



**A DOUBLE-BLIND CLINICAL TRIAL TO EVALUATE AND COMPARE THE
EFFICACY OF FIVE DIFFERENT DENTIFRICES ON DENTAL HYPERSENSITIVITY:
AN EIGHT WEEK STUDY**

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ABSTRACT

Dentin Hypersensitivity is growing in population with exposure to junk food, drugs and poor oral hygiene. A randomized double blind clinical trial was performed for comparative efficacy among five different toothpaste groups for dental hypersensitivity. The trial was performed with 175 (one hundred seventy- five) number of subjects in total divided into four groups of 35 each. The subjects were evaluated for instant relief (dab on study) after 60 sec of application and a long-term relief from dental hypersensitivity after usage for 8 weeks. Test group 1 (Potassium nitrate, Alum, Herbal extract, essential oils) & test group 2 (Potassium nitrate, Hydroxyapatite, Alum, Herbal extract, essential oils) showed a statistically significant improvement in long term dental hypersensitivity relief and a better efficacy in instant relief when compared to commercially available toothpaste 3 (Fluoride, Novamin based toothpaste) & 4 (Control group 1 Fluoride based toothpaste & 2 Fluoride, Potassium nitrate-based toothpaste). However, there were no significant results obtained against Control group 3.

KEYWORDS: Dentin Hypersensitivity, toothpaste, dentifrice, potassium nitrate, hypersensitivity.

INTRODUCTION

Exaggerated response to any stimuli which is generally not perceived in normal tooth is known as Dentin hypersensitivity.^[1] Scientifically it is defined as short, sharp pain arising from exposed dentin typically in response to chemical, thermal, tactile, or osmotic stimuli that cannot be explained by the presence of other forms of dental defect or pathology. Dentin under normal is covered by enamel or cement and is not directly exposed to the buccal environment.^[2] However, due to gingival recession, periodontal treatment, improper brushing habits or a combination of more than one factor the enamel or cementum may be removed or denuded abrasion, erosion, attrition to root surface exposure causing dental hypersensitivity.^[3]

In many parts of the world, dentin hypersensitivity is a prevalent oral problem^[4-6]. 70% of periodontal patients experience dentin hypersensitivity with potential high risk.^[7] The condition can last for days, weeks or indefinitely unless treatment is provided. The impact of dental hypersensitivity ranging from minor inconvenience to the patient, limiting dietary choices, impeding effective oral hygiene, negatively affecting appearance, and significantly affecting individual's quality of life.^[8]

The management of dentin hypersensitivity generally encompasses treatment that addresses its etiological and predisposing factors. A correct diagnosis is based on history and examination. The signs and symptoms must be compatible with the clinical description of dentin hypersensitivity and must be differentiating and distinguishing from other conditions that can give rise to similar symptoms. Etiological and predisposing factors such as incorrect tooth brushing and corrosive dietary habits should be identified. Individualized oral hygiene instruction and dietary advice and analysis should also be provided. Treatment should aim to alleviate the pain and concern of the patient^[9].

Everyday solution to the problem includes OTC toothpaste containing potassium nitrate, hydroxyapatite, bio-glass, arginine-based toothpaste.

But the most widely used and economical method is products based out of potassium nitrate. During pain sensation in dentin hypersensitivity, sodium potassium channel at the end of the nerve sends the signal, which is processed as pain at a particular site of tooth. So, one of the approach is to interrupt the neural response to pain stimuli by inserting potassium ions through the dentin tubules to the A-fibres of the nerves, thereby decreasing the excitability of these nerves^[10]. Potassium from potassium nitrate provides excess potassium ions

