Dent Res Oral Health 2019; 2(4): 081-088 DOI: 10.26502/droh.0015

Research Article

Efficacy Study of Sensitive Tooth Paste with Natural Extract

Sudhir Sawarkar, Jayaganesh Sankar*, Furtado Mellissa Andrea

Dabur Research and Development, International Business Division, Dubai, United Arab Emirates

***Corresponding Author:** Jayaganesh Sankar, Dabur Research and Development, International Business Division, Dubai, P. O. Box. 6399, United Arab Emirates, E-mail: **sjayaganesh@gmail.com**

Received: 14 September 2019; **Accepted:** 01 October 2019; **Published:** 16 November 2019

Citation: Sudhir Sawarkar, Jayaganesh Sankar, Furtado Mellissa Andrea. Efficacy study of sensitive tooth paste with natural extract. Dental Research and Oral Health 2 (2019): 081-088.

Abstract

People notice the pain is aggravated after a bite of ice cream or spoon of hot soup intake. The tooth sensitivity otherwise called as 'Dentin Hypersensitivity'; the Dentin hypersensitivity is not a personal problem and it is easily rectified by the regular oral hygiene method. The main objective of the study was to evaluate the clinical efficacy of sensitive tooth paste with herbal extract to decrease the Dentinal Hypersensitivity issue. The primary objective is to estimate of this study sensitivity of teeth through the Mean Visual Analogue Scale Scores method. The secondary objective is to estimate the recovery of gum inflammation reduction, gum strengthening, smoothening effect, cleaning. The Primary efficacy analysis was done by comparison of Screening and EOS of all variables using Non Parametric (Non Normal) Wilcoxon Signed Ranks Tes; it is similar to Paired t test. Mean visual Analogue scale score reduced up-to 66.3% in Air evaporative stimuli and 74.6% in Thermal stimuli. Gingival index score reduced before and after treatment. Gum strengthening was confirmed by reduction of redness, edema and glazing from the all the patients who have used the Sensitive toothpaste. Gum Soothening was confirmed from the reduction towards bleeding on probing after the use of sensitive toothpaste by the patients. The plaque Index score helps to quantify the deposit of plaque on the teeth. There was a considerable decrease in plaque Index score from screening to End Of Study (EOS). Mean change of plaque index score at screening was 1.56 and it was declined to 0.96 at EOS. The present study confirms that the toothpaste decreases plaque and gingivitis scores at significant levels. It is suggested that an herbal extract containing toothpaste could be a useful approach for gingivitis prevention and that it may be recommended for daily oral hygiene procedures. Regular use of herbal active tested tooth paste will helps to relief from the sensitivity issue and makes a happy smile.

Keywords: Sensitive teeth; Licorice extract; Cinnamon extract; Potassium nitrate oral hygiene

1. Introduction

In general the pain was noticed during the intake of hot or cold foods and it is caused by the cavity in teeth or the presence of sensitive teeth. People noticed the pain is aggravated after a bite of ice cream or spoon of hot soup intake. The tooth sensitivity otherwise called as 'Dentin Hypersensitivity'; the Dentin hypersensitivity is not a perineal problem and it is easily rectified by the regular oral hygiene method. Dentin hypersensitivity is not defects of pathology associated with teeth, it is medically explained as a painful response to thermal, chemical, mechanical treatment or osmotic stimulant applied to opened dentinal tubules [1]. Dentin hypersensitivity affects the people with any age and predominately it affects the age group between 20 and 50 and the issue is higher in female when compared to male. Dentinal tubules are responsible and play a crucial role in Dentin hypersensitivity, it helps to transfer the stimulant and irritant potential up to the pulp. Blocking of dentinal tubules and reduce the diameter of dentinal tubules are helpful to get rid-off from the sensitivity issue of teeth. The enamel thinner is responsible for the tooth sensitivity and it is presented in the outer layer of the teeth and protect the teeth. However the hard brush usage, improper brushing, frequently eating acidic food, acidic juices also cause the enamel layer damage [1- 3]. Many researchers proved and exclusively studied the effect of potassium nitrate on teeth sensitive issue [1, 2, 4]. Many scientists proved that the toothpaste containing the 5% potassium and its salt usage up to 5 to eight weeks reduced the Dentin hypersensitivity. However, there is no authentic reaction mechanism proved yet. Many scientists revealed that the potassium ions get deposited in the dentin cavities and prevent the sensitive issue temporally; and continuous usage is helpful to deposit the more amount of potassium ions. Recently, many scientists proved the efficacy of sensitive toothpaste after mouth rinsing or certain period. So in recent days, many dentists recommended to brush with sensitive toothpaste at least twice per day. Recent days, many people move towards the natural remedy especially for the health and hygiene segment. Many herbal combinations, materials are helpful to solve the teeth sensitive issue [5-7]. We have exclusively worked out with the synergistic combination of chemical and natural active against the teeth sensitive and develop the tooth sensitive tooth paste. The main objective of the study was to evaluate the clinical efficacy of sensitive tooth paste with herbal extract to overcome or decrease the Dentinal Hypersensitivity issue. The primary objective is estimate the sensitivity issue of teeth through the Mean Visual Analogue Scale Scores method and the secondary objective is recovery of gum inflammation reduction, gum strengthening, smoothening effect, cleaning. This study also aimed to study the any adverse effect of the developed tooth paste through the clinical study.

