International Journal of Community Medicine and Public Health
Mishra A et al. Int J Community Med Public Health. 2025 Dec;12(12):5747-5752
http://www.ijcmph.com
pISSN 2394-6032 | eISSN 2394-6040

DOI: https://dx.doi.org/10.18203/2394-6040.ijcmph20254058

Original Research Article

A multicentric observational single arm study to evaluate the effectiveness of toothpaste containing fluoro calcium phosphosilicate (Biomin) in the long-term relief of dentine hypersensitivity

Amit Mishra[1]*, Varun Suryawanshi[2], Rakesh Thaper[3]

[1]Shataayu Dental Clinic, Kesar Bagh Road, Indore, Madhya Pradesh, India
[2]Dr. Suryawanshi's Dental Care and Implant Centre, Sukhshanti Nagar, Indore, Madhya Pradesh, India
[3]Thaper Dental Clinic, 1 Navjeevan Chambers, Vinoba Marg, Ashok Nagar, Jaipur, Rajasthan, India

Received: 04 November 2025
Accepted: 24 November 2025

***Correspondence:**
Dr. Amit Mishra,
E-mail: dramitluvsu@gmail.com

ABSTRACT

Background: Dentin hypersensitivity (DH) is an acute, transient pain from exposed dentin in response to stimuli not attributable to other dental defects or diseases. Among treatment options, fluoro-calcium phosphosilicate (Biomin) toothpaste has shown promising results in recent studies. The objective was to evaluate the long-term effectiveness, safety, and tolerability of Biomin toothpaste in Indian patients with DH.
Methods: This was a prospective, investigator-initiated, multicenter, single-arm, open-label, observational study. Patients used the investigational toothpaste (Hydent Pro) twice daily for 24 weeks. Endpoints included changes in SCASS, VAS pain scores, DHEQ-15, gingival health and supra-gingival plaque scores. Safety and tolerability were monitored throughout.
Results: A total of 121 patients (male: female, 71:50; mean age, 41.1 years) were enrolled. At week 24 significant ($p<00.001$) reductions were observed in SCASS (−1.8), VAS (−57.9), DHEQ-15 (−51.3) scores, and both mean Gingival health and supra-gingival-plaque scores also declined significantly ($p<0.001$) by -1.8, respectively. Investigators rated the effectiveness and tolerability of the toothpaste as excellent to very good in 89.9% and 92.5% patients respectively. No adverse events or other pharmacovigilance relevant information were reported.
Conclusion: Twenty-four weeks of Biomin toothpaste treatment resulted in significant sensitivity relief. Improved overall oral-health-related quality of life; gingival health and anti-plaque action highlight its long-term therapeutic value. Moreover, 24 weeks of treatment with Biomin toothpaste was well-tolerated and can be an effective therapeutic option in the management of DH.

Keywords: Dentin hypersensitivity, Fluoro-calcium phosphosilicate, SCASS, VAS, Desensitizing toothpaste, Long-term management, India

INTRODUCTION

Dentin hypersensitivity (DH) has been defined as a "short, sharp pain arising from exposed dentin in response to stimuli typically thermal, evaporative, tactile, osmotic or chemical, which cannot be ascribed to any other form of dental defect or pathology".[1] The reported prevalence of DH in the Indian population is approximately 20%,but it is notably higher, up to 59.3%, among individuals within the age group of 35-45 years.[2,3] The primary causative factors of DH are gingival recession or loss of enamel, due to erosion or abrasion, which can lead to dentin exposure with open dentinal tubules.[4] Improper oral hygiene practices, such as vigorous brushing using hard-bristled toothbrushes, along with poor dietary habits like frequent intake of acidic foods and beverages, as well as underlying conditions like gastroesophageal reflux or reduced salivary flow, are also associated with a higher risk of developing

DH.[5] According to the hydrodynamic theory, pain associated with DH arises due to the movement of fluid within the exposed dentinal tubules. This fluid shift, triggered by external stimuli, activates mechanoreceptors near the dental pulp, resulting in the characteristic sharp pain response.[6]

