. Follow-up assessments were conducted to evaluate the sustainability of pain relief after discontinuation of the study product. The modified Bass technique involved positioning the toothbrush at a 45-degree angle to the gingival margin, brushing two to three teeth at a time using gentle circular motions, and directing the brush away from the gum line. All tooth surfaces—including outer, inner, and occlusal surfaces—as well as the tongue were cleaned using the same technique.

Participants were instructed to adhere to all study-related guidelines and restrictions throughout the study duration.

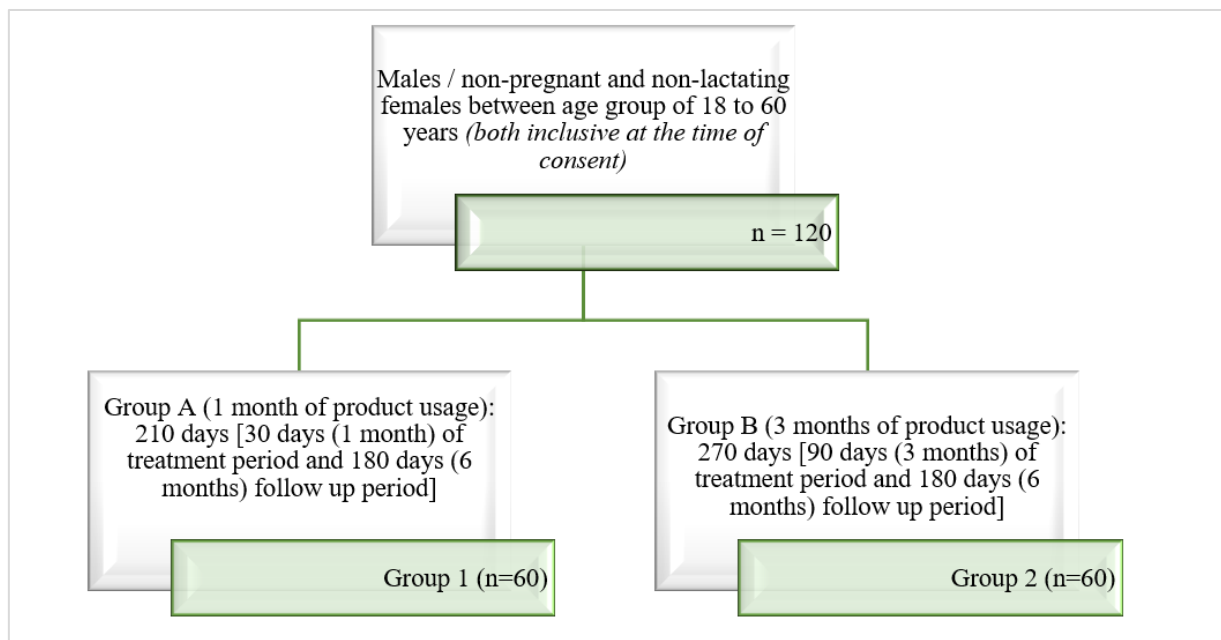


Figure 1: Schematic Diagram of Group Allocation

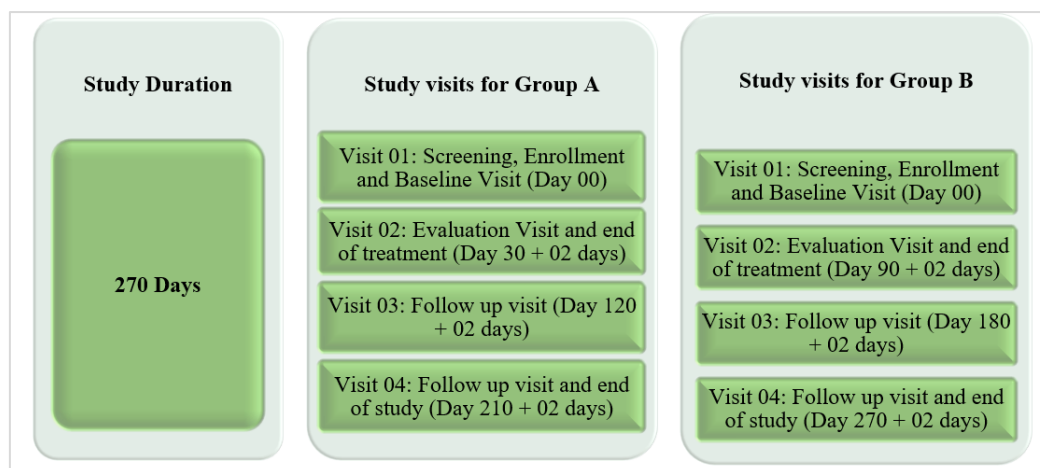


Figure 2: Schematic diagram of study visits

The sample size was determined based on feasibility considerations and anticipated participant retention. Assuming an approximate 20% dropout rate, a total of 120 participants were planned to be enrolled,

with 60 participants allocated to each group, to ensure that at least 100 participants (50 per group) would be evaluable at the end of the study.

Table 1: Study participants

Disposition	Group A (<i>1-month usage</i>) (N=60) n (%)	Group B (<i>3-month usage</i>) (N = 60) n (%)	Overall (N=120 n (%))
Screened participants	-	-	120 (100)
Screen fail participants	-	-	0 (0)
Enrolled participants	60 (100)	60 (100)	120 (100)
Study completed participants	60 (100)	60 (100)	120 (100)
Discontinued/withdrawn participants	0 (0)	0 (0)	0 (0)

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

A total of 120 participants were screened, all of whom met the eligibility criteria and were enrolled. Participants were equally allocated to Group A (1-month product usage; n = 60) and Group B (3-month product usage; n = 60), with no screen failures. All participants completed the study in accordance with the protocol, with no withdrawals or discontinuations. Data from all 120 participants were included in the final analysis (Table 1).

2.3 Ethics

The study was conducted in accordance with the approved protocol and adhered to the ethical standards specified in the Indian Council of Medical Research (ICMR) Ethical Guidelines, the International Council for Harmonisation (ICH) Good Clinical Practice guidelines (E6 R3, Step 5), the New Drugs and Clinical Trials Rules, 2019, and the Declaration of Helsinki. Ethical review and approval of the study protocol (Version 01) and all associated study documents were obtained from the OM Institutional Ethics Committee, registered with the Central Drugs Standard Control Organization (CDSCO), on 19 October 2024, prior to study commencement. The trial was prospectively registered with the Clinical Trials Registry of India (CTRI) under the reference number CTRI/2024/11/076135, before participant enrollment.

Written informed consent was obtained from all participants prior to their participation in the study. Participant confidentiality was safeguarded throughout the study, and data was collected, stored, and managed in accordance with applicable ethical and regulatory requirements.

2.4 Test Product(s)

The test product used in this study was Vantej Toothpaste, a desensitizing toothpaste manufactured by Dr. Reddy's Laboratories Ltd., India. The formulation contains 5% calcium sodium phosphosilicate, along with abrasive and precipitated silica, surfactants, humectants, binding agents, flavouring agents, and other excipients commonly used in dentifrice formulations.

Calcium sodium phosphosilicate is intended to aid in the occlusion of exposed dentinal tubules, thereby reducing dentinal hypersensitivity. The overall formulation is designed to support effective oral hygiene while providing relief from dentinal hypersensitivity with regular use.

2.5 Inclusion Criteria

Eligible participants included male and non-pregnant, non-lactating female adults aged 18 to 60 years (inclusive) at the time of consent, who were diagnosed

with localized or generalized dentinal hypersensitivity. Participants were required to present with moderate to severe dentinal hypersensitivity, defined by a Visual Analogue Scale (VAS) score of 4 to 9 as assessed by thermal testing. Inclusion also required a history of dentinal hypersensitivity triggered by cold stimuli such as ice cream, iced beverages, or a rapid jet of cool air applied to one or more teeth. Participants were required to be in good general health, as determined by the investigator based on medical history, physical and dental examination, and assessment of vital signs, and to be willing and able to comply with the study protocol and scheduled visits.

2.6 Exclusion Criteria

Participants who met any of the following criteria were excluded from the study: pregnancy, breastfeeding, or planning pregnancy during the study period, or unwillingness to use acceptable contraception where applicable; presence of dental caries; gingival index score > 1; clinical tooth mobility score > 1; eroded or damaged enamel with a severity grade > 3 on the ordinal scale for dental erosion; need for periodontal surgery; presence of orthodontic bands or partial removable or fixed partial dentures; tumors of the soft or hard tissues of the oral cavity; advanced or poor

periodontal condition (purulent exudate, tooth mobility, or extensive attachment/bone loss); prior treatment for dentinal hypersensitivity; use of desensitizing dental products or procedures (including toothpastes, mouthwashes, fluoride treatments, or dental sealants) within one month prior to study initiation; antibiotic use within one month prior to study initiation; alcohol consumption; smoking or use of any form of tobacco; participation in a similar clinical study within the preceding 30 days; or any other condition that, in the investigator's judgment, could interfere with study participation or outcomes.

