

Research Article

A Natural Approach to Managing Tooth Hypersensitivity: A Randomized Clinical Trial

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Abstract

This study aimed to evaluate the safety and efficacy of a herbal oral care product in promoting oral health among individuals aged 20 to 55 years over a 60-day period. The formulation included traditional herbal ingredients such as Maricha, Pippali, Shunthi, Tomar, Lavanga, Karpura, Pudina and Gairic Powder, each known for their antimicrobial, anti-inflammatory, analgesic and astringent properties.

The investigation was designed as a double-blind, three-arm, randomized, intervention-based, prospective clinical trial. It enrolled healthy adults aged 18 to 65 years with self-reported dentine hypersensitivity. The study protocol included four visits: Visit 1 (Day 01) involved participant screening, baseline assessments and initial product use; Visits 2 (Day 30 ± 2 days) and 3 (Day 60) were follow-up evaluations for safety and efficacy; and Visit 4 (Day 61) served as the final assessment. Key oral health parameters-plaque index, gingivitis, root caries, dentine hypersensitivity and long-lasting freshness-were evaluated using standardized tools including the International Caries Detection and Assessment System (ICDAS), the Visual Analog Scale (VAS) and TANITA devices.

The results demonstrated that all participants reported a sense of well-being, with no adverse events recorded throughout the study duration. Statistically significant improvements were observed in plaque reduction, gingival health, root caries control and decreased dentine hypersensitivity. Additionally, participants experienced enhanced gum strength and sustained oral freshness. These findings support the product's safety and effectiveness as a holistic and natural solution for comprehensive oral care.

Keywords: Ayurvedic Herbs; Teeth hypersensitivity; Toothpaste; Safety; Efficacy; Clinical Study; Natural

Introduction

Tooth hypersensitivity is a prevalent dental condition characterized by sharp, transient pain in response to thermal, tactile or chemical stimuli, often resulting from exposed dentin. While conventional treatments offer symptomatic relief, there is increasing interest in natural, holistic approaches that address both the symptoms and underlying causes. Ayurveda, the ancient Indian system of medicine, offers a rich repository of herbal and mineral-based remedies known for their therapeutic efficacy in oral health care [1,2].

The present study investigates a herbal oral care formulation enriched with eight Ayurvedic ingredients traditionally used for their analgesic, anti-inflammatory, antimicrobial and astringent properties. Maricha (*Piper nigrum*), Pippali (*Piper longum*) and Shunthi (*Zingiber officinale*)-collectively known as Trikatu are renowned for their bioavailability-enhancing and anti-inflammatory effects, which may help reduce nerve sensitivity and oral inflammation [1,2]. These herbs are well-documented in classical Ayurvedic texts such as the Charaka Samhita and Bhavaprakash Nighantu for their roles in managing pain, inflammation and microbial infections [1,2].

Lavanga (*Syzygium aromaticum*), rich in eugenol, is widely used in dental care for its potent analgesic and antiseptic properties, particularly in managing toothache and microbial infections [2][3]. Karpura (*Cinnamomum camphora*) and Pudina (*Mentha spp.*) contribute cooling, soothing and antimicrobial actions, offering symptomatic relief and freshness [3,4]. Tomar (*Zanthoxylum armatum*) is traditionally used for its anti-inflammatory and pain-relieving effects, supporting gum health and reducing discomfort associated with dentine exposure [4,5]. Gairic Powder (red ochre), a mineral-based astringent, is known for its wound-healing and gum-strengthening properties, which may indirectly alleviate hypersensitivity by promoting gingival integrity [3,5].

Together, these ingredients form a synergistic blend aimed at addressing the multifactorial nature of tooth hypersensitivity while promoting overall oral wellness. This study aims to clinically evaluate the safety and efficacy of this Ayurvedic formulation through a randomized, controlled trial.

