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

Sônia Saeger Meireles<sup>a</sup>, Marília Leão Goettems<sup>b</sup>,  
Raquel Venâncio Fernandes Dantas<sup>b</sup>, Álvaro Della Bona<sup>c</sup>,  
Iná S. Santos<sup>d</sup>, Flávio Fernando Demarco<sup>e,\*</sup>

<sup>a</sup>Department of Operative Dentistry, Federal University of Paraíba, Brazil

<sup>b</sup>Post-Graduate Program in Dentistry, Federal University of Pelotas, Pelotas, RS, Brazil

<sup>c</sup>Post-Graduate Program in Dentistry, University of Passo Fundo, RS, Brazil

<sup>d</sup>Post-Graduate Program in Epidemiology, Federal University of Pelotas, Pelotas, RS, Brazil

<sup>e</sup>Post-Graduate Programs in Dentistry and Epidemiology, Federal University of Pelotas, Pelotas, RS, Brazil

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## ABSTRACT

**Objectives:** This study aimed to assess changes in oral health-related quality of life (OHRQoL) in individuals enrolled 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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\* Corresponding author at: Federal University of Pelotas, School of Dentistry, Gonçalves Chaves St., 457, 5th Floor, Center, Pelotas, RS, Brazil. Tel.: +55 53 3222 6690.

E-mail addresses: [soniasaeger@hotmail.com](mailto:soniasaeger@hotmail.com) (S.S. Meireles), [mariliagoettems@hotmail.com](mailto:mariliagoettems@hotmail.com) (M.L. Goettems), [raquelvenancio@hotmail.com](mailto:raquelvenancio@hotmail.com) (R.V.F. Dantas), [dbona@upf.br](mailto:dbona@upf.br) (&D. Bona), [inasantos@uol.com.br](mailto:inasantos@uol.com.br) (I.S. Santos), [ffdemarco@gmail.com](mailto:ffdemarco@gmail.com) (F.F. Demarco).

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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.<sup>1</sup> 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.<sup>2</sup> Also in a paediatric survey in US, 20% of parents and 31% of children were reporting dissatisfaction with tooth color.<sup>3</sup> 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.<sup>4</sup>

Thus, bleaching treatments have become increasingly popular especially among young patients,<sup>5,6</sup> influencing the individuals' aesthetic perception, facial attractiveness and oral health state.<sup>7,8</sup> 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.<sup>9–11</sup> 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 gold-standard for tooth discoloration.<sup>10</sup> Higher concentration of CP gels have been advocated in order to accelerate or improve the bleaching effect<sup>13</sup>; however, the short time and long time clinical trials have disclosed similar results when compared to 10% CP.<sup>1,14,15</sup>

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.<sup>4</sup> 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,<sup>16,17</sup> 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.<sup>16</sup> 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.<sup>17</sup>

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).<sup>18</sup> 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.<sup>1,13,15</sup>

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).<sup>19</sup> 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 enrolled.

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

concentration that was being delivered. Yet, the ADA approved 10% CP<sup>10</sup> was considered the study control group.

Each participant received three bleaching gel tubes and custom trays, fabricated using a 3-mm thick soft vinyl material (FGM Dental Products) and a vacuum-formed process. The excess on the buccal and lingual surfaces was trimmed just short of the gingival margin. They were instructed to use the dispensed gel 2 h per night during three weeks. Both arches were bleached simultaneously. The subjects also received toothbrushes and dentifrices without whitening agents in order to standardize their oral hygiene regimen.

Participants were instructed to record tooth sensitivity on a daily basis for three weeks. They used a standardized grading scale ranked as follows: 0 = no sensitivity; 1 = mild sensitivity; 2 = moderate sensitivity; 3 = considerable sensitivity and 4 = severe sensitivity.<sup>20</sup> Patients who experienced more than a moderate degree of tooth sensitivity received potassium nitrate desensitizing gel (Desensibilize KF 2%, FGM Dental Products). They were instructed to place the desensitizing gel in a tray and wear it for 20 min once a day, as recommended by the manufacturer.

