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Prospective, Open Label, Two-Group, Comparative Clinical Study to Evaluate the Effectiveness of a Test Product (I.E., Toothpaste Containing Potassium Nitrate, Sodium Fluoride, Sodium Monofluorophosphate) on Subjects with Dentinal Hypersensitivity

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Abstract **Original Research Article**

Dentinal hypersensitivity is much common clinical condition that exhibits intense pain or discomfort and affects Quality of Life. The condition is often characterized by sharp, intense pain or discomfort occurring in teeth with exposed cervical dentin, and has become a rising concern worldwide. Exploring new treatment options for effective management of the condition is prerequisite. A prospective, open label, two-arm, comparative study was carried out to evaluate the safety and effectiveness of the test product i.e., toothpaste (containing Potassium Nitrate, Sodium Fluoride and Sodium Monofluorophosphate) on subjects with dentinal hypersensitivity. Five volunteers in group 2 were also added to compare the impact of brushing technique on product efficacy, if any. For Hot Gutta Percha and Cold Spray test, a reduction of 5.56%, 25.56%, 62.22% and 88.89% was recorded for Group 1 after 30 seconds, 15 days, 30 days and 60 days respectively. For VAS score, there was a reduction by 33.41%, 56.22%, 81.81% and 95.85% respectively. For Group 2 on the other hand, statistically not significant reduction by 10%, 30%, 50% and 100% was observed for the similar timepoints for Hot Gutta Percha and Cold Spray test. However, there was statistically significant reduction in VAS score by 32.33%, 54.67% 84.33% and 100% respectively. The results exhibited product efficacy in managing tooth sensitivity and pain. The test product also helped in protecting the enamel by reducing mean score of severity of dental erosion by 21.11% after 30 Days and 42.59% after 60 days. Subjective questionnaire based assessments demonstrated that the test product helps in pain and sensitivity reduction, teeth staining and bad breath. There was improvement in teeth appearance and strong gums after the constant use of product for specified study duration. The test product was found to be efficacious in providing fast relief from Dentinal Hypersensitivity starting from 30 seconds post-brushing and throughout the study duration till last visit. It also protected the enamel by reducing the severity of dental erosion. The test product was found effective in reducing dentinal hypersensitivity, teeth staining and bad breathe; improving the appearance of teeth and making the gums feel tight/strong. There was no statistically significant difference on the efficacy results in both the groups using different brushing techniques. The product was found to be safe as per recommended mode of application.

Keywords: Dentinal hypersensitivity, Toothpaste, Potassium nitrate, Sodium fluoride, Sodium monofluorophosphate.

1. INTRODUCTION

Dentinal hypersensitivity (DH), often referred to as tooth sensitivity is a rising concern worldwide [1]. DH is a bothersome clinical condition, often characterized by sharp, intense pain or discomfort occurring in teeth with exposed dentin mostly in cervical area, and less common in coronal and radicular area [2, 3]. It may arise in response to various stimuli viz., thermal, evaporative, tactile, osmotic or chemical [4] from the exposed dentin, which is the inner layer of the tooth. Once there is tissue loss such as enamel wear, loss of cementum and gingival tissue, it manifests as DH [5]. It is a persistent clinical problem examined by clinicians

in routine dental examinations that affects patients' quality of life [6].

The condition is more prevalent in the age group of 30-40 years, though DH can be witnessed within 20-50 years age commonly [7]. Various clinical studies suggest that it may affect women more often than men, though the data is inconsistent and the gender difference could not be established as statistically significant. According to an estimation, DH may affect about one fourth of the adult population, however, most of them do not attempt to consult the dentist since it is not considered a life threatening ailment, though it affects quality of life. In a study conducted on the rural Indian population with reported DH symptoms, only 15.1% received the treatment, whereas 72.6% patients did not plan to attempt the treatment [8]. Addressing the condition effectively in research, dental education, prevention, and treatment is inevitable [9]. The potential causes of DH include vigorous tooth brushing, erosion, gingival recessions, tooth attrition or abfractions that leads to exposed cervical dentin, open dentin tubules and painful sensations to various stimuli [9-12]. Available literatures predict DH prevalence ranging from 13-57% for self-administered questionnaire, and 4-74% for professional clinical examination based method [13]. Although DH may affect any tooth, but is more prevalent in canine and premolar teeth [14].