2. Materials and Methods

The study protocol was designed as an open label, non-randomized and single arm study. The safety and efficacy of natural active based sensitive toothpaste study carried out in adult subjects with having the Dental hypersensitivity issue. An overall study conducted with 30 subjects and subjects is divided into 15 male and 15 female; the overall all study period is 30 days. The trial conducted in line with the ICMR' Ethics Guidelines and followed the regular Indian Good clinical practice (GCP) and ICH-GCP E6 guidelines. The study was conducted in one common center located in Coimbatore, Tamil Nadu, India, however the subjects were sourced and brought to the common center for the study and investigation. Descriptive information was considered from Treatment group for Subject disposition, demographic and screening information.

The Primary efficacy analysis was done by comparison of Screening and EOS of all variables using Non Parametric (Non Normal) Wilcoxon Signed Ranks Test and it is similar to Paired t test. Mean Visual Analogue Scale Scores after being exposed to air evaporative stimuli (VAS - A) and Mean Visual Analogue Scale Scores after being exposed to thermal stimuli (VAS - C) from Screening through End of the study was calculated using the Wilcoxon Signed Ranks Test. Similarly the gingival and plaque index score was calculated based on visual analogue scale score. Cotton Gauze Method performed to estimate the smell test and it performed by the end of the study period. Yellowish stains measured by the mean sulfide production level. Data Entry, Editing and Checking was done by Clinical Data Management personnel at Consortium Clinical Research Pvt. Ltd., and the data are examined by the statistical standard method with proper sample size. The present study was designed as a non- randomized, unblinded, observational trial carried out from the Month of September 2018 and completed in November 2018. Both Male and Female subjects with Hyper Sensitivity in Teeth/Tooth were enrolled in the study All the Subjects enrolled were from an urban area with age group of 18 to 55 (inclusive) years. After meeting the eligibility criteria along with the good general health and a baseline plaque index (PI) mean > 1.0 and presence of established gingivitis were included in the study. A mean gingivitis score should be > 1.0, according to the criteria used by Binny *et al*. Subjects who were not using any other treatment for at least past 3 months were enrolled in this study.

Sample Composition details

Tested sensitive toothpaste prepared with international regulatory bodies approved ingredients and INCI list details are as below;

Composition details

Sorbital, silica, Aqua, Polyethylene glycol 1500; Glycerin, Potassium nitrate; titanium dioxide, Sodium carbody methyl cellulose, herbal extract derived from *Anacyclus pyrethrum, Acacia Arabica, Mimusops elengi, Symplocos racemose, Syzygium cumini*; flavor, tri sodium ortho phosphate, sodium benzoate, *Glycyrrhiza glabra extract*, sodium saccharin, methyl paraben, propyl paraben. They applied 1.0 gm/use (approximately 1 inch) of the Tooth Paste on their wet Tooth Brush and brushed at-least for 2-3 minutes at each application after brushing rinse mouth only with thoroughly plain water. Brushing was done twice a day- Morning after waking up and just before going to bed (nothing was eaten or drunk except plain water after brushing at night). They returned back to the study examination center on the date as requested by the site team along with the left over tooth paste and used tooth brush for the estimation of tooth sensitivity and safety study.

3. Results

The sensitivity of teeth was reduced significantly at EOS when compared to screening period, which was confirmed further from the sensitivity parameters VAS-A (Air Evaporative Stimuli) Score and VAS-C (Thermal Stimuli) Score. Mean visual Analogue scale score reduced up-to 66.3% in Air evaporative stimuli and 74.6% in Thermal stimuli (Table 1). Mean changes of VAS score from screening and end of study pictorial data furnished in the Figure1 and Figure 2. The graphical representation clearly indicates that, the significant improvement in the before and after treatment due to the continuous usage of sensitive tooth paste.

