

# A randomized single blind clinical trial to evaluate the safety and efficacy of Himalaya Herbal Dental Cream

SHAMA RAO H.N., AVINASH S., RIMPAL RAO, PRALHAD S. PATKI, MITRA S.K.

## ABSTRACT

The aim of the study was to evaluate the efficacy and safety of Himalaya Herbal Dental Cream in comparison to fluoride dental cream. 30 patients with established dental plaque were randomly assigned to either Himalaya Herbal Dental Cream or fluoride dental cream group for 6 weeks in a single blind design. Improvement in plaque index, oral hygiene status and gingival index was evaluated in these patients.

The study indicated a significant reduction in plaque index, gingival index and improvement in hygiene index in both the groups. No adverse effects occurred and the dental creams were well tolerated. This study indicates that Himalaya Herbal Dental Cream is as safe and effective as fluoride dental cream. It has better acceptance by the patients.

## INTRODUCTION

Dental caries is decay of tooth structure resulting from acid production by bacteria residing in dental plaque. Caries extensive enough to expose the pulp can cause sensitivity and pain; advance caries can cause infection. Some of the causes of dental caries include inadequate oral hygiene, infrequent dental examinations and cleanings, salivary gland dysfunction, frequent snacking and removable partial dentures, which can trap plaque around teeth and create an environment conducive to caries formation<sup>1,2</sup>.

The single best way to remove harmful plaque from teeth and gums is to brush teeth regularly and properly<sup>3</sup>. Brushing with toothpaste helps remove plaque, resist decay, promote remineralization, clean and polish teeth, remove teeth stains etc. A number of anti-plaque agents in dental creams have been formulated and evaluated for the management of

dental plaque<sup>4</sup>. The commonly used synthetic dentifrices comprises of chemical agents which are known to produce harmful side effects on prolonged use. Ayurveda describes different methods for regular practice to maintain optimal dental health. Himalaya Herbal Dental Cream is a recently launched dental cream which consists of powders of *Ajamoda satva*, *Vaikranta bhasma* and *Azadirachta indica*, and extracts of *Zantoxylum alatum*, *Punica granatum*, *Acacia arabica*, *Vitex negundo*, *Embelia ribes* and *Triphala*<sup>5</sup>. A single blind comparative study was conducted to compare the safety and efficacy of novel Herbal Dental Cream vis a vis Fluoride Dental Cream in patients with dental plaque.

## MATERIALS AND METHODS

### Procedure

Adult patients, both males and females, attending the out patient dept., of Dental Care Centre, Malleshwaram, Bangalore were evaluated for dental caries during June and September 2008. Patients with a minimum of 20 permanent dentures having dental plaque but showed good health were included in the study. Pregnant women, patients with orthodontic appliances or history or allergy to any medication were excluded from the study. Patients were randomly assigned, using latin square to receive either Himalaya Herbal Dental Cream or fluoride dental cream

in a single blind fashion. They received the dental creams in the form of a tube containing 100 gms. The patients underwent systematic dental examination for caries, plaque, gingival bleeding, bleeding index and gingival index. The patients were asked to brush their teeth twice a day with the assigned dental cream for 6 weeks. They were told to refrain from other toothpastes except the directed ones. Patient's compliance was monitored using compliance chart which were provided to them at the beginning of the study. Adverse effects if any were recorded during each visit for a period of 6 weeks. The patients underwent dental checkup on entry, at 4<sup>th</sup> week and 6<sup>th</sup> week.

### Statistical analysis

The results obtained were analysed by using ANOVA.

