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Clinical efficacy of a bleaching enzyme-based toothpaste. A double-blind controlled clinical trial

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ABSTRACT

Objectives: To assess the efficacy of a bleaching enzyme-based toothpaste.
Material and methods: A randomized clinical trial was carried out, comprising 48 participants with teeth exhibiting color A3 or higher according to the Vita Classical guide. One-half of the sample received the bleaching enzyme-based toothpaste (White Kin®), while the other received placebo toothpaste. Both products were supplied in identical containers and had the same composition except for the active components. The teeth color was measured with a spectrophotometer. The patients were instructed to brush their teeth three times a day during 3 min with the assigned product, during 12 weeks. The color measurements were repeated after 3, 6, 9 and 12 weeks of treatment. Color variation was based on the CIE $L^*a^*b^*$ coordinates, ΔE and the EW index. The relationship of these variables at different observation times were performed using a generalized estimating equations model, which evaluated the effect of treatment, time and interaction.
Results: The patients using the bleaching enzyme-based toothpaste showed an increase in lightness (80.14 -treatment- versus 79.25 -control group-) and a reduction in component b^*. ΔE was found higher in the treatment group ($p = 0.064$), close to statistical significance.
Conclusions: The bleaching enzyme-based toothpaste could be potentially efficient in the modification in tooth color progressing from the third to ninth week of treatment, tending to stabilize after the ninth week.
Clinical relevance: A very low carbamide peroxide concentration, with the incorporation of lactoperoxidase, tooth paste, tends to offer clinically satisfactory results, in terms of modifications in tooth color, nevertheless no significant differences were founded when compared to the control group, with an oral hygiene controlled along the study.

1. Introduction

Dental bleaching is a very popular conservative option for the treatment of dental discoloration [1]. Hydrogen peroxide (HP) and its precursor, carbamide peroxide (CP), are presently in the active agents most widely used both in dental clinics and at home [2]. These two bleaching substances can maintain their effects over the middle and long term, and are well tolerated by the oral tissues [3].

In recent years, systems with different peroxide concentrations and involving different application methods and activation mechanisms have been developed with the purpose of offering products that are effective, easy to use and well tolerated by the oral tissues [4].

One of the aims of research in dental bleaching is to define activation mechanisms capable of affording optimum free radical action with the lowest HP concentration possible [5–7]. Such activation mechanisms include the use of physical agents (particularly different light sources), chemicals [8–11] and enzymes [5]. In this context, enzymatic bleaching involving the use of enzymes such as catalase, oxidoreductases and peroxidases, acts by increasing the HP decomposition rate [12–14]. Salivary peroxidase intervenes in the transformation of HP into a harmless substance. This effect constituted the basis for the inclusion of this enzyme in the composition of dental bleaching products [7,15–17].

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It has been shown that lactoperoxidase (LP) can be employed to catalyze peroxide decomposition, and its stability makes it usable in gel formulations [5]. A bleaching toothpaste (White Kin® Bleaching System, Laboratorios KIN, Barcelona, Spain) containing this enzyme has been developed. This product contains 3% carbamide peroxide and 5% lactoperoxidase, with the purpose of reducing the peroxide concentration and thus the risk of undesirable effects [5,17].

A previous clinical study carried out by our group in volunteers using this bleaching enzyme-based toothpaste recorded a significant improvement in tooth color after 21 days of treatment (three daily applications) [6].

The present clinical trial was designed to test the following null hypothesis: the enzymatically activated bleaching toothpaste (White Kin®) has the same bleaching efficacy as a placebo formulation when used during 12 weeks.

The objective was to evaluate the efficacy of a bleaching product based on 3% carbamide peroxide and 5% lactoperoxidase, used during 12 weeks, and to compare it with a placebo formulation.

2. Materials and methods

2.1. Sample selection and criteria, randomization and blinding

The present study was approved by the Ethics Committee of San Carlos Clinic Hospital (Madrid Complutense University, Madrid, Spain) (CP-CI 10/355-E).

A two-center randomized clinical trial (RCT) was carried out (universal trial number: U111-1154-9986) in the Dental Clinic of the Lluís Alcanyís Foundation of the University of Valencia (Valencia, Spain) and in the Dental Clinic of Madrid Complutense University (Madrid, Spain). Each center enrolled 24 participants between 18 and 60 years of age (Fig. 1).