concentration outside the channel leading the signal blocking to brain. Hence brushing with toothpaste containing potassium nitrate helps in management of pain from dental hypersensitivity^[11]. Certain essential oils like Clove which contains eugenol as major component, has an obtundent effect which numbs nerves and controls pain^[25,26,27]. The oil is also known to have antibacterial action against *Streptococcus mutans* which is involved in dental caries^[19]. Cinnamon oil is another well-known essential oil and contains cinnamaldehyde as major constituent. It is very well known to possess antibacterial properties against gram negative and gram positive bacteria responsible for oral diseases like cavities, malodour etc^[20]. Metal salts like of zinc, aluminium etc are also widely used in maintaining oral hygiene. The metals salts are known to possess antibacterial action^[28] and acts by various mechanism to inhibit the growth of bacteria and other disease causing germs. Aluminium has significantly proven to reduce the ability of streptococci to colonize on enamel surfaces and decreasing the colloidal stability of oral bacteria and thus has antimicrobial activity against cariogenic streptococci as well as the normal oral flora and periodontal pathogens^[29]. Alum or Spatika is also a well-known ingredient in ancient Ayurveda text to possess properties like astringent, anti-plaque, anti-gingivitis, antimicrobial, antiseptic, anti-calculus, decreasing dentinal hypersensitivity, prevention of halitosis, reduction of enamel dissolution, and symbiotic activity with fluoride^[21-23]. *Anacyclus Pyrethrum* also known as toothache tree is another wonder plant reported in many ancient and traditions across the globe. It has been reported in Iranian and Indian ancient medicinal system for dental care. Particularly roots of the plant has found to be sialagogue and has been reported in prevention and treatment toothpain and other oral diseases^[30]. It is also found useful as a remedy for paralysis of the tongue and throat muscles, and in neuralgic problems of the teeth^[24]. These herbs alone or in combination like clove oil, cinnamon oil, Alum, extracts of roots of *Anacyclus pyrethrum* etc has also been reported in Ayurveda literatures to give symptomatic relief^[12]. Apart from individual herbs, certain traditional composition are well known to provide symptomatic relief from dental hypersensitivity. One such classical composition mention in one of the ancient Ayurveda sculpture is Irimedadi oil^[31]. The composition mentions odd 20 herbs prepared in a systemic manner to produce sesame oil based oil. The classical formula is known to provide relief from toothache, dental caries, bleeding gums and malodur.

METHODOLOGY

A 8 weeks, double blind, five-arm, parallel group, randomized clinical study involving subjects with at least two hypersensitive teeth. After baseline assessments, subjects (n = 175) were randomly assigned to one of five study groups.

Inclusion Criteria

- The subject between the age of 18-60 years exhibit dental hypersensitivity to at least two teeth.
- Patients with at least two sensitive teeth assessed by Tactile test having Visual Analogue Scale (VAS).

Exclusion Criteria

- Dental pathology which caused due to dentinal hypersensitivity
- Orthodontic appliances or restorations that may interfere with evaluation.
- Dentures interfering evaluation.
- Periodontal surgery within the previous 6 months
- Ongoing treatment with antibiotics and/or anti-inflammatory drugs or tooth hypersensitivity or anticonvulsants, antihistamines, antidepressants, sedatives, tranquilizers, anti-inflammatory drugs, or daily analgesics.
- Pregnancy or lactation
- Any treatment taken for dental sensitivity other than the dentifrice product (toothpaste).

Statistical Software

SPSS 19.0 will be used to analyze the data and Microsoft excel for graphs, tables, etc.

Clinical Examination

Dental and complete mouth examination was done at base line, 60 seconds, 2 weeks, 4 weeks and 8 weeks. At each visit a minimum of two & up to four hypersensitive teeth were assessed using the most common and validated stimuli tests and summary of the test points are summarized in table no 1:-

1. **Tactile test^[18]**: A sharp dental explorer (EXD 11-12, Hu-Friedy, Chicago, IL, USA) passed across the facial area of the tooth, perpendicular to its long axis, at an approximated constant force. The test will be repeated three times before a score is recorded.

VAS scale: visual analog scale (VAS) is a psychometric response scale.

The degree of hypersensitivity was reported according to VAS. Score was given on a 10 cm sensitivity VAS, which had ratings from:

- 0 to 1 no pain,
- 2-3 for mild pain,
- 4-6 for moderate,
- 7-10 for severe pain.

Subjects with baseline values 4-6 on VAS was accepted into the present study.

2. **Air Blast test^[17,18]**: A blast of air directed onto the affected area of the tooth for 1 s from a distance of 10 mm, while the adjacent teeth isolated using cotton rolls, using a standard dental unit syringe of 40–65 psi at a temperature of 17–21.1°C.

The Schiff Cold Air Sensitivity Scale

For evaluating the air blast hypersensitivity, the tooth to be examined was isolated from the adjacent teeth by

placing the examiner's fingers over the adjacent teeth. Air to be delivered from a standard dental unit air syringe at 60 psi (± 5 psi) and 70°F (± 3 °F), directed at the exposed buccal surface of the hypersensitive tooth for one sec from a distance of approximately one cm.

The Schiff Cold Air Sensitivity Scale to be used to assess subject response to this stimulus, as follows:

- 0 = Subject did not respond to air stimulus;
- 1 = Subject responded to air stimulus but did not request discontinuation of stimulus;
- 2 = Subject responded to air stimulus and requested discontinuation or moved from stimulus;

- 3 = Subject responded to air stimulus, considered stimulus to be painful, and requested discontinuation of the stimulus.

