The change of color by whiteness indexes and its psychosocial and self-perception effects when using low vs. high concentration whitening gels: a one-year follow-up.

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Bleaching, Randomized clinical trial, Low concentration, OHIP-14, PIDAQ
Abstract

Background: Dental bleaching in traditional concentrations generates greater sensitivity, in this respect new systems of lower concentration of hydrogen peroxide for tooth whitening appeared, with color stability unknown over time. The aim of this study was to compare the change and stability of color with low-concentration (6%) hydrogen peroxide gel in an in-office bleaching setting relative to conventional 37.5% gel including their effects on psychosocial and esthetic self-perception at one year.

Methods: Patients (n=25) were assessed at 12 months post bleaching treatment (whitening with 6% activated chemo gel of alkaline formula v/s traditional concentration 37.5%). Color changes were measured objectively using total variation in color (ΔE) and subjectively using Vita Classical and Vita Bleached scale (ΔSGU) by calibrated evaluators (Kappa=0.85). The Psychosocial Impact of Dental Aesthetics Questionnaire (PIDAQ) and Oral Health Impact Profile (OHIP-14) aesthetic questionnaires were administered to measure self-perception and the psychosocial impact of the whitening procedure.

Results: The effect (ΔE) of 37.5% HP (8.37 ± 2.73) was significantly better than that of 6% HP (5.27 ± 2.53) in terms of color rebound at one year of follow-up. There were significant differences in psychosocial impact and esthetic self-perception measurements prior to bleaching versus the one-year post-whitening time points; positive effects were maintained.

Conclusions: Low concentration (6%) achieved effective bleaching with good stability at one year. This was accompanied by a positive psychosocial impact and enhanced self-perception at follow-up. Trial registration: NCT03217994 Keywords:
BACKGROUND

Teeth whitening is a safe and widely used procedure which is frequently requested by patients searching for aesthetic improvement, despite some reported biological side effects [1]. As a routine procedure, the quantification of tooth whitening and the efficacy of its effects has turned into a crucial concern. Traditionally, dentists determine the color of human teeth via visual comparison to a reference standard set called a shade guide. Alternatively, the instrumental assessment provides quantitative and objective data which through the use of some indexes widely used allow for proper interpretation of them. The list of indexes includes the CIE whiteness index WIC, the whiteness index according to ASTM E-313-73 WI, and the Z% index. Recently, a whiteness formula (WIO) that optimizes the original CIE whiteness formula (WIC) has been developed, rendering the best performance for the prediction of tooth whiteness [2, 3].

Regarding the bleaching product, traditionally a chemically activated gel of low concentration of hydrogen peroxide has shown lower efficiency than a higher concentration one; however, a new alkaline formulation has shown color changes of over 5 \( \Delta E \) units [4]. This low-concentration product has demonstrated promising results including high efficacy with very low postoperative sensitivity [5]. The alkalinity of this product would play a key role accelerating the chemical reaction and improving the effectiveness when compared to others systems of similar concentration [6].

At the same time, despite their importance, reports about longevity [7-9], and the relationship between dental whitening and quality of life [10-12] are limited,
besides relatively few clinical studies have assessed the effectiveness, and psychological effects of tooth whitening in a long-term follow-up [13, 14]. In this sense, it is essential to study patients’ self-perception concerning to whitening psychosocial impact and whitening duration [15]. Recent studies suggest that extra and intracoronal tooth whitening can produce positive psychosocial outcomes and increase the self-image of the patients [16]. However, there are no reports of the psychosocial and self-perception effects of low concentration gels (6% hydrogen peroxide) in a prospective and longitudinal follow-up study.

This study compared the stability and color rebound at twelve months after using a low concentration alkaline 6% hydrogen peroxide gel versus a conventional 37.5% gel in an office whitening procedure. The color was assessed using regression by standard methodologies and whiteness indexes. Additionally, the psychosocial effects and effects on self-perception were evaluated during one year of follow up. This study tested two null hypotheses: 1) there will be no color rebound after one year of follow-up in patients treated either with 6% or 35% hydrogen peroxide gel and 2) there will be no variation in the psychosocial and self-perception effects in the patients, after teeth whitening, a year later.