The gum Inflammation reduction was confirmed by the results of the gingival Index score as well as it was observed from the patients before and after use of the

Herbal Sensitive toothpaste; around 0.85 Gingival index score reduced before and after treatment (table 2). Gum strengthening was confirmed by reduction of redness, edema and glazing from the all the patients who have used the Sensitive toothpaste. Gum Soothening was confirmed from the reduction towards bleeding on probing after the use of sensitive toothpaste by the patients. The plaque Index score helps to quantify the deposit of plaque on the teeth. There was a considerable decrease in plaque Index score from screening to EOS. Mean change of plaque index score at screening was 1.56 and it was declined to 0.96 at EOS and it is highly significant as shown in the (table 3) and (Figure 3). This is also a proof of the effect of tooth decay alleviation of Tooth Paste when used in the Subjects as per package instructions. (Table 4) reflects the change in the smell of breath from screening to End of study. There was a significant change in the mean of smell of breath score that is 4.83 at screening changed to 1.97 on the EOS.

S. No.	Efficacy Parameters	Screening	End of Study	Results (Reduction VAS Score in%)
1.	Mean Visual Analogue Scale Scores to air evaporative stimuli (VAS-A)	5.97 (0.48)	2.01 (0.39)	66.3%
2.	Mean Visual Analogue Scale Scores to thermal stimuli (VAS-C)	6.44 (0.56)	1.63 (0.26)	74.6%

Values in the parenthesis indicated the standard deviation values of (n=30) tested subjects

Table 1: Mean Visual Analogue Scale Scores (VAS-A) from Screening to 30 days (EOS) in the subjects

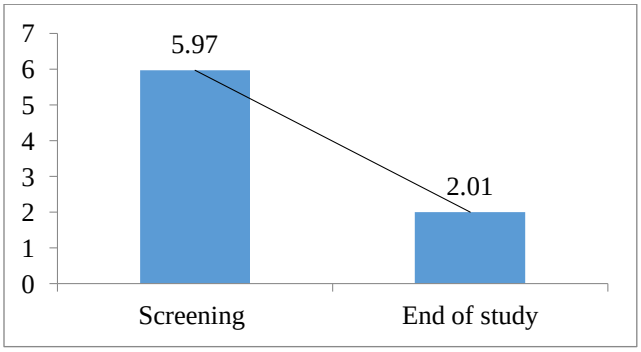

Figure 1: Mean changes of VAS-A score for air evaporative stimuli from screening to 30 days

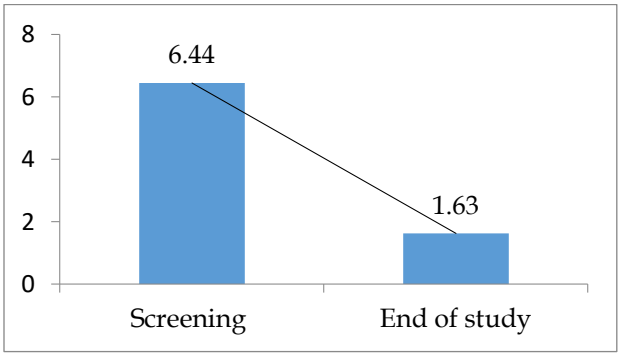

Figure 2: Mean changes of VAS-A score for Thermal stimuli from screening to 30 days

Variables		Screening	EOS	Mean Change
Gingival Index scores	Mean	1.77	0.92	0.85
	N	30	30	
	Std. Deviation	0.25	0.09	

Table 2: Mean Change of Gingival Index Score from Screening to 30 days (EOS) in the Subjects

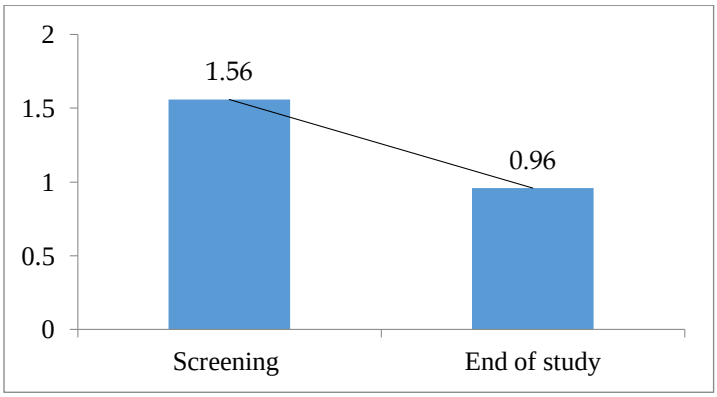

Figure 3: Mean changes of Plaque Index score from screening to 30 days

Variables		Screening	EOS	Mean Change
Plaque Index Score	Mean	1.56	0.96	0.6
	N	30	30	
	Std. Deviation	0.25	0.08	