2.7 Efficacy Endpoint (s)

2.7.1 Primary Endpoint (s)

The primary efficacy endpoint was the comparative assessment of dentinal hypersensitivity between the two groups, evaluated using Schiff's Sensitivity Scale in response to air blast and tactile stimuli (Table 2). Assessments were performed at the corresponding post-treatment and follow-up time points to evaluate sustained pain relief, specifically comparing Group A at Day 30 with Group B at Day 90, Group A at the 3-month follow-up with Group B at the 3 month follow up, and Group A at the 6 month follow up with Group B at the 6 month follow up.

Table 2: Schiff Sensitivity Scale

Grade	Description
0	No Response
1	Subject responds to air stimulus but does not require withdrawal of stimulus
2	Subject responds to air stimulus and requests withdrawal of stimulus or moves from stimulus
3	Subject responds to air stimulus, considers stimulus to be painful, and requests discontinuation of stimulus

2.7.2 Secondary Endpoint(s)

Secondary efficacy outcomes were evaluated to determine the reduction in dentinal hypersensitivity following product use, the recurrence of hypersensitivity during the post-treatment follow-up period, and participant-reported outcomes related to dentinal sensitivity and oral health. All assessments were conducted at pre-specified study visits using validated clinical and subjective evaluation instruments.

In Group A, efficacy was assessed at Day 30 (vs. baseline), with recurrence monitored at 3 months and 6 months (vs. Day 30). In Group B, efficacy was evaluated at Day 90 (vs. baseline), with recurrence assessed at 3 months and 6 months.

Clinician-assessed dentinal hypersensitivity was evaluated using Schiff's Sensitivity Score (0–3 scale) following standardized air blast and tactile stimuli. Self-perceived dentinal hypersensitivity was assessed using a 10-cm Visual Analog Scale (VAS), where 0 represented no sensitivity and 10 represented the worst imaginable sensitivity. Daily diaries tracked recurrence frequency and mean episode duration. The proportion of participants requiring re-treatment was recorded at each follow-up visit.

Subjective evaluation of dentinal hypersensitivity was further assessed using standardized participant questionnaires administered at all study visits. General oral hygiene practices and self-reported dental health status were evaluated using participant questionnaires administered at the end of the respective treatment periods.

Safety was monitored throughout the study through the continuous recording of adverse events (AEs) and serious adverse events (SAEs) during scheduled study visits and via participant 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. All statistical tests were two tailed and conducted at a significance level of $\alpha \leq 0.05$. The primary endpoint, dentinal hypersensitivity assessed using Schiff's Sensitivity Score (air blast and tactile stimuli), was summarized descriptively and compared

between Group A and Group B at corresponding post-treatment and follow-up visits using the Wilcoxon rank-sum test. Secondary efficacy endpoints included within-group changes in dentinal hypersensitivity, self-perceived sensitivity, recurrence, and participant-reported outcomes. Within-group changes in Schiff's Sensitivity Score were analyzed using the Wilcoxon signed-rank test, while self-perceived dentinal hypersensitivity assessed using a 10-cm Visual Analog Scale (VAS) was analyzed using the paired t-test.

Recurrence and re-treatment rates were summarized using frequencies and percentages and analyzed using the McNemar test. Safety outcomes, including adverse events (AEs) and serious adverse events (SAEs), were summarized descriptively without inferential statistical analysis.

3. RESULTS

3.1. Participant Demography

Table 3: Demography

Category/Statistics	Group A (1-month usage) (N = 60)	Group B (3-month usage) (N = 60)	Overall (N = 120)
Age (Completed Years)			
n	60	60	120
Mean ± SD	37.2 ± 10.86	37.2 ± 10.13	37.2 ± 10.46
Median	35.5	38.0	37.0
Min, Max	22, 59	19, 59	19, 59
p-value*	0.9654		
Gender [n (%)]			
Male	24 (40.00)	26 (43.33)	50 (41.67)
Female	36 (60.00)	34 (56.67)	70 (58.33)
p-value	0.1371		
Predominant Race [n (%)]			
Asian	60 (100)	60 (100)	120 (100)
Other	0 (0)	0 (0)	0 (0)
p-value	NA		
Abbreviation(s): Max = maximum; Min = minimum; N = number of participants in the specified group; n = number of participants in the specified category; SD = standard deviation. Note 1: The p-values are calculated using chi square and p-value* is calculated using two sample t-test. Note 2: Percentages are based on the number of participants in the specified group.			

A total of 120 Asian participants (50 males, 70 females) were enrolled in the study, with a mean age of 37.2 years (range: 19 to 59 years). Participants were randomized equally (n=60 per group) into Group A (1-month usage) and Group B (3-month usage).

Group A comprised 24 males and 36 females, with a mean age of 37.2 years (range: 22 to 59 years). Group B included 26 males and 34 females, with a mean age of 37.2 years (range: 19 to 59 years).

As shown in Table 3, no significant differences were observed between groups regarding age or gender distribution, ensuring balanced demographic representation for the study.

3.2 Efficacy Assessments

3.2.1 Comparison of Dentinal hypersensitivity by recording Schiff's sensitivity score using different stimuli (air blast and tactile)

Air Blast Stimuli: Participants in Group A (1-month usage) showed a reduction in sensitivity to air blast stimuli over 30 days, with the mean Schiff score decreasing from 2.2 to 0.9. In contrast, Group B (3-month usage) exhibited reduction over 90 days, with the mean score decreasing from 2.4 to 0.3. At the end of their

respective treatment periods, the difference between the two groups was statistically significant ($p < 0.0001$). Group B demonstrated a 0.61 times greater reduction in air blast sensitivity compared to Group A, equating to a 38.71% greater improvement in clinical outcomes (Table 4, Figure 3a).

Tactile Stimuli: Participants in Group A (1-month usage) showed a reduction in sensitivity to tactile stimuli over 30 days, with the mean Schiff score decreasing from 1.9 to 0.5. In contrast, Group B (3-month usage) exhibited reduction over 90 days, with the mean score decreasing from 2.0 to 0.2. On comparison, the difference between groups was statistically significant ($p = 0.0004$). Group B was 0.80 times more effective than Group A, translating to a 20.19% greater improvement in tactile comfort (Table 4, Figure 3b).

Post-Discontinuation Phase: At the 6-month follow-up, both groups demonstrated a recurrence of dentinal hypersensitivity symptoms following discontinuation of the desensitizing toothpaste. However, at the 3-month post-discontinuation time point, Group B showed significantly less recurrence of tactile-stimuli-induced sensitivity compared to Group A ($p = 0.0014$), indicating that the longer 3-month treatment duration conferred

more durable protection against tactile triggers. For air-blast stimuli, although both groups experienced recurrence by the 6-month time point, the comparative

pattern differed: Group A showed a more sustained effect at 6 months, with significantly lower recurrence than Group B for air-blast sensitivity ($p = 0.0021$).

Table 4: Comparison of Dentinal hypersensitivity

Visit	Statistics	Group A (N =60)	Group B (N =60)
AIR BLAST			
Visit 01	Mean \pm SD	2.2 \pm 0.55	2.4 \pm 0.49
	Median	2.0	2.0
Visit 02	Mean \pm SD	0.9 \pm 0.41	0.3 \pm 0.48
	Median	1.0	0.0
CFB to Visit 02	Mean \pm SD	-1.3 \pm 0.45	-2.1 \pm 0.61
	Median	-1.0	-2.0
	p-value	<.0001	
	% Difference	38.71	
	X times improvement	0.61	
Visit 03	Mean \pm SD	1.0 \pm 0.32	0.4 \pm 0.49
	Median	1.0	0.0
CFB* to Visit 03	Mean \pm SD	0.1 \pm 0.35	0.1 \pm 0.29
	Median	0.0	0.0
	p-value	0.3930	
	% Difference	100.00	
	X times improvement	2.00	
Visit 04	Mean \pm SD	1.4 \pm 0.50	1.2 \pm 0.44
	Median	1.0	1.0
CFB* to Visit 04	Mean \pm SD	0.5 \pm 0.50	0.8 \pm 0.57
	Median	0.0	1.0
	p-value	0.0021	
	% Difference	-40.82	
	X times improvement	0.59	
TACTILE STIMULI			
Visit 01	Mean \pm SD	1.9 \pm 0.48	2.0 \pm 0.45
	Median	2.0	2.0
Visit 02	Mean \pm SD	0.5 \pm 0.50	0.2 \pm 0.46
	Median	1.0	0.0
CFB to Visit 02	Mean \pm SD	-1.4 \pm 0.52	-1.7 \pm 0.61
	Median	-1.0	-2.0
	p-value	0.0004	
	% Difference	20.19	
	X times improvement	0.80	
Visit 03	Mean \pm SD	0.7 \pm 0.45	0.2 \pm 0.46
	Median	1.0	0.0
CFB* to Visit 03	Mean \pm SD	0.2 \pm 0.42	0.0 \pm 0.26
	Median	0.0	0.0
	p-value	0.0014	
	% Difference	NE	
	X times improvement	NE	
Visit 04	Mean \pm SD	1.3 \pm 0.47	1.2 \pm 0.47
	Median	1.0	1.0
CFB to Visit 04	Mean \pm SD	0.8 \pm 0.51	1.0 \pm 0.57
	Median	1.0	1.0
	p-value	0.1464	
	% Difference	-15.79	
	X times improvement	0.84	
<p>Abbreviation(s): CFB = change from baseline; N = number of participants in specified group; n = number of participants in specified category; SD=standard deviation. Note 1: Group A = The toothpaste was used twice daily for 1month, Group B = The toothpaste was used twice daily for 3 months. Note 2: CFB= Post Baseline - Baseline.; CFB* = Post Baseline – Visit 02. Note 3: X times improvement= Group A/Group B</p>			

Note 4: % Difference = ((Group A-Group B)/abs(Group B))*100

Note 5: The p-values are calculated using the Wilcoxon rank sum test.

