

## A Hospital-Based a Single-Blind Parallel Clinical Trial Assessing the Antiplaque Efficacy of Propolis-Based Herbal Toothpaste

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Conflict of interest: Nil

### Abstract

**Aim:** The aim of this study was to evaluate the antiplaque efficacy of an herbal toothpaste containing propolis in comparison with a control group

**Material & Methods:** A single-blind parallel clinical trial at Department of Dentistry, Netaji Subhas Medical College and Hospital, Bihta, Patna, Bihar, India including 100 dental students (50 females and 50 males) All subjects were given verbal and written information about the study, and after entering the study, they signed a written consent form regarding all information received.

**Results:** Out of 50 subjects, 25 were males and 25 were females with mean age of 20.82±1.48 years. There was no significant difference in the mean MGMPPI scores between the three groups (Propolis, Dabur, Pepsodent) at baseline. But when they were compared after 24 h significantly (P = 0.01) highest mean MGMPPI score was observed in Pepsodent group (46.44±5.07) followed by Dabur (38.42±2.29). Propolis showed significantly least mean MGMPPI score (36.74±2.40) after 24 h. On comparing the mean difference (baseline and 24 h) of the three groups, significantly (P = 0.01) lowest mean difference was elicited by Propolis group.

**Conclusion:** The herbal toothpaste containing propolis was more effective in reducing plaque accumulation in comparison with the control group. Considering the effect of propolis-containing toothpastes on the reduction of dental plaque accumulation, these can be used as an effective oral hygiene product.

**Keywords:** Dental Plaque, Herbal, Oral Hygiene, Toothpastes, Propolis

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### Introduction

Dental plaque forms continuously on tooth surfaces in all age groups and must be removed to promote oral hygiene. [1] It is considered to be the key factor associated with both dental caries and gingival inflammation; [2] if untreated may extend beyond the gingival margin and progress to periodontitis. This may ultimately lead to the loss of teeth. [3] Maintenance of proper oral hygiene is one of the most important measures for controlling gingivitis, periodontitis, and dental caries. [2] Self-performed mechanical plaque removal is one of the most accepted methods of controlling plaque [5] and gingivitis but most people experience difficulty in maintaining adequate levels of plaque control; therefore, chemical agents that could supplement patient-dependent mechanical plaque removal have been studied in different essays. [3,4]

Most people experience difficulty in maintaining adequate levels of plaque control, particularly at interproximal sites, necessitates the use of

chemicals for control of plaque as an adjunct to mechanical plaque control procedures. [6] There has been a search for years for chemical agents that could supplant patient-dependent mechanical plaque control and thus reduce or prevent oral disease. [7] Over the last several years, a worldwide tendency has been noted towards the use of natural products due to their pharmacological effect on caries prevention. [8] Propolis, also known as bee putty [9] or bee glue, is a natural resinous mixture produced by honeybees collected from buds and exudates of certain trees and plants and stored inside beehives. This substance has been widely consumed in medicine due to its multidirectional biological properties. Propolis has other beneficial properties, such as antioxidant, antifungal, antiviral [10,11], anti-inflammatory, cytostatic, and cariostatic properties. [8,12] It also accelerates epithelial repair and controls dentinal hypersensitivity. [13]

Different studies have evaluated the efficacy of propolis-based toothpastes. These studies have shown the effectiveness of herbal toothpastes in the inhibition of oral pathogenic microorganisms [14], reduction of dental plaque, [2] improvement of marginal periodontitis, and changes in the oral bacterial spectrum. [15] At low concentrations, it has bacteriostatic activity, while it can be bactericidal at high concentrations. [8]

Considering the properties of propolis, the aim of this study was to evaluate the antiplaque efficacy of a propolis-based herbal toothpaste as a clinical study.

### Material & Methods

A single-blind parallel clinical trial at Department of Dentistry, Netaji Subhas Medical College and Hospital, Bihta, Patna, Bihar, India including 100 dental students (50 females and 50 males). All subjects were given verbal and written information about the study, and after entering the study, they signed a written consent form regarding all information received.

