Original Article

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Comparison of Clinical Efficacy of Two Herbal Dentifrices in Control of Plaque induced Gingivitis: A double Blind Clinical Trial

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Abstract

Background: Herbal products, including dentifrices, appear to have become an attractive alternative for some consumers and their use has gained appreciable acceptance all over the world. A double-blinded controlled clinical trial was designed to investigate the effectiveness of two herbal-based toothpastes containing different active ingredients in the control of plaque and gingivitis. The efficacy of Dabur- New Meswak over Dabur- Old Meswak toothpaste was assessed in this study. *Objective:* To evaluate and compare the clinical efficacy of two herbal dentifrices containing different active ingredients in control of plaque induced gingivitis. *Materials and Methods:* 80 subjects with gingivitis participated in the study. All participants had at least 20 natural teeth with no probing depths greater than 3 mm and a plaque index score of 2 or more at baseline. At baseline, the clinical parameters like plaque index (PI), gingival index (GI) and gingival bleeding index (GBI) were estimated. Paired t-test was used to compare the difference within the groups and unpaired t-test was used to compare the difference between the groups at baseline and at 6 weeks. *Results:* A total of 80 adults (41 males and 39 females), who were allotted two experimental groups (New Meswak and Old Meswak), completed the 6 weeks clinical trial. At the end of the study, there were statistically significant reductions in the PI, GI and gingival bleeding scores within the test group. However, there were no statistically significant differences between two groups. *Conclusion:* Continuous application of herbal tooth pastes provided significant improvement of oral hygiene level in patients with plaque –induced gingivitis. It was however concluded that the Dabur- New Meswak toothpaste was as effective as the Dabur- Old Meswak in the control of plaque and gingivitis.

Keywords: Herbal Dentifrices; Dental Plaque; Gingivitis; Plaque Inhibition; Plaque Index (PI); Gingival Index (GI); Gingival Bleeding Index (GBI); Oral Hygiene.

Introduction

Gingivitis, the mildest form of periodontal disease, is an inflammatory process confined to the gingiva. It is caused by a nonspecific, long-term accumulation of plaque on the teeth and is usually reversible. Plaque-induced gingivitis is the most common form of periodontal disease. There is ample evidence to implicate dental plaque as the primary etiological agent response for inflammatory gingival and periodontal disease [1].

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Herbal products, including dentifrices, appear to have become an attractive alternative for some consumers and their use has gained appreciable acceptance all over the world. This could be partly due to the perception that herbal toothpastes like other herbal products are "natural", devoid of chemicals and therefore superior to regular toothpastes. 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. This alternative form of therapy appears to be the latest fad, as a number of herbal products are readily available to consumers. Dentifrices are commonly used for oral hygiene with some formulated with antimicrobial herbal agents to control plaque [2,3]. There is little information regarding the effects of dentifrices on controlling dental plaque and gingivitis amongst Indian subjects. A number of articles have been written on the efficacy or otherwise of herbal dentifrices. Some reports indicate that the lack of a

consensus among dental professionals on the subject matter has made it difficult for dentists to provide information on the product safety and efficacy. A dearth of scientific studies on natural and herbal products in peer reviewed dental literature has also been cited as posing a conundrum for health care professionals in dealing with these products. In addition, few research efforts have been directed toward addressing the potency or quality of herbal ingredients used in these dental products. Reports have also indicated that since only a limited number of in vivo studies on herbal dentifrices have been published, it has not been determined whether they are superior, equivalent or substandard to conventional dentifrices in reducing plaque.

Toothpaste may be classed as either a cosmetic or a medicine depending on the claims that are made and the level of certain constituents. The primary function of toothpaste is to clean the teeth; which is considered to be a cosmetic benefit. The use of words such as 'protects', 'cleans', 'freshens breath', 'fights bacteria which may cause gum problems', 'whitens' or 'fights tartar' are considered to be cosmetic claims. A medicine is considered to be any substance used wholly or mainly for the purpose of treating or preventing disease. Claims such as 'reduces hypersensitivity, 'reduces gingivitis', 'reduces gingival bleeding' or 'controls periodontitis', "prevents/treats dental caries" are medicinal claims. As some of these substances may have undesirable side effects, such as tooth staining and taste alteration, phytotherapic agents with antimicrobial and anti inflammatory properties have been investigated [4,5].