The above stimuli tests were applied in the above order, with a minimum 5- min. gap between the applications of different stimuli.

For instant relief measurement: the test products were massaged onto the tooth exhibiting dentin hypersensitivity only once with a gloved finger by the investigator for a minute (60 sec) after the initial baseline examination.

Table No 1: Evaluation time points.

| Time points | Parameters | |
|---------------------------------------|------------|--------------|
| | Air blast | Tactile Test |
| Visit 1/ baseline | √ | √ |
| Visit 1/Day 0/Instant Relief (60 Sec) | √ | X |
| Visit 2 (2 weeks) | √ | √ |
| Visit 3 (4 weeks) | √ | √ |
| Visit 4 – (8 weeks) | √ | √ |

The oral tissue examination includes visual assessment of the soft and hard palate, gingival and buccal mucosa, mucogingival fold areas, tongue, sublingual and

submandibular areas, salivary glands, and the tonsillar and pharyngeal areas.

Material used

Table No 2: Product details.

| Groups | Details | Active Ingredients |
|----------------------------------|--|--|
| Test Group 1 toothpaste | Dabur Sensitive Gel toothpaste | Potassium Nitrate (Shora) Potash Alum (Spartika) Herbal Extracts (Pipali, Tomar, Maricha, Sunthi) and essential Oils Excipients (Gel Base): q.s |
| Test Group 2 toothpaste | Dabur Sensitive Gel Advanced Toothpaste | Potassium Nitrate (Shora) Hydroxyapatite Potash Alum (Spartika) Herbal Extracts (Pipali, Tomar, Maricha, Sunthi) and essential Oils Excipients (Gel Base): q.s |
| Control Group 1 - toothpaste | Commercial toothpaste- Dental Cream | Sodium Monofluorophosphate, in Calcium carbonate base |
| Control Group 2- Gel | Commercial sensitivity toothpaste - Freshmint | Sodium Fluoride & Potassium nitrate in Gel base |
| Control Group 3 – Gel Toothpaste | Commercial sensitivity toothpaste - Repair & Protect | Sodium monofluorophosphate , Novamin in Gel base |

Commercially available soft-bristle toothbrushes were provided to the panellists for use during the study. Safety

studies were also performed on all the above test and control products and no adverse effects were observed.

RESULTS

The patients were clinically analysed as per defined protocols for 60 sec dab study for instant relief and upon prolong usage (8 weeks twice a day) for long lasting relief from dental hypersensitivity. Upon completion of study, it was found that both the test group 1 & 2 were statistically significant to provide instant sensitivity relief than Control group 1.

Also, test group 1 & test group 2 were statistically significant in providing long lasting sensitivity relief than Control group 1 & control group 2 as summarized in table 3, table 4 and table 5 respectively.

The percentage reduction in air blast test and tactile test for estimation of long-term sensitivity relief when compared to control group 1 and control group 2 are

summarized in table 6, 6A, 7 & 7B respectively. These percentage reductions are calculated as change from baseline values. However, test group 1 & 2 showed no

statistical difference than control group 3 in instant and long-term sensitivity relief.

Table 3: Instant relief day 1 brushing compared to ordinary Fluoride toothpaste.

| Group | INSTANT RELIEF | | Total | “X” times Instant Relief (as compared to ordinary fluoride toothpaste i.e. Control group 1- toothpaste) |
|--|----------------|-------|--------|---|
| | YES | NO | | |
| Control group 2- Gel n/% | 19 | 16 | 35 | 2.1X |
| | 54.3% | 45.7% | 100.0% | |
| Control group 3- Gel toothpaste n/% | 24 | 11 | 35 | 2.6X |
| | 68.6% | 31.4% | 100.0% | |
| Control group 1- toothpaste n/% | 09 | 26 | 35 | X |
| | 25.7% | 74.3% | 100.0% | |
| Test Group 1 toothpaste n/% | 27 | 08 | 35 | 3.0X |
| | 77.1% | 22.9% | 100.0% | |
| Test Group 2 toothpaste n/% | 28 | 07 | 35 | 3.1X |
| | 80.0% | 20.0% | 100.0% | |
| Total N/% | 107 | 68 | 175 | |
| | 61.1% | 38.9% | 100.0% | |

Pearson Chi-Square Test = 29.006, df = 4, p – Value < 0.001 (Very Highly Significant)

Table 4: Tactile test for teeth hypersensitivity (long term sensitivity relief) at different time points.