Before starting bleaching treatment, demographic, socioeconomic variables and perception about general health and OHRQoL were assessed by a questionnaire. The assessed demographic variables were gender and age (years), while the socioeconomic variables were the monthly income in Brazilian currency – Real (latter classified by the mean income in up to R\$ 2500.00/month or  $\geq$ R\$ 2500.00/month) and level of education (elementary; middle school; high school; college/university degree incomplete; college/university complete – latter categorized in middle/high school or college/university degree incomplete or complete). The self reported general health was based on a Likert scale: excellent; very good; good; regular; bad (latter categorized in excellent/very good and good/regular).<sup>13</sup> The Brazilian version<sup>21</sup> of the oral impact on daily performance (OIDP)<sup>22</sup> was used to assess the OHRQoL. After one month (one week after bleaching conclusion), the

subjects answered again the OIDP questionnaire to assess changes in oral health perception after treatment. According to the instrument, each individual was asked whether during the past of four weeks, there was any problem about his oral health that caused difficulties with: eating and enjoying food, speaking and pronouncing clearly, cleaning his/her teeth, sleeping and relaxing, smiling, laughing, and showing his/her teeth without embarrassment, maintaining his/her emotional state without becoming upset, carrying out his/her major work or social role, and/or enjoying contact with other people. The possible answers were yes and no. In the case of any individual reported an impact on his/her daily performance, he/she was asked about the major symptom (pain, discomfort, work limitation, dissatisfaction with own appearance or other) and the main oral condition that on his/her opinion had likely caused the difficulty.

Because there was no difference between CP10 and C16 groups with regard to tooth colour at baseline, 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, the outcome (OIDP score) was initially divided into two categories: with (OIDP > 0) and without impact (OIDP = 0). Differences in the frequency of impact at baseline and after one week of bleaching treatment according to the studied variables were assessed using chi-square test. Presence of oral impact on daily performance according to the domains of the instrument was compared before and after treatment using the McNemar test. The symptoms and main oral conditions that generated impact on daily performance were also compared before and after treatment using the McNemar test. Differences were considered statistically significant when  $p \leq 0.05$ .

### 3. Results

Fig. 1 shows the flow chart of the study, with the volunteers that walked in to have the bleaching treatment, those that

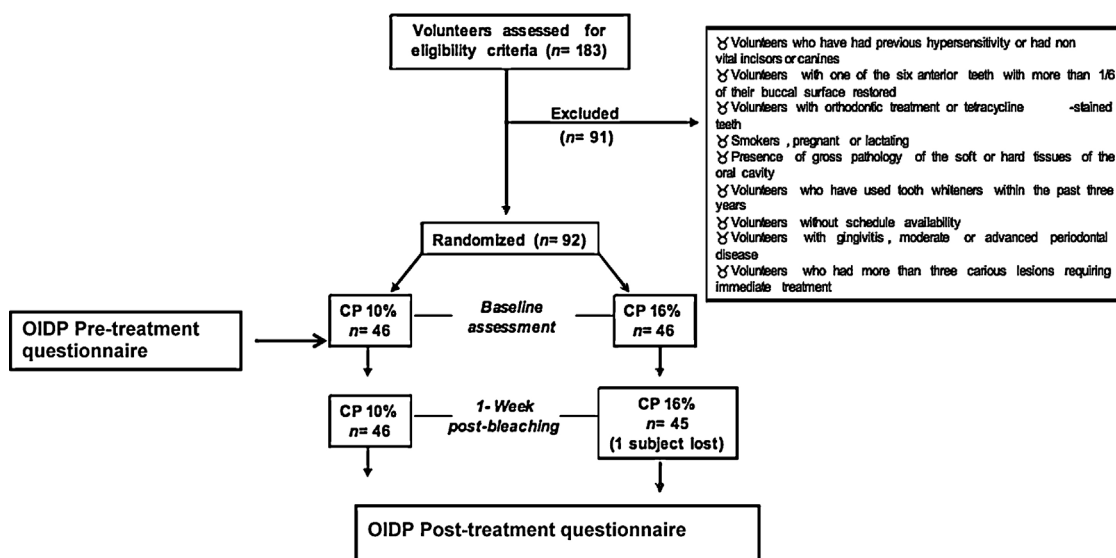


Fig. 1 – Flowchart of the trial.