The main purpose of this study was to evaluate the effectiveness of two herbal toothpastes for the improvement of oral hygiene and the reduction of gingival inflammation in patients with gingivitis.

Aim of the Study

To evaluate and compare the clinical efficacy of two herbal dentifrices containing different active ingredients in Control of Plaque induced Gingivitis after twice-daily brushing for a period of 6 weeks.

Materials and Methods

A convenient sample size of 80 subjects aged between 20 and 60 years was selected for the study. 80 adult subjects (41 males and 39 females) from the OPD, Inderprastha Dental College and Hospital, Sahibabad- Ghaziabad, India were enrolled in this double-blind, controlled clinical trial. The permission to conduct the trial was obtained from the institutional ethical committee (IEC). All randomly screened participants were informed about the nature of the study and signed an informed consent form. Selected subjects had to have at least 20 natural teeth and no periodontal pockets greater than 3 mm, with a gingival index ≥1 at more than 60% of the sites examined. At baseline, all the subjects had to have a plaque index of greater than 2, as measured by Turesky et al. in 1970 (modification of the Quigley Hein plaque index, 1962) and gingival index (Loe and Sillness) were also recorded. The random allocation sequence was generated and was concealed from the main investigator. The investigator and the study subjects were unaware of the contents of each toothpaste. This study was conducted during August 2016 to October 2016. The subjects were entered in this study based upon the following criteria:

The Subjects

- Had to be between the ages between 20-60 years, in generally good health and had to have signed an Informed Consent form
- Had to be available for the duration of the study
- Had to possess at least 20 uncrowned permanent natural teeth (excluding third molars)
- With plaque index (PI) scores ≥1.5 according to the Quigley-Hein PI scoring procedure and a gingival index (GI) score ≥1.0
- Had to perform adequate oral hygiene with no signs of oral neglect, good periodontal health and no >5 periodontal pockets of 5 mm.

The Subjects were Excluded if

- They had five or more decayed untreated dental sites at screening, other disease of the hard or soft oral tissues,or impaired salivary function.
- They had taken medications that could affect the study outcome, including but not limited to certain antibiotics or antimicrobial drugs, within 1-month prior to the start of the study or while participating in the study.
- They were pregnant or lactating women.
- Individuals who were participating in any other clinical study or who had participated in a study within 1-month prior to enrollment.
- They presented orthodontic bands; or partial or removable dentures; or received a dental prophylaxis anytime during the 2-week prior to the first dental examination.

- They had a history of tobacco, alcohol or drug abuse.
- They had a history of allergies to the test products, or allergies to oral care/personal care consumer products or their ingredients.
- They had used a triclosan-containing dentifrice up to 3 months prior to the start of the study.

They were randomly assigned to one of two treatment groups according to baseline gingival and plaque indices scores: (1) A dentifrice containing Meswak Extract, Zinc gluconate and p-thymol (New Meswak), and (2) a dentifrice containing Meswak Extract and triclosan (Old Meswak). After 6-weeks use of their assigned dentifrice, all subjects were recalled for post treatment plaque and GI examinations. 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 herbal toothpastes to be tested and resort to no other active treatment intervention during the study period. The tubes containing the dentifrices were previously coded to warrant that neither the examiner nor the volunteers knew their content, which was revealed only after completion of the study. The subjects were asked to return their dentifrice tubes that were weighted by a digital balance previously and after the trial, so that compliance could be indirectly evaluated. They were instructed to refrain from all other oral hygiene products (including mints, chewing gums, mouth rinses).. The statistical software SPSS (version 16.0) was used to analysis of the data and Microsoft excel have been used to generate graphs, tables, etc.

Presentation of Toothpastes

Toothpastes used in this study were manufactured by Dabur India Limited, India.

AS 206 (New Meswak)/ Group 1

Ingredients: Calcium carbonate, Sorbitol, Water, Silica, Sodium lauryl sulphate, Flavour, Meswak Extract, Cellulose gum, Carrageenan, Sodium Silicate, PVM/MA Copolymer, Sodium Saccharin, Zinc gluconate, Sodium Benzoate, Benzyl alcohol, CI 77891, p-Thymol.