Accurate diagnosis of DH requires stimulus response assessment and exclusion of other causes such as caries, pulpitis, fractures, defective restorations, and gingival inflammation.[5] To correct improper brushing habits, patients are advised to avoid abrasive toothpastes and to delay brushing for at least one hour after consuming acidic beverages.[7] DH is primarily managed by desensitizing agents that either decreases neural transmission or blocks dentinal tubules.[4] Desensitizing agents are further classified based on their mode of application - at-home, which is simple, and self-administered; or in-office, which is comparatively complicated and require professional assistance.[8] Toothpaste is the most common desensitizing product used for at-home management of DH.[8] Various molecules like potassium salts help desensitize nerves by reaching the pulp through dentinal tubules, stabilizing nerve activity over 2-4 weeks.[4] Other molecules like calcium sodium phosphosilicate also known as bioactive glass, releases calcium and phosphate, which deposit in tubules and occlude them.[9] The resultant layer of hydroxyapatite layer on the surface of dentin prevents further decay due to acid food and beverages.[9]

A comparative study of dentifrices containing 5% fluoro-calcium phosphosilicate, 5% calcium sodium phosphosilicate, and fluoride over 15–60 days showed significant DH reduction in all groups, with fluoro-calcium phosphosilicate being most effective and providing immediate relief after scaling and root planing.[10] Similarly, a randomized trial by Patel et al reported that 5% fluorocalcium phosphosilicate toothpaste was significantly more effective than 8% arginine with calcium carbonate and placebo in reducing DH over 30 days.[11] A recent systematic review on at home-use of desensitizers containing Biomin noted that while some studies assessed outcomes over short durations of up to 2 weeks, most reported follow-ups of only up to 4 weeks.[12] Long-term follow-up is more appropriate to assess the true effectiveness of home-based desensitizing agents and minimize the Hawthorne effect, yet remains underrepresented in the literature.[12] Therefore, this study was designed to evaluate whether Biomin toothpaste offers long-term relief from DH in Indian patients over a treatment duration of 24 weeks.

METHODS

Patients

This was a prospective, investigator-initiated, multicenter, single-arm, open-label, observational study, conducted from June 2024 to April 2025 (CTRI/2024/06/069581; date of registration 26 June 2024), to evaluate the effectiveness of 24-week treatment with Biomin toothpaste in the management of DH in Indian patients.

Inclusion criteria

The inclusion criteria for the study enrolled patients aged 18 to 70 years with a self-reported history of DH and who had been prescribed Biomin toothpaste by the investigator. It was ensured that enrolled patients had no significant medical or oral abnormalities that could compromise their safety or affect the study outcomes. Additional requirements included maintaining good general oral health, having at least 20 natural teeth, and presenting with at least two teeth showing sensitivity based on an evaporative air test (Schiff sensitivity score ≥2). All patients were required to provide written informed consent and adhere to study procedures.

Exclusion criteria

Exclusion criteria included patients with active dental caries, extensively restored or fractured teeth, presence of orthodontic or prosthetic appliances, signs of localized or generalized gingivitis, pulpitis, or heavy calculus. Patients using desensitizing toothpaste, mouthwash, or related products, as well as those who had undergone vital tooth bleaching within two weeks prior to study initiation, were not eligible. Patients with known allergies to any components of the investigational product, pregnant or breastfeeding women, and women of reproductive age who were not using reliable contraception were also excluded.

Study design

The enrolled patients continued the use of Biomin toothpaste (Hydent Pro), twice daily for a period of 24 weeks, as per the study protocol. Patients were followed up in the clinic at weeks 4, 6, 8, 12, 16, and 24. Before recording baseline scores, the patient underwent oral prophylaxis (scaling and root planning) on a treatment need basis as assessed by disclosing solutions and clinical judgment of the investigator. The study was carried out in accordance with Good Clinical Practice guidelines and the New Drugs and Clinical Trials Rules, 2019 (India), to ensure the protection of patients' rights, safety, and well-being, in alignment with the ethical principles outlined in the Declaration of Helsinki. Prior to the start of the study, the protocol and informed consent documents were reviewed and approved by the ethics committee at each participating site. Informed consent for the collection and use of medical data was obtained from all patients before any study-related procedures were performed.

Study endpoints

Effectiveness was assessed by measuring the reduction in clinical symptoms associated with DH.

