

## A Clinical Trial to Evaluate Efficacy of a Dentifrice Containing Sodium Fluoride & 8% Strontium Acetate, Strontium Acetate (in Herbal Base) and two Herbal Dentifrices in Reducing Dentinal Hypersensitivity

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### Abstract

**Background:** A parallel design clinical study evaluated reduction in dentin hypersensitivity after brushing for 6 weeks with Sensodyne Rapid relief toothpaste (containing sodium fluoride and strontium acetate), Dabur Hypersensitive toothpaste (containing strontium acetate and herbal extracts), Dabur Red toothpaste- with akarkara and Dabur Red toothpaste (containing herbal extracts). **Objective:** To evaluate and compare the efficacy of a dentifrice containing sodium fluoride and strontium acetate, strontium acetate (in herbal base) and two herbal dentifrices in reducing dentinal hypersensitivity. **Materials and Methods:** 139 outdoor patients (83 males, 56 females) in 20-60 years age group (mean age =  $33.36 \pm 9.87$  years); attending the OPD at Inderprastha Dental College and Hospital, Sahibabad - Ghaziabad, India; made up the study population. Subjects identified with two hypersensitive teeth using the tactile and air blast (Schiff's Scale) hypersensitivity methods were assigned to their treatment group. Dentin hypersensitivity and oral tissues were evaluated at baseline, immediately after the single application, 3 weeks and after 6 weeks. **Results:** The 6 week scores as compared to baseline scores for tactile and air blast tests in the two groups showed a reduction in tooth hypersensitivity. Test Product A (Sensodyne Rapid relief toothpaste) was found to reduce Tactile sensitivity better than Test Product B (Dabur Hyper sensitive toothpaste) and much better than Test Product C (Dabur Red Tooth Paste with akarkara) and D (Dabur Red Tooth Paste). But Test Product B was found to reduce Evaporative air blast sensitivity slightly better than Test Product A and much better than Test Product C, and D. Instant relief from dentin hypersensitivity was reported on single application with test products A (Sensodyne Rapid relief toothpaste) and B (Dabur Hyper sensitive toothpaste) but not with products C (Dabur Red Tooth Paste with akarkara) and D (Dabur Red Tooth Paste). **Conclusion:** Two of the four products reduced dentinal hypersensitivity in the study subjects at the end of the 6-week period. However, there was no statistically significant difference in reduction in hypersensitivity between these two products.

**Keywords:** Dentin Hypersensitivity; Herbal Dentifrices; Strontium Acetate; Sodium Fluoride; Instant Relief; Desensitizing Toothpastes.

### Introduction

The oral cavity presents an assorted variety of diseases, among which dental caries and periodontal disease are two of the most common. A less common yet painful condition affecting the oral cavity is dentinal hypersensitivity. Dentinal hypersensitivity has been recorded for over two millennia, and the earliest documented treatment method was opium

therapy, which dates back to 400 BC, being advocated as recently as 1000 AD. Dentin hypersensitivity, or what patients may describe as "sensitive teeth," is defined as a short, sharp pain arising from exposed dentin in response to thermal, evaporative, tactile, electrical, osmotic or chemical stimuli. It is widely accepted that dentin hypersensitivity is an uncomfortable condition that also affects function and quality of life [1].

Although sensitivity affects all ages, previous studies showed that there is a strong correlation between age and dentinal hypersensitivity. It was reported that dentin hypersensitivity was frequently seen between the ages of 20 and 50, but especially between the ages of 20 and 30 [2].

Dentin may become exposed by several means. The most common clinical cause of exposed dentinal tubules is gingival recession. The more bone loss that

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occurs, the more dentinal tubules are exposed, which results in more dental hypersensitivity. Brushing habits, diet, chewing tobacco and some diseases, including gastroesophageal reflux, can also cause dentin hypersensitivity. Extremely hard brushing, especially with hard-bristled brushes, is known to thin enamel and cause the gingiva to recede, exposing the softer subgingival cementum [3]. The uses of herbal remedies have assumed a global dimension. They are used in the treatment of various ailments in both developed as well as developing countries. More than 60% of the Chinese use herbal therapy and a significant part of the rural population in the Indian subcontinent rely on indigenous medical systems that use herbs, ash and heavy metals [4,5]. Dentinal hypersensitivity, while neither life-threatening nor a serious dental problem, can be a particularly uncomfortable and unpleasant sensation for patients and can dictate types of food and drink ingested. The condition is, nevertheless, of sufficient concern to warrant appropriate and proper management. In most instances, the condition can be managed by patients through appropriate home care using properly prescribed over-the-counter products.