Note 6: Reduction in dental hypersensitivity was assessed by comparing Visit 02 data versus baseline. Recurrence of dental hypersensitivity was assessed by comparing Visit 03 and Visit 04 data versus Visit 02.

Note 7: Visits for Group A: Visit 01: Screening, Enrollment and Baseline Visit (Day 00); Visit 02: Evaluation Visit and end of treatment (Day 30 + 02 days); Visit 03: Follow up visit (Day 120 + 02 days) and Visit 04: Follow up visit and end of study (Day 210 + 02 days)

Note 8: Visits for Group B: Visit 01: Screening, Enrollment and Baseline Visit (Day 00); Visit 02: Evaluation Visit and end of treatment (Day 90 + 02 days); Visit 03: Follow up visit (Day 180 + 02 days) and Visit 04: Follow up visit and end of study (Day 270 + 02 days)

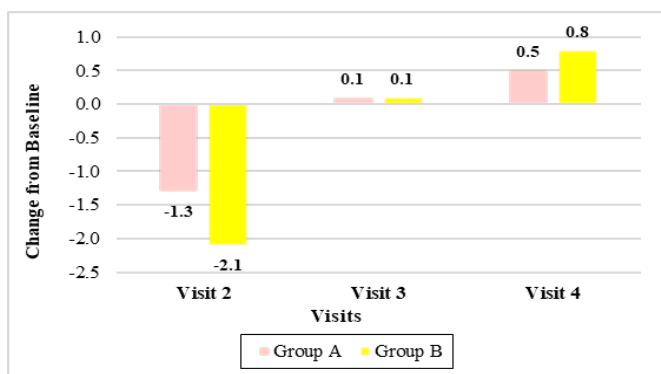


Figure 3a: Mean values of Schiff's sensitivity score using air blast

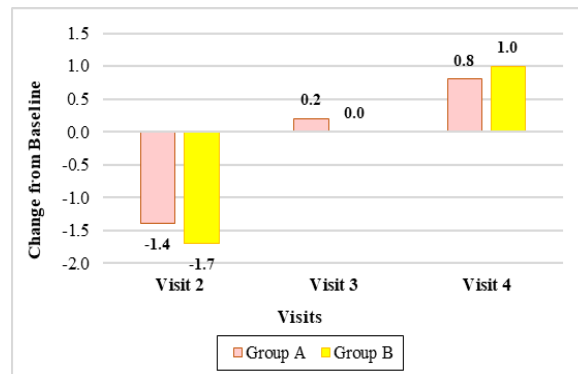


Figure 3b: Mean values of Schiff's sensitivity score using tactile stimuli

Figure 3: Assessment of Dentinal hypersensitivity (Comparative)

3.2.2 Assessment of Dentinal hypersensitivity by recording Schiff's sensitivity score using different stimuli (air blast and tactile)

Group A: One-Month Treatment Phase and Post-Discontinuation Follow-Up: Participants in Group A exhibited a 58.61% reduction in air blast sensitivity over 30 days, with mean Schiff scores decreasing from 2.2 to 0.9 (p<0.0001). For tactile stimuli, a 74.44% reduction was observed, with mean scores decreasing from 1.9 to 0.5 (p<0.0001). These results translate to a 2.36-fold and 3.68-fold improvement in air blast and tactile sensitivity, respectively. Following discontinuation of Hypersensitivity Toothpaste, a significant recurrence of hypersensitivity was observed. At the 3 month follow up, air blast scores rose to 1.0 (p=0.0327) and tactile scores to 0.7 (p=0.0002) compared to the Day 30 post-treatment baseline. This trend continued to the 6-month follow-up, where scores reached 1.4 for air blast and 1.3 for tactile stimuli (p<0.0001 for both), representing a 0.39-fold recurrence in tactile sensitivity relative to the end of treatment (Table 5, Figure 4a, 4b).

Group B: Three-Month Treatment Phase and Post-Discontinuation Follow-Up: Participants in Group B demonstrated an 86.39% reduction in air blast sensitivity over 90 days, with mean scores declining from 2.4 to 0.3 (p<0.0001). Tactile sensitivity showed an 87.50% reduction, with scores decreasing from 2.0 to 0.2 (p<0.0001). This reflects a 7.20-fold and 8.43-fold improvement in air blast and tactile thresholds, respectively, following 90 days of consistent use. Post-discontinuation analysis at the 3-month timepoint revealed no significant change in sensitivity compared to the Day 90 baseline (air blast: 0.4; tactile: 0.2), suggesting a sustained therapeutic benefit for 90 days post-treatment. However, by the 6 month follow up, scores for both stimuli significantly increased to 1.2 (p<0.0001), indicating a partial recurrence. This translates to a 0.29-fold and 0.20-fold recurrence for air blast and tactile stimuli, respectively, after long-term discontinuation of the product (Table 5, Figure 4a, 4b).

Table 5: Assessment of Dentinal hypersensitivity by recording Schiff's sensitivity score using different stimuli (air blast and tactile) – versus Baseline

Visit	Statistics	Group A (N =60)	Group B (N =60)
AIR BLAST			
Visit 01	Mean ± SD	2.2 ± 0.55	2.4 ± 0.49
	Median	2.0	2.0
Visit 02	Mean ± SD	0.9 ± 0.41	0.3 ± 0.48
	Median	1.0	0.0
CFB to Visit 02	Mean ± SD	-1.3 ± 0.45	-2.1 ± 0.61
	Median	-1.0	-2.0

	p-value	<.0001	<.0001
	X times improvement	2.36	7.20
%CFB to Visit 02	Mean ± SD	-58.611 ± 17.2201	-86.389 ± 20.0027
	Median	-50.000	-100.000
Visit 03	Mean ± SD	1.0 ± 0.32	0.4 ± 0.49
	Median	1.0	0.0
CFB* to Visit 03	Mean ± SD	0.1 ± 0.35	0.1 ± 0.29
	Median	0.0	0.0
	p-value	0.0327	0.1819
	X times improvement	0.90	0.87
%CFB* to Visit 03	Mean ± SD	2.830 ± 20.6041	-5.000 ± 22.3607
	Median	0.000	0.000
Visit 04	Mean ± SD	1.4 ± 0.50	1.2 ± 0.44
	Median	1.0	1.0
CFB* to Visit 04	Mean ± SD	0.5 ± 0.50	0.8 ± 0.57
	Median	0.0	1.0
	p-value	<.0001	<.0001
	X times improvement	0.66	0.29
%CFB* to Visit 04	Mean ± SD	41.509 ± 49.7454	30.000 ± 47.0162
	Median	0.000	0.000
TACTILE STIMULI			
Visit 01	Mean ± SD	1.9 ± 0.48	2.0 ± 0.45
	Median	2.0	2.0
Visit 02	Mean ± SD	0.5 ± 0.50	0.2 ± 0.46
	Median	1.0	0.0
CFB to Visit 02	Mean ± SD	-1.4 ± 0.52	-1.7 ± 0.61
	Median	-1.0	-2.0
	p-value	<.0001	<.0001
	X times improvement	3.68	8.43
%CFB to Visit 02	Mean ± SD	-74.444 ± 26.1220	-87.500 ± 26.5082
	Median	-66.667	-100.000
Visit 03	Mean ± SD	0.7 ± 0.45	0.2 ± 0.46
	Median	1.0	0.0
CFB* to Visit 03	Mean ± SD	0.2 ± 0.42	0.0 ± 0.26
	Median	0.0	0.0
	p-value	0.0002	1.0000
	X times improvement	0.70	1.00
%CFB* to Visit 03	Mean ± SD	0.000 ± 0.0000	-15.385 ± 37.5534
	Median	0.000	0.000
Visit 04	Mean ± SD	1.3 ± 0.47	1.2 ± 0.47
	Median	1.0	1.0
CFB* to Visit 04	Mean ± SD	0.8 ± 0.51	1.0 ± 0.57
	Median	1.0	1.0
	p-value	<.0001	<.0001
	X times improvement	0.39	0.20
%CFB* to Visit 04	Mean ± SD	51.613 ± 50.8001	30.769 ± 48.0384
	Median	100.000	0.000

Abbreviation(s): CFB = change from baseline; N = number of participants in specified group; n = number of participants in specified category; SD=standard deviation.

Note 1: Group A = The toothpaste was used twice daily for 1month, Group B = The toothpaste was used twice daily for 3months.

Note 2: CFB= Post Baseline –Baseline. CFB* = Post Baseline – Visit 02.

Note 3: X times improvement = Baseline/Post Baseline

Note 4: % CFB = ((Post Baseline –Baseline)/Baseline) *100; % CFB* = ((Post Baseline – Visit 02)/Visit 02) *100.