DH has gathered much attention now a days and there is a considerable advancement and development in its management. A range of recommended treatments are available to reduce the pain and symptoms of DH that encompass nerve-desensitizing substances, protein-precipitating agents, dentin adhesive sealants, agents that block dentinal tubules, laser-assisted therapy, along with few remedies of holistic and alternative treatment system [15]. The most effective and least invasive remedy to get relief from severe pain is using desensitizing toothpaste [16]. Sometimes clinicians opt for restoration techniques such as tooth restoration, surgical root coverage etc. when there is no improvement in symptoms [17]. There is no "gold standard" treatment for DH [18]. Non-invasive desensitizing agents such as dentifrice, mouthwash, gels etc. are most widely used. These agents act by dentinal tubule occlusion, nerve desensitization and protein precipitation. In order to relieve DH, desensitization is vital that might be attained by potassium nitrate or stannous fluoride, oxalates, fluoride gels or dentin bonding agents. The two most-commonly implemented approaches followed for the treatment of DH include tubular occlusion and blockage of nerve activity by means of direct ionic diffusion, and increasing the concentration of potassium ions acting on the pulpal nerve sensorial activity [19]. Apart from the aforesaid agents, Sodium fluoride and Sodium monofluorophosphate are also recognized as a conspicuous desensitizing agents in scientific literature. Clinical studies have revealed that fluoride enhances mineral uptake during continuous remineralization, and inhibits mineral loss during demineralization.

The present clinical study was carried out in order to explore the potential of the test product (dentrifice) formulated with active ingredients viz. Potassium Nitrate, Sodium Fluoride and Sodium Monofluorophosphate for the treatment of DH and to aid enamel protection and remineralization. Simultaneously, a small subgroup comparative analysis was also performed to understand if the leave on technique provides a faster relief in comparison to only brushing technique. Potassium Nitrate has exhibited huge potential in reducing DH effectively by interfering with the nerve impulse, blocking nerve transmission and lowering nerve excitation, resulting decreased excitability of the tooth.

2. MATERIAL & METHODS

2.1. Study Design and Participants

This clinical study was a prospective, open label, two-arm, comparative study to evaluate the effectiveness of the test product on subjects with DH. The treatment duration was 60 days and consisted of 04 visits (Figure 1). The study visits included one screening and enrolment visit on Day 01 and three subsequent evaluation visits i.e. Visit 02, Visit 03 and Visit 04 on Day 15, Day 30 and Day 60 respectively. The potential subjects were screened as per the inclusion and exclusion criteria after obtaining written informed consent. Apart from recording the demographic data, medical history, wellbeing, physical and dental examination, and concomitant medication, all eligible subjects underwent dental assessments and subjective assessments. Safety was assessed throughout the study by monitoring adverse events. The enrolled participants were further divided into 2 subgroups to compare the effectiveness of product application methodology, if any. Subjects in Group 1 had to apply the toothpaste and keep it for 60 sec before brushing. Group 2 participants used the test product directly for brushing.

The study participants of Group 1 applied the test product directly on the affected teeth for 60 seconds, followed by brushing their teeth as per modified Bass technique for 2 minutes using pea size toothpaste and standard soft bristle toothbrush, post-which, the mouth was rinsed with water, whereas Group 2 subjects directly brushed their teeth. The test product was used twice daily for the treatment period. On all the study visits, test product usage and brushing was done at the clinical facility itself. The participants were instructed to follow the provided instructions and restrictions during the study and the compliance check was ensured on the visit days.

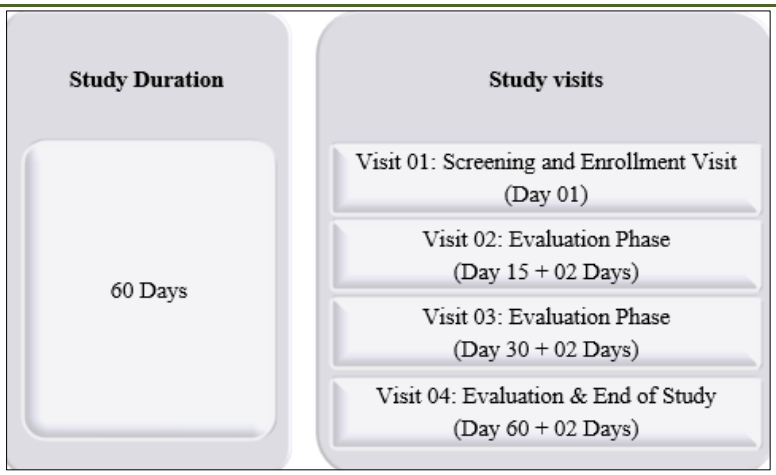

Figure 1: Schematic diagram of study visits

A statistical sample size calculation was performed using PASS 2022 software (Version 22.0.2). A sample size of 37 achieves 91% power to detect a mean of paired differences of 1 with an estimated standard deviation of paired differences of 1.8 and with a significance level (alpha) of 0.05 using a two-sided paired t-test. Anticipating a 20% dropout rate, 47 subjects should be enrolled to obtain a final sample size of 37 subjects. In addition, 5 subjects (Group 2) were planned to enroll in this study for subgroup comparative analysis.