Material and Methods

This study was a double-blind, three-arm, randomized, intervention-based, prospective clinical trial designed to assess the tolerability, safety and efficacy of a teeth sensitivity toothpaste in healthy adults aged 18 to 65 years with teeth sensitivity. The trial was registered with the Clinical Trial Registry of India (CTRI) under the registration number CTRI/2024/07/071115. The primary aim of the study was to evaluate the safety and efficacy of the test product in reducing plaque deposition, managing plaque-induced gingivitis, reducing teeth sensitivity and addressing root caries, providing a comprehensive assessment of its benefits for oral health. A total of 35 subjects were enrolled and 29 subjects completed the trial. Written informed consent was obtained from all participants following a thorough discussion of the study procedures, with copies of the consent form provided to each subject. Additionally, subjective feedback regarding the test product usage was collected through a structured questionnaire.

All raw data underwent a thorough review prior to statistical analysis, which was conducted using IBM® SPSS® (Version 29.0.1.0(171)) and Microsoft Excel. Statistical significance was set at a 5% level to ensure robust interpretation of the results.

The study design consisted of four visits:

- Visit 1 (Day 01): Screening, baseline evaluations, initiation of test product usage and post-use evaluation at the test site
- Visit 2 (Day 30 ± 2 days) and Visit 3 (Day 60): Follow-up assessments of safety and efficacy
- Visit 4 (Day 61): Final assessment of outcomes

Key safety and efficacy parameters evaluated included (Table 1):

- Plaque index: Assessed using a two-tone solution followed by a dentist's evaluation [6]
- Gingivitis Index and Root Caries: Evaluated using the International Caries Detection and Assessment System (ICDAS) [7]
- Dentine Hypersensitivity: Measured using the Visual Analog Scale (VAS) for pain [8]
- Long-lasting freshness: Assessed on Days 60 and 61 using TANITA [9]

Test Treatment	Dabur Red Paste
Ingredient	Maricha (<i>Piper Nigrum</i> , Fr., Powder), Pippali (<i>Piper Longum</i> , Fr., powder), Shunthi (<i>Zingiber officinale</i> , Rz., powder), Tomar (<i>Zanthoxylum armatum</i> , Sd., powder)- each 31.04 g), Lavanga (<i>Syzygium aromaticum</i> , Fl.bud, oil)-0.50 g, Karpura (<i>Cinnamomum camphora</i> , Lf., satva)-0.50 g, Pudina (<i>Menta species</i> , Pl., satva)-0.50 g, Gairic powder-1.80 g. Preservative (Sodium benzoate)
Manufactured By	Dabur India Limited (India)
Route of Administration	Topical
Mode of Application	Apply a pea-sized amount of toothpaste on the toothbrush bristles. Angle the toothbrush at 45 degrees to your gums and gently move it back and forth to clean your front teeth.

Table 1: Test product details.

Results and Discussion

Plaque Index

Compared to the baseline, a 38.04% reduction in plaque was observed at 1 minute and 30 minutes after brushing on Day 1. After 30 days of continuous use of Dabur Red Paste, a statistically significant 59.88% reduction in plaque was recorded at both time points. By Day 60, the reduction was 71.00% at 1 minute and 30 minutes post-brushing. On Day 61, prior to using the test product, a 53.84% reduction in plaque was observed compared to the baseline on Day 1. The results demonstrated consistent and statistically significant plaque reduction across all time points (p-value < 0.0001).

Gingivitis Index

Compared to the baseline, no change in gingivitis was observed on Day 1 at 1 minute and 30 minutes after brushing. By Day 30, a 28.34% reduction in gingivitis was recorded at the same time points (p-value < 0.0001). After 60 days of continuous use of Dabur Red Paste, a 52.51% reduction in gingivitis was observed at 1 minute and 30 minutes post-brushing (p-value < 0.0001). On Day 61, prior to brushing, a statistically significant 52.51% reduction in gingivitis was noted compared to the baseline on Day 1 (p-value < 0.0001). These findings indicate that the test product effectively reduces gingivitis with consistent use over time.

Root Caries

On Day 01, 19 subjects (65.52%) scored as Code 1, indicating a demarcated area on the root surface or at the cementoenamel junction that was discolored but without cavitation (loss of anatomical contour < 0.5 mm). Additionally, 10 subjects (34.48%) scored as Code 2, indicating discoloration accompanied by cavitation (loss of anatomical contour \geq 0.5 mm). With the usage of the test product there was no any change observed in the root caries throughout the study period.