| Test | Product | N | Mean | Std. Deviation | Std. Error |
|-----------------------------------|---------------------------------|-----|--------|----------------|------------|
| Tactile test score at baseline | Control group 2- Gel | 35 | 5.7143 | .45835 | .07748 |
| | Control group 3- Gel toothpaste | 35 | 5.6857 | .47101 | .07961 |
| | Control group 1- toothpaste | 35 | 5.6286 | .49024 | .08287 |
| | Test Group 1 toothpaste | 35 | 5.7143 | .45835 | .07748 |
| | Test Group 2 toothpaste | 35 | 5.3143 | .58266 | .09849 |
| | Total | 175 | 5.6114 | .51180 | .03869 |
| Tactile test score at 2 weeks | Control group 2- Gel | 35 | 5.2000 | .40584 | .06860 |
| | Control group 3- Gel toothpaste | 35 | 5.1143 | .32280 | .05456 |
| | Control group 1- toothpaste | 35 | 5.4286 | .50210 | .08487 |
| | Test Group 1 toothpaste | 35 | 4.9429 | .23550 | .03981 |
| | Test Group 2 toothpaste | 35 | 4.8000 | .40584 | .06860 |
| | Total | 175 | 5.0971 | .43779 | .03309 |
| Tactile test score at 4 weeks | Control group 2- Gel | 35 | 4.8857 | 1.27813 | .21604 |
| | Control group 3- Gel toothpaste | 35 | 4.7143 | 1.25021 | .21132 |
| | Control group 1- toothpaste | 35 | 5.2857 | .45835 | .07748 |
| | Test Group 1 toothpaste | 35 | 3.8571 | .97446 | .16471 |
| | Test Group 2 toothpaste | 35 | 3.5714 | .55761 | .09425 |
| | Total | 175 | 4.4629 | 1.15348 | .08719 |
| Tactile test score at 8 weeks | Control group 2- Gel | 35 | 4.6000 | 1.43895 | .24323 |
| | Control group 3- Gel toothpaste | 35 | 4.4000 | 1.75231 | .29619 |
| | Control group 1- toothpaste | 35 | 4.9714 | 1.01419 | .17143 |
| | Test Group 1 toothpaste | 35 | 3.2857 | 1.34101 | .22667 |
| | Test Group 2 toothpaste | 35 | 2.7143 | .75035 | .12683 |
| | Total | 175 | 3.9943 | 1.54807 | .11702 |

One way anova test to find out the tactile sensation among 5 groups at 4 different time intervals. It was found that Test Group 2 toothpaste and Test Group 1 toothpaste were showing highly significant reduction in tactile sensation at 8 weeks interval as compared to

Control group 2- Gel , Control group 1- toothpaste. Test Group 2 toothpaste is showing higher reduction in tactile sensation as compared to Test Group 1 toothpaste.

Table 5: Change from Baseline (CFB) Percentage Reduction of air blast test (ABT) (long term sensitivity relief) scores compared to ordinary fluoride toothpaste (control group 1 toothpaste); at various time points.

| Test Group | CFB% 2 weeks | CFB% 4 weeks | CFB% 8 weeks | "X" times Percent reduction hypersensitivity ABT at 8 weeks (as compared to least efficacy, i.e. Control group 1- toothpaste) |
|-----------------------------|-----------------|-----------------|-----------------|---|
| Control group 1- toothpaste | 1.81 | 9.08 | 14.50 | --- |
| Test Group 1 toothpaste | 10.50 | 43.80 | 50.80 | 3.50X |
| Test Group 2 toothpaste | 10.70 | 41.10 | 55.35 | 3.81X |

Table 5A: Change from Baseline (CFB) Percentage Reduction of air blast test (ABT) (long term sensitivity relief) scores compared to marketed gel containing only potassium nitrate (control group 2 gel); at various time intervals.

| Test Group | CFB% 2 weeks | CFB% 4 weeks | CFB% 8 weeks | "X" times Percent reduction hypersensitivity ABT at 8 weeks (as compared to Control group 2-gel) |
|----------------------------|-----------------|-----------------|-----------------|--|
| Control group 2 gel | 3.38 | 13.50 | 16.90 | ---- |
| Test Group 1 toothpaste | 10.50 | 43.80 | 50.80 | 3.00X |
| Test group 2 toothpaste | 10.70 | 41.10 | 55.35 | 3.15X |

Table 6: Change from Baseline (CFB) Percentage Reduction of tactile test (TT) (long term sensitivity relief) compared to ordinary fluoride toothpaste (control group 1 toothpaste); at various time intervals.