#### Inclusion Criteria

- Age- 24-30 years old, who volunteered to participate in the study and agreed to continue oral hygiene using the prescribed toothpaste, were included.

#### Exclusion Criteria

- Participants who met the exclusion criteria, such as having periodontal pockets with a depth of more than 3 mm, having orthodontic appliances, having a history of smoking, xerostomia, and systemic diseases, having untreated dental caries, and having a history of using Herbox mouthwash or toothpaste.

#### Sample selection

A convenient sample of 50 dental students comprising of both males and females was selected.

#### Informed consent

After explaining the purpose and detailed procedure of the study, a written informed consent was obtained from all the subjects, prior to the beginning of the study.

#### Training and calibration

All the examinations were carried out by a single examiner. Before the commencement of the study, the examiner was standardized and calibrated for Modified Gingival Marginal Plaque-Index (MGMPI) in the Department of Public Health Dentistry by a senior faculty member to ensure uniform interpretations, understandings, and application of the codes and criteria to be observed and recorded and to ensure consistent examination.

The examiner first practiced the index on a group of 10 subjects. Then the examiner applied the criteria by examining a group of 10 subjects, twice on successive days. The intra-examiner reliability was assessed using Kappa statistics, which was found to be 90%.

### Materials used in the study

- Forever Bright Tooth gel (containing Propolis) (forever living products)
- Pepsodent
- Dabur Toothpaste (Dabur India Ltd.)
- Disclosing agent (The Bombay Burmah Trading Corporation India, Ltd.)

### Methodology

Before starting the study, oral prophylaxis was performed. All subjects were given a washout product, Regular Flavour toothpaste and a soft manual toothbrush, with the instructions to use only these products and to brush twice daily for the washout period (1-week). After the washout period was complete, subjects reported to the Department of Public Health Dentistry and were randomly allocated to three groups of 10 participants each. Each group was randomly assigned to one of the three toothpastes (1 - Forever Bright Tooth gel, 2 - Pepsodent, 3 - Dabur toothpaste). Randomization was performed using lottery method. Then they were made to brush with Colgate Regular Toothpaste for 1-min followed by 1-min brushing with assigned test product. All products were blinded to both the subject and the examiner by way of an over-wrap. After this, all teeth were disclosed with disclosing agent. The Xu and Barnes probe [16] was gently placed along the margin of the gingiva, and the baseline MGMPI plaque scores were recorded. Subjects were then refrained from oral hygiene for 24 h, and were recalled to be re-disclosed and re-measured for plaque formation. The above-mentioned procedure was repeated after a washout period (2 weeks) in accordance with the crossover design, so that all three products could be tested on each subject. To ensure allocation concealment, the allocation methods were not revealed to the examiner. A statistician was not directly involved in recruiting patient generated the randomization sequence. Recruitment and assignment of patients to their groups was carried out by the trial coordinator.

### Statistical Analysis

Data were analyzed using SPSS 18 software (SPSS Inc., Chicago, IL, USA). The normal distribution of data was analyzed using Shapiro-Wilk test. Due to in all groups, quantitative variables were analyzed by parametric tests, such as independent t-test, and

the mean and standard deviation (SD) were reported.  $P > 0.05$  was considered statistically significant.

## Results

**Table 1: Distribution of study subjects**

Groups	Male	Female	Mean±SD
Propolis	25	25	20.82±1.48
Pepsodent			
Dabur			

Out of 50 subjects, 25 were males and 25 were females with mean age of 20.82±1.48 years.

**Table 2: Comparative assessment of the mean MGMPi scores at baseline and 24 h and their differences for each of three toothpastes**

Groups	Baseline (mean ± SD)	24 h (mean ± SD)	P	Difference (mean ± SD)
Propolis	15.65±1.28	36.74±2.40	0.01	21.09±1.12
Pepsodent	15.30±1.32	46.44±5.07	0.01	31.14±3.75
Dabur	15.45±1.26	38.42±2.29	0.01	22.97±1.03
P Value	0.75	-	0.01	-

There was no significant difference in the mean MGMPi scores between the three groups (Propolis, Dabur, Pepsodent) at baseline. But when they were compared after 24 h significantly ( $P = 0.01$ ) highest mean MGMPi score was observed in Pepsodent group (46.44±5.07) followed by Dabur (38.42±2.29). Propolis showed significantly least mean MGMPi score (36.74±2.40) after 24 h. On comparing the mean difference (baseline and 24 h) of the three groups, significantly ( $P = 0.01$ ) lowest mean difference was elicited by Propolis group.