Teeth Sensitivity- Tactile Method

After using Dabur Red Paste, a 16% (1.19X) reduction in tooth sensitivity was observed on Day 1 at 1 minute and 30 minutes post-brushing. By Day 30, the reduction was 36.50% (1.57X) at the same time points. Following 60 days of continuous use, the reduction reached 57.50% (2.35X) at 1 minute and 30 minutes post-brushing. The results were statistically significant across all time points (p-value < 0.001). These findings highlight the test product efficacy in significantly reducing tooth sensitivity with consistent use over time (Table 2).

Teeth Sensitivity (Tactile Method)										
	Visit 01 (Day 01)			Visit 02 (Day 30)			Visit 03 (Day 60)			Visit 04 (Day 61)
Statistics	Baseline	T1 min	T30 min	Baseline	T1 min	T30 min	Baseline	T1 min	T30 min	Baseline
Mean	6.90	5.79	5.79	5.34	4.38	4.38	3.90	2.93	2.93	3.21
X% from baseline	-	-16.00	-16.00	-22.50	-36.50	-36.50	-43.50	-57.50	-57.50	-53.50
X time from baseline		1.19	1.19	1.29	1.57	1.57	1.77	2.35	2.35	2.15
P-value	-	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

Table 2: Teeth sensitivity - tactile method.

Teeth Sensitivity - Air Blast Method

After using Dabur Red Paste, a 35.95% (1.56X) and 37.19% (1.59X) reduction in tooth sensitivity was observed at 1 minute and 30 minutes post-brushing on Day 1, respectively. Following 30 days of continuous use, a reduction of 57.85% (2.37X) was recorded at both time points. By Day 60, the reduction further reached 79.75% (79.75X) at 1 minute and 30 minutes post-brushing, with statistical significance observed across all time points (p-value < 0.001). These findings demonstrate that continuous use of Dabur Red Paste effectively reduces tooth sensitivity over time (Table 3).

Teeth Sensitivity (Air Blast Method)										
	Visit 01 (Day 01)			Visit 02 (Day 30)			Visit 03 (Day 60)			Visit 04 (Day 61)
Statistics	Baseline	T1 min	T30 min	Baseline	T1 min	T30 min	Baseline	T1 min	T30 min	Baseline
Mean	8.34	5.34	5.24	5.90	3.52	3.52	3.48	1.69	1.69	2.45
X% from baseline	-	-35.95	-37.19	-29.34	-57.85	-57.85	-58.26	-79.75	-79.75	-70.66
X time from baseline	-	1.56	1.59	1.42	2.37	2.37	2.40	4.94	4.94	3.41
P-value	-	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

Table 3: Teeth sensitivity - air blast method.

Teeth Sensitivity - Cold Water Method

After using the test product, a reduction in tooth sensitivity of 32.01% (1.47X) and 32.81% (1.49X) was observed at 1 minute and 30 minutes post-brushing on Day 1, compared to the baseline. Following 30 days of use, tooth sensitivity decreased by 59.53% (2.47X) at both time points. With continuous use for 60 days, a significant reduction of 84.19% (6.33X) in tooth sensitivity was observed at 1 minute and 30 minutes post-brushing. These findings indicate that the test product effective in reducing tooth sensitivity with consistent use over time (Table 4).

Teeth Sensitivity (Cold Water Method)										
	Visit 01 (Day 01)			Visit 02 (Day30)			Visit 03 (Day 60)			Visit 04 (Day 61)
Statistics	Baseline	T1 min	T30 min	Baseline	T1 min	T30 min	Baseline	T1 min	T30 min	Baseline
Mean	7.91	5.38	5.31	5.53	3.20	3.20	3.06	1.25	1.25	2.00
X% from baseline	-	-32.02	-32.81	-30.01	-59.53	-59.53	-61.26	-84.19	-84.19	-74.70
X time from baseline	-	1.47	1.49	1.43	2.47	2.47	2.58	6.33	6.33	3.95
P-value	-	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

Table 4: Teeth sensitivity-cold water method.