**Table 1 – Before and after oral health related quality of life according to demographic and socioeconomic characteristics and self-reported general health (Pelotas, RS, Brazil).**

Characteristic	n (%)**	Impact n (%)		p-Value*
		Baseline	Endline	
Sex				0.01
Male	31 (33.7)	7 (22.6)	7 (22.6)	
Female	61 (66.3)	21 (34.3)	31 (50.8)	
Age				0.49
18–20	45 (48.9)	13 (28.9)	19 (42.2)	
21–30	47 (51.1)	15 (31.9)	19 (40.4)	
Education level				0.72
Middle and high school	44 (47.8)	13 (38.6)	17 (38.6)	
Complete/incomplete college/university	48 (52.2)	15 (31.3)	21 (43.8)	
Monthly income				0.06
Up to R\$ 2500	44 (48.9)	17 (38.6)	22 (50.0)	
≥R\$ 2500	46 (51.1)	11 (23.9)	14 (30.4)	
General health				0.04
Excellent/very good	61 (67.0)	16 (26.2)	25 (41.00)	
Good/regular	30 (33.0)	12 (40.0)	12 (40.00)	

1R\$ = 0.52US\$ (2006).  
 \* McNemar test.  
 \*\* Number different of responses means that volunteers may not have answered that specific question.

were included in the RCT and the loss of one volunteer (16% CP group), as well as the moment that OIDP instrument was applied (before and after bleaching treatment).

As reported in previous publications of this randomized clinical trial, there was no significant difference regarding gender, educational level and profession between the two groups. Most of the participants were female, with high educational level (incomplete/complete university degree) and from higher socioeconomic level ( $\geq$ R\$ 2500.00/month).<sup>13</sup> Approximately 50% of the volunteers were 18–20 year-old and the remaining were 21–30 years old. In relation to the tooth colour and tooth sensitivity, there were none significant difference between groups after bleaching using 10% or 16% CP.<sup>13</sup>

OIDP scores varied from 0 to 3 before and after treatment, with a mean of 0.42 (sd 0.74) before and 0.60 (sd 0.83) after

treatment. Table 1 exhibits the number of individuals that informed any OIDP according to demographic and socioeconomic characteristics and self-reported general health. The frequency of female and subjects with good/regular general health with at least one impact reported increased after treatment.

In Table 2, the effect of bleaching on daily life activities is described. When comparing before-and-after bleaching treatment, an increase in negative impact reports was observed (from 30.4% at baseline to 41.3% at endline), without statistical significance ( $p = 0.08$ ). In relation to the different activities evaluated, the proportion of participants who reported difficulty with oral hygiene had increased from 9.8% at baseline to 22.8% at endline ( $p = 0.02$ ). On the other hand, the proportion that reported problems with smiling decreased from 9.8% to 3.3% at baseline and endline, respectively ( $p = 0.03$ ). For the other activities there was none significant difference before and after bleaching.

Table 3 shows the symptoms and main oral conditions that generated the impact on daily performance. In relation to negative symptoms, there was higher number of participants reporting pain after treatment than at baseline ( $p = 0.05$ ). In opposite, statistically significant decrease was observed in individuals reporting being unhappy with their appearance ( $p = 0.03$ ).

Before treatment, only six patients reported having impact related to dental pain, while after treatment this number was more than five times higher ( $n = 33$ ) ( $p < 0.001$ ). On the contrary, five participants reported that the oral condition responsible for the impact at baseline was dental colour, whereas none reported to have impacts in response to dental colour after bleaching ( $p = 0.03$ ). The number of participants reporting impact due to other oral conditions (difficulty to open their mouth, ulcers, gingival bleeding, etc.) was also significantly reduced with treatment ( $p = 0.05$ ).