SK 104 (Old Meswak)/ Group 2

Ingredients

Calcium carbonate, Sorbitol, Water, Silica, Sodium lauryl sulphate, Flavour, Meswak Extract, Cellulose gum, Carrageenan, Sodium Silicate, PVM/MA Copolymer, Sodium Saccharin, Sodium Benzoate, CI 77891, Triclosan.

Results

80 adult subjects (41 males and 39 females) in the age group 20-60 years from the OPD, Inderprastha Dental College and Hospital, Sahibabad- Ghaziabad, India completed the 6 weeks clinical trial. The test dentifrices had a good acceptance and did not show adverse effects, such as formation of abscess and ulcerations or allergic reactions. The data were found to be normally distributed and comparisons were analyzed by the t-test. Data obtained from the study are represented in the given tables and graphs.

The subjects in Group 1 (New Meswak) had a mean age of 36.40 ± 10.97 years; while Group 2 (Old Meswak) had a mean age of 36.28 ± 9.75 years (Table 1). Gender distribution is shown in graph 1. At day 0 (i.e. Baseline), in all the data collected, most of study subjects were showing quite similar scores of GI, PI, GBI for all groups, that means they were well balanced. It was found that:

1. Both test products (AS 206 and SK 104) were found to be significantly reducing plaque, gingival and gingival bleeding scores at the end of 6 weeks clinical trial period.
2. The difference in decrease in plaque, gingivitis and gingival bleeding sites was statistically non significant between two test products AS206 (New Meswak) and SK104 (Old Meswak); after twice-daily brushing for a period of 6 weeks.

Signs of gingival inflammation reduced significantly in both herbal test groups. Intra-group comparisons in the test groups using t-test for PI, GI and GBI showed a statistically significant difference in the plaque and gingival scores. When a comparison was made, using the unpaired t-test, between the test and the control groups for the PI, GI and GBI; no statistically significant difference was obtained.

Adverse Events

Throughout the study, there were no adverse events on the oral soft and hard tissue of the oral cavity observed by the examiner, or reported by the subjects when questioned.

Table 1: Age distribution of subjects

Group	Age (in years)	
	Mean	SD
AS206	36.40	10.977
SK104	36.28	9.751
Total	36.34	10.316

Table 2a: Intra and Inter-group comparison of plaque index (PI) values

Group	Baseline		3 Weeks		6 Weeks	
	Mean	SD	Mean	SD	Mean	SD
AS206	1.530	0.2643	1.318	0.1999	1.138	0.1659
SK104	1.510	0.2499	1.300	0.2075	1.118	0.1880
Independent t test	0.348		0.384		0.505	
p - value	0.729		0.702		0.615	

Plaque was found to be reducing in both groups at 3 weeks and 6 weeks, but there was insignificant difference between AS206 and SK104 at 3 weeks and 6 weeks.

Table 2b: Decrease in mean values of PI

Group	3 Weeks - Baseline		6 Weeks – Baseline	
	Mean	SD	Mean	SD
AS206	0.2125	0.0722	0.3925	0.1118
SK104	0.2100	0.0545	0.3925	0.0693
Independent t test	0.175		0.000	
p - value	0.862		1.000	

Plaque was found to be reducing more in AS206 compared to SK104 at 3 weeks but reduced equally at 6 weeks; but difference in decrease in plaque was insignificant between AS206 and SK104 at 3 weeks and 6 weeks.

Table 3a: Intra and Inter-group comparison of Gingival index (GI) values

Group	Baseline		3 Weeks		6 Weeks	
	Mean	SD	Mean	SD	Mean	SD
AS206	0.840	0.1215	0.748	0.0905	0.680	0.0758
SK104	0.880	0.1181	0.780	0.0758	0.700	0.0784
Independent t test	1.493		1.741		1.160	
p - value	0.140		0.086		0.250	

Gingivitis was found to be reducing in both groups at 3 weeks and 6 weeks, but there was insignificant difference between AS206 and SK104 at 3 weeks and 6 weeks.

Table 3b: Decrease in mean values of GI

Group	3 Weeks - Baseline		6 Weeks – Baseline	
	Mean	SD	Mean	SD
AS206	0.0925	0.0693	0.1600	0.0671
SK104	0.1000	0.0640	0.1800	0.0607
Independent t test	0.502		1.396	
p - value	0.617		0.167	

Gingivitis was found to be reducing more in SK104 compared to AS206 at 3 weeks and 6 weeks; but difference in decrease in gingivitis was insignificant between AS206 and SK104 at 3 weeks and 6 weeks.