Note 5: The p-values are calculated using the Wilcoxon sign rank test.

Note 6: Reduction in dental hypersensitivity was assessed by comparing Visit 02 data versus baseline. Recurrence of dental hypersensitivity was assessed by comparing Visit 03 and Visit 04 data versus Visit 02.

Note 7: Visits for Group A: Visit 01: Screening, Enrollment and Baseline Visit (Day 00); Visit 02: Evaluation Visit and end of treatment (Day 30 + 02 days); Visit 03: Follow up visit (Day 120 + 02 days) and Visit 04: Follow up visit and end of study (Day 210 + 02 days)

Note 8: Visits for Group B: Visit 01: Screening, Enrollment and Baseline Visit (Day 00); Visit 02: Evaluation Visit and end of treatment (Day 90 + 02 days); Visit 03: Follow up visit (Day 180 + 02 days) and Visit 04: Follow up visit and end of study (Day 270 + 02 days)

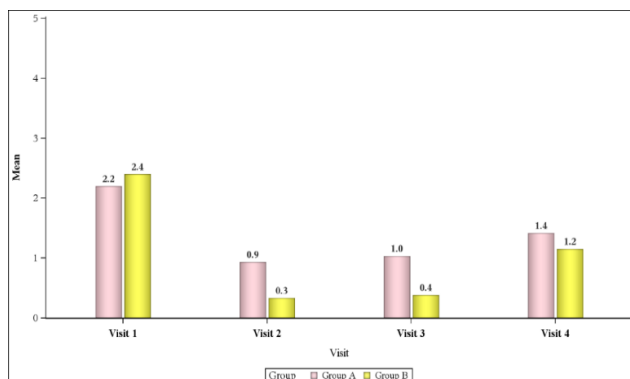


Figure 4a: Mean values of sensitivity score using air blast

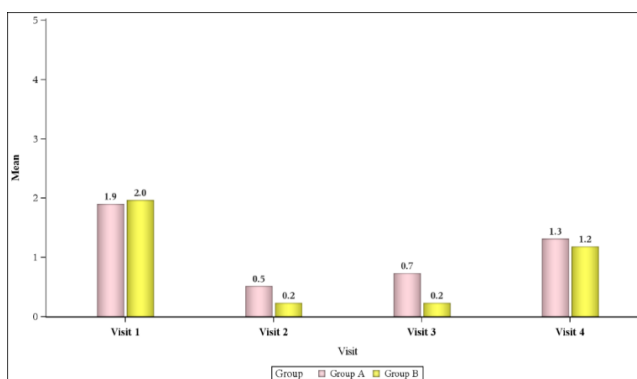


Figure 4b: Mean values of sensitivity score using tactile stimuli

Figure 4: Assessment of Dentinal hypersensitivity (Versus Baseline)

3.2.3 Assessment of self-perceived sensitivity score by participants using visual analog scale (VAS)

Group A: One-Month Treatment Phase and Post-Discontinuation Follow-Up: Participants in Group A demonstrated a 79.58% reduction in self-perceived sensitivity over 30 days, with mean Visual Analogue Scale (VAS) scores decreasing from 7.7 to 1.6 (p<0.0001). This reflects a 4.78-fold improvement in patient-reported comfort following consistent product use. Upon discontinuation of Hypersensitivity Toothpaste, a significant recurrence of sensitivity was observed. Compared to the Day 30 post-treatment baseline, VAS scores increased by over 100% to 3.5 at the 3-month follow up (p<0.0001) and 5.7 at the 6-month follow up (p<0.0001). In practical terms, this represents a 0.46-fold and 0.28-fold recurrence at the 3-month and 6-month time points, respectively, relative to the end of the treatment period (Table 6, Figure 5).

Group B: Three-Month Treatment Phase and Post-Discontinuation Follow-Up: In Group B, a 91.26% reduction in self-perceived sensitivity was recorded over 90 days, with mean VAS scores declining from 8.0 to 0.7 (p<0.0001). This equates to an 11.38-fold improvement in sensitivity management after 90 days of regular use. Following product discontinuation, significant recurrence was noted compared to the Day 90 baseline. At the 3 month follow up, VAS scores increased to 1.8, representing a 75.28% increase (p<0.0001). By the 6 month follow up, scores further increased to 3.9 (more than 100% increase; p<0.0001). This translates to a 0.39-fold recurrence at the 3 month follow up and a 0.18-fold recurrence at the 6 month follow up relative to the end-of-treatment scores. Despite this recurrence, the self-perceived sensitivity at the 6-month follow-up remained lower than the baseline recorded at Day 00 (Table 6, Figure 5).

Table 6: Assessment of self-perceived sensitivity score by participants using visual analog scale (VAS)

Visit	Statistics	Group A (N =60)	Group B (N =60)
Visit 01	Mean ± SD	7.7 ± 0.82	8.0 ± 0.66
	Median	8.0	8.0
Visit 02	Mean ± SD	1.6 ± 0.74	0.7 ± 0.87
	Median	2.0	0.5
CFB to Visit 02	Mean ± SD	-6.1 ± 0.64	-7.3 ± 1.04
	Median	-6.0	-7.0
	p-value	<.0001	<.0001
	X times improvement	4.78	11.38
%CFB to Visit 02	Mean ± SD	-79.583 ± 8.6054	-91.257 ± 10.9393
	Median	-77.778	-94.444
Visit 03	Mean ± SD	3.5 ± 1.07	1.8 ± 1.04
	Median	3.5	2.0
CFB* to Visit 03	Mean ± SD	1.9 ± 0.98	1.1 ± 0.77
	Median	2.0	1.0

	p-value	<.0001	<.0001
	X times improvement	0.46	0.39
%CFB* to Visit 03	Mean ± SD	134.211 ± 97.2550	75.278 ± 74.6795
	Median	100.000	75.000
Visit 04	Mean ± SD	5.7 ± 0.94	3.9 ± 1.10
	Median	6.0	4.0
CFB* to Visit 04	Mean ± SD	4.1 ± 0.79	3.2 ± 1.11
	Median	4.0	3.0
	p-value	<.0001	<.0001
	X times improvement	0.28	0.18
%CFB* to Visit 04	Mean ± SD	283.918 ± 133.1459	235.000 ± 130.0862
	Median	250.000	300.000

Abbreviation(s): CFB = change from baseline; N = number of participants in specified group; n = number of participants in specified category; SD=standard deviation.

Note 1: Group A = The toothpaste was used twice daily for 1month, Group B = The toothpaste was used twice daily for 3months.

Note 2: CFB= Post Baseline –Baseline. CFB* = Post Baseline – Visit 02.

Note 3: X times improvement = Baseline/Post Baseline

Note 4: % CFB = ((Post Baseline –Baseline)/Baseline) *100; % CFB* = ((Post Baseline – Visit 02)/Visit 02) *100.

Note 5: The p-values are calculated using the Paired t-test.

Note 6: Visits for Group A: Visit 01: Screening, Enrollment and Baseline Visit (Day 00); Visit 02: Evaluation Visit and end of treatment (Day 30 + 02 days); Visit 03: Follow up visit (Day 120 + 02 days) and Visit 04: Follow up visit and end of study (Day 210 + 02 days)

Note 7: Visits for Group B: Visit 01: Screening, Enrollment and Baseline Visit (Day 00); Visit 02: Evaluation Visit and end of treatment (Day 90 + 02 days); Visit 03: Follow up visit (Day 180 + 02 days) and Visit 04: Follow up visit and end of study (Day 270 + 02 days)

Note 8: Reduction in dental hypersensitivity was assessed by comparing Visit 02 data versus baseline. Recurrence of dental hypersensitivity was assessed by comparing Visit 03 and Visit 04 data versus Visit 02.

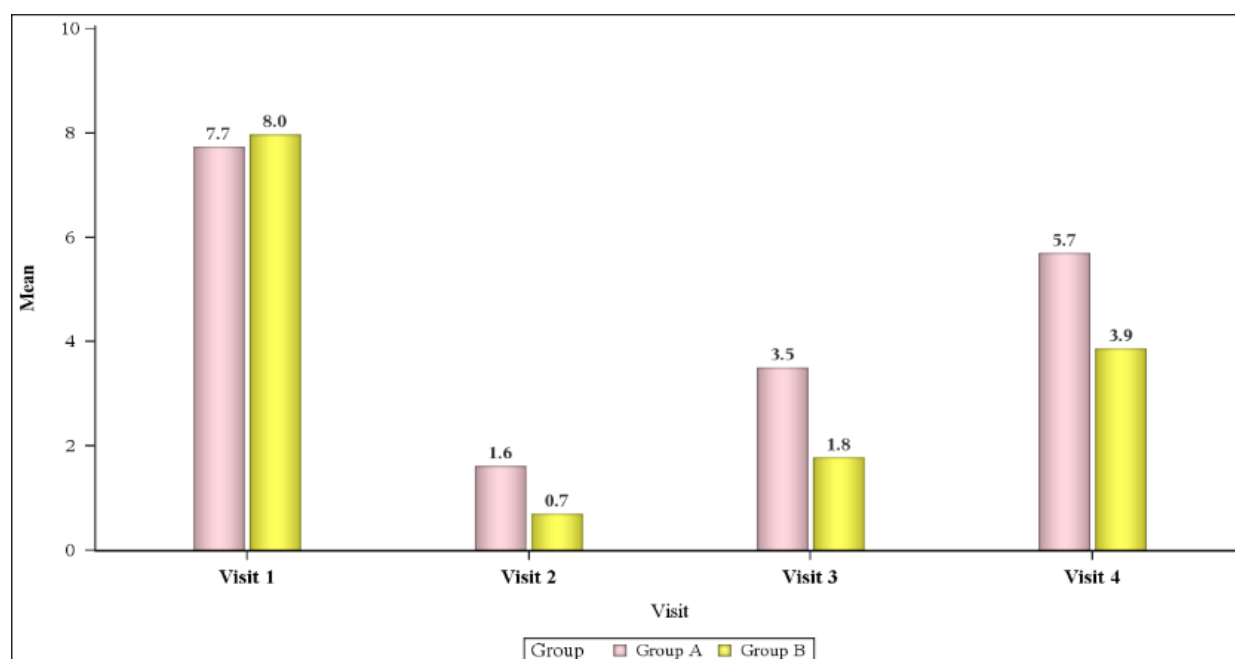


Figure 5: Assessment of self-perceived sensitivity score by participants using visual analog scale (VAS)