A large number of treatment options are available for managing dentinal hypersensitivity [6]. Continued advances in science and technology have helped the development of multifunctional toothpastes that prevent or treat caries and gingivitis, remove stains, improve oral odor, and reduce tooth sensitivity. The commercial market is flooded with various brands of desensitizing dentifrices with different desensitizing agents. However, the ultimate test of any treatment is how well it works in alleviating the symptoms experienced by the patient, which is comprehended by the subjective opinion of the patient as well as that of the practitioner. Pain perception, however, is dependent on a number of variables, including the significance of pain, individual personality, psychological factors, cultural attitudes, anticipation of pain and degree of apprehension. The unreliability of subjective opinions alone necessitates that well-designed, double-blind, controlled clinical trials be conducted to scientifically establish the effectiveness of hypersensitivity treatment procedures [7].

Only a few studies have evaluated the effectiveness of the desensitizing agents *in vivo*. Hence, it was considered worthwhile to assess the efficacy of these desensitizing agents in providing short-term relief from dentin hypersensitivity and to help the clinician choose the most effective treatment solution for dentin hypersensitivity. There is a definite need to evaluate the effectiveness of these commercially available dentifrices, and the present study was conducted

with the purpose of comparing the efficacy of three herbal toothpastes as compared with other benchmark products in reducing dentinal hypersensitivity among the adult population in Ghaziabad, India.

### **Aim of the study**

To evaluate and compare the efficacy of a dentifrice containing sodium fluoride and strontium acetate, strontium acetate (in herbal base) and two herbal dentifrices in reducing dentinal hypersensitivity.

### **Materials and Methods**

The present study was a 6 weeks clinical trial on 139 OPD patients in the age group 20-60 years; attending Inderprastha Dental College and Hospital, Sahibabad- Ghaziabad, India. The permission to conduct the trial was obtained from the institutional ethical committee and prior informed consent was taken from the participants. This study was conducted during the period July- October 2013. Patients who visited the outpatient clinic of Inderprastha Dental College and Hospital, Sahibabad- Ghaziabad, India; for dental hypersensitivity complaints were assessed for inclusion into the study group. The exclusion criteria for the study were as follows: patients who had dental pathology causing pain similar to cervical dentinal hypersensitivity (such as teeth with caries, the presence of orthodontic appliances and restorations and/or the presence of a history of periodontal surgery in the area of the tooth during the previous three months), patients who had taken any medication, patients who received professional treatment with desensitizing agents in the previous six months, patients who received any treatment in the past 30 days, those patients who were pregnant or lactating and patients who had any systemic diseases and/or the presence of a vital bleaching history.

All enrolled participants underwent a thorough oral examination before entering the study. Then they were randomly put in four experimental groups viz. Group A: Toothpaste A/ Sensodyne Rapid relief Toothpaste; Group B: Toothpaste B/ Dabur Hyper sensitive toothpaste; Group C: Toothpaste C/ Dabur Red Tooth Paste with akarkara and Group D: Toothpaste D/ Dabur Red Tooth Paste. All subjects were advised to use their respective dentifrice with the toothbrushes provided to them (Colgate Zigzag

toothbrush with soft bristles; Colgate-Palmolive India Ltd.) by their regular brushing method twice daily for 6 weeks. The participants were told to restrict themselves to the test toothpastes to be tested and resort to no other active treatment intervention during the study period. They underwent thorough clinical examination on entry, 3 weeks and 6 weeks. The subjects were allowed to voluntarily withdraw from the study, though efforts were made to ascertain the reason for dropout. Sensitivity was assessed by means of tactile and evaporative stimuli. For the measurement of tactile hypersensitivity, the instrument was calibrated daily following manufacturer's instructions. Scores were recorded in terms of the quantified reproducible force that was required to elicit discomfort using the established procedures. Briefly, the subject was instructed to respond at the point where he or she first experienced discomfort. The explorer tip of the probe was applied to the buccal surface of each hypersensitive tooth at the CEJ. The explorer tip was stroked perpendicular to the tooth beginning at a pre-set force of 10 grams, and increased by 10-gram increments until the subject experienced discomfort, or until 50 grams of force was applied. For evaluating the air blast hypersensitivity, the tooth to be examined was isolated from the adjacent teeth (mesial and distal) by placing the examiner's fingers over the adjacent teeth. Air was delivered from a standard dental unit air syringe at 60 psi ( $\pm 5$  psi) and 72°F ( $\pm 3^\circ$ F), directed at the exposed buccal surface of the hypersensitive tooth for one second from a distance of approximately 1 cm. The Schiff Cold Air Sensitivity Scale was 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 oral soft and hard tissue examination included 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. All the stimuli were applied on the cervical region of the experimental teeth and the adjacent teeth were isolated with cotton rolls and a suction device [8]. The statistical software SPSS (version 16.0) was used to analyse the data and Microsoft excel have been used to generate graphs, tables, etc. The desensitizer agents were compared