The primary effectiveness endpoint was the mean change in the evaporative stimulus response, evaluated using the

Schiff cold air sensitivity scale (SCASS) score from baseline (day 0) to week 6 post-treatment with the investigational product in patients with DH.[13]

The main secondary endpoints were the mean change in evaporative stimulus response evaluated using the SCASS score, oral health-related quality of life oral (OHRQoL) as measured by the DH experience questionnaire-15 (DHEQ-15), and dentin pain relief as measured by a 10-point visual analog scale (VAS) from baseline (day 0) to week 4, 8, 16, and 24 post-treatments with the investigational product. Further, mean change in gingival health, assessed by the modified gingival index (MGI) scale score, and supra-gingival plaque levels assessed by Turesky modification of the Quigley–Hein index (TMQHI) scale score, were evaluated from baseline (day 0) to week 12 and 24 post-treatment with investigational product in patients with DH.[14-18] Safety was evaluated by monitoring the occurrence of adverse events (AEs) and other pharmacovigilance relevant information (OPRI), along with overall tolerability as reported by both physicians and patients at week 24.

Statistical analysis

The sample size of the study was computed to detect a significant improvement in SCASS score after 6 weeks of treatment. In a previous study, the standard deviation (SD) of the change on this scale was estimated to be 0.75.[19] Assuming that an effect size of 0.25 on this scale was clinically meaningful, a sample size of 97 patients was estimated to detect this change with 90% power at the 5% level of significance. To account for dropouts, 121 patients were enrolled in the study.

Patients who received at least one dose of the investigational product were included in the safety analysis set. Those who had at least one follow-up visit were part of the intention-to-treat (ITT) population. Patients in the ITT group who completed the study according to the protocol formed the per-protocol (PP) set for the effectiveness analysis. Continuous data were summarized using mean (SD), and statistical significance was assessed using paired t-tests at a 5% significance level. Categorical data were expressed as counts (n) and percentages (%). All statistical analyses were performed using statistical package for the social sciences (SPSS) version 26.

RESULTS

Demographics and baseline characteristics

A total of 121 (male: female, 71:50) patients with a mean (SD) age of 41.1 (13.6) years were enrolled in the study. Scaling and root planning were performed in 97.5% of patients at the baseline. Out of 121 patients enrolled, 119 (98.3%) patients completed the study as per protocol, and two (1.7%) patients were reported to be non-compliant with study procedures and were not considered for effectiveness analysis; hence per-protocol (PP) analysis set consisted of 119 patients. The demographic and baseline characteristics of the subjects are summarized in Table 1.

Table 1: Patient demographics and baseline characteristics – ITT population.

Parameter	Overall (n=121)
Sex, N (%)	
Male	71 (58.7)
Females	50 (41.3)
Age (years), mean (SD)	41.1 (13.6)
Height (cm), mean (SD)	164.6 (11.0)
Weight (kg), mean (SD)	71.5 (12.9)
BMI (kg/m^2), mean (SD)	25.9 (4.7)
Scaling and root planning, N (%)	118 (97.5)

Percentages are calculated using 'N' as the denominator; BMI: body mass index; ITT: intention-to-treat; SD: standard deviation

Effectiveness of Biomin toothpaste

Significant improvement in symptoms of DH was reported, post 24 weeks of treatment with Biomin toothpaste.

The mean (SD) SCASS scale score declined significantly by -0.2 (0.7) (95% CI -0.3, -0.1; p<0.001) at week 4, by -0.5 (0.6) (95%CI -0.6, -0.4; p<0.001) at week 6, by -0.7 (0.7) (95% CI -0.8, -0.6; p<0.001) at week 8, by -1.6 (0.6) (95%CI -1.7, -1.5; p<0.001) at week 16 and by -1.8 (0.7) (95%CI -1.9, -1.7; p<0.001) at week 24, compared to the baseline score of 2.5 (0.5) (Figure 1).