Mean values of self-perceived sensitivity score using VAS

3.2.4 Assessment of participant reported recurrence/episodes of Dental hypersensitivity

Group A: One-Month Treatment Follow-Up:
In Group A, no participants reported a recurrence of

dental hypersensitivity at the 3-month follow-up. However, by the end of 6 months, a 100% recurrence rate was observed across the group. During the post-treatment follow-up period, symptoms recurred on an average of 3.6 days. Notably, 68.33% of participants in this group required re-treatment to manage the return of hypersensitivity symptoms (Figure 6).

Group B: Three-Month Treatment Follow-Up:

In Group B, the therapeutic effect was more sustained, with no participants reporting recurrence at the 3 month follow up. By the 6-month follow-up, the recurrence rate reached 91.67%. During this period, the average duration

of recurrence was 2.3 days, and significantly fewer participants (21.82%) required re-treatment compared to Group A. These findings suggest that a 3-month treatment duration provides a more durable clinical outcome and reduces the necessity for subsequent intervention (Figure 6).

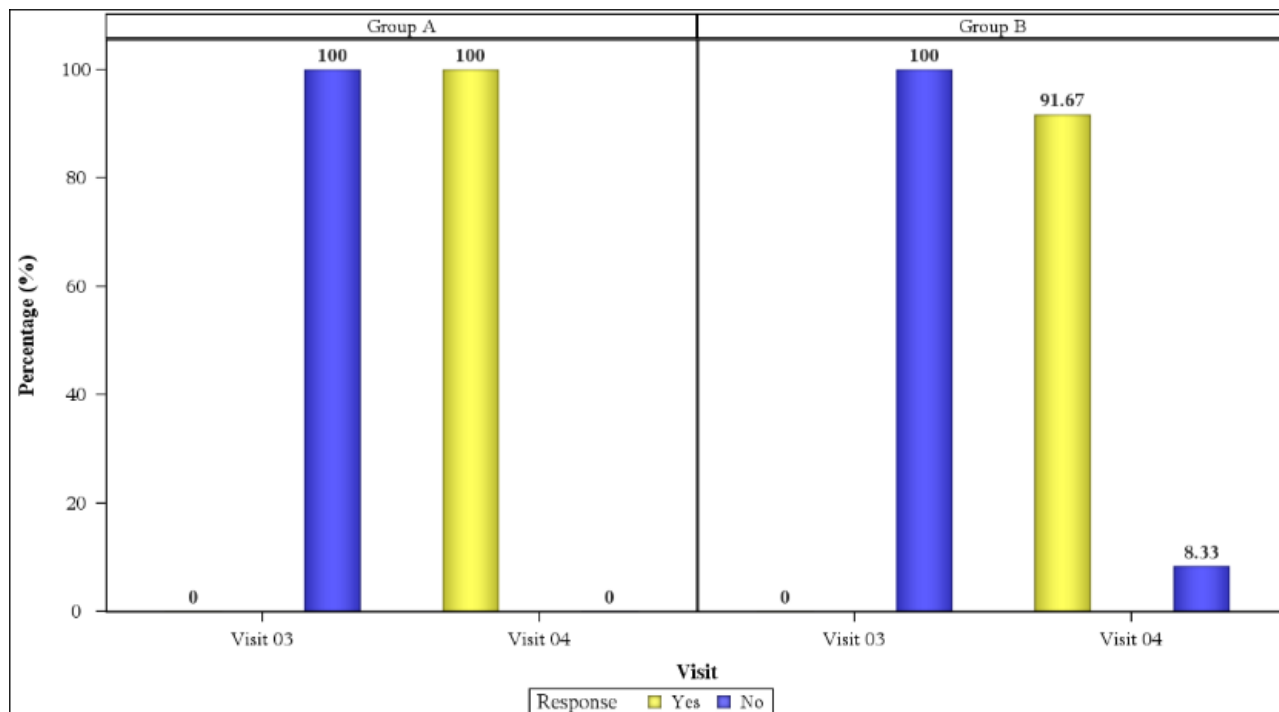


Figure 6: Assessment of participant reported recurrence/episodes of Dental hypersensitivity

Percentage of participants showing recurrence

3.2.8 Assessment of Subjective evaluation questionnaires

Group A (1-Month Usage):

For reduction in dental hypersensitivity (DH), all participants (100%) reported symptoms at baseline. Following regular use of Hypersensitivity Toothpaste, 100% of participants reported a reduction in DH by Day 30. After discontinuation, symptoms remained resolved in 26.7% of participants at the 3 month follow up and in 10% of participants at the 6 month follow up (Table 7, Figure 7a).

Regarding sharp pain on eating hot and cold food, 95% of participants reported symptoms at baseline, with 100% reporting reduction by Day 30. During the post treatment period, 30% of participants remained symptom free at the 3 month follow up, and 23.33%

remained symptom free at the 6 month follow up (Table 7, Figure 7c).

Group B (3-Month Usage):

In Group B, all participants (100%) reported dental hypersensitivity (DH) at baseline, with 100% achieving symptom reduction by Day 90. Notably, after discontinuation, the therapeutic effect was more durable than in Group A: 30% of participants remained symptom free at the 3 month follow up, increasing to 41.67% at 6 month follow up (Table 7, Figure 7b).

For sharp pain from thermal stimuli, 98.3% of participants reported symptoms at baseline, with 100% achieving reduction by Day 90. Following discontinuation, high levels of sustained relief were observed, with no recurrence reported by 38.3% of participants at the 3 month follow up and 61.67% at the 6 month follow up (Table 7, Figure 7d).

Table 7: Subjective evaluation questionnaire

Group A (N = 60) n (%)						Group B (N = 60) n (%)					
Question 1											
Do you have Dental Hypersensitivity?											
Response	Strongly disagree	Disagree	Neither nor	Agree	Strongly agree	Response	Strongly disagree	Disagree	Neither nor	Agree	Strongly agree
Visit 01 (Day 00)	0 (0%)	0 (0%)	0 (0%)	36 (60.00%)	24 (40.00%)	Visit 01 (Day 00)	0 (0%)	0 (0%)	0 (0%)	30 (50.00%)	30 (50.00%)
Question 1A											
After using the test product, there is reduction in your Dental Hypersensitivity.											
Response	Strongly disagree	Disagree	Neither nor	Agree	Strongly agree	Response	Strongly disagree	Disagree	Neither nor	Agree	Strongly agree
Visit 02 (Day 30)	0 (0%)	0 (0%)	0 (0%)	13 (21.67%)	47 (78.33%)	Visit 02 (Day 90)	0 (0%)	0 (0%)	0 (0%)	14 (23.33%)	46 (76.67%)
Question 1B											
After stopping the usage of the test product, do you have Dental Hypersensitivity?											
Response	Strongly disagree	Disagree	Neither nor	Agree	Strongly agree	Response	Strongly disagree	Disagree	Neither nor	Agree	Strongly agree
Visit 03 (Day 120)	9 (15.00%)	7 (11.67%)	25 (41.67%)	17 (28.33%)	2 (3.33%)	Visit 03 (Day 180)	5 (8.33%)	13 (21.67%)	24 (40.00%)	13 (21.67%)	5 (8.33%)
Visit 04 (Day 210)	2 (3.33%)	4 (6.67%)	12 (20.00%)	25 (41.67%)	17 (28.33%)	Visit 04 (Day 270)	9 (15.00%)	16 (26.67%)	20 (33.33%)	8 (13.33%)	7 (11.67%)
Question 2											
Can you eat hot and cold food without having sharp pain in teeth?											
Response	Strongly disagree	Disagree	Neither nor	Agree	Strongly agree	Response	Strongly disagree	Disagree	Neither nor	Agree	Strongly agree
Visit 01 (Day 00)	10 (16.67%)	47 (78.33%)	3 (5.00%)	0 (0%)	0 (0%)	Visit 01 (Day 00)	14 (23.33%)	45 (75.00%)	1 (1.67%)	0 (0%)	0 (0%)
Question 2A											
After using the test product, you can eat hot and cold food without having sharp pain in teeth.											
Response	Strongly disagree	Disagree	Neither nor	Agree	Strongly agree	Response	Strongly disagree	Disagree	Neither nor	Agree	Strongly agree
Visit 02 (Day 30)	0 (0%)	0 (0%)	0 (0%)	21 (35.00%)	39 (65.00%)	Visit 03 (Day 180)	0 (0%)	0 (0%)	0 (0%)	15 (25.00%)	45 (75.00%)
Question 2B											
After stopping the usage of the test product, can you eat hot and cold food without having sharp pain in teeth?											
Response	Strongly disagree	Disagree	Neither nor	Agree	Strongly agree	Response	Strongly disagree	Disagree	Neither nor	Agree	Strongly agree
Visit 03 (Day 120)	5 (8.33%)	12 (20.00%)	25 (41.67%)	4 (6.67%)	14 (23.33%)	Visit 03 (Day 180)	8 (13.33%)	8 (13.33%)	21 (35.00%)	13 (21.67%)	10 (16.67%)
Visit 04 (Day 210)	14 (23.33%)	18 (30.00%)	14 (23.33%)	9 (15.00%)	5 (8.33%)	Visit 04 (Day 270)	2 (3.33%)	9 (15.00%)	12 (20.00%)	22 (36.67%)	15 (25.00%)
Abbreviation(s): N = number of participants in the specified group; n = number of participants in the specified category.											