Teeth Sensitivity: Acidic Solution Method

As compared to the baseline, 15.34% (1.17X) and 22.96% (1.19X) reduction observed post brushing at 1 min and 30 min of the brushing on Day 01. 41.23% (1.70X) reduction observed post 1 min and 30 mins of the brushing on Day 30. While continuous 60 days of the usage of the test product the reduction reached to 72.22% (3.60X) and 71.76% (3.54X) at 1 min and 30 mins of the brushing respectively. The results were found to be statistically significant across all the timepoint with p-value <0.001 (Table 5).

Teeth Sensitivity (Acidic Solution Method)										
	Visit 01 (Day 01)			Visit 02 (Day 30)			Visit 03 (Day 60)			Visit 04 (Day 61)
Statistics	Baseline	T1 min	T30 min	Baseline	T1 min	T30 min	Baseline	T1 min	T30 min	Baseline
Mean	6.75	5.75	5.69	5.20	3.97	3.97	3.44	1.88	1.91	2.53
X% from baseline	-	-14.81	-15.74	-22.96	-41.23	-41.23	-49.07	-72.22	-71.76	-62.50
X time from baseline	-	1.17	1.19	1.30	1.70	1.70	1.96	3.60	3.54	2.67
P-value	-	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

Table 5: Teeth sensitivity - acidic solution method.

Teeth Freshness – TANITA

On Day 60, before brushing, 4 subjects (13.79%) scored 0, indicating no odour, 16 subjects (55.17%) scored 1, indicating slight odour, 8 subjects (27.59%) scored 2, indicating moderate odour and 1 subject (3.45%) scored 3, indicating strong odour. On Day 61, before brushing, 7 subjects (24.14%) scored 0, indicating no odour, 15 subjects (51.72%) scored 1, indicating slight odour and 7 subjects (24.14%) scored 2, indicating moderate odour.

Organoleptic Assessment- Dentist Assessment

On Day 60, before brushing, 9 subjects (31.03%) scored 0, indicating no odour, 15 subjects (51.72%) scored 1, indicating barely noticeable odour, 2 subjects (6.9%) scored 2, indicating slight but clearly noticeable odour, 2 subjects (6.90%) scored 3, indicating moderate odour and 1 subject (3.45%) scored 4, indicating strong odour. On Day 61, before application of the test product, 9 subjects (31.03%) scored 0, indicating no odour, 15 subjects (51.72%) scored 1, indicating barely noticeable odour and 5 subjects (17.24%) scored 2, indicating slight but clearly noticeable odour.

Instant and 24 Hours Reduction in Plaque

At baseline on Day 01, the mean was 2.93 ± 0.56 which shifted to 1.81 ± 0.40 after application of the test product at T1 min indicates that test product provides instant reduction in the plaque deposition. While on Day 60 before brushing the mean was reduced to 1.47 ± 0.38 and on Day 61 (before brushing), the mean was reduced to 1.34 ± 0.39 indicates that test product provides protection against the plaque up to 24 hours.

Instant and 24 Hours Reduction in Gingivitis

In the gingivitis assessment, mean was 2.29 ± 0.20 at baseline and post 1 min of the brushing indicates that there was no any instant change observed. At Day 60 and Day 61 (before brushing), again the mean was same, 1.09 ± 0.31 indicates that no change in the gingivitis post 24 hours of brushing.

Change in Teeth Sensitivity After 24 Hours (Table 6).

Tactile Method: On visit 03, Day 60, mean VAS Pain score was 3.90 which reduced to 3.21 at Day 61 (before brushing) indicates that test product reduced the test sensitivity upto 24 hours.

Air Blast Method: On visit 03, Day 60, mean VAS Pain score was 3.48 which reduced to 2.45 to Day 61 (before brushing) indicates that test product reduced the teeth sensitivity upto 24 hours.

Cold Water: On visit 03, Day 60, mean VAS Pain score was 3.03 which reduced to 1.79 at Day 61 (before brushing) indicates test product provides upto 24 hours reduction in tooth sensitivity.

Acidic Solution: On visit 03, Day 60, mean VAS Pain score was 3.38 which reduced to 2.55 at Day 61 (before brushing) indicates that test product provides upto 24 hours teeth sensitivity.