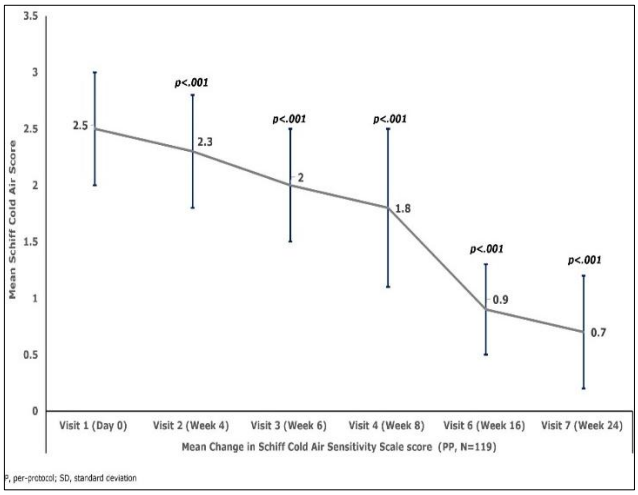

Figure 1: Mean (±SD) dentine hypersensitivity by Schiff cold air sensitivity scale score - (per protocol population, n=119).

Compared to the baseline mean (SD) dentine pain score of 81.0 (8.8), the mean SD score as measured by VAS declined significantly by -6.5 (7.8) (95% CI -7.9, -5.0; p<0.001) at week 4, by -14.4 (10.3) (95% CI -16.2, -12.5; p<0.001) at week 8, by -45.5 (15.9) (95% CI -48.3, -42.5;

p<0.001) at week 16 and by -57.9 (13.4) (95% CI -60.3, -55.4; p<0.001) at week 24 (Figure 2).

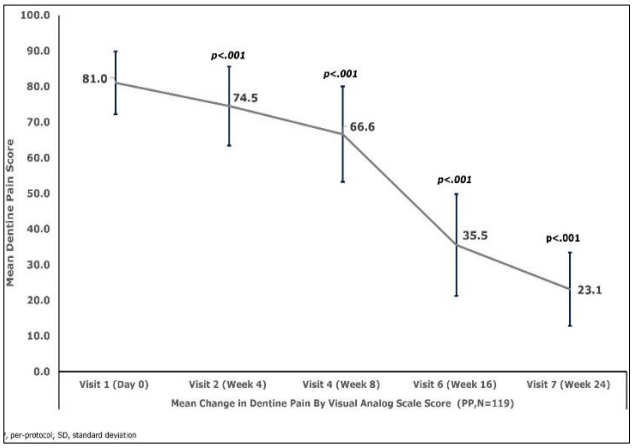

Figure 2: Mean (±SD) dentine pain score assessed by visual analog scale - (per protocol population, n=119).

This led to the mean (SD) OHRQoL score declining significantly by -8.3 (4.0) (95% CI -9.0, -7.6; p<0.001) at week 4, by -20.7 (8.1) (95% CI -22.1, -19.2; p<0.001) at week 8, by 35.2 (10.9) (95% CI -37.2, -33.2; p<0.001) at week 16 and by -51.3 (7.5) (95% CI -52.6, -49.9; p<0.001) at week 24, compared to the baseline mean (SD) score of 80.6 (6.8) (Figure 3).

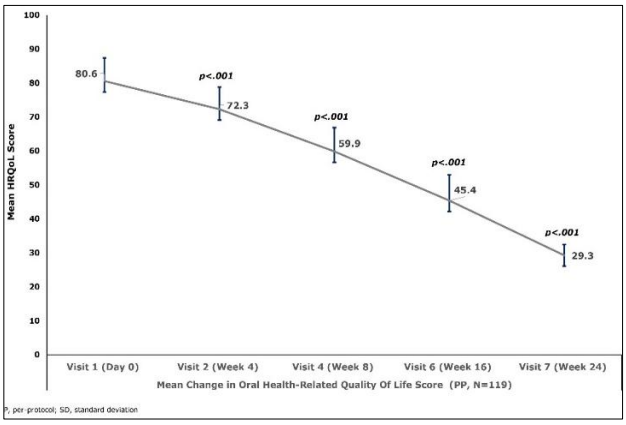

Figure 3: Mean (±SD) oral health-related quality of life (QOL) score - (per protocol population, n=119).

The mean (SD) MGI score declined significantly (p<0.001) by -1.3 (0.9) at week 12 and by -1.8 (0.7) at week 24, compared to the baseline mean (SD) score of 2.7 (0.6). Likewise, compared to the baseline mean (SD) TMQHI score of 2.9 (0.8), the mean (SD) TMQHI score declined significantly (p<0.001) by -1.4 (1.0) at week 12 and by -1.8 (0.8) at week 24. Results are summarized in Table 2.