in terms of mean values, and ANOVA was used for testing differences among the groups ( $p < 0.05$ ). For multiple comparisons to see significant differences is due to differences in which group Post hoc Bonferroni was applied.

#### *Presentation of toothpastes*

- ▲ Toothpaste A/ Sensodyne Rapid relief Tooth paste.  
Active ingredient: Strontium Acetate, Sodium Fluoride.
- ▲ Toothpaste B/ Dabur Hyper sensitive toothpaste  
Active ingredient: Strontium Acetate, Gairic powder, Herbal Extract (Anacylus pyrethrum, Piper nigrum, Piper longum, Zingiber officinale, Zanthoxylum armatum).
- ▲ Toothpaste C/ DRTP- A : Dabur Red Tooth Paste with akarkara.  
Active ingredient: Herbal Extract (Anacylus pyrethrum, Piper nigrum, Piper longum, Zingiber officinale, Zanthoxylum armatum), Gairic Powder.
- ▲ Toothpaste D/ DRTP: Dabur Red Tooth Paste  
Active ingredient: Herbal Extract (Piper nigrum, Piper longum, Zingiber officinale, Zanthoxylum armatum), Gairic Powder.  
Toothpastes B, C and D used in this study were manufactured by Dabur India Limited, India.

#### **Results**

140 adults (84 males, 56 females) in the age group 20-60 years (mean age =  $33.36 \pm 9.87$  years), attending the OPD at Inderprastha Dental College and Hospital, Sahibabad- Ghaziabad, India; made up the study population (Table 1, Graph 1). A total of 139 patients, 83 males (59.7%) and 56 females (40.3%), who were allotted four experimental groups (toothpastes A,B,C and D)), completed the 6 weeks clinical trial. Table 2 show the results of hypersensitivity scores by tactile and air-blast tests at baseline, 3 weeks and 6 weeks. Mean Tactile scores at baseline were 1.620/ 1.666/ 1.605 and 1.680 for A, B, C and D respectively. While Air blast scores for them were 5.220/ 5.713/ 5.216 and 5.740 for A, B, C and D respectively. At 6 weeks, the Tactile scores were 0.760/ 0.844/ 1.36 and 1.34 for A, B, C and D respectively and Air blast scores were 2.72/ 3.08/ 4.57 and 4.88 for A, B, C and D respectively.

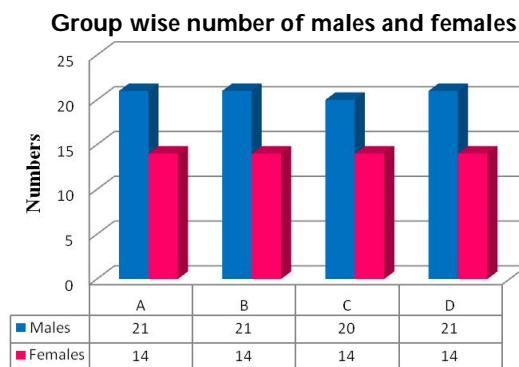
Table 2 & Table 3: Test Product A (Sensodyne Rapid relief toothpaste) was found to reduce Tactile sensitivity better than Test Product B (Dabur Hyper sensitive toothpaste) and much better than Test Product C (Dabur Red Tooth Paste with akarkara) and D (Dabur Red Tooth Paste). But Test Product B was found to reduce Evaporative air blast sensitivity slightly better than Test Product A and much better than Test Product C, and D.

On applying ANOVA test between Test Products A, B, C and D; there was significant difference for multiple comparison; to see significant differences is due to differences in which group post hoc Bonferroni was applied. There was no significant difference between Test Product A and B, also no significant difference between Test Product C and D. But there was highly significant difference of Test Products A and B with Test Products C and D.