**Table 2 – Oral impact on daily performance according to the domains of the OIDP before ( $n = 92$ ) and after bleaching treatment ( $n = 91$ ) (Pelotas, RS, Brazil).**

Variables	Impact n (%)		
	Baseline ( $n = 28$ )	Endline ( $n = 38$ )	p-Value*
Eating	17 (18.5)	26 (28.3)	0.10
Speaking	1 (1.1)	2 (2.2)	1.00
Hygiene	9 (9.8)	21 (22.8)	0.02
Smiling	9 (9.8)	3 (3.3)	0.03
Social relations	–	–	–
Emotional state	1 (1.1)	–	1.00
Occupational activities	1 (1.1)	3 (3.3)	0.60
Sleeping-relaxing	1 (1.1)	–	1.00
Total	28 (30.4)	38 (41.3)	0.08

\* McNemar test.



**Table 3 – Symptoms and main oral conditions that generated impact on daily performance, before (*n* = 92) and after treatment (*n* = 91) (Pelotas, RS, Brazil).**

	Affected subjects <i>n</i> (%)		
	Baseline	Endline	<i>p</i> -Value <sup>*</sup>
Symptoms			
Discomfort	15 (16.3)	24 (26.1)	0.09
Pain	10 (10.9)	19 (20.7)	0.05
Appearance	8 (8.7)	3 (3.3)	0.03
Function	1 (1.1)	–	0.31
Others	1 (1.1)	–	0.31
Main oral condition			
Dental pain	6 (6.5)	33 (35.9)	<0.001
Dental position	3 (3.3)	6 (6.5)	0.18
Dental colour	5 (5.4)	–	0.03
Thrush	–	–	–
Others	4 (4.4)	–	0.05

<sup>\*</sup> McNemar test.

#### 4. Discussion

The overall result of this study showed that bleaching treatment has produced changes in the OHRQoL of the subjects, confirming the study hypothesis. In general, frequency of impacts increased after bleaching treatments, however with no statistical significance. Nevertheless, a significant decrease in frequency of impact was observed for activities related to aesthetics, after bleaching conclusion. In the baseline, nine subjects reported impact on smiling, laughing, and showing teeth without embarrassment; after bleaching protocols, only three reported impact on these items. Also, none participant reported impact due to the dental colour after bleaching procedures, while five participants reported that dental colour was the main oral condition responsible for the negative perception about oral health before the treatment. The number of participants that reported complaints related to their dental appearance before bleaching was significantly reduced after the treatment. Other conditions, such as complain with gingival bleeding, ulcerations, etc., had their impact reduced after bleaching.

The main reason for this is the efficacy of home bleaching gel used in a custom tray in producing a significant whitening effect. A systematic review showed that vital bleaching using 10% carbamide peroxide was effective to whitening teeth compared to a placebo group.<sup>10</sup> Yet, bleaching gels containing 10% CP have the seal of approval from the American Dental Association (ADA).<sup>23</sup> Published data for the present randomized clinical trial, which compares the efficacy of 10% and 16% CP to bleaching vital teeth, showed a greater bleaching effect when using 16% CP (5.9), as compared to 10% CP (5.4). Indeed, the perception about OHRQoL was similar for both bleaching agents after treatment. It is important to highlight that this randomized clinical trial did not find any difference on the whitening effect between 10% CP and 16% CP gels after six months, 1 and 2 years after treatment.<sup>1,13,15</sup> After 2 years follow-up, even with subjects consuming a diet with potential staining components, more than 80% of the individual in both treatments (10% or 16% CP) maintained the colour shade obtained in the first evaluation after bleaching conclusion,

demonstrating the longevity of the treatment, contradicting the general believing that patients should bleaching their teeth again in intervals of 2 years.<sup>1</sup>