Table 1: Study participants

Disposition	**Group 1 (N = 47) n (%)**	**Group 2 (N = 5) n (%)**	**Overall (N = 52) n (%)**
Screened subjects	-	-	56
Screen fail Subjects	-	-	4
Enrolled subjects	47 (100)	5 (100)	52 (100)
Study completed subjects	45 (95.74)	5 (100)	50 (96.15)
Discontinued/withdrawn subjects	2 (4.26)	0 (0)	2 (3.85)
Abbreviation(s): N = number of subjects in the specified group; n = number of subjects in the specified category. Subject numbers 41 and 45 were discontinued due to loss to follow-up.			

Considering the sample-size estimation, 56 otherwise healthy subjects were screened, of which, 04 subjects were failed on eligibility criteria during the screening. Total 52 screen passed subjects were enrolled (47 in Group 1 and 05 in Group 2), of which, 50 subjects (45 in Group 1 and 05 in Group 2) had completed all the study visits. First 5 completer subjects of Group 1 were considered for the analysis of the primary endpoint VAS score of Group 1 and Group 2 comparison. Two subjects were discontinued prior to completion of the study. These 2 subjects (Subject 041 and 045) were failed to appear for scheduled visits without stating an intention to withdraw their consent. Telephonic follow-ups were attempted till the end of study since they were unable to visit in person. However they were considered lost to follow-up by the investigator at the end of study (Table 1).

2.3 Ethics

The clinical study was conducted in accordance with the protocol, pertinent requirements of the ICMR ethical guidelines and ICH (Step 5) 'Guidance on Good Clinical Practice' and "The code of ethics of the world medical association" (Declaration of Helsinki). The Institutional Ethics committee registered with Central Drugs Standard Control Organization (CDSCO) had reviewed and approved the study Protocol (Version 01) on 29 November 2023 and Version 02 on 17 April 2024. The trial was prospectively registered with Clinical Trial Registry of India (CTRI) on 28 December and modification according to changes in protocol was done on 23 and 25 April 2024 prior to study initiation. Informed Consent Form (ICF) was voluntarily signed by the participants. Following General Data Protection Regulation (GDPR), the subject's identity was kept confidential and the data was handled as per applicable regulations.

2.4 Test Product(s)

The test product was an upgraded formulation of toothpaste containing Potassium Nitrate, Sodium Fluoride and Sodium Monofluorophosphate as active ingredients (Manufactured by: Dr. Reddy's Laboratories Ltd., India).

2.5 Inclusion Criteria

Males and non-pregnant /non-lactating female subjects of age 18 to 60 years (both inclusive), with good general health as determined by the Investigator based on medical history and vital signs were enrolled in the study. Subjects with localized and generalized DH (preferably with equal number of localized and generalized DH in each group); subjects with mild to moderate DH (tested by thermal testing); subjects complaining of DH following a cold stimulus such as ice cream, iced drink, or a rapid jet of cool air to a particular tooth or teeth and subjects with eroded/damaged enamel (Grade 2 – 3 as per Ordinal scale for severity of dental erosion) were key inclusion criteria.

2.6 Exclusion Criteria

Subjects who met any of the following criteria were excluded from the study: pregnant or breastfeeding or planning pregnancy during the study period; subjects with orthodontic bands; partial removable dentures and fixed partial dentures; tumor(s) of the soft or hard tissues of the oral cavity; advanced periodontal disease (purulent exudate, tooth mobility, and/or extensive loss of periodontal attachment or alveolar bone); history of treatment for DH; poor periodontal condition; used antibiotics during past one month; alcohol consuming subjects; smoking cigarettes or consuming any other form of tobacco; participated in a similar clinical study within 30 Days; any other condition which could have warranted exclusion from the study, as per the investigator's discretion.

2.7 Efficacy Endpoint(s)

The primary and secondary endpoints for present study have been tabulated (Table 2).

Table 2: Study endpoints

Endpoint(s)	Parameter	Group	Timepoints	Evaluation criteria/ Scale
Primary	Relief in DH by thermal testing using hot gutta percha and cold spray [20]	1 and 2	Day 01 [baseline (30 mins before product application), 30 (+5 secs) after brushing], Day 15, Day 30, Day 60	4-point grading scale, where 0 = Absent 1 = Mild 2 = Moderate 3 = Severe
	Self-perceived sensitivity using visual analog scale (VAS)	1 and 2	Day 01 [baseline (30 mins before product application), 30 (+5 secs) after brushing], Day 15, Day 30, Day 60	10-pointer scale, whereas 0 = no pain 10 = the worst pain
Secondary	Enamel protection by grading erosion for severity of dental erosion on buccal and lingual surfaces of maxillary anterior teeth [21]	1	Baseline (30 mins before product application), Day 15, Day 30, Day 60	5-point ordinal scale, whereas 0 = No visible changes, Developmental structures remain, Macro-morphology intact 1 = Smoothened enamel. Developmental structures have totally or partially vanished. Enamel surface is shiny, matt, irregular, 'melted', rounded or flat. Macro-morphology generally intact 2 = Enamel surface as described in grade 1. Macro-morphology clearly changed. Faceting or concavity formation within the enamel. No dentinal exposure 3 = Enamel surface as described in grades 1 and 2. Macro-morphology greatly changed (close to dentinal exposure of large surfaces) Or Dentin surface exposed 5 1 /3 4 = Enamel surface as described in grades 1, 2 and 3. Dentin surface exposed > 1/3 Or Pulp visible through the dentin
	Subjective evaluation questionnaires on DH	1	Baseline, Day 15, Day 30, Day 60	Questions pertaining to general oral hygiene and dental health
Safety	Safety of the test product	1 and 2	Throughout the study	Recording incidence of undesirable / adverse event (AE) or Serious Adverse Event (SAE) during the scheduled study visits by the investigator, along with the self-reporting by the subjects