Methods

Sample and ethical approval

This study was a randomized and prospective double-blind clinical trial with one year of follow-up. The design is shown in Figure 1 and follows the CONSORT (Consolidated Standards of Reporting Trials) recommendations and the principles of the Helsinki Convention. The study was approved by the local Committee of Ethics approval number and registered in ClinicalTrials.gov (pending to blind review).
Selection of the Sample

Thirty-five patients were recruited from the Faculty of Dentistry of the University of Chile. These patients had asked for a whitening treatment and volunteered to participate in the study by signing an informed consent form approved by the Ethics Committee of the Faculty of Dentistry.

All of these patients met the following inclusion criteria:

- Age 18 or older (both sexes).
- At least six upper healthy frontal teeth.
- No restorations or crowns in these teeth.
- A color A3 or less (using the Vita classical scale) as determined using a spectrophotometer (Vita Easy Shade® Compact, Vita Zahnfabrik) in the middle third on the buccal surface of central incisors.

The following exclusion criteria were used:

- Pregnancy or lactation.
- Bruxism or tooth sensitivity.
- Teeth with prior whitening treatment (either at home or in-office).
- Teeth with visible dental cracks, developmental defects, or tetracycline or fluorosis discoloration.
- Presence of non-carious cervical lesions
- Nonvital discolored teeth.

Study Design

Patients who had any pathology that prevented them from entering the study (such as caries, periodontal disease, or tooth sensitivity) were referred to the dental clinic of the Faculty of Dentistry at the local University for proper treatment.

The sample size was determined following similar studies [17, 18] with a significance level of 5% and a statistical power (1-β) of 0.90. As a result, it was estimated a minimum of 32 patients.

Since it was expected a 5% dropout; the initial number of participants was 35 individuals. Treatments were carried out in the clinic of the Faculty of Dentistry; the researchers monitored the participants.

The study used a split-mouth randomized design with a 37.5% hydrogen peroxide (Polaoffice + 37.5%, SDI, Victoria, Australia) and a 6% hydrogen peroxide (Polaoffice
as whitening agents. Both products were used in each participant, applying the 6% to one hemi-arcade (canine, central, and lateral incisors) and the 37.5% to the other. The whitening systems were assigned using SPSS 21 software (SPSS, IBM, New York, USA). To blind the operators, each product was properly masked with coded labels. Auto-mix syringes of Polaoffice + in the office teeth whitening system were used (SDI Limited). The syringes contained hydrogen peroxide in concentration of 37.5% or 6% in the form of a thixotropic gel with similar features of color and viscosity.

Different operators than those who performed the whitening procedure conducted all color measurements in both upper central incisors. The follow-up was performed similarly.

**Preliminary phase**

The color of each upper central incisor was measured with a spectrophotometer (Vita Easy Shade® Compact, Vita Zahnfabrik) that was previously calibrated according to the manufacturer instructions. To standardize this evaluation, a silicone matrix was made (Zetaplus, Zhermack, Rovigo, Italy) with a 6mm-diameter window on the buccal surface that allowed the positioning of the tip of the spectrophotometer on the middle third of the labial surface of the teeth.

**Intervention: Whitening Protocol**

Each participant had two whitening sessions separated by an interval of one week. At the beginning of each session, dental prophylaxis was performed using a dental brush and stone pumice with water at low speed. A plastic lip retractor and a gingival barrier (Gingival barrier; SDI Limited, Victoria, Australia) were used to protect the soft tissues. Whitening gels were applied evenly to each hemi-arcade on their vestibular surface.
The Protocol included three applications of the whitening gel for twelve minutes (36 minutes each session). Between each application, the gel was removed with rolls of cotton moistened with water and then the teeth were dried carefully. At the end of the third application, the gel was removed using copious amounts of water, and the gingival barrier and lip retractor were removed. The patients received indications and were scheduled to the next visit.

**Controls**

At the end of the first session, tooth color was measured subjectively (Color scales) and objectively with a spectrophotometer (Vita Easy Shade® Compact, Vita Zahnfabrik)[19]. The measurements were repeated after a week, a month, six months and a year after whitening.

**Color evaluation**

**Subjective extraction and treatment data**

The color was assessed visually under standardized light conditions (same place, time, natural light source, all assessments were performed between 10:00 AM and 3:00 PM) by two previously calibrated operators, who showed a previous agreement (Visual Scales) of at least 85% as determined using weighted k-statistics. The viewing geometry, object-observer distance, visual angle, and background color were held constant. Each operator evaluated three times each tooth. If both operators coincided in their selection, the determined value remained as definitive, if there was a discrepancy, a calibrated third operator (professor of restorative dentistry) defined between both colors.