Table 4a: Intra and Inter-group comparison of Gingival Bleeding index (GBI) values

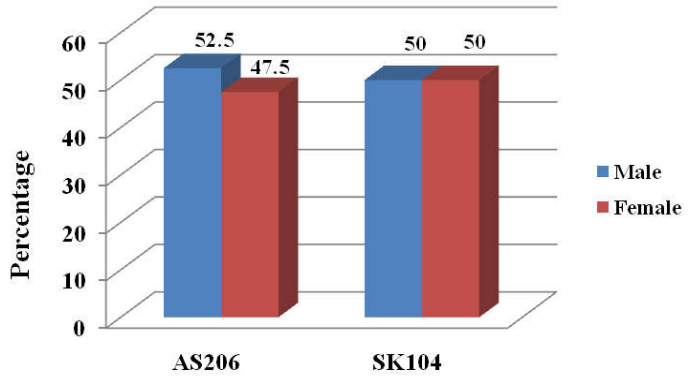
Group	Baseline		3 Weeks		6 Weeks	
	Mean	SD	Mean	SD	Mean	SD
AS206	3.6000	0.9281	1.6500	0.5795	0.2500	0.4385
SK104	3.8000	0.8828	1.7000	0.4641	0.2000	0.4051
Independent t test	0.987		0.426		0.530	
p - value	0.326		0.671		0.598	

Gingival Bleeding Sites was found to be reducing in both groups at 3 weeks and 6 weeks, but there was insignificant difference between AS206 and SK104 at 3 weeks and 6 weeks.

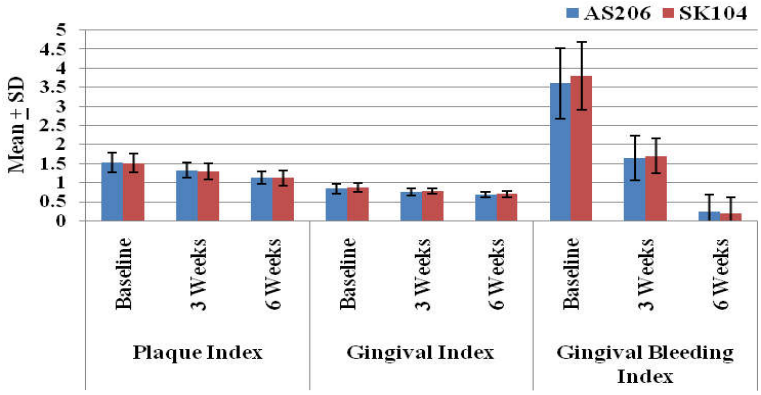
Table 4b: Decrease in mean values of GBI

Group	3 Weeks - Baseline		6 Weeks - Baseline	
	Mean	SD	Mean	SD
AS206	1.9500	0.5970	3.3500	0.6621
SK104	2.1000	0.5453	3.6000	0.6717
Independent t test	1.173		1.676	
p – value	0.244		0.098	

Gingival Bleeding Sites was found to be reducing more in SK104 compared to AS206 at 3 weeks, 6 weeks and between 3 weeks to 6 weeks, but difference in decrease in gingival bleeding sites was insignificant between AS206 and SK104 at 3 weeks and 6 weeks.

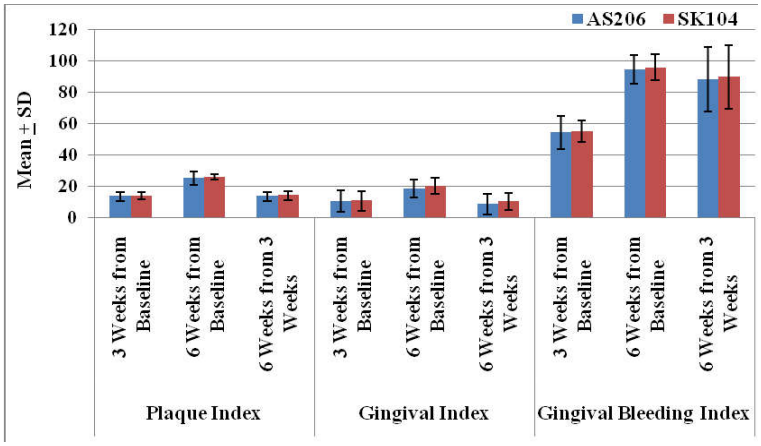


Graph 1: Genderwise distribution of subjects



Graph 2: Mean values of PI, GI, GBI at baseline, 3 weeks, 6 weeks

Percentage wise difference in decrease in plaque, gingivitis, gingival bleeding sites was statistically non significant between AS206 and SK104 at 3 weeks and 6 weeks.