Generally, the home bleaching with gels applied in custom tray is considered advantageous due to the simple technique and reduced chair time, and it is the most recommended by the dentists.<sup>24</sup> Yet, the most common adverse effect reported is the tooth sensitivity. The occurrence of this side-effect is probably caused by the increase in enamel permeability, due to the chemical removal of mineral ions from enamel surface and subsurface by the bleaching agent.<sup>12,25</sup> This ion removal is generally reversed by the deposition of ions present in saliva,<sup>25</sup> which explain the low level of hypersensitivity reported and the relatively reduced time of this adverse effect, being usually reversed by the interruption of the bleaching agent application or by the application of a remineralizing agent, such as fluoride or sodium potassium.<sup>12,14,26,27</sup> In fact, when observing the tooth sensitivity reported in the present clinical trial, more than 40% of the participants (41.3% from 10% CP group and 44.5% from 16% CP) have reported some sensitivity after 3 weeks of bleaching application. However, more than 80% of the reported sensitivity in the two bleaching protocols was classified as mild, indicating the low level of side effects observed with this technique. Despite the low level of sensitivity observed in the trial, it has produced a negative impact in the study participants, being the most likely reason for the increase in the overall frequency of impacts observed. Indeed, after bleaching treatment, subjects reported more impact in oral hygiene, meaning that the participants had more difficulties to brush their teeth. In addition, gingival irritation, another adverse effect reported with tooth bleaching,<sup>28</sup> could impair the tooth brushing ability. However, the participants had not been asked about occurrence of gingival irritation and this is a limitation of the study. In relation to the negative impact observed after bleaching protocols, more volunteers reported feeling discomfort and pain and the main oral condition affected was dental pain. Such observations are in agreement with the figure of more than 40% of the participants experiencing some degree of tooth sensitivity following bleaching treatment. Even tooth sensitivity being a minor side effect, it has produced negative impact in patients who underwent at home vital bleaching. Therefore, clinicians should be aware of this potential impact caused by tooth sensitivity and offer proper instructions to prevent it or treatment to reduce the impact.

Quality of life is a relatively new concern in dentistry, but OHRQoL instruments are being increasingly used in oral health surveys, especially for adults or elderly populations.<sup>29,30</sup> Frequently only clinical parameters are not able to measure the extension that different disorders may disrupt normal function.<sup>29</sup> So, traditional measures could be considered a limited one-dimensional aspect of oral health and should be supplemented by information obtained from the patient or by proxy reports to document the consequences of oral disorder on OHRQoL.<sup>31</sup> Recently, OHRQoL has been used as an endpoint to evaluate treatments in clinical trials and also to assess changes after dental treatment, since it is recognized that patients' perceptions of oral health are important in assessing oral health needs and determining outcomes from oral health care and oral health activities.<sup>32</sup> Cortes et al. had

shown that dental restoration can improve the quality of life in children that have suffered dental trauma in anterior teeth.<sup>21</sup> Another study has compared the satisfaction with denture use and the OHRQoL, applying questionnaires before and after denture placement. It was demonstrated that chewing and oral condition domains were affected by the denture satisfaction.<sup>33</sup> When evaluating the impact in quality of life produced by dental implants, it was found that screwed implant restorations provide better OHRQoL than fixed-detachable hybrid prostheses and the authors observed that this impact was modulated by several variables (gender, education level, complaints about the mouth, perception of treatment needs, and prosthetic status).<sup>30</sup>

The presence of tooth discoloration can produce impact in OHRQoL. In a survey evaluating more than 1000 12-year old Thai children, moderate/high intensity impacts attributable to tooth discoloration were reported by 2.6% of the participants.<sup>34</sup> In the present study, OHRQoL was measured before and after bleaching treatment, so it was possible to determine the impact that the treatment has produced in the individuals enrolled in the trial. Indeed, bleaching has increased negative impacts (discomfort, pain, difficult to perform oral hygiene), but positive impacts were also observed, with a lower number of individuals reporting problems to smile or being unsatisfied with their appearance, demonstrating benefit of treatment. When considering previous studies evaluating the impact of whitening procedures on OHRQoL, there are some differences. In a clinical trial enrolling 62 individuals over 50 years, the participants were divided in two groups, a control group with no whitening product and an experimental group with a whitening product used twice daily for three weeks. The Oral Health Impact Profile (OHIP) was used as pre- and post-test measure. Significant increases in physical pain subscale ( $p = 0.0029$ ) and in the handicap subscale ( $p = 0.05$ ) were observed. The increase in pain subscale was related to the tooth sensitivity experienced by experimental group. In relation to the handicap subscale, experimental group reported an improved OHRQoL feeling more willing to work. Differences were not observed in the overall OHIP score for functional factors, psychological disabilities, psychological discomforts, physical disabilities and social disabilities and the authors concluded that vital whitening treatment did not improve OHRQoL in older adults.<sup>17</sup> This lack of consistency may be due to differences in characteristics of the studied population. In fact, the mean age in our study was around 25 years old and it has been demonstrated that older individuals are more resilient, being more used with their dental appearance than younger ones. It was reported that the elderly noticed less impact regarding aesthetics and dental sensibility to hot, cold and sweet.<sup>35</sup> In opposite, younger individuals are more concerned with their teeth alignment and their teeth colour,<sup>6–8</sup> and so, they might favour the observation of a “positive” impact of the bleaching treatment. If the volunteers (study population) were older, perhaps the results could be different, yet that remains to be investigated.