The primary study outcome was color change evaluated by ΔE. This therefore was the variable used for the determination of sample size. Considering patient as an experimental unit, the sample size was calculated to obtain a ΔE difference at the end of the study of 1 unit between both groups, with a statistical power of 80%, and a significance level of 5%. The resulting sample size was 21 patients by group. Assuming a loss of 15% in the course of the study, the final sample size was defined as 24 participants per group.

The inclusion criteria were: patients between 18 and 60 years of age, with fully erupted upper and lower incisors and canines without dental or periodontal disease or restorations, and with at least one maxillary tooth presenting color score A3 or darker, as measured with the Vita Classical guide (Vita Zahnfabrik, Bad Säckingen, Germany) ordered by brightness [19]. The exclusion criteria were: patients with systemic diseases or oral mucosal disorders, previous bleaching treatment, patients undergoing orthodontic treatment, pregnant women, people with known allergy to the product ingredients, smokers, and alcohol abusers.

The treatment product was the White Kin® Bleaching System gel + toothpaste (Laboratorios KIN, Barcelona, Spain), supplied in the form of two tubes, each with an independent dosifier allowing administration of the contents in equal portions. One tube contained toothpaste with 5% LP, together with other ingredients (sodium fluoride, xylitol and excipients), while the other contained a gel with 3% CP and excipients.

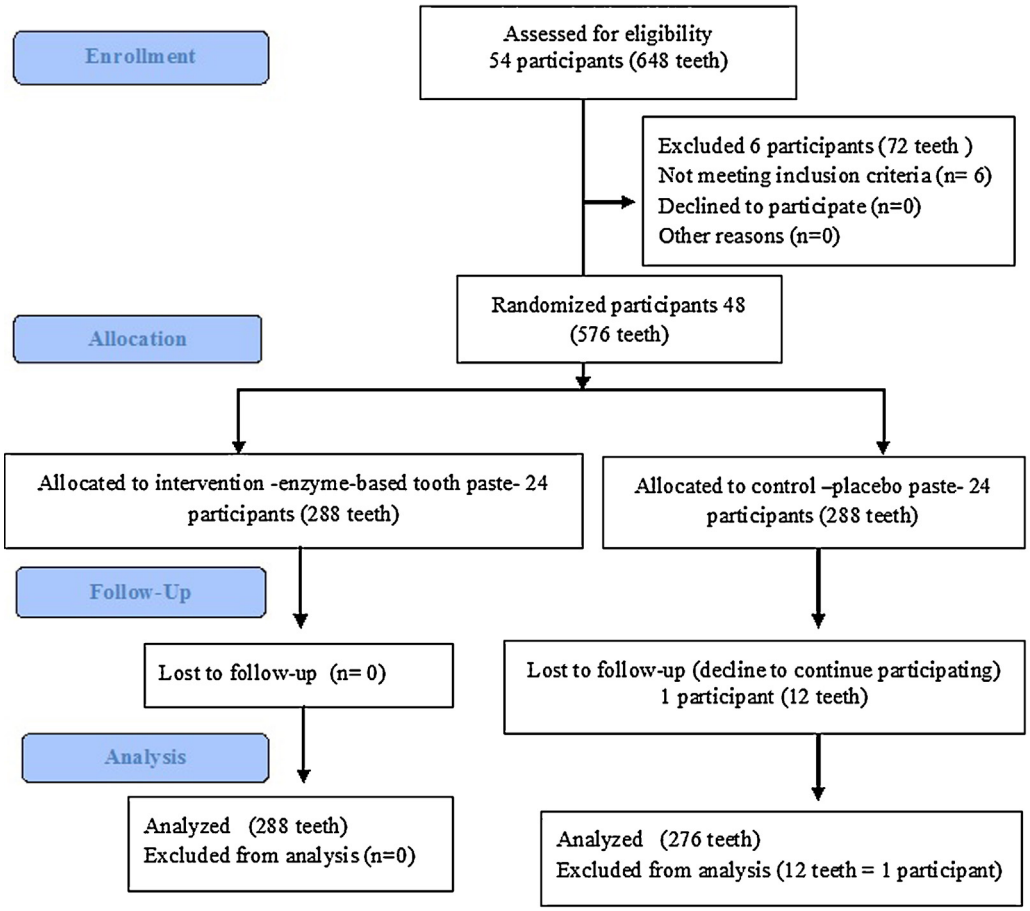

Fig. 1. Flowchart of the trial.