Investigators ranked the effectiveness of Biomin toothpaste as excellent to very good in 89.9% and good in 10.1% of patients with DH; likewise, 83.2% of patients ranked the effectiveness of Biomin toothpaste as excellent to very good, and 16.8% of patients ranked it good (Figure 4).

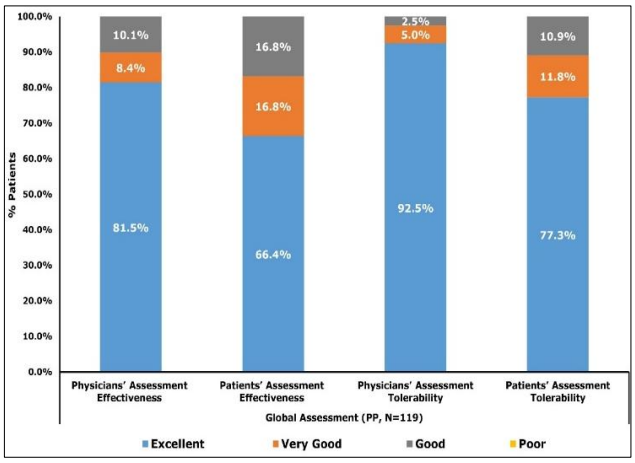

Figure 4: Global assessment of effectiveness and tolerability by physician and patient - (per protocol population, n=119).

Safety and tolerability

No AEs or OPRI were reported during the 24 weeks of treatment with the investigational product in Indian patients with DH. The 24-week use of Biomin toothpaste was generally well-tolerated. Investigators rated tolerability as excellent in 92.5%, very good in 5.0%, and good in 2.5% of patients. Similarly, patient feedback showed that 77.3% rated the product's tolerability as excellent, 11.8% as very good, and 10.9% as good (Figure 4).

Table 2: Mean change in gingival health and supra-gingival plaque levels after 12 and 24 weeks of treatment compared to baseline (PP, N=119).

Variables	Baseline mean (SD)	Week 12 mean (SD)	Mean (SD) difference (95% CI)	P value[a]	Week 24, mean (SD)	Mean (SD) difference (95% CI)	P value[a]
Gingival health - modified gingival index scale	2.7 (0.6)	1.4 (0.9)	-1.3 (0.9) (-1.5, -1.2)	<0.001	0.9 (0.7)	-1.8 (0.7) (-1.9, -1.6)	<0.001
Supra-gingival plaque levels-Turesky modification of the Quigley–Hein index scale	2.9 (0.8)	1.5 (0.9)	-1.4 (1.0) (-1.6, -1.3)	<0.001	1.1 (0.7)	-1.8 (0.8) (-2.0, -1.76)	<0.001

N=Number of patients in PP set; CI: confidence interval; PP: per protocol; SD: standard deviation; [a]analyzed using paired sample T-test

DISCUSSION

Dentin hypersensitivity arises from the exposure of dentinal tubules, which may result from gingival recession, abfraction, abrasion, attrition, erosion, or a combination of these factors.[4] Management of DH ranges from home-based remedies with over-the-counter desensitizing products to professional clinical procedures. Desensitizing toothpaste represents the most affordable, non-invasive home-based treatment for DH, with bioactive glass, such as Biomin, emerging as a desirable agent due to its ability to completely occlude the dentinal tubules.[12] While the short-term efficacy of BioMin toothpaste is documented, evidence on its sustained effectiveness with long-term home-based use remains limited.[12] Given the chronic and recurrent nature of DH, evaluating interventions over extended periods is critical to determine their clinical utility. Accordingly, the present study aimed to investigate the long-term effectiveness and safety of Biomin toothpaste in the management of DH in the Indian population over a 24-week observation period.