## RESULTS

All the 30 patients (15 on Himalaya Herbal Dental Cream and 15 on Fluoride Dental Cream) completed the study. The mean age of the patients in Himalaya Dental Cream was  $32.25 \pm 8.2$  and  $33.17 \pm 7.8$  years in Fluoride Dental Cream group. Both the groups were comparable on entry regarding dental parameters like plaque index, gingival index, bleeding index and oral hygiene score. Plaque index, oral hygiene index and gingival index showed a significant linear

Dr. H.N. Shama Rao\*, MDS.,  
Dr. Avinash S. MDS.,  
Dr. Rimpal Rao, BDS.,  
Dental Care Centre, Malleshwaram, Bangalore.  
\*Principal, M.S. Ramaiya Dental College, Bangalore.  
Dr. Pralhad S. Patki\*, M.D.,  
Head - Medical Services & Clinical Trials  
Dr. S.K. Mitra, M.D.,  
Executive Director,  
R&D Center, The Himalaya Drug Company,  
Bangalore-562 123 (India).  
\*Corresponding author.

Specially Contributed to "The Antiseptic"  
Vol. 105 No. 12 & P : 601 - 602

decrease from base line at 4<sup>th</sup> week and 6<sup>th</sup> week. However, there was no significant difference between the parameters measured in the 2 groups. None of the patients showed any adverse effects with either of the creams. More patients on herbal dental cream said that they would like to use it again (12/15 in Himalaya Herbal Dental Cream group and 8/15 in Fluoride Dental Cream group).

## DISCUSSION

Lately, there has been growing interest in natural products especially in dentistry. Even though the studies in animal and *in vitro* may show the beneficial properties of several of these products, there is no other way of knowing their real clinical benefit without conducting a randomized clinical trial<sup>6-8</sup>.

The primary etiology factor for dental disease is plaque. The formation of the plaque on the teeth is characterized by progression and deposition of bacterial flora leading to dental plaque. This leads to both the surfaces getting coated with defense, complex microbial community. The bacterial activity of the fluoride dental cream is due to fluoride and triclosan<sup>9</sup>. But studies have shown that fluoride may lead to adverse effects like dental and skeletal fluorosis. Herbal medicine has made significant contribution to modern medical practice and a number of plants have been proved to be of great help in maintaining dental hygiene. In many plaque studies in the dental research literature, Quigley-Hein index as originally published or a modified by Turesky, Gilmore and Glickman<sup>10</sup> has been one of the primary methods used to evaluate the anti plaque effectiveness of test agents or products. Recently, the modified gingival margin plaque index has been developed to measure plaque length along with the gingival margin of the facial surfaces of all natural teeth<sup>11</sup>.

Present study indicates good efficacy and safety of Himalaya dental cream. Its ingredients may be working synergistically to achieve the beneficial effects<sup>12-16</sup>.

**Table 1: Demographic data**

Parameter	Himalaya Herbal Dental Cream (n=15)	Fluoride Dental Cream (n=15)
Age ( years )	32.25 ± 8.2	33.17 ± 7.8
Mean weight (kg)	53.85 ± 6.3	51.62 ± 7.14
Sex ratio (M:F)	9:6	8:7
Diet (Veg:Nonveg)	7:8	10:5
Smokers	6	7
Plaque index	1.31 ± 0.41	1.24 ± 0.38
Gingival index	1.11 ± 0.36	1.03 ± 0.23
Bleeding index	2.35 ± 0.39	2.44 ± 0.40
Oral hygiene score	4.27 ± 0.40	4.25 ± 0.32

Values represent mean ± SD

**Table 2: Effect of Himalaya Herbal Dental Cream on dental parameters**

Parameters	Himalaya Herbal Dental Cream(n=15)			Fluoride Dental Cream(n=15)		
	Baseline	4 <sup>th</sup> week	6 <sup>th</sup> week	Baseline	4 <sup>th</sup> week	6 <sup>th</sup> week
Plaque index	1.31 ± 0.41	0.86 ± 0.36*	0.55 ± 0.29*	1.24 ± 0.38	0.92 ± 0.26*	0.54 ± 0.21*
Gingival index	1.11 ± 0.36	0.72 ± 0.36*	0.57 ± 0.29*	1.03 ± 0.23	0.71 ± 0.27*	0.59 ± 0.23*
Bleeding index	2.35 ± 0.39	2.16 ± 0.74*	1.88 ± 0.69*	2.44 ± 0.40	2.17 ± 0.48*	1.93 ± 0.71*
Oral hygiene score	4.27 ± 0.40	3.19 ± 0.18*	2.79 ± 0.51*	4.25 ± 0.32	3.52 ± 0.20*	2.81 ± 0.27*

