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Efficacy test of a toothpaste in reducing extrinsic dental stain

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Abstract. This clinical trial compared the external dental stain reduction achieved by tested toothpaste versus placebo in adult patients. In this double-blind, parallel, randomised clinical trial, 45 female volunteers with a mean age of 20 years old were included. All study subjects front teeth were topically applied with Silver Diamine Fluoride (SDF) to create external dental stains. Subjects were randomized into test (n=22) and control (n=23) groups. Toothpastes were used for two days to analyse the effects of removing external stains on the labial surfaces of all anterior teeth. VITA Easyshade Advance 4.0 was used to measure dental extrinsic stains changes. The analysis showed statistically significant efficacy of the tested toothpaste in reducing external dental stain caused by SDF, comparing to the placebo toothpaste, after one and two days of usage. The tested toothpaste was effective in reducing dental stain.

1. Introduction

Toothpaste manufacturers develop various whitening and stain removal toothpaste, due to the relative high consumer's reports on dissatisfaction with their tooth colour. One of the key functional ingredients in whitening toothpaste is the abrasive system. In general, these have been designed to give effective removal of extrinsic stains and help prevent tooth stains from reforming [1]. The tooth colour is also determined by the effect of intrinsic colour, which is influenced by light absorption properties of enamel and dentine with dentine having the major role in determining the overall tooth colour. Intrinsic stain originated from deeper tooth surface and caused by hereditary disorder, medications, fluorosis and trauma. Extrinsic stain is located in tooth surface, and these stains may be related to poor oral hygiene, smoking habit, and chromogenic food such as coffee and tea, which is prevalent in the community, causing a high demand on stain removal toothpaste as an effective and efficient approach to overcome this problem [2].

Tooth whitening treatment can broadly be divided into two methods, tooth bleaching and routine prophylactic procedures, such as brushing with whitening toothpaste. Tooth bleaching can improve intrinsic tooth colour and typically contain hydrogen peroxide. Whitening toothpaste has formulations that have an enhanced physical and chemical cleaning ability. Whitening toothpaste has been shown to



effectively remove and prevent extrinsic stain [3]. Because bleaching procedure is more expensive than prophylactic procedure using whitening toothpaste, many people choose to use whitening toothpaste than expensive clinical setting bleaching procedure. The whitening effects of whitening toothpastes are usually achieved by incorporation of bleaching and abrasive components. An ideal whitening toothpaste should remove extrinsic stain effectively while causing minimal effect on tooth structure [4].

Whitening toothpaste continues to be expanding areas of study interest that have been driven by the consumer's demand for attractive smiles. They are based on optimised abrasive technology to remove and control extrinsic stains which form in the acquired pellicle [5]. Extrinsic stains form naturally on the tooth surface when chromagens from dietary sources (e.g. tannins from tea and coffee) or habits (e.g. tar from smoking) are incorporated into the salivary pellicle. Other factors, such as poor techniques of oral hygiene maintenance and the ability of a dentifrice to control stain by removal or prevention, also influence the accumulation of stains. An important part of the evaluation process for whitening toothpaste is determining its clinical efficacy in terms of removing extrinsic tooth stains [6,7]. The research problem of this study is that evidence-based dentistry which analysis the efficacy of over the counter toothpastes in Indonesia are not yet widely published. The working hypothesis of this study is that the tested toothpaste have higher efficacy in reducing extrinsic dental stain than the control toothpaste. The aim of this study was to evaluate the efficacy of commercially available toothpastes in extrinsic stain removal, in a randomised, double-blind, parallel, and controlled comparison test.

2. Materials and Methods

This is a double-blind, parallel, randomised clinical trial, comparing tested toothpaste with placebo. The placebo used in this study was toothpaste which contains the same formulation as the tested toothpaste but without the active ingredients. The ingredient of tested toothpaste are Calcium Carbonate, Sorbitol, Water, Silica, PEG-8, Sodium Lauryl Sulfate, Alumina, Flavour, Sodium Monofluorophosphate, Zinc Oxide, Xanthan Gum, Carrageenan, Sodium Benzoate, Methylparaben, Butylparaben, Sodium Saccharin, Caprylic/ Capric Triglyceride, and Sodium Silicate. Both the examiner and the patients were blinded to the type of toothpaste treatment. A single examiner method was used to minimise potential biases from examination variation. Subject's front teeth were analysed for their colours. VITA Easyshade Advance 4.0 was used to measure the colour of each tooth and also the changes in existing dental extrinsic stains (Figure 1). Further, those teeth were painted with Silver Diamine Fluoride (SDF) to create dental extrinsic stain [8]. After SDF application, subjects were retained from brushing their teeth and using any oral health care products for a 24 hour period. All examinations were conducted in the dental room setting with adequate equipment for a clinical study. After 24 hours of the SDF application, the level of visible extrinsic stain was assessed. Subjects were assigned randomly to equal numbers of test and control groups. Subjects were instructed to brush their teeth twice a day with provided dentifrice and identical soft toothbrushes as part of their normal oral hygiene regimen. Oral soft tissues were assessed at each examination for detecting any adverse event such as possibilities of allergic effect [9]. Evaluation of the toothpaste effects on removing stains were assessed after one and two days of toothpaste use. Scaling, prophylaxis, and polishing was conducted at the end of the study to clean subjects' teeth thoroughly.