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. Safety endpoints were listed only, wherein no statistical calculation was performed. All statistical tests used significance level of $\alpha \leq 0.05$. Two tailed tests were performed for all analysis that used statistical testing.

3. RESULTS

3.1. Subject Demography

In the present study, total 52 Asian subjects (26 males and 26 females) were enrolled. Age of the subjects ranged between 19 to 59 years with average being 33.7 years (Table 3).

Table 3: Demography

Category/Statistics	Group 1 (N=47)	Group 2 (N=5)	Overall (N=52)
Age (Completed Years)			
n	47	5	52
Mean ± SD	32.6 ± 10.77	43.8 ± 12.28	33.7 ± 11.30
Median	32.0	43.0	33.5
Min, Max	19, 52	30, 59	19, 59
Gender [n (%)]			
Male	22 (46.81)	4 (80.00)	26 (50.00)
Female	25 (53.19)	1 (20.00)	26 (50.00)
Predominant Race [n (%)]			
Asian	47 (100)	5 (100)	52 (100)
Other, please specify	0 (0)	0 (0)	0 (0)

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: Percentages are based on number of subjects in the specified group.

3.2 Efficacy Assessments

3.2.1 Assessment of DH by Thermal Testing using Hot Gutta Percha and Cold Spray

Table 4: Severity of DH by Thermal Testing

Group	Visit 01 (Day 01) Baseline		Visit 01 (Day 01) After 30 secs (+5 secs)			Visit 02 (Day 15 + 02 Days)			Visit 03 (Day 30 + 02 Days)			Visit 04 (Day 60 + 02 Days)		
	Mean ± SD	Median	Mean ± SD	CFB Mean ± SD (%CFB)	Median	Mean ± SD	CFB Mean ± SD (%CFB)	Median	Mean ± SD	CFB Mean ± SD (%CFB)	Median	Mean ± SD	CFB Mean ± SD (%CFB)	Median
Group 1 (n=45)	1.5 ± 0.51	2.0	1.4 ± 0.50	-0.1 ± 0.32 (-5.56)	1.0	1.0 ± 0.42	-0.5 ± 0.55 (-25.56)	1.0	0.6 ± 0.49	-0.9 ± 0.38 (-62.22)	1.0	0.2 ± 0.42	-1.3 ± 0.46 (-88.89)	0.0
p-value Within Group				0.0625[1]			<.0001[1]			<.0001[1]			<.0001[1]	
Group 2 (n=5)	1.6 ± 0.55	2.0	1.4 ± 0.55	-0.2 ± 0.45 (-10.00)	1.0	1.0 ± 0.00	-0.6 ± 0.55 (-30.00)	1.0	0.8 ± 0.45	-0.8 ± 0.45 (-50.00)	1.0	0.0 ± 0.00	-1.6 ± 0.55 (-100.00)	0.0
p-value Within Group				1.0000[1]			0.2500[1]			0.1250[1]			0.0625[1]	
p-value Between Group				1.0000[2]			0.6507[2]			1.0000[2]			0.3109[2]	

Abbreviation(s): CFB = change from baseline; n = number of subjects in specified group; SD = standard deviation.
Subject numbers 41 and 45 were excluded from analysis.
1 p-value is calculated using Wilcoxon sign rank test.
2 p-value is calculated using Wilcoxon rank sum test.

For Hot Gutta Percha and Cold Spray test, the mean score was 1.5 for Group 1 at baseline, which was reduced to 1.4 after 30 seconds of brushing that shows 5.56% reduction in DH, though the reduction was statistically not significant (p value 0.0625). However, the score was significantly reduced to 1.0 (25.56%), 0.6 (62.22%) and 0.2 (88.89%) on Day 15, Day 30 and Day 60, respectively (all p values <.0001) as compared to baseline. The improvement from baseline data exhibited 1.1, 1.4, 2.4 and 6.8 times reduction from baseline after 30 seconds, Day 15, Day 30 and Day 60 respectively.