Graph 3: Percentage Reductions in PI, GI and GBI

Discussion

Plaque control is the foundation of any attempt to prevent and control periodontal disease. It is well accepted that most people fail to achieve a level of oral hygiene commensurate with periodontal health [6]. Periodontal disease is initiated by plaque bacteria, and oral health focus has centered on the possibility of enhancing oral hygiene by incorporating chemotherapeutic agents into dentifrices formulations. Agents that, among others, have been shown to have antiplaque properties are triclosan, stannous salts, Meswak and zinc salts [1].

Lately, there has been a growing interest in natural products. The principal ingredients of the toothpastes used in this study may possess many medicinal properties. However, data pertaining to the substantivity of these products is sparse. It is imperative that clinical trials verify the efficacy of any new product, and the present study was carried out in this context. Studies by Saxer et al and Mullaly et al have shown that there is a significant reduction in both plaque index and gingival index within the group but no significant difference between the groups when herbal toothpastes were used. Likewise, in this study, the PI, GI and GBI were significantly reduced in the test group but not so in the control group and no statistically significant difference was found between the groups [7,8].

Triclosan, alone and in

combination with a Polyvinyl methyl ether/maleic acid (PVM/MA) copolymer, has consistently shown antigingivitis and antiplaque efficacy in numerous clinical studies [9]. Triclosan, a phenolic antibacterial and anti-inflammatory agent with low toxicity and a broad spectrum of activity, has been shown to be effective against Gram-positive and Gram-negative bacteria [10]. Zinc salts have been combined with stannous salts or used alone. The two most used zinc salts are citrate and chloride, both shown to have some antiplaque efficacy [11].

Meswak, (Peelu, Pîlu, Salvadora indica, or toothbrush tree, mustard tree) is a species of Salvadora. Research suggests that it contains a number of medically beneficial properties including abrasives, antiseptics, astringent, detergents, enzyme inhibitors, and fluoride. Meswak extracts have both anti- plaque and anti-gingivitis action [12,13,14].

There has been growing interest in natural products especially in dentistry. The herbs which have properties to influence on the oral hygiene have been of interest in people. Toothpaste is a personal care product that is commonly used by consumers starting at a very young age. For the majority of people, herbal toothpastes, when used properly, are safe and help to maintain dental health [15].

The use of herbal dentifrices led to a considerable reduction in dental plaque accumulation both on smooth and proximal tooth surfaces. Final values of plaque indices in herbal test groups were significantly lower compared to baseline data and to corresponding values in the conventional group. Using the herbal extracts dentifrices increased the effectiveness of plaque control, especially in difficult interproximal areas. Probably, active ingredients of the herbal extracts dentifrices penetrate the biofilm and prevent plaque accumulation [16]. Results of other clinical studies confirm the long-term plaque- and gingival bleeding-reduction properties of herbal dentifrices [2,17-23].

Conclusion

The results of this investigation show that the herbal toothpaste is an effective agent in the control of plaque and gingivitis. However, the New Meswak seems to have no significant clinical advantage over Old Meswak toothpaste. It can be inferred from the above results that these 2 toothpastes may be used as an alternative for people interested in natural products. Future studies may be carried out to compare the split mouth technique using both toothpastes. It may be suggested that clinical trials should verify the efficacy of any new product instead of just assuming that the product is efficient based on laboratory studies. Many healthcare providers may want to empirically recommend alternative flavored toothpaste, but even this can be challenging. The formulation and use of these dentifrices need to be standardized and regulated. It may be thus concluded that herbal extract dentifrices tested in this study can be recommended to adults with gingivitis for plaque control and to reduce gingival inflammation. But still further research is required to know the dental benefits of herbal products being incorporated in to the commercially available dentifrices.

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