The Vita classical Guide (Vita Classic, Vita Zahnfabrik) and Bleached guide (Vita Bleached Guide, Vita Zahnfabrik) were used for subjective evaluation using the tab arrangement proposed by Ontiveros and Paravina [20]. The observers assessed the
color of both central incisors at the start of the study, at each session of whitening, and one week, one month, six months and one-year post-treatment. The color was recorded on the middle third of the labial surface as established by the guidelines of the American Dental Association [21]. The difference in tooth color was calculated as the number of units that the tooth changed according to the shade guide arrangement (ΔSGU).

**Objective treatment data**

Objective data were evaluated according to the three axes of the CIELAB system (L*, a* and b*). The ΔE was also calculated using the Pythagorean theorem as follows:

\[ \Delta E = \left[ (\Delta L)^2 + (\Delta a)^2 + (\Delta b)^2 \right]^{1/2} \]

The variation on each parameter at different time points was calculated about the initial value (i.e., the measurement of color before the first session of whitening). Also, the color difference was calculated by means of the CIEDE2000 formula proposed by Luo in 2001 [22] and Whiteness Index proposed by Gerlach in 2002 [23].

**Self-perception and psychosocial impact assessment**

Before whitening treatment, participants completed two questionnaires: the psychosocial impact dental aesthetic questionnaire (PIDAQ) and the oral health impact profile (OHIP-14). These questionnaires were repeated after a week, one, six and twelve months post whitening treatment. They were completed under the supervision of an examiner who was available to answer every question. The PIDAQ is psychometric testing to measure the psychosocial consequences of dental aesthetics [24]. It consists of 23 items on a five-point Likert-type scale from 0 (total disagreement) and to 4 (complete agreement). A patient may receive a total
score of 0 to 72 points. The evaluation is also divided into four subscales: one positive (dental confidence [six questions]) and three negative (psychological impact [eight questions], aesthetic concern [three questions], and social impact [six questions]). A more positive subscale score indicates greater confidence in itself, while higher scores on the negative subscales indicate the adverse effects of cosmetic dentistry.

The OHIP-14 is an assessment used to evaluate the aesthetic perception [25]. The survey is scored on a five-point Likert-type scale. Each option partners with a score: very often (4), often (3), from time to time (2), almost never (1), or never or not (0). A higher score indicates poor patient self-perception of the cosmetic dentistry. To calculate the score of OHIP-14 for each patient, we added the total score of 14 questions to generate a total score between 0 and 56 points.

**Statistical Analysis**

The data were tabulated, and their normal distribution was analyzed using the Shapiro-Wilk test. The Mann-Whitney test was used to compare the efficiency of the results between groups, whereas, for comparisons between two assessment times and to assess color rebound in each group the Wilcoxon and T-Student tests were used.

PIDAQ and OHIP-14 test scores were determined, and the results for each time point were compared using the Wilcoxon test. Data were statistically analyzed using SPSS 21.0 (Lead Technologies INc., Charlotte, NC, USA). The data were considered statistically significant when p < 0.05.

**Results**

**Features of the sample**
After one year of follow-up, twenty-five participants were evaluated. The average age was 27.11 years old (total range 20/54 SD = 7.5) and 13 were men and 12 women; other features are summarized in Table 1.

**Effectiveness values**

At one year after treatment, significant changes in tooth color were observed for both concentrations of hydrogen peroxide when compared to baseline. The ΔE and ΔSGU values were similar; however, the 37.5% hydrogen peroxide gel was more effective than 6% hydrogen peroxide gel, and this difference remained after twelve months of follow-up. The statistically significant improvement was seen either in objective and subjective assessments. Conversely, the color rebound was considered minimal and was not statistically significant (Tables 2-6). The results for the CIEDE2000 formula (Table 5) and Whiteness Index (Table 6) showed a non-significant difference between both groups (p > 0.05).

**PIDAQ and OHIP-14**

In PIDAQ all the factors were statistically significant at one year of follow-up (p < 0.05) (Table 7). In OHIP-14 the changes remained statistically significant at one year of follow-up (p < 0.05) for all the factors and the overall sum (Table 8).

**DISCUSSION**

This study evaluated the rebound in tooth color after using a low concentration (6%) of hydrogen peroxide gel compared to a standard 37.5% hydrogen peroxide gel in a split-mouth design. Both gels were effective and did not show a significant clinical rebound after one year of follow-up; however, each of them had different effectiveness. The positive psychosocial impact and aesthetic self-perception remained without changes up to one year. Thus, the first null hypothesis was
accepted because the rebound was insignificant both in subjective and objective assessments. The second null hypothesis was rejected because the positive psychosocial impact and aesthetic self-perceptions remained stable after twelve months of whitening.