| Test group | CFB% 2 weeks | CFB% 4 weeks | CFB% 8 weeks | "X" times Percent reduction hypersensitivity TT at 8 weeks |
|-----------------------------|-----------------|-----------------|-----------------|--|
| Control group 1- toothpaste | 3.60 | 6.09 | 11.60 | ---- |
| Test Group 1 toothpaste | 13.40 | 32.50 | 42.50 | 3.66X |
| Test Group 2 toothpaste | 9.67 | 32.80 | 48.90 | 4.21X |

Table 6A: Change from Baseline (CFB) percentage Reduction of tactile test (TT) (long term sensitivity relief) scores compared to marketed gel containing only potassium nitrate (control group 2 gel); at various time intervals.

| Test group | CFB% 2 weeks | CFB% 4 weeks | CFB% 8 weeks | "X" times Percent reduction hypersensitivity TT at 8 weeks |
|-------------------------|-----------------|-----------------|-----------------|---|
| Control group 2 gel | 9% | 17.40% | 19.50% | ---- |
| Test Group 1 toothpaste | 13.40% | 32.50% | 42.50% | 2.18X |
| Test group 2 toothpaste | 9.67% | 32.80% | 48.90% | 2.50X |

It was found that the percentage reduction in air blast test scores and tactile score were greater in test group 1 toothpaste and test group 2 toothpaste when compared to control group 1 toothpaste and control group 2 gel.

DISCUSSION

Dentin hypersensitivity is a common oral health problem that can last for days, weeks or indefinitely unless treatment is provided.^[1] Some of the reasons for tooth hypersensitivity includes incorrect tooth brushing method and gingival recession.^[3] The clinical trial found a significant immediate pain reduction and a long-lasting sensitivity relief from tooth hypersensitivity after desensitizing toothpaste containing herbs and potassium nitrate or combination of potassium nitrate with hydroxyapatite was applied for 60 seconds to tooth dentine. The study was a practitioner-based clinical, and thus had the advantage of creating study patient accrual

rates. It also broadened the pool of study patients in clinical trials, thus making study results more generalizable.^[13]

A blast of compressed cold air delivered from a three-in-one syringe to the tested teeth was used in the dental clinics to assess hypersensitivity. This is a common assessment method that has been used in several clinical studies.^[14,17,18] The 5% potassium nitrate (KNO₃) desensitizing toothpaste is primarily for home use.^[2] This treatment is effective. Subjects, as well as the investigators, were blinded to their study group assignment. The second evaluation of self-perceived

sensitivity score was performed right after the 60 seconds of toothpaste application, the variations between subjects would be small and unlikely to affect the outcome measured.

Brushing with potassium nitrate containing toothpaste is effective in pain relief due to dentin hypersensitivity.^[15] Additionally, the hydroxyapatite is believed to occlude open dentins and thus provides relief in dental hypersensitivity. The trial suggests the synergistic effect of potassium nitrate containing toothpaste with the herbs used in formulation of test group 1 toothpaste. Another method of reducing the pain from tooth hypersensitivity is to occlude the open tubules to block the hydrodynamic mechanism.^[16] Test group 2 toothpaste suggest further synergy of herbs along with potassium nitrate and hydroxyapatite. Both the test products have shown statistically significant results when compared to control 1 toothpaste and control 2 gel when measured for long term sensitivity relief at 8 weeks. Superior efficacy when compared to Control 1 toothpaste that lacks sensitivity control agents. However, the superiority shown over Control 2 is of point of interest. Here the Test 1 and Test 2 formula containing an admixture of Herbs, Minerals and Essential Oils along with Potassium Nitrate is postulated to provide an edge over the regular Potassium Nitrate based gel product.

CONCLUSION

It can be concluded that test product 1 (Potassium Nitrate, Alum, Herbal Extracts, essential oil) and Test 2 (Potassium Nitrate, Hydroxyapatite, Alum, Herbal Extracts, essential oil) were found to be statistically significant in reducing the dentin hypersensitivity long-term when used for 8 weeks duration twice daily as compared to the two-control marketed products Control 1 and Control 2.

Test 1(Potassium Nitrate, Alum, Herbal Extracts, essential oil) and Test 2 (Potassium Nitrate, Hydroxyapatite, Alum, Herbal Extracts, essential oil) were effective for instant sensitivity dab on relief when compared to control 1 toothpaste.

There was no statistically significant comparison of Test 1(Potassium Nitrate, Alum, Herbal Extracts, essential oil) and Test 2(Potassium Nitrate, Hydroxyapatite, Alum, Herbal Extracts, essential oil) when compared to control group 3.

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