Compared to the baseline (day 0) SCASS score of 2.5 (0.5), a gradual decline was observed at subsequent time points: -0.2 (0.7) at week 4, -0.5 (0.6) at week 6, -0.7 (0.7) at week 8, -1.6 (0.6) at week 16, and -1.8 (0.7) at week 24. These findings are in line with results from a recent randomized trial, which reported similar reductions in SCASS scores at week 4 and week 6 using Biomin toothpaste, with statistically greater efficacy compared to arginine and strontium acetate-based desensitizing dentifrices.[19]

The pattern of symptom improvement was further corroborated by changes in VAS scores, reflecting subjective pain perception. Starting from a baseline mean (SD) of 81.0 (8.8), the VAS score showed a significant and sustained decline by -6.5 (7.8) at week 4, -14.4 (10.3) at week 8, -45.5 (15.9) at week 16, and -57.9 (13.4) at week 24. These findings are supported by previous investigations, which also demonstrated significant VAS score reductions at Weeks 4 and 6 post-treatment using Biomin toothpaste.[19] Moreover, independent investigations further support these outcomes, reporting significant reductions in VAS scores at week 2, 4, and 8 post-treatment using Biomin toothpaste.[10,11] Notably, the magnitude of VAS reduction was found to be greater in Biomin toothpaste users compared to those using calcium sodium phosphosilicate-based dentifrice.[10]

In addition to improvements in sensitivity, the study also documented substantial gains in OHRQoL. From a baseline OHRQoL score of 80.6 (6.8), patients reported significant reductions by -8.3 (4.0) at week 4, -20.7 (8.1) at week 8, -35.2 (10.9) at week 16, and -51.3 (7.5) at week 24. These data provide early evidence that desensitizing therapy using the investigational product may have meaningful, sustained impacts on patient's perceived daily well-being and oral health function.

Poor gingival health and plaque accumulation promotes acidogenic bacterial activity that can also lead to the development of DH.[20] This study observed significant improvements in gingival health and plaque control. The MGI score, with a baseline mean (SD) of 2.7 (0.6), decreased significantly by -1.3 (0.9) at week 12 and -1.8 (0.7) at week 24. Similarly, TMQHI score, initially at 2.9 (0.8), declined by -1.4 (1.0) and -1.8 (0.8) at weeks 12 and 24, respectively. These findings are consistent with previous investigations demonstrating significant reductions in gingival index and plaque index with Biomin toothpaste by week 2 post-treatment.[11]

The investigational product was rated as excellent to very good in 89.9% and good in 10.1% of DH cases by investigators. Similarly, 83.2% of patients rated its effectiveness as excellent to very good, and 16.8% as good. Further, the 24-week treatment with Biomin toothpaste was well-tolerated with no AEs or OPRIs, and investigators rated its tolerability as excellent in 92.5%, very good in 5.0%, and good in 2.5% of patients. Most patients also reported its tolerability as excellent (77.3%), very good (11.8%), or good (10.9%).

CONCLUSION

The present study demonstrates that 24 weeks of Biomin toothpaste use significantly reduces DH, with sustained improvements in SCASS, VAS, and OHRQoL scores. The 24 weeks of treatment with Biomin toothpaste also improved gingival health and plaque control, indicating broader oral health benefits. Both investigators and patients rated its effectiveness and tolerability as excellent to very good, with no reported AEs or OPRIs. These findings demonstrate that 24 weeks of treatment with Biomin toothpaste was effective, well-tolerated, with an acceptable safety profile in the management of DH.

ACKNOWLEDGEMENTS

The authors would like to thank the participating institutions and patients for their involvement in the study, and medONE Pharma Solutions (CRO) for their support in study conduct. Authors also acknowledge Dr. Priyanka Rani Paul and Sandeep K. Bhat from medONE Pharma Solutions, Delhi NCR, India for their writing assistance in the preparation of this manuscript.

Funding: The study was funded by Abbott Healthcare Private Limited
Conflict of interest: The Authors received a research grant for conducting this investigator-initiated study
Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