Figure 1. of SDF application, SDF staining after 24 hours, and tooth colour measurement using the VITA Easyshade Advance 4.0

The outcome variable for each subject were quantitative numerical numbers detected by the Vita Easyshade Advance 4.0 and were noted by the examiner. Parametric independent statistical tests were accounted to compare the efficacy in stain removal between tested toothpaste and placebo toothpaste. While the mentioned statistical tests were deployed if normal distribution was acquired. If normal distribution of data was not acquired, non-parametric calculation was conducted. Sample size estimation suggests that a cell size of 20 subjects in each group completing the study will be sufficient to detect as statistically significant ($p < 0.05$) difference between placebo and tested toothpaste with a power of 95%, assuming a difference of 50% between placebo and tested toothpaste. At least a total of 46 subjects meeting the inclusion criteria will be recruited onto the study, including additional 15% of the total samples accounting for lost of follow up. The aim is to complete the study with at least 40 subjects.

Inclusion criteria were female subjects aged 18-25 years, willing to participate and have signed informed consent, no medical or pharmacotherapy history that might compromise the outcome of the study, able to comply with the study procedures, no medical conditions that prevent a person from brushing their teeth, has minimum of 20 natural healthy teeth with no indication of extraction, non-smoking, no fixed or removable orthodontic appliances or removable prosthesis. Further, the exclusion criteria were the occurrence of an adverse event, withdrawal, sickness that could bias the results, not complying with the study procedures that could bias the research results, such as using xylitol gum, CCP ACP, gargling solution and using any other medications. Subjects may discontinue from the clinical study at any time. Subjects are participating this study with their freewill, with full consciousness and without any coercion. Moreover, the principal investigator has the right to withdraw a subject for any reason that is stated in the exclusion criteria and also for any reason that is in the best interests of the subject, such as force major. Adverse events were monitored throughout the study.

3. Results and Discussion

3.1 Results

The colour measurements were conducted to 45 subjects, comprising of 23 subjects in the placebo group and 22 others as the test group. No side effect nor adverse events occurred. Mean and standard deviation colour at baseline, day one and day two after toothpaste use based on tested toothpaste and placebo are described in Table 1.

Table 1. Mean \pm standard deviations of tooth colour at baseline, day one & day two based on toothpaste measured by the VITA Easyshade Advance 4.0

Tooth Color	Placebo	Tested Toothpaste
Baseline	14.07 \pm 5.88	14.63 \pm 5.29
Day 1	13.51 \pm 5.77	12.67 \pm 4.90
Day 2	13.26 \pm 5.73	12.42 \pm 4.91

Further research results are represented in Table 2, showing the analysis of mean of colour change (stain reduction) measurements results before and after one and two days toothpaste usage. Mann-Whitney statistical test was employed to compare the efficacy in stain removal between tested toothpaste and placebo.

Table 2. Comparison of mean \pm standard deviations of stain reduction comparison between placebo and tested toothpaste

Stain Reduction	Placebo	Tested Toothpaste	p-value (Mann-Whitney)
Baseline to day 1	0.56 \pm 0.81	1.96 \pm 2.9	<0.001
Comparison Ratio	1	3.5	
Baseline to day 2	0.81 \pm 0.86	2.21 \pm 2.69	<0.001
Comparison Ratio	1	2.7	

Table 2 showed statistically significant difference in external dental stain removal efficacy between placebo and tested toothpaste. Moreover, the non-parametric Mann–Whitney statistical analysis showed that the tested toothpaste could reduce stain 3.5 times better than the placebo toothpaste, after one day of toothpaste use. Further, after two days of toothpaste use, the tested toothpaste showed 2.7 times more effective in reducing external dental stain comparing to the placebo toothpaste. The average of day one and day two colour change is 3.1, emphasising the efficacy of tested toothpaste in reducing external dental stain comparing to the placebo. Tested toothpaste showed potentially more effective in reducing of external stains, caused by SDF staining, compared to placebo. The tested toothpaste was able to reverse the tooth colour into its initial colour.