Table 3: Mean Change of Plaque Index Score from Screening to 30 days (EOS) in the Subjects

Variables		Screening	EOS	Mean Change
Smell of Breath Score	Mean	4.83	1.97	2.86
	N	30	30	
	Std. Deviation	0.75	0.76	

Table 4: Mean Change of Smell of Breath Score from Screening to 30 days (EOS) in the Subjects.

S. No.	Parameters analyzed	Median Value		ρ values (At 5%)
		Screening	EOS	
1.	VAS-A (Air Stimuli)	6	2.1	< 0.05
2.	VAS-C (Thermal Stimuli)	6.4	1.6	< 0.05
3.	Gingival Index Score	1.77	0.92	< 0.05
4.	Plaque Index Score	1.48	0.96	< 0.05
5.	Odor of Breath Score	5	2	< 0.05
6.	Sulfide Color Score	5	2	< 0.05

Table 5: Parameters Analysed from Screening to EOS and their respective "ρ values" Sensitive Toothpaste study.

Overall six parameters were used in the Sensitive Toothpaste study to assess the various aspects of teeth, namely Air stimuli, thermal Stimuli, Gingival index score, Plaque index score, Sulfide color score and odor of breath score. VAS-A (Air Stimuli) and VAS-C (Thermal Stimuli) used to assess the sensitivity of the teeth, the results of VAS-A score depicts the considerable change in the median value of 6.00 at screening in 2.1 on the EOS. VAS -C score from 6.4 to 1.6 from screening to EOS respectively, which in turn showed the p Value is <0.05. Both Air-stimuli and Thermal Stimuli score significantly decreased at 5% statistical level, it confirms that the tested toothpaste work in sensitive teeth and help to get rid-off from the sensitive issues.

Gingival index score was used to assess the reduction in gum inflammation, gum strengthening and gum soothening. Median gingival Index score changed from screening to EOS which confirmed the reduction in the gum inflammation in the screening value of 1.77 to 0.92 at the EOS and the p value is < 0.05. The plaque index score used to assess the plaque formation and tooth decay alleviation, the median change of plaque index score from 1.48 at screening to 0.96 at EOS showed the considerable reduction in the plaque formation and tooth decay alleviation the p value is highly significant p <0.05. Freshness of breath was assessed using mean smell test score and mean sulfide production level. Median value changed from 5 at screening to 2 at the end of study for both mean smell test and mean sulfide production level. For both the parameters the p value is < 0.05.

4. Discussion

The efficacy endpoints VAS-A score showed 66.3% reduction and VAS-C showed 74.6% reduction when compared from baseline, Gingival Index, Plaque Index, Smell of breath and Sulfide production test was compared between screening and the last visit. All the parameters showed considerable reduction when compared with baseline. The mean change differences between screening and End of study was statistically significant and the p <0.05 for all the parameters analyzed. Recently, there has been a growing interest in natural products. The plaque-reducing effects of other herbal-based active agents have previously been described by various studies. In the present study, the application of testing sensitive toothpaste containing natural herbal ingredients showed considerable reductions in plaque accumulation and gingival inflammation. Anti-gingivitis properties of *Acacia Arabica* exclusively studied by Tangade et al. [8]. Through the clinical study, the incorporation of 1% of *Acacia Arabica* significantly reduced the sensational issues [9]. Glycyrrhiza glabra uralensis extract having the higher anti-microbial activity [10], many researchers proved that the activity of anti-microbial and prevent the dental caries [11].

Many researchers proved that the cinnamon bark help to improve the oral hygiene, in addition to that, the combination of cloves and cinnamon bark helps to improve the sensitive teeth [12, 13]. An herbal active are mainly helping to maintain the oral hygiene and kills the bacteria in the mouth; oral hygiene directly proportional to the teeth helps and helps to prevent the tooth decay, enamel decay, teeth ulcer, yellowing of teeth and sensitivity etc. [12, 14]. Chemical active like potassium nitrate helps prevent the teeth from the high heat or cold intake, it helps and forms a new dentin layer and prevent from the external high heat/cold affect. Similarly the herbal actives are helping to prevent the enamel damage and improve the oral hygiene. The improvement of oral hygiene is immensely useful to prevent the dentin layer and helps to maintain the chemical deposition layers peel off. The present study confirms that the synergistic effect of herbal actives along with potassium nitrate helps to prevent the teeth from sensitivity issue and helps to make a happy smile.