At baseline, the mean score was 1.6 for Group 2, which was reduced to 1.4 after 30 seconds of brushing that exhibited 10.00% reduction in DH, though the reduction was statistically not significant (p value 1.0000). The mean DH score was reduced to 1.0 (30%), 0.8 (50%) and 0.0 (100%) on Day 15, Day 30 and Day 60, respectively as compared to baseline. However, the reduction at all time points was statistically not significant (p values 0.2500, 0.1250 and 0.0625 respectively). A reduction of 1.1, 1.6 and 2 times from baseline was recorded after 30 seconds, Day 15 and Day 30 respectively (Table 4).

It is interesting to annotate that no statistically significant difference observed for both the groups at all assessment timepoints. It is therefore evident from the above observation that there is no impact of the brushing technique on product efficacy and the test product is likewise effective in reducing DH.

3.2.2 Assessment of Self-Perceived Sensitivity by Subjects using Visual Analog Scale (VAS).

Table 5: VAS score

Group	Visit 01 (Day 01) Baseline		Visit 01 (Day 01) After 30 secs (+5 secs)			Visit 02 (Day 15 + 02 Days)			Visit 03 (Day 30 + 02 Days)			Visit 04 (Day 60 + 02 Days)		
	Mean ± SD	Median	Mean ± SD	CFB Mean ± SD (% CFB)	Median	Mean ± SD	CFB Mean ± SD (% CFB)	Median	Mean ± SD	CFB Mean ± SD (% CFB)	Median	Mean ± SD	CFB Mean ± SD (% CFB)	Median
Group 1 (n=45)	4.1 ± 1.44	4.0	2.9 ± 1.45	-1.2 ± 0.48 (-33.41)	2.0	2.0 ± 1.19	-2.2 ± 0.61 (-56.22)	2.0	0.9 ± 0.86	-3.2 ± 0.93 (-81.81)	1.0	0.2 ± 0.48	-3.9 ± 1.19 (-95.85)	0.0
p-value Within Group				<.0001[1]			<.0001[1]			<.0001[1]			<.0001[1]	
Group 2 (n=5)	4.8 ± 1.30	5.0	3.2 ± 0.84	-1.6 ± 0.89 (-32.33)	3.0	2.2 ± 0.84	-2.6 ± 0.89 (-54.67)	2.0	0.8 ± 0.45	-4.0 ± 1.00 (-84.33)	1.0	0.0 ± 0.00	-4.8 ± 1.30 (-100.00)	0.0
p-value Within Group				0.0161[1]			0.0029[1]			0.0009[1]			0.0012[1]	
p-value Between Group				0.4282[2]			0.1693[2]			0.0943[2]			0.1141[2]	

Abbreviation(s): CFB = change from baseline; n = number of subjects in specified group; SD = standard deviation; VAS = visual analog scale.
Subject numbers 41 and 45 were excluded from analysis.
1 p-value is calculated using Paired t - test.
2 p-value calculated using Two sample t - test.

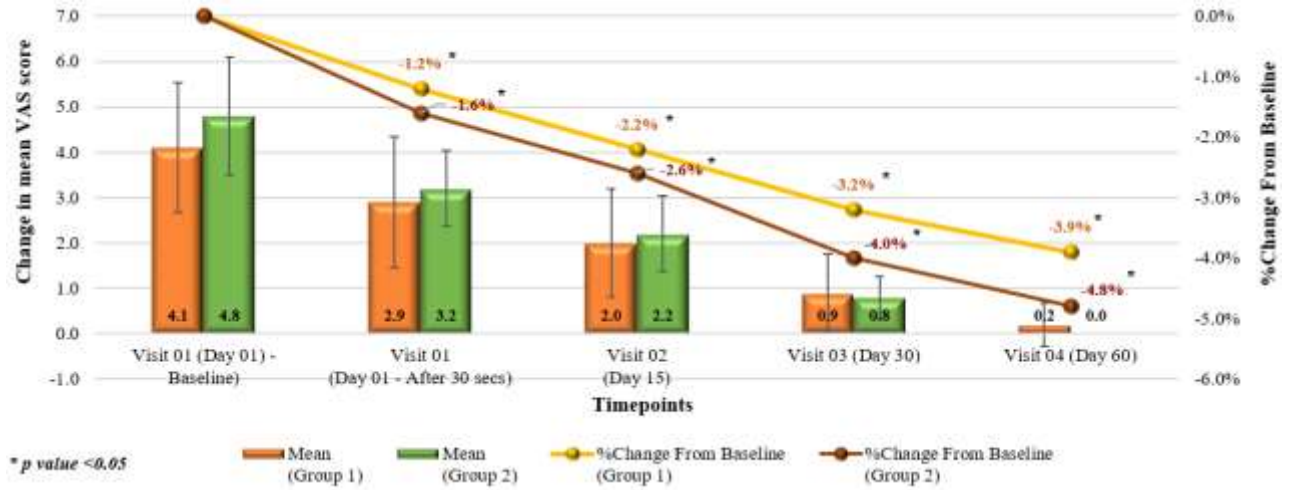

Figure 2: Assessment of Self-Perceived Sensitivity by Subjects using Visual Analog Scale (VAS)