Additionally, the participants enrolled in the present trial had high educational level and were from higher socioeconomic levels, considering the Brazilian average standard. It is expected that such patients would show lower levels of negative impact than in individuals with low education and

income.<sup>36</sup> However, individuals had searched treatment in order to receive dental bleaching. Thus, they had demonstrated concerns regarding their aesthetic appearance, and had not searched treatment due to traditional dental treatment needs, i.e. dental caries, periodontal disease or prosthodontics. Therefore, they were more prone to exhibit impact when an aesthetic treatment was implemented. Noteworthy, individuals participating in a clinical trial can be subject to the Hawthorne effect, meaning that they might have a positive response, only because they are being studied.<sup>37</sup> This positive effect cannot be discarded in the present study and it could have some residual impact in our results.

Several different instruments have been developed to measure the OHRQoL. In the present study we used the OIDP.<sup>22</sup> The OIDP has been widely used and it is the only OHRQoL measure designed to link specific oral problems leading to the impacts on quality of life, thereby associating such impacts to the specific oral condition that may need attention.<sup>22</sup> It is based conceptually on the International Classification of Impairments Disabilities and Handicaps<sup>38</sup> created by the World Health Organization in 1980. This indicator is based on three main dimensions that could be hypothetically affected by oral health conditions: pain and discomfort, dental aesthetics and function limitation. Thus, it was considered appropriate to measure the impact of dental bleaching, although measures have been developed to assess the aesthetic perception.<sup>39</sup>

It is important to point out some aspects that strength this study. It is an independent study part of a long-term double blind controlled randomized clinical trial, which was properly designed to follow the CONSORT guidelines. In relation to the potential limitations, the socioeconomic background (high income and high educational level) and the age (younger individuals) of the sample could be considered bias, because in these individuals the concerns about aesthetics tend to be superior. Perhaps in older patients or individuals with lower socioeconomic level the impact could be less noticed, but this remains to be determined. Noteworthy, individuals seeking for dental bleaching often present similar profile to the participants of the present study, which support our findings. Other frequent limitations in randomized clinical trials are the sample size and the attrition of the participants, especially in long time follow-ups. However, this was not a problem in our study, since we have lost only one participant and we had a sample size large enough to find statistically significant differences in relation to the outcome. Also, in several studies the statistical analysis approach may be a problem when performing a RCT,<sup>40</sup> but in the present study we have carried out appropriate statistical method, that strictly followed the recommendations of the clinical epidemiology.<sup>40</sup>

The findings of this study showed that at-home bleaching could have positive and negative impacts in the OHRQoL, supporting that professionals should handle with care patients under bleaching treatment in order to obtain the best improvement in aesthetics, with minimal side effects. Also, future studies should address the impact in OHRQoL comparing other modalities of bleaching treatments (e.g., in office bleaching vs at home bleaching), since the quality of life related to oral health is an important part in the overall evaluation of a treatment.

## 5. Conclusions

Within the limitations of this study, it can be concluded that at a short term at-home vital tooth bleaching may impact in the OHRQoL of younger adults, improving their satisfaction with dental appearance, but in opposite producing more discomfort and pain.

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