**Table 1:** Demographic profile of subjects

	Group A	Group B	Group C	Group D	Total
Males [n (%)]	21 (60.0%)	21 (60.0%)	20 (58.82%)	21 (60.0%)	83 (59.71%)
Females [n (%)]	14 (40.0%)	14 (40.0%)	14 (41.18%)	14 (40.0%)	56 (40.29%)
Total [N (%)]	35 (100.0%)	35 (100.0%)	34 (100.0%)	35 (100.0%)	139 (100.0%)
Age [Mean ± (SD)]	32.69 (10.39)	33.28 (9.80)	33.76 (9.70)	33.71 (9.97)	33.36 (9.87)

**Graph 1:** Gender Distribution of subjects



**Table 2:** Hypersensitivity scores for subjects (at Baseline, 3 weeks and 6 weeks)

		N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean	
						Lower Bound	Upper Bound
Tactile Test Score At BaseLine	A	35	1.6200	.33589	.05678	1.5046	1.7354
	B	35	1.6667	.30332	.05055	1.5640	1.7693
	C	34	1.6054	.46365	.07622	1.4508	1.7600
	D	35	1.6800	.30370	.05134	1.5757	1.7843
	Total	139	1.6427	.35672	.02983	1.5837	1.7016
Tactile Test Score After 3 Weeks	A	35	.9000	.19251	.03254	.8339	.9661
	B	35	.9833	.19494	.03249	.9174	1.0493
	C	34	1.4459	.42334	.06960	1.3048	1.5871
	D	35	1.4200	.26767	.04524	1.3281	1.5119
	Total	139	1.1895	.37748	.03157	1.1271	1.2519
Tactile Test Score After 6 Weeks	A	35	.7600	.15185	.02567	.7078	.8122
	B	35	.8444	.18738	.03123	.7810	.9078
	C	34	1.3649	.41847	.06880	1.2253	1.5044
	D	35	1.3400	.26144	.04419	1.2502	1.4298
	Total	139	1.0797	.38994	.03261	1.0153	1.1442
Evaporative Air Blast Test Score At Base Line	A	35	5.2200	.74114	.12528	4.9654	5.4746
	B	35	5.7139	.84791	.14132	5.4270	6.0008
	C	34	5.2162	.76176	.12523	4.9622	5.4702
	D	35	5.7400	.84547	.14291	5.4496	6.0304
	Total	139	5.4706	.83200	.06958	5.3331	5.6082
Evaporative Air Blast Test Score After 3 Weeks	A	35	3.5200	.43710	.07388	3.3698	3.6702
	B	35	3.9972	.61667	.10278	3.7886	4.2059
	C	34	4.7973	.68576	.11274	4.5687	5.0259
	D	35	5.1600	.75272	.12723	4.9014	5.4186
	Total	139	4.3720	.89948	.07522	4.2233	4.5207
Evaporative Air Blast Test Score After 6 Weeks	A	35	2.7200	.41288	.06979	2.5782	2.8618
	B	35	3.0833	.55678	.09280	2.8949	3.2717
	C	34	4.5757	.65718	.10804	4.3566	4.7948
	D	35	4.8800	.68333	.11550	4.6453	5.1147
	Total	139	3.8203	1.09548	.09161	3.6392	4.0014

