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Efficacy of Extrinsic Stain Removal by Novel Dentifrice Containing Papain and Bromelain Extracts

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ABSTRACT

To evaluate the stain removal efficacy of a novel dentifrice containing papain and bromelain extracts (Glodent) in comparison with a control dentifrice (Colgate regular). This was a randomized, positive-controlled, double-blinded, clinical study. Subjects were randomly divided into one of the two study groups. Pre-treatment and post treatment photographs of the 4 anterior teeth were recorded under standardized conditions and analyzed for lightness or luminosity values using Adobe Photoshop. The difference between the mean pre-treatment luminosity of test and control groups was not statistically significant. In both test and control groups, the post-treatment luminosity was significantly higher than pre- treatment luminosity ($P < 0.001$ and $P = 0.003$ respectively). The mean post-treatment luminosity for test group was found to be significantly higher than control group. The mean percentage removal of stains for test group was significantly higher than control group. The test dentifrice showed significant stain removal when compared to control which could be attributed to the role of proteolytic enzymes in the test dentifrice.

Key words: Bromelain, extrinsic stains, image analysis, papain, proteolytic enzymes, stain removal

INTRODUCTION

Teeth color is a combination of intrinsic color of the teeth and the presence of extrinsic stains that might accumulate on the tooth surface.[1,2] Extrinsic stains are linked with the adsorption of materials into the acquired pellicle on the enamel surface.[3] Factors influencing extrinsic stain formation include poor tooth brushing technique, smoking, areca nut chewing, dietary intake of colored foods (e.g. red wine, coffee and tea consumption), subject's age and the use of certain cationic agents such as chlorhexidine or metal salts like tin and iron.[1,3,4]

Consumers and patients have always had a strong desire for white teeth which has given rise to a growing trend in the increased use of 'over-the-counter' tooth whitening products. Manufacturers of oral care products are constantly developing new approaches for tooth whitening in order to meet the expectations of patients and consumers. Thus, today there is a huge range of products and technologies available that are self-applied and require no professional involvement.[5]

The majority of these products work in two possible

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ways. It can be by bleaching of the teeth, or by addition of specific abrasives or chemical agents to toothpaste for the removal and control of extrinsic stain. Abrasives have been shown to effectively remove extrinsic stains along with food debris and plaque and also help in preventing extrinsic teeth stains from reforming.[5]

Toothpaste abrasion of dental hard tissues is an important factor in terms of its trade off with cleaning efficacy during the formulation of whitening toothpastes. Hence whitening toothpastes contain additional chemical agents which augment the abrasive cleaning by aiding the removal and/or prevention of extrinsic stains. Many substances like surfactants, peroxides, enzymes, citrate, pyrophosphates and hexametaphosphate were studied previously for their stain removal efficacy.[5]

Since extrinsic stains are primarily incorporated into the pellicle, it is possible that enzymes such as proteases could help degrade the stained films and potentiate their removal. Early clinical evidence demonstrated that a highly proteolytic mixture of enzymes of fungal origin formulated into toothpaste were effective at reducing extrinsic stain levels as compared to a negative control toothpaste after 6-months of use.[6] Clinical studies have demonstrated the stain removal efficacy of dentifrice containing papain, alumina and sodium citrate.[7-9] Recently an *in vitro* study reported that a papain and bromelain (proteolytic enzymes) containing dentifrice was more effective in removing stains than the control dentifrice.[10]

The methods used to measure extrinsic stain levels in clinical studies include subjective clinician determinations based on indices and objective instrumental methods. The objective instrumental methods used in the past were Vita shade guides,[11] colorimeters,[12] and image analysis of digital photographs of teeth.[13] Digital image analysis can be utilized for assessing stains and overcomes some of the problems associated with some of the subjective and instrumental approaches.[13]

Hence the present study aimed to evaluate the stain removal efficacy of a novel commercially available dentifrice containing papain and bromelain (Glodent, Group Pharmaceuticals Ltd, Mumbai, India) in comparison with a control dentifrice (Colgate Regular, Colgate Palmolive India Ltd, Mumbai, India) using a customized digital image analysis system.

MATERIALS AND METHODS

Subjects and study design

This study was randomized and double blinded (participants and investigators) who compared the novel dentifrice containing papain and bromelain (Glodent) with control dentifrice (Colgate regular). The composition of test dentifrice was Papain, Bromelain, Miswak, Neem and 1000 ppm fluoride and while that of control was calcium carbonate, sorbitol, titanium dioxide, sodium silicate, sodium saccharin and 1000 ppm fluoride dentifrice. Papain and Bromelain are proteolytic enzymes derived from Papaya (Carica papaya) and Pineapple (Ananas comosus).

Before the start of the study, the protocol was approved by the Institute Ethics Committee of Manipal University, Manipal and subjects gave informed consent prior to their participation. For inclusion in the study, the subjects were required to have visible stains on maxillary incisors with Lobene score of >1; at least 4 maxillary anterior teeth without restorations; no oral prostheses; no untreated caries. Lobene stain index (1968) involves assessment of extent and intensity of stain on the gingival and body regions of the labial surface of incisor teeth. Intensity scores were: 0- no stain, 1- light stain, 2- moderate stain, 3- heavy stain. Extent scores were: 0- no stain, 1- stain covering up to $1/3^{rd}$ of the region, 2- stain covering $>1/3^{rd}$ to $2/3^{rd}$ of the region and 3- stain covering $>2/3^{rd}$ of the region. Many stain indices proposed recently were mainly to determine the efficacy of anti-stain agents, or to investigate the interaction between chlorhexidine and dietary constituents. Subjects were excluded from participating in the study if there were generalized recession of the gingiva, or generalized malocclusion, or overlapping/spacing of anterior teeth, inability to comply with brushing instructions (e.g,dexterity or comprehension issues), obvious periodontal disease, or facial calculus on the anterior teeth. A total of 100 subjects were screened in out-reach centers of Manipal College of Dental Sciences, Manipal out of whom 29 subjects satisfied the inclusion criteria. Out of these 24 subjects consented to participate in the study. This study was conducted for 2-months (November-December 2010).

Eligible subjects were randomly assigned to one of the two treatment groups and called to record the baseline photographs of their 4 maxillary anterior teeth. After briefing the purpose of the study to the participants, oral hygiene and tooth brushing instructions were given. Subjects who were divided into two groups were provided with the assigned products (either of the toothpaste and Colgate classic toothbrush with soft bristles) and were required to brush in front of a mirror for 2 minutes twice a day, covering the entire toothbrush head with the dentifrice each time. Test and control dentifrices tubes were painted in white color and delivered by a person not involved in examination. All investigators and participants