3.2 Discussion

At present, there would appear to be considerable demand for oral hygiene products which whiten teeth by eliminating or reducing extrinsic dental stain. Tooth stain is also common among children and influences the esthetics of teeth [10]. Whitening toothpaste can be easily acquired by patients who want to get whiter teeth at a lower cost. The main purpose of whitening toothpaste is removing the external dental stain, either mechanically or chemically. The mechanical ingredients in whitening toothpaste are abrasives such as hydrated silica and calcium carbonate, which together with toothbrush bristles, remove the outer stained [11]. An ideal whitening toothpaste should remove stain effectively without causing any side effects. Nonetheless, there is lack of evidence about the efficacy of external dental stain removing toothpaste to improve the perceptively ideal tooth colour, especially in the Indonesian context. The effectiveness of any new whitening toothpaste can be evaluated by several methods, which are, removal of induced stain, prevention of induced stains, removal of pre-existing/natural stains or prevention of natural stain build-up. This study intended to compare the effectiveness of a tested toothpaste comparing to placebo in the removal of induced stain which was caused by SDF. It was observed that the tested toothpaste reduced the induced SDF stain more effectively than the placebo, with a statistically significant comparison analysis.

The use of both toothpastes were applied using toothbrush as part of their normal oral hygiene regimen. Using the toothpaste with a toothbrush could benefit stain removal by both a physical (abrasive) and chemical action [12]. Both pastes applied this way were seen to be associated with a reduction in stain area and intensity. For stain area, this could be expected simply from the abrasive effects of the pastes and the physical use of the toothbrush. The reduction in stain might be the result of thinning of stain layers by the abrasive action of the toothbrush and toothpaste, alteration of stain colour characteristics, e.g. brown to yellow by a chemical action [13]. The placebo toothpaste also showed a reduction of stain, although mild, it is likely that a common ingredient in both, such as detergent, could account for any chemical effect if present. Indeed, detergent could reduce stain. In

literature, tooth discoloration has been obtained as a result from a nano zinc oxide-eugenol sealer as well [14]. Some of the toothpaste are effective to remove to extrinsic dental stains, in spite of the fact that we shouldn't forget that the mechanical effect of brush is also effective for the extrinsic stained plaque removal by all kinds of tooth paste [15]. Further, it was described that the anti-calculus and whitening effects of toothpaste are to some extent based on the same active ingredients which are compounds of high affinity for tooth mineral. Due to this affinity, crystal growth may be hindered becoming anti-calculus, and chromophores be displaced whitening effects [16].

Sound clinical evidence of toothpaste efficacy to support laboratory data overall remains patchy. In the present study, a stain removal toothpaste was evaluated to determine whether induced stain could be removed more effectively than placebo. The findings of the study showed evidence that the tested toothpaste was superior to placebo, helping to eliminate or reduce extrinsic dental staining. The incorporation of abrasives in particular toothpaste may help to physically remove stain, but since virtually all toothpaste contain abrasives, some benefit may be expected even by conventional products [13]. The concept of whitening formulations containing specific chemicals that reduce stain independent of a physical effect would appear to be particularly attractive since reduced staining may be apparent in sites of the dentition where the abrasive effects of the toothpaste would be less obvious. Various types of chemicals have been suggested to be of potential value by lightening existing stain or by physical desorption of adherent stain [11]. An in vitro study screening assay has been assessed to clean dental staining, and its benefit might be useful in the near future [17]. This study showed a significant reduction in stain accumulation on the teeth compared with placebo. As such the tested toothpaste would be expected to be of benefit in controlling extrinsic dental staining.

4. Conclusion

The scientific rationale of this study is that whitening or stain removal toothpaste products are sold as over the counter products. Unfortunately, consumers might have inadequate knowledge to choose the appropriate one for them. Therefore clinical studies to confirm the efficacy of tooth paste are essential. The findings of this study indicate that the tested toothpaste has in average 3.1 times better stain removal properties, after two days of use, compared to the placebo toothpaste, with statistically significant difference in reduction of external dental stain induced by SDF.

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