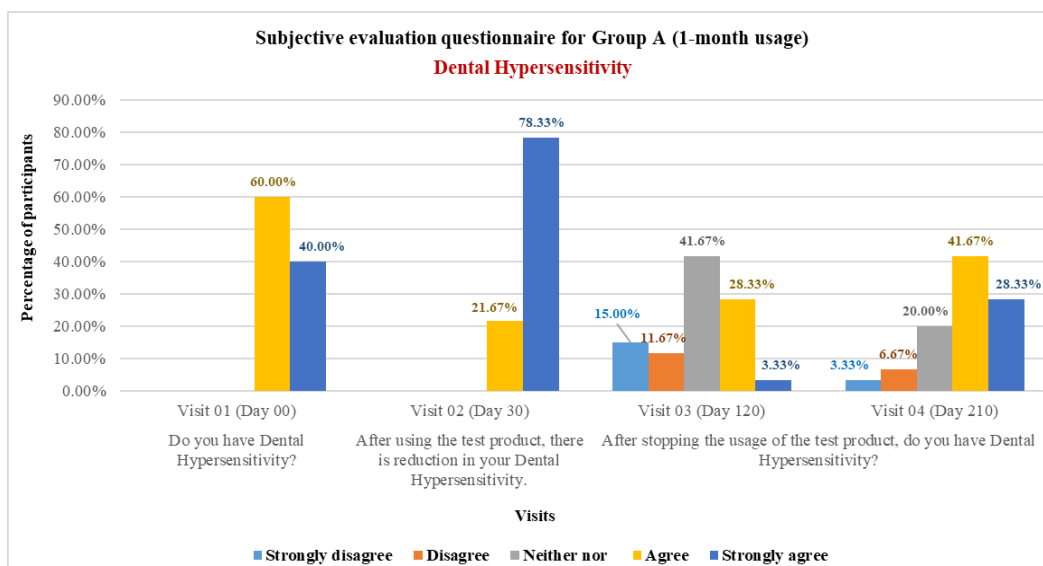


Figure 7a: Dental Hypersensitivity (Group A)

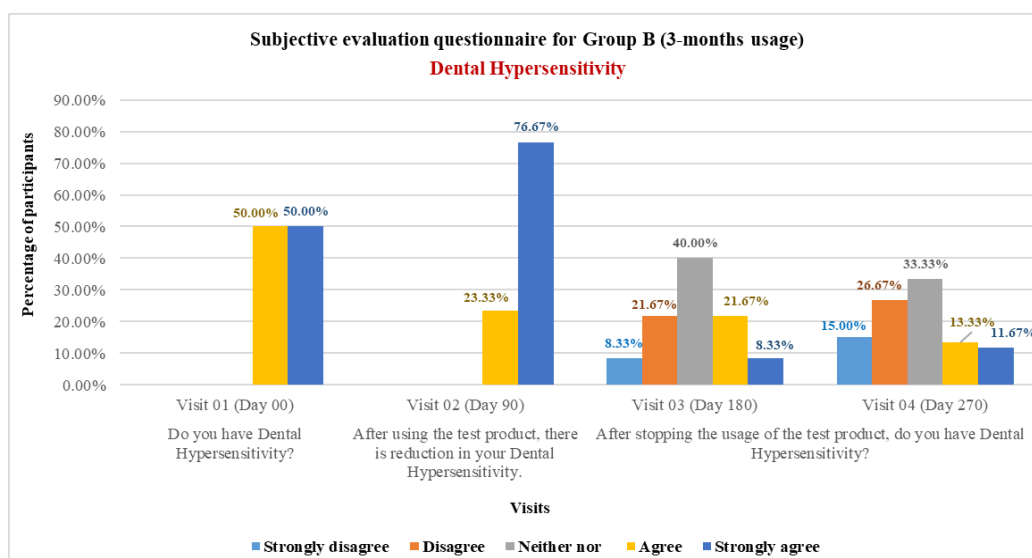


Figure 7b: Dental Hypersensitivity (Group B)

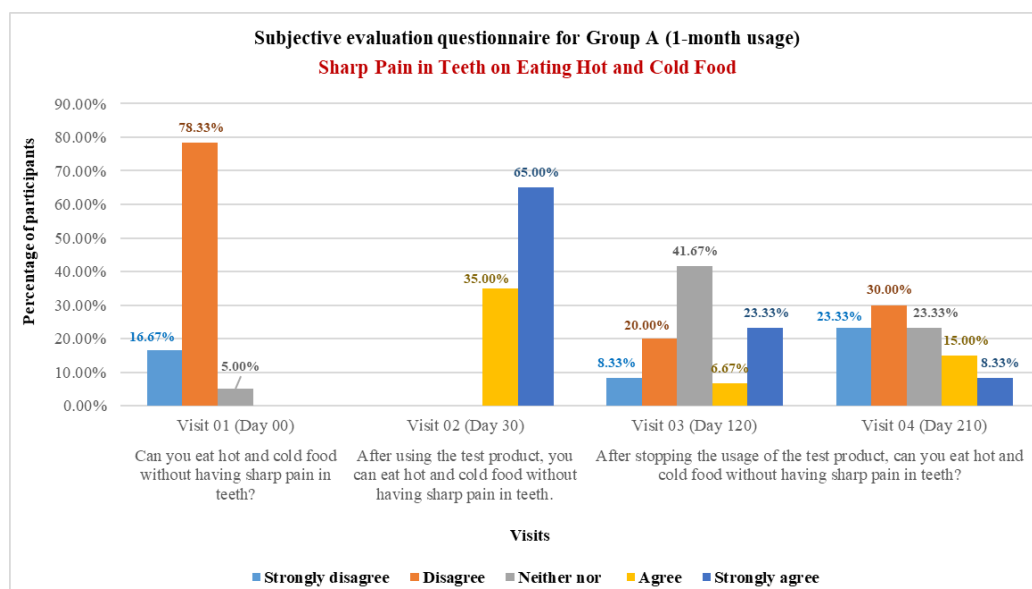


Figure 7c: Sharp Pain in Teeth on Eating Hot and Cold Food (Group A)