\**p*<0.05 as compared to respective week 0 values

## CONCLUSION

The present study indicates comparable efficacy and safety of Himalaya Herbal Dental Cream in the management of dental plaque and is as safe and effective as fluoride dental cream. It can be inferred, by our results, that the Himalaya Herbal Dental Cream was as efficacious as the one with fluoride and may be an advantageous alternative for people interested in natural products.

## REFERENCES

- Patro BK, Ravikumar B, Goswami A, Mathur VP. Prevalence of dental caries among adults and elderly in an urban colony of New Delhi. *Indian J. Dental Res.* 2008; 19: 95-98.
- Carranza FA Jr. Glickman's Clinical Periodontology. 7<sup>th</sup> Asian Edition, W.B. Saunders: 1990; 342-372 and 684-711.
- Binney A, Addy M, Newcombe RG. The plaque removal effects of single rinsings and brushings. *J Periodontol* 1993; 64: 181-185.
- Batwa M, Bergstrom J. The effectiveness of chewing sticks Meswak on plaque removal. *Saudi Dental J* 2006; 18: 125-133.
- Limsong J, Benjavongkulchai E, Kuvatanasuchati J. Inhibitory effect of some herbal extracts on adherence of *Streptococcus mutans*. *J Ethnopharmacol* 2004; 92: 281-289.

- Fabiana O, Claudio MP, Ana VI, Wellington P, *et al.* Efficacy of a herbal toothpaste on patients with established gingivitis – a randomized controlled trial. *Braz Oral Res* 2006; 20(2): 172-177.
- Mullaly BH, James JA, Coulter WA, Linden GJ. The efficacy of a herbal based toothpaste on the control of plaque and gingivitis. *J Clin Periodontol* 1995; 22: 685-689.
- Pannuti CM, Mattos JP, Ranoya PN, *et al.* Clinical effect of a herbal dentifrice on the control of plaque and gingivitis. *Pesq Odontol Bras* 1962; 25: 26-29.
- Susheela AK. Dental fluorosis. In: *A Treatise on Fluorosis. Fluorosis Research and Rural Developmental Foundation, Delhi: 2003:43-57.*
- Turkey S, Gilmore NO, Glickman I. Reduced plaque formation by the chloromethyl analog of vitamin C. *J Periodontol* 1970; 41: 41-43.
- Addy M. Chlorhexidine compared with other locally delivered antimicrobials. *J Clin Periodontol* 1986; 13: 957-964.
- Wolinsky LE, Mania S, Nachnani S, Ling S. The inhibiting effect of aqueous *Azadirachta indica* (Neem) extract up on bacterial properties influencing *in vitro* plaque formation. *J Dent Res* 1996; 75: 816-822.
- Pai MR, Acharya LD, Udupa N. Evaluation of antiplaque activity of *Azadirachta indica* leaf extract gel. *J Ethnopharmacol* 2004; 90: 99-103.
- Satvaha G, Yotnuengnit P, Booncag P. Adjunctive periodontal treatment with *Centella asiatica* and *Punica granatum* extracts: A preliminary study. *J Int Acad Periodontol* 2003; 5: 106-107.
- Clark DT, Gazi MI, Cox SW, Eley BM, Tinsley AF. The effect of *Acacia arabica* gum on the *in vitro* growth and protease activities of periodontopathic bacteria. *J Clin Periodontol* 1993; 20: 238-243.
- Chitra M, Devi CS, Sukumar E. Antibacterial activity of embelin. *FitoTerapia* 2003; 74: 401-403.