5. Conclusion

The study concluded that the sensitivity of teeth was reduced significantly at EOS when compared to screening period, which was confirmed from the sensitivity parameters VAS-A (Air Evaporative Stimuli) Score and VAS-C (Thermal Stimuli) Score. Herbal actives toothpaste is free from fluoride and no harm chemicals, the natural active ingredients improve the teeth and protect the teeth naturally. The present study also confirms that the decrease plaque and gingivitis scores at significant levels. It is suggested that an herbal extract containing toothpaste could be a useful approach

for gingivitis prevention and that it may be recommended for daily oral hygiene procedures. Natural active ingredients along with the potassium ions helps fill and block the exposed nerves thereby reducing the exposure to outside objects. Regular use of herbal active tested tooth paste will helps to relief from the sensitivity issue and makes a happy smile.

Acknowledgement

The researchers thank Mr. Krishna Kumar Chutani, CEO and Mr. Subba Rao - Head of operation for their constant encouragement and support for the study.

References

1. Pradeep AR, Sharma A. Comparison of clinical efficacy of a dentifrice containing calcium, sodium phosphosilicate to a dentifrice containing potassium nitrate and to a placebo on dentinal hypersensitivity: a randomized clinical trial. J Periodontol 8 (2010): 1167–1173.
2. Frechoso SC, Menéndez M, Guisasola C, Arregui I, Tejerina JM, et al. Evaluation of the efficacy of two potassium nitrate bioadhesive gels (5% and 10%) in the treatment of dentin hypersensitivity. A randomized clinical trial. J Clin Periodontol 30 (2003): 315–320.
3. Cai L, Wu CD. Compounds from Syzygium aromaticum possessing growth inhibitory activity against oral pathogens. J Nat Prod 59 (1996): 987–990.
4. Schiff T, Zhang YP, DeVizio W, Volpe AR, Proskin HM. et al. A randomized clinical trial of the desensitizing efficacy of three dentifrices. Compend Contin Educ Dent 21 (2000): 4–10.
5. Prabu seenivasan, Jayakumar M, Ignacimuthu S. In vitro antibacterial activity of some plant essential oils. BMC Complement Altern Med 6 (2006): 39.
6. Bajaj N, Tandon S. The effect of Triphala and Chlorhexidine mouthwash on dental plaque, gingival inflammation, and microbial growth. Int J Ayurveda Res 2 (2011): 29–36.
7. Chanda D, Shanker K, Pal A, Mani D, Darokar MP, et al. Safety evaluation of Trikatu, a generic Ayurvedic medicine in Charles Foster rats. J Toxicol Sci 34 (2009): 99–108.
8. Tangade PS, Mathur A, Tirth A, Kabasi S, et al. Anti-gingivitis Effects of Acacia arabica-containing Toothpaste. The Chinese Journal of Dental Research 15 (2012): 49-53.
9. Mariyam Roqaiya, Wajeeha Begum, Rumaiza Jahufer. Acacia Arabica (Babool) - A - review on ethnobotanical and Unani traditional uses as well as phytochemical and pharmacological properties. Int J Pharm Phytopharmacol Res 4 (2015): 315-321.
10. Kim HJ, Jang HN, Bae JY, Ha JH, Park SN. Antimicrobial activity, quantification and bactericidal activities of Licorice active ingredients. Korean J Microbiol Biotechnol 42 (2014): 386-392.
11. Young-Soon Choi, Jin-Young Kim, Ha-Ram Nah, Bo-Geum Seo, Do-Hyun An , et al. Anti-caries effect of the Glycyrrhiza uralensis extract. Biomedical Research 28 (2017): 8271-8275.
12. Prajapati PK, Sarkar PK, Nayak SV, Joshi RD, Ravishankar B. Safety and toxicity profile of some metallic preparations of Ayurveda. Anc Sci Life25 (2006): 57–63.
13. Shoji S. A drug over the millennia: pharmacognosy, chemistry, and pharmacology of licorice. Yakugaku zasshi 120 (2000): 849-862.

14. Lynch RJ. Zinc in the mouth, its interactions with dental enamel and possible effects of caries; a review of the literature. Int Dent J61 (2011): 46–54.
15. Pradeep AR, Happy D, Garg G. Short-term clinical effects of commercially available gel containing Acacia arabica: a randomized controlled clinical trial. Australian Dental Journal 55 (2010): 65–69.