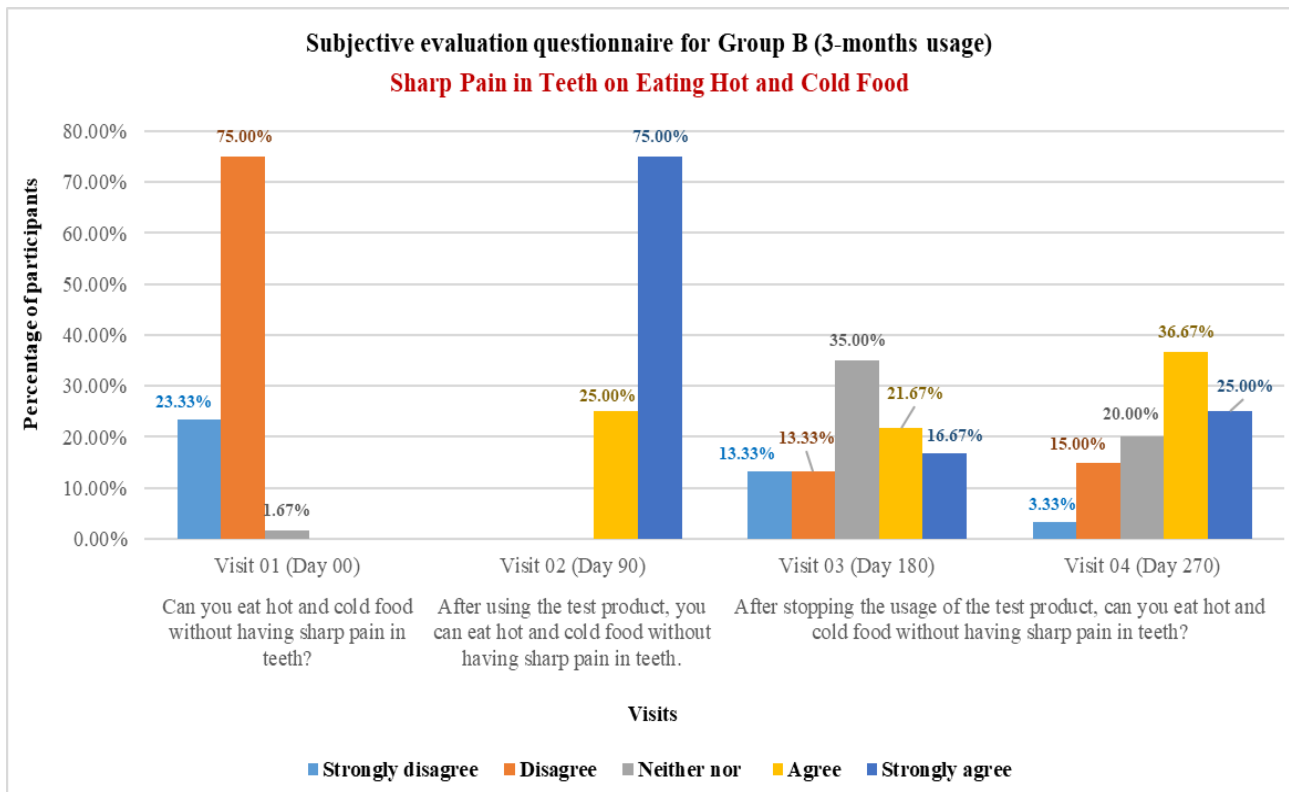


Figure 7d: Sharp Pain in Teeth on Eating Hot and Cold Food (Group B)
 Figure 7: Assessment of Subjective evaluation questionnaires

3.2.9 Assessment of questions regarding general oral hygiene and dental health

Group A (1-Month Usage)

For reduction in bad breath, all participants (100%) reported improvement after one month of consistent product use. Regarding aesthetic outcomes, 95.0% of participants observed an improvement in the appearance of their teeth. Furthermore, 90.0% of participants reported a subjective feeling of tight or strong gums by Day 30, indicating a perceived improvement in gingival tone (Table 8, Figure 8).

Group B (3-Month Usage)

In Group B, the 3-month usage period yielded high levels of participant satisfaction across all parameters. Consistent with Group A, 100% of participants reported a reduction in bad breath by Day 90. Aesthetic improvement was noted by 96.7% of the cohort. Notably, gingival perceived strength showed a higher positive response rate than the 1-month group, with 98.3% of participants reporting that their gums felt tight or strong by the end of the treatment period (Table 8, Figure 8).

Table 8: Assessment of questions regarding general oral hygiene and dental health

Response	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
Question 1	On using the test product, there is reduction in bad breath.				
Group A (N =60) n (%)	0 (0%)	0 (0%)	0 (0%)	27 (45.00%)	33 (55.00%)
Group B (N =60) n (%)	0 (0%)	0 (0%)	0 (0%)	23 (38.33%)	37 (61.67%)
Question 2	On using the test product, there was improvement in the appearance of teeth.				
Group A (N =60) n (%)	0 (0%)	0 (0%)	3 (5.00%)	35 (58.33%)	22 (36.67%)
Group B (N =60) n (%)	0 (0%)	0 (0%)	2 (3.33%)	18 (30.00%)	40 (66.67%)
Question 3	On using the test product, the gums feel tight/strong				
Group A (N =60) n (%)	0 (0%)	0 (0%)	6 (10.00%)	36 (60.00%)	18 (30.00%)
Group B (N =60) n (%)	0 (0%)	0 (0%)	1 (1.67%)	17 (28.33%)	42 (70.00%)

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

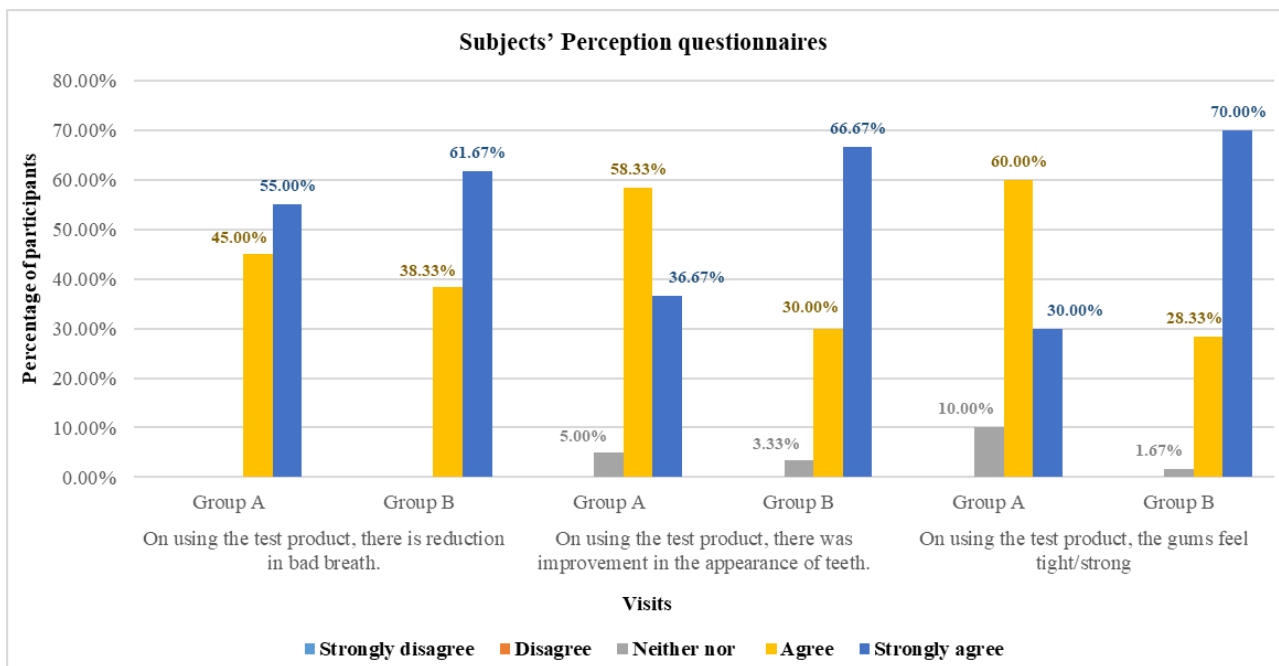


Figure 8: Appealing Taste, Freshness, Cooling Effect
Figure 8: Assessment of questions regarding general oral hygiene and dental health

3.3 Safety Assessments

No instances of local intolerance were observed in any participant throughout the study period. Furthermore, no adverse events (AEs) or serious adverse events (SAEs) were reported during the active treatment phases (up to Day 30 for Group A and Day 90 for Group B) or throughout the post-discontinuation follow-up periods. These results support a favourable safety profile for the test product under the investigated conditions of use.

4. DISCUSSION

Dentinal hypersensitivity (DH) represents a prevalent clinical challenge characterized by acute, transient pain arising from exposed dentin in response to external stimuli [Canadian Advisory Board on Dentin Hypersensitivity, 2003]. This condition is primarily driven by the exposure of dentinal tubules due to enamel wear or gingival recession, facilitating fluid movement that triggers pulpal mechanoreceptors—a process described by Brännström's Hydrodynamic Theory [Alwan, 2016; Porto *et al.*, 2009]. Once tubules become patent, they are typically more numerous and wider in hypersensitive individuals, making the condition resistant to standard oral hygiene measures alone [Migliani *et al.*, 2010, Arora *et al.*, 2021].

The management of DH focuses on two primary pathways: desensitising nerve endings or physically occluding dentinal tubules to arrest fluid flow [Mason *et al.*, 2017]. While potassium-based salts provide temporary relief by disrupting neural transmission, tubule-occluding agents like Calcium Sodium Phosphosilicate (CSPS) offer a more structural solution. CSPS is a bioactive glass that, upon contact with saliva, initiates a cation exchange and a localized pH increase.

This biochemical reaction facilitates the precipitation of a resilient, hydroxycarbonate apatite (HCA) layer that chemically and physically seals the exposed dentin [Greenspan, 2010, Efflandt *et al.*, 2002, LaTorre & Greenspan, 2010, Earl *et al.*, 2011a, Earl *et al.*, 2011b].

In this context, the duration of treatment is critical to ensuring the longevity of the mineralized barrier. Previous studies have demonstrated that 5% CSPS formulations significantly reduce sensitivity within 2 to 4 weeks, but data on the durability of this effect post-discontinuation remain limited [Mason *et al.*, 2017]. Bioactive glasses have gained attention not only for their rapid action but also for their resistance to dietary acid challenges, which typically degrade traditional smear layers. Evidence suggests that prolonged usage of CSPS enhances the density and stability of the occlusive layer, potentially offering more sustained relief compared to short-term applications.

