Combined Bleaching Technique: Efficacy and Tooth Sensitivity - A Randomized, Double Blind Clinical Trial

ClinicalTrials.gov ID: NCT03089216

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Objective

This study evaluated the efficacy, color stabilization, and tooth sensitivity (TS) during and after the use of a combined bleaching technique, varying the application time of 35% hydrogen peroxide (HP) and the use of a desensitizing dentifrice containing arginine (ARG).

Study design

This is a randomized controlled clinical trial, parallel and double blinded, with a similar allocation rate between groups, registered at clinicaltrials.gov under the identification number NCT03089216. The study has being conducting at the School of Dentistry of the Federal University of Goias (UFG), following CONSORT statement, after the approval of the Ethics Committee of the Federal University of Goias, Brazil (CAAE: 52047115.2.0000.5083).

One hundred and eight participants were randomly assigned to 4 groups (n = 27): OFF40 (without ARG): two 20-minute HP applications (2x20); D-OFF40 (with ARG): two 20-minute applications (2x20); OFF20 (without ARG): one 20-minute HP application (1x20); and D-OFF20 (with ARG): one 20-minute HP application (1x20). In all groups, at-home bleaching was performed with 10% carbamide peroxide (CP) for two hours daily for 16 days. Color evaluations were performed before bleaching and at 5, 8, 12, and 16 days from the beginning of the procedure, and 7 and 30 days after the end of the treatment, with VITA Classical and VITA Bleachedguide 3D-MASTER shade guides (ΔSGU) and a digital spectrophotometer, VITA Easyshade (VITA Zahnfabrik). The TS evaluation was performed with a visual analogue scale (0-10) and numerical scale (0-4) in different periods.

Statistical Analysis Plan

Statistical analyses will be performed using SPSS 20.0 (SPSS Inc., Chicago, IL, USA) with $\alpha = 0.05$. The means of the SGU at baseline and after different assessments will be calculated for each group. In order to evaluate whether the bleaching therapies were effective or not, the data from the SGUs will be analyzed using the Kruskal-Wallis and Mann-Whitney tests for between-group comparisons,

and the Friedman and Wilcoxon tests with Bonferroni correction (α = 0.002) for within-group comparisons. The ΔE values will be submitted to two-way analysis of variance (ANOVA).

The Tooth Sensitivity intensity will be analyzed using Kruskal- among-group comparisons within each evaluation time (baseline, immediately after the in-office bleaching, daily during the at-home bleaching, and up to 48 hours after the treatment). The comparisons among the assessment times within each group will be performed using the Friedman and Wilcoxon tests with Bonferroni correction (α = 0.008).