Low concentrations of alkaline hydrogen peroxide gel showed good stability without significant rebounds in tooth color during the extension of this study, which could mean that during the first year, the concentration of hydrogen peroxide would not have a substantial impact on color rebound. Although the initial color differences between both hemi-arcades remained, the patients did not perceive them negatively, probably due to the perception threshold of each patient [26, 27]. That is, they were not able to discriminate between less than three $\Delta E$. The local Ethics Committee required that the researchers retreated any hemi-arcades to match the color if any patient noticed a difference; however, no patient raised this issue. This point denotes the critical difference between subjective and objective measurements, to the limit of having a cohort of patients, who did not perceive major differences between their bleached hemi-arcades, which showed statistical differences in objective measurements. This phenomenon should help to understand that from the patients’ perspective, an effective whitening can be achieved with a gel of low concentration, which also exhibited good stability at the one-year control, even when measured by CIEDE2000 and Whitening indexes, which according to the literature, reflect more precisely the rebound of whitening treatments [3, 22].

The importance of aesthetic dentistry in recent years has led to technological developments that improve dental aspects [28]. The dental appearance exerts a powerful aesthetic influence on patients. Thus, it is essential to understand the psychosocial impact of treatment [29, 30]. However, these effects are poorly
understood. The new definition of oral health recently declared by the FDI includes the psychological aspects of the patients. Therefore a procedure that improves these aspects is relevant for the mental health of them [31]. The results of this study showed that there were significant changes in PIDAQ and OHIP-14 scores after whitening, indicating that whitening had a positive impact on the subjects’ psychosocial and aesthetic perceptions. This effect remained for the duration of the study.

Dental self-confidence was measured using the PIDAQ. This positive subscale measures the influence of esthetic dentistry on an individual’s self-perceived image. The appearance of the mouth and smile play a vital role in the evaluation of the facial appeal. The results suggest that extra-coronal tooth whitening increases dental confidence. This finding shows that this factor is associated with more favorable attitudes toward oral health and a higher degree of satisfaction with regard self-perception [15, 32].

The PIDAQ also measures three negative psychosocial impact dimensions: social impact, psychological impact, and aesthetic concerns. Social impact evaluates potential problems that an individual has in social situations due to the unfavorable subjective aspects of their teeth. The psychological impact evaluates feelings of inferiority or unhappiness that an individual has when compared to others. Aesthetic concern includes data referring to the concern or disapproval of dental appearance an individual has when that person faces the mirror or view photographs or videos of themselves [30]. The results show a decrease in these scores at one-year post-whitening when compared to the baseline. Therefore, extra-coronal tooth whitening generates a positive psychosocial effect—both in the immediate and in the long term.
The OHIP-14 showed a statistically significant decrease in scores at all time points after whitening compared to baseline. This decrease indicates that whitening produces a substantial improvement in the perception of patients and a noticeable reduction in all dimensions of physical, psychological, and social disability. These values significantly decreased with treatment providing important biopsychosocial implications. Usually, these perceptions of physical, mental, and social impairment are experienced by people with cosmetic dental problems and can profoundly affect their self-esteem, interactions, environmental adaptations, relationships, personal, job opportunities, and fundamental aspects that affect the quality of life [33].

To experience any positive change after the whitening treatment, patients require interaction with their social environment. In the current study, the results were perceived soon after the treatment. Moreover, since all dimensions in the OHIP-14 at one-year post whitening kept better than baseline suggests that the psychosocial results were not only immediate but also had a long-term effect.

The limited available literature on the self-perception of the aesthetics and psychosocial impact generated by teeth whitening has shown psychosocial changes resulting from patients' self-perception of aesthetics [10, 13, 16]. Nevertheless, more research is needed to support these results more conclusively. On the other hand, even though simple and short-term interventions do not affect personality factors [34], it can be emphasized that there is an impact on psychosocial factors and personal perception, intervening positively on the patient's self-esteem and finally on their health status.

Finally, it is advisable that future research also studied the changes in the psychosocial well being of patients subjected to at home whitening with different concentrations of gel, and to assess the effects of tooth whitening better, the
psychosocial impact of whitening could be compared to untreated patients.

Conclusions

Low concentrations (6%) and traditional concentrations of hydrogen peroxide gels (37.5%) were effective and stable at one-year post whitening, even though their effectiveness was statistically different. Both treatments kept a positive effect on psychosocial and self-perception during a year of follow-up.