Our study findings align with these observations. Hypersensitivity Toothpaste, containing 5% CSPS, achieved a 91.26% reduction in self-perceived sensitivity (VAS) over 90 days in Group B, compared to a 79.58% reduction in Group A over 30 days. Clinician-assessed Schiff scores mirrored this trend, with Group B exhibiting an 86.39% reduction in air blast sensitivity, significantly outperforming Group A's 58.61%. Crucially, the 3-month regimen (Group B) provided a more robust sustained effect; no recurrence was observed at the 3-month post-treatment follow-up, whereas Group A experienced significant recurrence at the same time point. By the end of the 6-month follow-up, only 21.82% of Group B required re-treatment, compared to 68.33% of Group A.

The superior outcomes observed with a longer treatment duration can be attributed to the progressive accumulation of the HCA layer. Extended application allows for deeper and more complete tubule occlusion, as supported by studies from Miglani, S., *et al.*, (2010). Furthermore, participants reported significant secondary benefits, including a 100% reduction in bad breath and improved gingival tone, with 98.3% of Group B reporting stronger gums compared to 90.0% in Group A. This suggests that the alkaline environment created by the CSPS reaction supports broader oral health parameters beyond simple desensitisation [Zhu *et al.*, 2015].

Importantly, while 1-month usage provides substantial initial relief, the 3-month regimen achieved a 7.20-fold and 8.43-fold improvement in air blast and tactile thresholds, respectively. This confirms that a 3-month initial treatment duration is the most effective clinical regimen for preventing the early relapse of hypersensitivity. These results are particularly significant for clinicians seeking to minimize the "rebound effect" and ensure long-term patient comfort post-discontinuation.

No local intolerance, adverse events (AEs), or serious adverse events (SAEs) were reported, confirming Hypersensitivity Toothpaste's favorable safety profile for extended daily use in the management of dentinal hypersensitivity.

5. CONCLUSION

The findings highlight that Hypersensitivity Toothpaste delivers superior relief and long-term management of dentinal hypersensitivity in Asian participants. Its advanced formulation, centered on 5% Calcium Sodium Phosphosilicate (CSPS), utilizes a bioactive mechanism that precipitates a resilient, hydroxycarbonate apatite-like layer to physically occlude exposed dentinal tubules. While a 1-month treatment duration provides substantial initial reduction in sensitivity, the 3-month regimen significantly enhances clinical outcomes, offering a 7.20-fold and 8.43-fold improvement in air blast and tactile thresholds, respectively.

Importantly, the extended treatment duration ensures a more durable therapeutic effect, as evidenced by the minimal recurrence of symptoms and a drastically reduced necessity for re-treatment (21.82% vs. 68.33%) long after product discontinuation. Additionally, the formulation supports overall oral health by effectively eliminating bad breath and improving perceived gingival strength. Thus, Hypersensitivity offers a comprehensive, multi-mechanistic approach to managing dentinal hypersensitivity, with a 3-month initial duration identified as the optimal clinical regimen for ensuring sustained patient comfort and preventing symptom relapse.

Limitations: The authors acknowledge several limitations of the study, including the relatively small sample size and the limited follow-up duration, which may affect the broader generalizability of the findings. These factors underscore the need for larger, multi-centre longitudinal trials to further validate the long-term durability of the therapeutic effect.

Conflict of Interest

This study was funded by Dr. Reddy's Laboratories Ltd. Preeti Kumbhar, Arti Sanghavi, Navita Budhiraja and Dr Syed Mujtaba Hussain Naqvi are employees of the sponsoring organization. The other authors declare no competing interests. All authors have reviewed and approved the final manuscript and concur with the presented data and conclusions.

Acknowledgments

The authors express their sincere appreciation to the study participants for their cooperation and to the clinical team at Cliantha Research for their invaluable technical assistance and support in the execution of this trial.

Running Title: Sustained Pain Relief in Dentinal Hypersensitivity

Data Availability statement

The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request.

Ethics statement

This study was conducted in accordance with applicable ethical standards and regulatory requirements. All required ethical approvals were obtained prior to the initiation of the trial. Ethical approval was obtained from the OM Institutional Ethics Committee (CDSCO registered). Written informed consent was obtained from all study participants before enrollment. The trial was prospectively registered with the Clinical Trials Registry of India (CTRI/2024/11/076135).

Funding

This study was funded by Dr. Reddy's Laboratories Ltd, who provided financial support for the conduct of the study.

REFERENCES

- Canadian Advisory Board on Dentin Hypersensitivity. (2003). Consensus-based recommendations for the diagnosis and management of dentin hypersensitivity. *Journal of the Canadian Dental Association*, 69(4), 221–226.
- Sharma, S., Shetty, N.J., & Uppoor, A. (2012). Evaluation of the clinical efficacy of potassium nitrate desensitizing mouthwash and a toothpaste in the treatment of dentinal hypersensitivity. *Journal of Clinical and Experimental Dentistry*, 4(1), e28–e33. <https://doi.org/10.4317/jced.50665>

- Dimitrios Dionysopoulos, Gerasimidou, O., & Beltes, C. (2023). Dentin Hypersensitivity: Etiology, Diagnosis and Contemporary Therapeutic Approaches—A Review in Literature. *Applied Sciences*, 13(21), 11632–11632. <https://doi.org/10.3390/app132111632>
- Dentine Hypersensitivity: An Update. (2025). *Journal of Dental and Maxillofacial Research*, 8(1). <https://doi.org/10.31038/jdmr.2025812>
- Arora, A., Gupta, U., & Gupta, I. (2021). Dentin hypersensitivity. *International Journal of Health Sciences*, 63–72. <https://doi.org/10.53730/ijhs.v5ns1.5345>
- Sufyan Garoushi, N. B. (2015). Dentine Hypersensitivity: A Review. *Dentistry*, 05(09). <https://doi.org/10.4172/2161-1122.1000330>
- Miglani, S., Aggarwal, V., & Ahuja, B. (2010). Dentin hypersensitivity: Recent trends in management. *Journal of Conservative Dentistry*, 13(4), 218. <https://doi.org/10.4103/0972-0707.73385>
- Mason, S., Kingston, R., Shneyer, L., & Harding, M. (2017). Clinical study to monitor dentinal hypersensitivity with episodic use of a desensitising dentifrice. *BDJ Open*, 3(1). <https://doi.org/10.1038/bdjopen.2017.11>
- Greenspan, D. C. (2010). NovaMin and tooth sensitivity—An overview. *Journal of Clinical Dentistry*, 21, 61–65.
- Efflandt, S. E., Magne, P., Douglas, W. H., & Francis, L. F. (2002). Interaction between bioactive glasses and human dentin. *Journal of Materials Science: Materials in Medicine*, 13(6), 557–565. <https://doi.org/10.1023/a:1015174726415>
- LaTorre, G., & Greenspan, D. C. (2010). The role of ionic release from NovaMin (calcium sodium phosphosilicate) in tubule occlusion: An exploratory in vitro study using radio-labeled isotopes. *The Journal of Clinical Dentistry*, 21(3), 72–76.
- Earl, J. S., Leary, R. K., Muller, K. H., Langford, R. M., & Greenspan, D. C. (2011). Physical and chemical characterization of dentin surface following treatment with NovaMin technology. *The Journal of Clinical Dentistry*, 22(3), 62–67.
- Earl, J. S., Topping, N., Elle, J., Langford, R. M., & Greenspan, D. C. (2011). Physical and chemical characterization of the surface layers formed on dentin following treatment with a fluoridated toothpaste containing NovaMin. *The Journal of Clinical Dentistry*, 22(3), 68–73
- Satyapal, T., Mali, R., Mali, A., & Patil, V. (2014). Comparative evaluation of a dentifrice containing calcium sodium phosphosilicate to a dentifrice containing potassium nitrate for dentinal hypersensitivity: A clinical study. *Journal of Indian Society of Periodontology*, 18(5), 581. <https://doi.org/10.4103/0972-124x.142447>
- Shetty, D., Rajesh, K., Hedge, S., & Arun Kumar, M. (2012). Evaluation of the efficacy of a 5% calcium sodium phosphosilicate (Novamin®) containing dentifrice for the relief of dentinal hypersensitivity: A clinical study. *Indian Journal of Dental Research*, 23(3), 363. <https://doi.org/10.4103/0970-9290.102228>
- Acharya, AB., Surve, SM., & Thakur, SL. (2013). A clinical study of the effect of calcium sodium phosphosilicate on dentin hypersensitivity. *Journal of Clinical and Experimental Dentistry*, e18-22. <https://doi.org/10.4317/jced.50955>
- Alwan, A. (2016). Prevalence and distribution of dentine hypersensitivity in a sample Sulaimani City.
- Porto, I. C. C. M., Andrade, A. K. M., & Montes, M. A. J. R. (2009). Diagnosis and treatment of dentinal hypersensitivity. *Journal of Oral Science*, 51(3), 323–332. <https://doi.org/10.2334/josnusd.51.323>
- Zhu, M., Li, J., Chen, B., Mei, L., Yao, L., Tian, J., & Li, H. (2015). The Effect of Calcium Sodium Phosphosilicate on Dentin Hypersensitivity: A Systematic Review and Meta-Analysis. *PLOS ONE*, 10(11), e0140176. <https://doi.org/10.1371/journal.pone.0140176>