Treatments	Statistics	VAS Pain Score for Tactile			VAS Pain Score for air blast		
		Visit 03 (Baseline)	Visit 03 (T1 min) (After Usage of Test Treatment)	Visit 04 (Before Usage of Test Treatment)	Visit 03 (Baseline)	Visit 03 (T1 min) (After Usage of Test Treatment)	Visit 04 (Before Usage of Test Treatment)
Test Treatment	N	29	29	29	29	29	29
	Mean	3.90	2.93	3.21	3.48	1.69	2.45
	X% from baseline		-	-17.70	-	-	-29.70
	X time from Baseline		-	0.82	-	-	0.70

Table 6: Teeth sensitivity- 24-hour protection.

Change in Teeth Sensitivity Instantly (Table 7).

Tactile Method: At baseline before brushing on Day 01, the mean was 6.90 which was reduces to 5.79 post 1 min of the brushing on Day 01 indicates that test product provides the instant reduction in teeth sensitivity.

Air Blast Method: At baseline before brushing on Day 01, the mean was 8.34 which was reduces to 5.34 post 1 min of the brushing on day 01 indicates that test product provides the instant reduction in teeth sensitivity.

Cold Water: At baseline before brushing on Day 01, the mean was 7.83 which was reduces to 5.34 post 1 min of the brushing on day 01 indicates that test product provides the instant reduction in teeth sensitivity.

Acidic Solution: At baseline before brushing on Day 01, the mean was 7.07 which was reduces to 5.72 post 1 min of the brushing on day 01 indicates that test product provides the instant reduction in teeth sensitivity.

Treatments	Statistics	VAS Pain Score for Tactile			VAS Pain Score for air blast		
		Visit 01 (Before Usage of Test Treatment)	Visit 01 (T1 min) (After Usage of Test Treatment)	Visit 01 (T30 min) (After Usage of Test Treatment)	Visit 01 (Before Usage of Test Treatment)	Visit 01 (T1 min) (After Usage of Test Treatment)	Visit 01 (T30 min) (After Usage of Test Treatment)
Test Treatment	N	29	29	29	29	29	29
	Mean	6.90	5.79	5.79	8.34	5.34	5.24
	X% from baseline	-	-16.00	-16.00	-	-35.95	-37.19
	X time from Baseline	-	1.19	1.19	-	1.56	1.59
Treatments	Statistics	VAS Pain Score for cold water			VAS Pain Score for acidic solution		
		Visit 01 (Before Usage of Test Treatment)	Visit 01 (T1 min) (After Usage of Test Treatment)	Visit 01 (T30 min) (After Usage of Test Treatment)	Visit 01 (Before Usage of Test Treatment)	Visit 01 (T1 min) (After Usage of Test Treatment)	Visit 01 (T30 min) (After Usage of Test Treatment)
Test Treatment	N	29	29	29	29	29	29
	Mean	7.83	5.34	5.28	7.07	5.72	5.72
	X% from baseline	-	-31.72	-32.60	-	-19.02	-19.02
	X time from Baseline	-	1.46	1.48	-	1.23	1.23

Table 7: Teeth sensitivity-instantly reduction.

Conclusion

The herbal oral care product demonstrated clinically validated efficacy in significantly reducing tooth sensitivity, plaque buildup, gingival inflammation and root caries, while delivering long-lasting freshness and enhanced gum strength. Over a 60-day period, participants experienced measurable improvements across all key oral health parameters, with zero reported adverse effects, confirming the product's excellent safety profile. Powered by a synergistic blend of traditional herbal ingredients such as Maricha, Pippali, Shunthi and Pudina; the formulation offers a natural, effective and well-tolerated solution for comprehensive oral care. These findings provide robust scientific validation for the product's positioning as a holistic, natural solution for effectively managing tooth hypersensitivity and enhancing overall oral health.

Conflict of Interest

The authors declare that they have no conflicts of interest with the contents of the article.

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Authors' Contributions

All authors have contributed equally to this work and have reviewed and approved the final manuscript for publication.

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