LIST OF ABBREVIATIONS

WIO Whiteness formula
WIC CIE whiteness formula
CONSORT Consolidated Standards of Reporting Trials
SGU Scale Guide Unit
CIE Commission Internationalede L’Eclairag
PIDAQ Psychosocial impact dental aesthetic questionnaire
OHIP-14 Oral health impact profile
FDI World Dental Federation

DECLARATIONS

Ethics approval and consent to participate

The study was approved by the ethics local committee of the faculty of dentistry of the university of chile (approval number 15/001).

Consent for publication

The authors give their consent for the publication of the article in the journal.

Availability of data and material
Competing interests

The authors declare that they have no conflicts of interests and the authors do not have any financial interest in the companies or products used in this study.

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Authors’ contributions

Phase of Design and planning of the study: JE, PA, CB, MP, EF

Experimental phase and data collection: JE, CB, MP

Phase of data analysis: PA, EF

Preparation of the article: JE, PA, CB, MP, EF

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Tables
Table 1. Participants’ characteristics at baseline.
| Baseline features | Groups |
|------------------|--------|
|                  | HP 37.5% | HP 6% |
| Age (years; mean ± SD) | 27 ± 7.5 |
| Minimum age (years) | 20 |
| Maximum age (years) | 54 |
| Male (%) | 52% |
| *L (mean ± SD) | 84.41 ± 2.95 | 86.17 ± 2.81 |
| *a (mean ± SD) | 0.08 ± 1.06 | 0.15 ± 1.24 |
| *b (mean ± SD) | 27.96 ± 3.18 | 28.42 ± 3.68 |
| Baseline Vita bleach SGU median (min:max) | 9 (7:11) | 9 (7:11) |
| Baseline Vita classical SGU median (min:max) | 9 (9:12) | 9 (9:12) |

SD = standard deviation

Table 2. Comparison of ΔSGU values by Vita Classic guide at different times. The median, minimum and maximum values are shown.

| Assessment points | Color change by ΔSGU |
|-------------------|----------------------|
|                   | 37.5% Hydrogen Peroxide | 6% Hydrogen |
| Baseline vs. 1-wk after bleaching | 7 (2:9) | 6 (2:5) |
| Baseline vs. 1-mth after bleaching | 7 (2:9) | 6 (1:5) |
| Baseline vs. 6-mths after bleaching | 7 (3:8) | 6 (1:8) |
| Baseline vs. 12-mths after bleaching | 6 (1:8)** | 5 (0:7) |

* for comparison between both groups in each assessment time; ** for comparison between two assessment time (1-month vs 12-month after bleaching) in each group. No significant difference was found (Wilcoxon test; p > 0.05).** for comparison between two assessment time (1-month vs 12-month after bleaching) in each group. No significant difference was found (Student t test for paired sample; p > 0.05).

Table 3. Comparison of ΔSGU values by Vita Bleach Guide 3D-Master at different times. The median, minimum and maximum value are shown.
Assessment points | Color change by ΔSGU
---|---
Baseline vs. 1-wk after bleaching | 3.5 (1:6) | 3 (2:6)
Baseline vs. 1-mth after bleaching | 3 (1:6) | 2 (0:6)
Baseline vs. 6-mths after bleaching | 3 (2:5) | 2 (0:4)
Baseline vs. 12-mths after bleaching | 3 (0:5)** | 2 (0:4)

* for comparison between both groups in each assessment time; ** for comparison between two assessment time (1-month vs 12-month after bleaching) in each group. No significant difference was found (Wilcoxon test; p > 0.05).** for comparison between two assessment time (1-month vs 12-month after bleaching) in each group. No significant difference was found (Student t test for paired sample; p > 0.05).

Table 4. Comparison of ΔE values at different times expressed as mean and SD.

| Assessment points | Color change by ΔCIEDE2000 |
|---|---|
| 37.5% Hydrogen Peroxide | 6% Hydrogen Peroxide |
Baseline vs. 1-wk after bleaching | 8.67 ± 2.61 | 5.59 ± 2.8
Baseline vs. 1-mth after bleaching | 9.05 ± 2.74 | 5.08 ± 1.51
Baseline vs. 6-mths after bleaching | 8.01 ± 2.84 | 5.07 ± 1.2
Baseline vs. 12-mths after bleaching | 8.37 ± 2.73** | 5.27 ± 2.1

* for comparison between both groups in each assessment time; ** for comparison between two assessment time (1-month vs 12-month after bleaching) in each group. No significant difference was found (Wilcoxon test; p > 0.05).** for comparison between two assessment time (1-month vs 12-month after bleaching) in each group. No significant difference was found (Student t test for paired sample; p > 0.05).