For within group treatment, the mean VAS score of self-perceived sensitivity was 4.1 at baseline in Group 1, which was reduced to 2.9 after 30 seconds of brushing. The score was further reduced to 2.0, 0.9 and 0.2 on Day 15, Day 30 and Day 60, respectively. There was statistically significant reduction by 33.41%, 56.22%, 81.81% and 95.85% (all p values <0.0001) recorded for the respective timepoints. For VAS score, 1.4, 2.1, 4.7 and 16.9 times reduction from baseline after 30 seconds, Day 15, Day 30 and Day 60 respectively was recorded. In Group 2, the mean VAS score at baseline was 4.8, which was reduced to 3.2, 2.2, 0.8 and 0.0 on subsequent assessment timepoints. A statistically significant reduction by 32.33% (p value 0.0161), 54.67% (p value 0.0029), 84.33% (p value 0.0009) and 100% (p value 0.0012) respectively was observed. For Group 2, reduction from baseline for VAS score was 1.5, 2.2 and 6 times reduction after 30 seconds, Day 15 and Day 30 respectively was observed. However, no significant difference between Group 1 and Group 2 was observed at any timepoint, which demonstrates that both the techniques are at par and the efficacy results are equivocal on self-perceived sensitivity (Table 5, Figure 2).

3.2.3 Assessment of Enamel Protection by grading Erosion using Ordinal scale for Severity of Dental Erosion

Table 6: Severity of Dental Erosion

Group	Visit 01 (Day 01) Baseline		Visit 02 (Day 15 + 02 Days)			Visit 03 (Day 30 + 02 Days)			Visit 04 (Day 60 + 02 Days)		
	Mean ± SD	Median	Mean ± SD	CFB Mean ± SD (%CFB)	Median	Mean ± SD	CFB Mean ± SD (%CFB)	Median	Mean ± SD	CFB Mean ± SD (%CFB)	Median
Group 1 (n=45)	2.4 ± 0.50	2.0	2.4 ± 0.54	-0.0 ± 0.15 (-1.11)	2.0	2.0 ± 0.74	-0.5 ± 0.51 (-21.11)	2.0	1.4 ± 0.50	-1.0 ± 0.00 (-42.59)	1.0
p-value Within Group				1.0000[1]			<.0001[1]			<.0001[1]	

Abbreviation(s): CFB = change from baseline; n = number of subjects in specified group; SD = standard deviation.
Subject number 41 and 45 were excluded from analysis.
[1] p-value is calculated using Wilcoxon sign rank test.

The mean score of dental erosion assessed using ordinal scale for severity of dental erosion was 2.4 at baseline. On regular usage of the test product till 60 days, the mean score was reduced to 2.0 and 1.4 on Day 30 and Day 60 respectively. There was a significant reduction by 21.11% on Day 30 (p value <.0001) and 42.59% on Day 60 (p value <0.0001), however, the reduction was not significant (p value 1.0000) on Day 15. There was 1.3 times improvement from baseline on Day 30 and 1.7 times improvement on Day 60 in dental erosion observed

during the study. The results clinically indicate effectiveness of the test product in protecting the enamel by reducing the severity of dental erosion by leave on technique (Table 6).