**Table 3:** Reductions in Hypersensitivity tests score for subjects (at 3 weeks and 6 weeks)

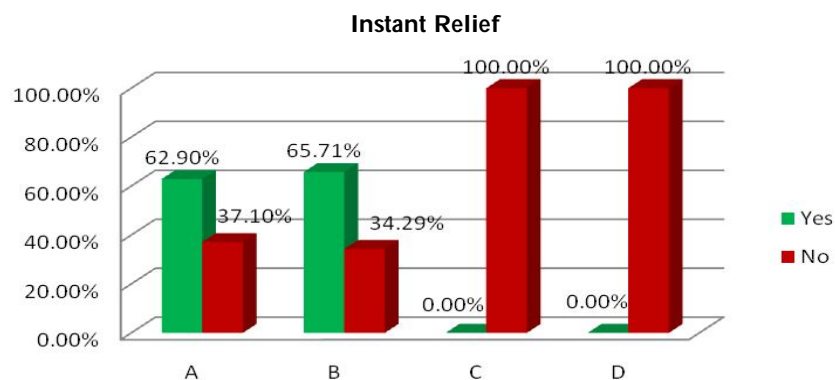
						95% Confidence Interval for Mean	
		N	Mean	Std. Deviation	Std. Error	Lower Bound	Upper Bound
Difference in Tactile Test Score	A	35	.7200	.14912	.02521	.6688	.7712
	B	35	.6833	.11832	.01972	.6433	.7234
	C	34	.1595	.04977	.00818	.1429	.1761
	D	35	.2600	.04971	.00840	.2429	.2771
	Total	139	.4531	.26953	.02254	.4086	.4977
Difference in Tactile Test Score	A	35	.8600	.18818	.03181	.7954	.9246
	B	35	.8222	.11738	.01956	.7825	.8619
	C	34	.2405	.04977	.00818	.2239	.2571
	D	35	.3400	.04971	.00840	.3229	.3571
	Total	139	.5629	.30203	.02526	.5130	.6129
Difference in Evaporative air blast Score	A	35	1.7000	.30774	.05202	1.5943	1.8057
	B	35	1.7167	.26458	.04410	1.6271	1.8062
	C	34	.4189	.07760	.01276	.3930	.4448
	D	35	.5800	.09941	.01680	.5459	.6141
	Total	139	1.0986	.64535	.05397	.9919	1.2053
Difference in Evaporative air blast Score	A	35	2.5000	.33343	.05636	2.3855	2.6145
	B	35	2.6306	.29935	.04989	2.5293	2.7318
	C	34	.6405	.10661	.01753	.6050	.6761
	D	35	.8600	.16485	.02787	.8034	.9166
	Total	139	1.6503	.94830	.07930	1.4936	1.8071

**Table 4:** Instant Relief from dentinal hypersensitivity in 4 groups

Group	Instant Relief		
	Yes	No	Total
A	22 (62.9%)	13 (37.1%)	35 (100.0%)
B	23 (65.71%)	12 (34.29%)	35 (100.0%)
C	00 (00.0%)	34 (100.0%)	34 (100.0%)
D	00 (00.0%)	35 (100.0%)	35 (100.0%)
Total	45 (32.37%)	94 (67.63%)	139 (100.0%)

Fischer Exact Test – 77.248, (p – value = < .001)

**Graph 2:** Instant relief in different study groups



Instant relief from dentin hypersensitivity was reported on single application with test products A (Sensodyne Rapid relief toothpaste) and B (Dabur Hyper sensitive toothpaste) but not with products C (Dabur Red Tooth Paste with akarkara) and D (Dabur Red Tooth Paste).

## Discussion

Dentinal hypersensitivity is one of the common complaints encountered in clinical practice and the ultimate goal in treatment of dentin hypersensitivity is the immediate and permanent relief of discomfort and/

or pain. In 1884, Calvo wrote that “there is a great need of a medicament, which while lessening the sensibility of dentine, will not impair the vitality of the pulp.” In spite of a considerable amount of research toward this objective over the past 100 years, the clinical management of hypersensitive teeth is largely empirical [9].

Dentin hypersensitivity is one of the most common and uncomfortable conditions affecting oral comfort and function. Studies regarding the prevalence of cervical dentin hypersensitivity have reported that 4% to 57% of adults experience cervical dentin hypersensitivity in one or more teeth [10].

At-home methods tend to be simple and inexpensive and can simultaneously treat generalized dentinal hypersensitivity affecting many teeth. Toothpastes are the most widely used dentifrices for delivering over-the-counter desensitizing agents. The duration for most studies that examined the effects of reducing dentinal hypersensitivity ranged from 4 to 12 weeks [11,12].

The present study evaluated the clinical effectiveness of four commercial dentifrices in reducing dentin hypersensitivity immediately after a single self-application, as well as after a subsequent twice-daily brushing for a period of 6 weeks. The test toothpaste contained 8% strontium acetate and 1040 ppm fluoride as NaF in a silica base, marketed as Sensodyne Rapid relief. The other three test products had herbal ingredients as already mentioned.

There has been growing interest in natural products especially in dentistry. The herbs which have properties to influence on oral health have been of interest in people. Various herbs and strontium acetate in combination; exhibits synergistic effect which helps to maintain oral health and provide relief from dentin hypersensitivity along with protection against dental diseases.

## Conclusion

The results of the present study show that two of four test products were effective in reducing the dentinal hypersensitivity of the study subjects over a 6-week period. However, Dabur Hypersensitive toothpaste might provide a means of alleviation of dentinal hypersensitivity at a reduced cost, which may be an important factor in developing countries such as India. However, there was no statistically significant difference between the two herbal products (C and D) tested. With a burgeoning middle-class in developing countries like India, the product B could find more usage considering that is proven to be as effective as established benchmarks, while concurrently more cost-effective.

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