Table 5. Color change using CIEDE2000 formula, with data from the Vita Easyshade spectrophotometer measurements, for each group of treatment in different time points. The mean, standard deviation, and statistical analysis are displayed.
* for comparison between both groups in each assessment time; ** for comparison between two assessment time (1-month vs 12-month after bleaching) in each group.
No significant difference was found (Wilcoxon test; p > 0.05).** for comparison between two assessment time (1-month vs 12-month after bleaching) in each group.
No significant difference was found (Student t test for paired sample; p > 0.05).

Table 6. Color change using IW, with data from the Vita Easyshade spectrophotometer measurements, for each group of treatment in different time points. The mean, standard deviation, and statistical analysis are displayed.

| Assessment points               | Color change | 37.5% Hydrogen Peroxide | 6% Hydrogen PI |
|---------------------------------|-------------|--------------------------|----------------|
| Baseline                        |             | 32.19 ± 2.88             | 31.79 ± 3..    |
| 1-wk after bleaching            |             | 24.91 ± 2.85             | 27.63 ± 4..    |
| 1-mth after bleaching           |             | 24.65 ± 2.94             | 28.20 ± 3..    |
| 6-mths after bleaching          |             | 25.53 ± 2.63             | 29.31 ± 3.     |
| 12-mths after bleaching         |             | 24.89 ± 2.69**           | 27.81 ± 3.3    |

* for comparison between both groups in each assessment time; ** for comparison between two assessment time (1-month vs 12-month after bleaching) in each group.
No significant difference was found (Wilcoxon test; p > 0.05).** for comparison between two assessment time (1-month vs 12-month after bleaching) in each group.
No significant difference was found (Student t test for paired sample; p > 0.05).

Table 7. PIDAQ results at different time points. A: Statistically significant differences (Wilcoxon test, <0.05) versus baseline. Expressed in median values (minimum/maximum). B: Statistically significant differences (Wilcoxon test, p<0.05) versus 1 week after bleaching.
Table 8. OHIP results at different time points. A: Statistically significant difference (Wilcoxon test, \(p<0.05\)) versus baseline. Expressed in median values (minimum/maximum). B: Statistically significant differences (Wilcoxon test, \(p<0.05\)).

| Dimension                      | Baseline | 1 week after bleaching | 1 m after bleaching |
|--------------------------------|----------|------------------------|---------------------|
| **Dental Self-Confidence**    | 16 (11:28) | 23 (15:28) A    | 2 (16:29)          |
| **Social Impact**             | 17 (9:34)  | 16 (8:27) A         | 1 (8:26)           |
| **Psychological Impact**      | 19 (8:26)  | 15 (6:22) A         | 1 (6:2)            |
| **Esthetic Concern**          | 7 (3:15)   | 6 (3:10) A          | 1 (3:1)            |

| Dimension                      | Baseline | 1 week after bleaching |
|--------------------------------|----------|------------------------|
| **Functional limitation**      | 3 (0:7)   | 3 (0:6) A              |
| **Physical pain**              | 3 (0:7)   | 2 (0:4) A              |
| **Psychological discomfort**   | 3 (0:7)   | 3 (0:5)                |
| **Physical disability**        | 1 (0:4)   | 0 (0:3) A              |
| **Psychological disability**   | 1 (0:5)   | 0 (0:3) A              |
| **Social disability**          | 0 (0:4)   | 0 (0:3) A              |
| **Handicap**                   | 0 (0:4)   | 0 (0:3) A              |
| **Sum**                        | 14 (6:31) | 10 (3:19) A            |
Figure 1. Flow diagram of the clinical trial.

- Assessed for eligibility (n=110)
  - Excluded (n=77)
    - Not meeting inclusion criteria (n=77)
    - Declined to participate (n=0)
  - Groups (half arch of teeth) 35 patients

- Enrollment

- Allocation

- Follow-Up
  - Lost to follow-up (did not attend appointments) (n=0)

- Analysis
  - Analysed (n=25)
    - Excluded from analysis (n=0)
Supplementary Files

This is a list of supplementary files associated with the primary manuscript. Click to download.

CONSORT 2010 Checklist.doc