3.2.4 Assessment of Subject Satisfaction Questionnaire

Table 7: Subject satisfaction questionnaire

Group 1 (N = 45) n (%)					
Response	**Strongly disagree**	**Disagree**	**Neither agree nor disagree**	**Agree**	**Strongly agree**
Question 1	**Do you have Dental Hypersensitivity (Dental pain caused due to exposed tooth responding to heat, cold, touch, pressure).**				
Visit 01 (Day 01)	0 (0%)	0 (0%)	0 (0%)	24 (53.33%)	21 (46.67%)
Question 1A	**After using the toothpaste, there is reduction in your Dental Hypersensitivity (Dental pain caused due to exposed tooth responding to heat, cold, touch, pressure).**				
Visit 02 (Day 15)	0 (0%)	0 (0%)	0 (0%)	45 (100%)	0 (0%)
Visit 03 (Day 30)	0 (0%)	0 (0%)	0 (0%)	22 (48.89%)	23 (51.11%)
Visit 04 (Day 60)	0 (0%)	0 (0%)	0 (0%)	3 (6.67%)	42 (93.33%)
Question 2	**Can you eat hot and cold food without having sharp pain in teeth.**				
Visit 01 (Day 01)	20 (44.44%)	25 (55.56%)	0 (0%)	0 (0%)	0 (0%)
Question 2A	**After using the toothpaste, you can eat hot and cold food without having sharp pain in teeth.**				
Visit 02 (Day 15)	0 (0%)	0 (0%)	11 (24.44%)	34 (75.56%)	0 (0%)
Visit 03 (Day 30)	0 (0%)	0 (0%)	1 (2.22%)	42 (93.33%)	2 (4.44%)
Visit 04 (Day 60)	0 (0%)	0 (0%)	0 (0%)	20 (44.44%)	25 (55.56%)
Question 3	**Do you have teeth staining.**				
Visit 01 (Day 01)	0 (0%)	0 (0%)	0 (0%)	32 (71.11%)	13 (28.89%)
Question 3A	**On using the test product, there was reduction in teeth staining.**				
Visit 02 (Day 15)	0 (0%)	0 (0%)	38 (84.44%)	7 (15.56%)	0 (0%)
Visit 03 (Day 30)	0 (0%)	0 (0%)	7 (15.56%)	38 (84.44%)	0 (0%)
Visit 04 (Day 60)	0 (0%)	0 (0%)	0 (0%)	37 (82.22%)	8 (17.78%)
Question 4	**On using the test product, there is reduction in bad breathe.**				
Visit 02 (Day 15)	0 (0%)	0 (0%)	24 (53.33%)	20 (44.44%)	1 (2.22%)
Visit 03 (Day 30)	0 (0%)	0 (0%)	0 (0%)	43 (95.56%)	2 (4.44%)
Visit 04 (Day 60)	0 (0%)	0 (0%)	0 (0%)	39 (86.67%)	6 (13.33%)
Question 5	**On using the test product, there was improvement in the appearance of teeth**				
Visit 02 (Day 15)	0 (0%)	0 (0%)	26 (57.78%)	19 (42.22%)	0 (0%)
Visit 03 (Day 30)	0 (0%)	0 (0%)	0 (0%)	43 (95.56%)	2 (4.44%)
Visit 04 (Day 60)	0 (0%)	0 (0%)	0 (0%)	9 (20.00%)	36 (80.00%)
Question 6	**On using the test product, the gums feel tight/strong**				
Visit 02 (Day 15)	0 (0%)	0 (0%)	1 (2.22%)	44 (97.78%)	0 (0%)
Visit 03 (Day 30)	0 (0%)	0 (0%)	0 (0%)	32 (71.11%)	13 (28.89%)
Visit 04 (Day 60)	0 (0%)	0 (0%)	0 (0%)	1 (2.22%)	44 (97.78%)
Abbreviation(s): N = number of subjects in the specified group; n = number of subjects in the specified category. Subject number 41 and 45 were excluded from analysis.					

- For reduction in DH: At baseline, 100% subjects reported that they had DH *(Dental pain caused due to exposed tooth responding to heat, cold, touch, pressure)*. After regular use of the test product, 100% subjects reported that there was reduction in DH at all study visits.
- For reduction in sharp pain in teeth while eating hot and cold food: At baseline, 100% subjects reported that they experienced sharp pain in teeth while eating hot and cold food. 75.56%, 97.77% and 100% subjects reported that they can eat hot and cold food without having sharp pain in teeth after using the toothpaste till 15 days, 30 days and 60 days, respectively.
- For reduction in staining of the teeth: At baseline, 100% subjects reported that they had stained teeth. 15.56%, 84.44% and 100% subjects reported that teeth staining had reduced on using the test product till 15 days, 30 days and 60 days, respectively.
- For reduction in bad breathe: 46.66%, 100% and 100% subjects reported that there was a reduction in bad breath on using the test product till 15 days, 30 days and 60 days, respectively.
- For improvement in the appearance of teeth: 42.22%, 100% and 100% subjects reported that there was improvement in the appearance of teeth on using the test product till 15 days, 30 days and 60 days, respectively.

- For gums feeling tight/strong: 97.78%, 100% and 100% subjects reported that the gums felt tight/strong on using the test product till 15 days, 30 days and 60 days, respectively.

The above results indicate that the test product is effective in reducing DH; staining of the teeth and bad breath; improving the appearance of teeth and making the gums feel tight/strong (Table 7).

3.3 Safety Assessments

No local intolerance was recorded in any of the participants during the conduct of present clinical study that endorse the safety of test product in human use. After regular use of test product for 60 days, no adverse events (AEs) or Serious Adverse Events (SAEs) were reported, or observed.

4. DISCUSSION

Tooth demineralization is an ongoing process due to various daily activities that provide exposer to bacteria found in saliva and oral cavity. Remineralization is a natural tooth repair process, in which body takes calcium and phosphate minerals from saliva and deposits them into teeth. It helps replace those lost minerals to keep the teeth strong and prevent DH. Remineralization is an effective approach and has significant potential to manage the development of cavities by preventing and even reversing the early stage of enamel damage and providing relief from DH. During the process of remineralization, deposition of essential minerals is facilitated onto the affected enamel, helping to restore both its structure and hardness of teeth. Despite significant advancements in the research of new remineralizing agents for enamel, the repairing of damaged enamel and restoring its original functions remains a significant challenge [22]. Dentin remineralization could be clinically important for treating dentin caries and dentin hypersensitivity [23]. However, a mineral source containing calcium and phosphorus must be provided [24].