1. Holland GR, Narhi MN, Addy M, Gangarosa L, Orchardson R. Guidelines for the design and conduct

of clinical trials on dentine hypersensitivity. J Clin Periodontol. 1997;24(11):808-13.
2. Haneet RK, Vandana LK. Prevalence of dentinal hypersensitivity and study of associated factors: a cross-sectional study based on the general dental population of Davangere, Karnataka, India. Int Dent J. 2016;66:49-57.
3. Mohan S, Thakur J, Verma SK, Jaiswal R, Verma A, Bhagat SK. Prevalence of dentin hypersensitivity in Bihar and Jharkhand- A multicentric study. Univ J Dent Sci. 2021;6:68-73.
4. Li R, Yang W, Grimaldi R, Zeng P, Smith G, Chen X. Efficacy of a stannous fluoride dentifrice for relieving dentinal hypersensitivity in Chinese population: an 8-week randomized clinical trial. Clin Oral Investig. 2024;28(4):230.
5. Chan AKY, Tsang YC, Yu OY, Lo ECM, Leung KCM, Chu CH. Clinical evidence for silver diamine fluoride to reduce dentine hypersensitivity: A systematic review. J Dent. 2024;142:104868.
6. Braennstroem M, astroem A. A study on the mechanism of pain elicited from the dentin. J Dent Res. 1964;43:619-25.
7. Davari A, Ataei E, Assarzadeh H. Dentin hypersensitivity: etiology, diagnosis and treatment; a literature review. J Dent (Shiraz). 2013;14(3):136-45.
8. Schmidlin PR, Sahrmann P. Current management of dentin hypersensitivity. Clin Oral Investig 2013;17(S1):55-9.
9. Kaimonov MR, Safronova TV. Materials in the Na2O-CaO-SiO2-P2O5 System for Medical Applications. Materials (Basel). 2023;16(17):5981.
10. Ashwini S, Swatika K, Kamala DN. Comparative Evaluation of Desensitizing Efficacy of Dentifrice Containing 5% Fluoro Calcium Phosphosilicate versus 5% Calcium Sodium Phosphosilicate: A Randomized Controlled Clinical Trial. Contemp Clin Dent. 2018;9(3):330-6.
11. Patel VR, Shettar L, Thakur S, Gillam D, Kamala DN. A randomised clinical trial on the efficacy of 5% fluorocalcium phosphosilicate-containing novel bioactive glass toothpaste. J Oral Rehabil. 2019;46(12):1121-6.
12. Al-Haddad A, Alarami N, Alshammari AF, Madfa AA. Efficacy of bioactive glass-based desensitizer compared to other desensitizing agents or techniques in dentin hypersensitivity: a systematic review. BMC Oral Health. 2025;25(1):899.
13. Schiff T, Delgado E, Zhang YP, Cummins D, DeVizio W, Mateo LR. Clinical evaluation of the efficacy of an in-office desensitizing paste containing 8% arginine and calcium carbonate in providing instant and lasting relief of dentin hypersensitivity. Am J Dent. 2009;22:8A-15A.
14. Baker SR, Gibson BJ, Sufi F, Barlow A, Robinson PG. The Dentine Hypersensitivity Experience Questionnaire: a longitudinal validation study. J Clin Periodontol. 2014;41(1):52-9.
15. Machuca C, Baker SR, Sufi F, Mason S, Barlow A, Robinson PG. Derivation of a short form of the Dentine Hypersensitivity Experience Questionnaire. J Clin Periodontol. 2014;41:46-51.
16. Lobene RR. A Modified Gingival Index for Use in Clinical Trials. Clin Prevent Dent. 1986;8:3.
17. Tobias G, Spanier AB. Modified Gingival Index (MGI) Classification Using Dental Selfies. Appl Sci. 2020;10:8923.
18. Turesky S, Gilmore ND, Glickman I. Reduced plaque formation by the chloromethyl analogue of victamine C. J Periodontol. 1970;41:41-3.
19. Arshad S, Zaidi SJA, Farooqui WA. Comparative efficacy of BioMin-F, Colgate Sensitive Pro-relief and Sensodyne Rapid Action in relieving dentin hypersensitivity: a randomized controlled trial. BMC Oral Health. 2021;21(1).
20. Tonetti MS, Greenwell H, Kornman KS. Staging and grading of periodontitis: Framework and proposal of a new classification and case definition. J Periodontol. 2018;89:S159-72.

Cite this article as: Mishra A, Suryawanshi V, Thaper R. A multicentric observational single arm study to evaluate the effectiveness of toothpaste containing fluoro calcium phosphosilicate (Biomin) in the long-term relief of dentine hypersensitivity. Int J Community Med Public Health 2025;12:5747-52.