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# Changes in oral health related quality of life after dental bleaching in a double-blind randomized clinical trial



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#### ABSTRACT

Objectives: This study aimed to assess changes in oral health-related quality of life (OHRQoL) in individuals enroled in a double-blind randomized clinical trial conducted to evaluate the efficacy and safety of two carbamide peroxide concentrations used in at-home vital bleaching in the city of Pelotas, Southern Brazil.

Methods: Ninety-two volunteers with a shade mean of C1 or darker for the six maxillary anterior teeth were randomized into two balanced groups (n=46) according to bleaching agent concentration: 10% or 16% carbamide peroxide. The patients were instructed to use the whitening agent in a tray for 2 h once a day for three weeks. To assess changes in OHRQoL, participants completed the oral impact on daily performance (OIDP) at the start and one week after the completion of treatment. Because there was no difference with regard to whitening effect or tooth sensitivity during or after treatment the two groups were merged for the analyses of the current article. Before-and-after changes in OIDP scores were assessed by chi-square and McNemar tests (p < 0.05).

Results: Mean pre- and post-treatment OIDP scores varied from 0.42 to 0.60. When the frequency of impacts for different activities were compared, there was an increase in difficulty in cleaning teeth (p = 0.02) and a significant reduction in smiling and showing teeth with embarrassment (p = 0.03). Regarding the symptoms and main oral conditions that generated impact, there was higher number of participants reporting pain (p = 0.05) after treatment. In opposite, significant decrease was observed in individuals reporting being unhappy with their appearance (p = 0.03). On the contrary, it was showed a decrease in impacts resulting from dental colour was observed after bleaching (p = 0.03).

Conclusion: Quality of life is complex and encompasses different domains. Although positive impact of the dental bleaching was detected, with patients showing more their teeth without embarrassment, difficult in dental hygiene and pain resulting from the treatment were also reported, and this can negatively impact daily performances. Dentists must consider these aspects when performing aesthetics procedures.

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#### 1. Introduction

Increased concern has been given to the aesthetic appearance in dentistry in recent years. The patients are not only willing a well-aligned smile, but they are also requesting whiter teeth. Not only they are aware of stained teeth, as they are also presenting dissatisfaction with their tooth colour. A study conducted in the US reported that 34% of the surveyed individuals were unhappy with their tooth shade. Also in a paediatric survey in US, 20% of parents and 31% of children were reporting dissatisfaction with tooth color. In a UK national survey, a 50% prevalence of self-reported stained teeth was detected and 20% dissatisfaction rate with their dental colour was reported.

Thus, bleaching treatments have become increasingly popular especially among young patients, 5,6 influencing the individuals' aesthetic perception, facial attractiveness and oral health state. 7,8 Several different bleaching protocols and bleaching agents have been proposed to improve tooth colour with most of the variations related to concentration and type of peroxide releasing agents. 9-11 Bleaching procedures can be carried out in the dental office by the dentist or at home by the patient with or without professional supervision.<sup>12</sup> Even though the large number of products available in the market, the treatment using custom-trays and 10% carbamide peroxide (CP) gel, performed at home under the dentist supervision, is still considered the goldstandard for tooth discoloration. 10 Higher concentration of CP gels have been advocated in order to accelerate or improve the bleaching effect 13; however, the short time and long time clinical trials have disclosed similar results when compared to 10% CP. 1,14,15

Aesthetics is mostly a subjective perception that varies from individual to individual. Therefore it is difficult to assess dental aesthetics or evaluate the effectiveness of any intervention aimed at altering it, considering 'normative' or professional assessment alone. Dental aesthetics is a key area in which patients' or publics' perception of outcome is important, if not essential.4 While the presence of discoloured teeth could interfere in the oral health-related quality of life (OHRQoL) of individuals, few studies have evaluated the effect of tooth bleaching on quality of life, 16,17 with different samples and results. One study evaluated the whitening effects in college-aged individuals and found that whiter teeth positively affected OHRQoL in the functional limitation subscale of the Oral Health Impact Profile (OHIP), once that they reported less difficulty chewing and better overall appearance of their teeth. 16 Another study evaluated a sample of older adults and the author did not detect a statistically significant difference in the overall OHIP after the whitening treatment. 17

In a previous double blind randomized clinical trial, we have evaluated the whitening effect of two CP concentrations and we had not observed significant differences between 10% or 16% CP in the bleaching efficacy or in relation to reported side-effects. <sup>1,15,14</sup> However, we have not reported the impact of these bleaching treatments in the OHRQoL. Thus, this study aimed to evaluate the changes in OHRQoL in the individuals, after at-home vital tooth bleaching using 10% or 16% CP concentrations. The primary hypotheses to be tested was that

bleaching treatment can produce changes in the OHRQoL of the subjects.

#### 2. Materials and methods

This study was part of a double-blind randomized, controlled clinical trial that evaluated two carbamide peroxide concentrations used for at home vital bleaching, which followed the guidelines published by Consolidated Standards of Reporting Trials (CONSORT). This study was approved by the local Human Research Ethics Committee (# 37/05). Prior to enrolment each individual signed an informed consent form with all the information regarding the risks and benefits of treatment. Additional information on this clinical trial is published. 1,13,15

Before starting the study, two examiners were calibrated to measure the tooth shade, using a digital spectrophotometer (Vita Easyshade, Vita Zahnfabrik, Bad Säckingen, Germany) and a value-oriented shade guide (Vitapan Classical, Vita Zahnfabrik). To detect the bleaching effect with a power of 0.90 when the significance level was  $\alpha = 0.05$ , a sample size of n = 80 volunteers was necessary. An additional 15% of volunteers were selected taking into consideration potential losses of follow-up, giving a total sample size of n = 92 volunteers (46 in each group).

To be included in the study volunteers should meet the following inclusion criteria: (a) six anterior maxillary teeth with a colour shade C1 or darker; (b) evaluated teeth should not have more than 1/6 of the buccal surface restored, and the restoration should not interfere with the spectrophotometer readings; (c) volunteers should have good oral health (no dental caries and periodontal disease); (d) good general health (no disease that could interfere with the study results; and (e) volunteers should be at least 18 years old.

The exclusion criteria were (a) volunteers under orthodontic treatment or with tetracycline stained teeth; (b) volunteers reporting past or present hypersensitivity or those having non vital anterior teeth; (c) volunteers that used tooth whiteners within the past three years; (d) smokers, pregnant or lactating women; and (e) volunteers without schedule availability.

One hundred eighty-three volunteers walked in to participate in this study, and the ninety-two individuals that met the inclusion criteria were enroled.

Prior to dental examination, each volunteer filled out a medical history form and a complete dental prophylaxis was performed to remove extrinsic stains. After initial evaluation, the baseline tooth shade was recorded using a Vita shade guide and a digital spectrophotometer on the middle third of the buccal surface of the six maxillary anterior teeth. A template was used to standardize the colour measurement location. Participants were then randomly assigned to two experimental groups (n = 46) according to bleaching agent concentration: 10% (CP10) or 16% (CP16) carbamide peroxide (Whiteness Perfect, FGM Dental Products, Joinville, Brazil). A randomization table to allocate the participants in each study group was prepared in advance by an epidemiologist who was not directly involved with the clinical part of the study. The product concentration label was removed, therefore, the examiners and participants were blinded to the agent

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