Application of desensitizing agents is often considered the most common non-invasive treatment option. The effectiveness of potassium nitrate for treating DH has been well established. Most patients can experience a decrease in sensitivity by brushing with potassium nitrate toothpaste or using potassium nitrate-fluoride gel [25]. One common theory suggests that potassium nitrate penetrates the dentinal tubules, reaching the nerve. The potassium ions may help to depolarize the nerve and prevent it from repolarizing, thereby preventing the transmission of pain signals to the brain. Potassium salts were thought to decrease the excitability of pulpal nerves that helps in reducing pain for long time [26].

Sodium fluoride is recognized as a leading desensitizing agent and widely utilized to address DH universally. Fluoride based toothpastes demonstrate impartial outcome on sensitive teeth when added with dentin fluid-obstructing agents viz. metal ions, potassium, and oxalates [27]. It is suggested that Sodium fluoride when applied, increases the time of fluoride function in contact with dentinal tubules, resulting declined sensitivity of teeth [28]. The presence of fluoride in saliva plays a significant role in promoting the remineralization process. Fluoride when present in the saliva in a lower concentration, can facilitate the nucleation and formation of mineral crystals, potentially leading to accumulation of minerals also known as hyper-remineralization [29]. Clinical evidences demonstrate that fluorides aid in remineralization by helping calcium ions in saliva to attach to tooth surfaces. Furthermore, fluoride can inhibit the adhesion and proliferation of bacteria by interfering with several enzyme activities [22]. Sodium monofluorophosphate is also a common active ingredient added in toothpastes as a desensitizing agent since long. Its effectiveness in relieving sensitivity has been well supported by numerous clinical research. The mode of action suggests that it blocks the dentinal tubules through calcification that helps to reduce tooth sensitivity [30, 31].

The test product examined in this clinical study is a desensitizing dentifrice formulated with Potassium nitrate, Sodium fluoride and Sodium monofluorophosphate as an active ingredients. It helps in managing DH by promoting desensitization and mineralization of enamel and dentin. The results of present clinical study exhibited the efficacy of test product on reducing teeth sensitivity as evident by the Hot Gutta Percha and Cold Spray test. For Group 1, a reduction of 5.56% was recorded after 30 seconds of brushing. The score was significantly reduced to 25.56%, 62.22% and 88.89% after applying the test product twice a day for 15 days, 30 days and 60 days respectively. For VAS score, there was a reduction by 33.41%, 56.22%, 81.81% and 95.85% respectively suggesting the product effectively helped in managing tooth sensitivity and pain. For Group 2, statistically not significant reduction by 10%, 30%, 50% and 100% was observed for the similar timepoints for Hot Gutta Percha and Cold Spray test. Moreover, there was statistically significant reduction in VAS score by 32.33%, 54.67% 84.33% and 100% respectively. Interestingly, a non-significant difference between both the groups validate that there is no impact of the brushing technique on product efficacy, and the test product is equally effective in reducing DH in both the groups.

The test product also helped in protecting the enamel by reducing mean score of severity of dental erosion by 21.11% after 30 Days and 42.59% after 60 days, where the reduction was statistically significant. Subjective questionnaire based assessments demonstrate that the test product helps in reducing DH, sharp pain in teeth while eating hot or cold food, teeth staining and bad breath. There was improvement in teeth appearance and

strong gums after the constant use of product for specified study duration. No local intolerance or reporting of adverse event further endorses the safety of the test product as per recommended product quantity and mode of application.

5. CONCLUSION

In the present clinical study, the test product i.e., toothpaste (containing Potassium Nitrate, Sodium fluoride, Sodium monofluorophosphate) was evaluated for its effectiveness and safety and was found to be efficacious in providing fast relief from DH starting from 30 seconds post completion of brushing and throughout the study duration till the last visit. It also protected the enamel by reducing the severity of dental erosion. The results of subjective feedback demonstrate products' efficacy in reducing DH, teeth staining and bad breathe; improving the appearance of teeth and making the gums feel tight/strong. The product was found to be safe based on no apparent or experienced discomfort, any intolerance or adverse reactions/events in oral cavity was evidenced in the trial.

Limitations: The authors acknowledge few limitations of the study, including an open label study design and no active control group to compare the results with other marketed products.

Conflict of Interest

KK, GD, AS, KKP and SK are employees of Dr Reddy's Laboratories Ltd. The other authors declare no conflict of interest. The authors are also agreed with the content of this research article.

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Data Availability Statement

The supporting data of the findings of this study will be made available after taking consent and prior approval of the corresponding author.

Ethics Statement

The authors hereby confirm that all necessary ethical approvals had been obtained before trial initiation. Written informed consent was obtained from the study participants. Protocol and study documents were reviewed and approved by OM Institutional Ethics committee registered with the Central Drugs Standard Control Organization (CDSCO). The trial was registered in Clinical Trial Registry of India (CTRI) with reference no. CTRI/2023/12/060912 on 28 Dec 23 prior to subject's enrolment.

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