## Discussion

Dental caries (particularly during childhood) and periodontal diseases are the most common oral cavity diseases. A positive correlation has been found between the number of *Streptococcus mutans* (*S. mutans*) in dental plaque and the development of dental caries. [17] Furthermore, dental plaque bacteria are known as the major etiologic factors of marginal periodontitis. [17,18] Maintenance of proper oral hygiene is one of the most important measures for controlling gingivitis, periodontitis, and dental caries. [17] Self-performed mechanical plaque removal is one of the most accepted methods of controlling plaque and gingivitis but most people experience difficulty in maintaining adequate levels of plaque control; therefore, chemical agents that could supplement patient-dependent mechanical plaque removal have been studied in different essays. [19,20] Over the last several years, a worldwide tendency has been noted towards the use of natural products due to their pharmacological effect on caries prevention. [18] Herbex (Parmoon, Tehran, Iran) is a natural product formulated to maintain oral health, which contains propolis extract, *Glycyrrhiza glabra*, *Satureja*, *Dianthus*, *Myrtus communis*, and *Eucalyptus*. [21]

Out of 50 subjects, 25 were males and 25 were females with mean age of 20.82±1.48 years. There was no significant difference in the mean MGMPi scores between the three groups (Propolis, Dabur, Pepsodent) at baseline. But when they were compared after 24 h significantly ( $P = 0.01$ ) highest mean MGMPi score was observed in Pepsodent group (46.44±5.07) followed by Dabur (38.42±2.29). Propolis showed significantly least mean MGMPi score (36.74±2.40) after 24 h. On comparing the mean difference (baseline and 24 h) of the three groups, significantly ( $P = 0.01$ ) lowest mean difference was elicited by Propolis group. Koo et al [22] evaluated the effect of propolis mouth rinse on dental plaque accumulation and found it to be effective against plaque build up. In another study, Hidaka et al [23] showed that Propolis reduced the rate of amorphous calcium phosphate transformation into hydroxyapatite and concluded that it had a potential as an anticalculus and antiplaque agent in toothpastes and mouthwashes. Ikeno et al [24] and Hayacibara et al [25] found that the insoluble glycan synthesis and glucosyltransferase activity were inhibited by the multiple action of Propolis. This could be because of the high content of phenolic compounds, including flavonoids and dramatic compounds such as caffeic acids. [26]

Fereidooni et al [27] investigated the effect of toothpastes containing propolis on plaque control and stated that the propolis toothpaste caused more reduction in dental plaque compared to the regular toothpaste; the results are in line with those of the present study. Akca et al [28] conducted a study in order to compare the antimicrobial effectiveness of ethanolic extract of propolis (EEP) with CHX gluconate in planktonic and biofilm states of oral microorganisms. The results of the study revealed that propolis was more effective in inhibiting Gram-positive bacteria in comparison with Gram-

negative bacteria in their planktonic state. Also, it was indicated that propolis was as effective as CHX in the biofilm state, which is an indicator of the antiplaque efficacy of propolis and supports the results of the present study. actual mechanism involved behind the antimicrobial activity of propolis extracts needs to be researched. Research on microbial biofilms is proceedings on many dimensions, with specific focus on elucidation of the genes specifically expressed by biofilm-associated organisms, assessment of different control approaches for either preventing or remediating biofilm colonization of medical devices, and development of new methods for evaluating the efficacy of these treatments. [29]

### Conclusion

The herbal toothpaste containing propolis was more effective in reducing plaque accumulation in comparison with the control group. Considering the effect of propolis -containing toothpastes on the reduction of dental plaque accumulation, these can be used as an effective oral hygiene product.

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