Syrian Arab Republic

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Faculty of dentistry

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Evaluation of tooth sensitivity and efficacy of two systems of OTC "over-the-counter" teeth whitening products compared to At-Home bleaching with carbamide peroxide CP: A randomized clinical controlled trial

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Introduction:

Teeth whitening is one of the most popular procedure in the dental clinic during the past few years because it is easy and has a great impact on the cosmetic aspects of the patient's smile (1). In addition, it is a conservative cosmetic treatment that gives good results in whitening vital and non vital colored teeth (2).

Teeth whitening can be performed under the supervision of a dentist such as in-office (I-O) whitening or at-home (A-H) whitening, and it can be performed completely by the patient by using over-the-counter(OTC) products (3,4).

Usually, in teeth whitening, a hydrogen peroxide gel with different concentrations is used, some of which reach 40%, where low concentrations are used for at-home bleaching (5), while high concentrations of whitening agents are indicated for in-office bleaching (6).

OTC products can be found in the markets, pharmacies and online stores. Patients can easily obtain these products and apply them at home by themselves (7) , and may prefer them to whiten their teeth as an alternative option with lower cost and less complicated than dentist-supervised bleaching (8). There are numerous types of OTC products on the market like strips, rinses, gels, pens or paint-on films and dentifrices. Whitening strips are the most popular OTC bleaching materials on the market (9).

this study will compare bleaching efficacy and tooth sensitivity of two different OTC whitening systems (paint-on and OTC trays with activated light).

Aim of the study:

this trial aims to study bleaching efficacy and tooth sensitivity of two different OTC bleaching systems (paint-on and OTC trays with activated light) compared to at-home conventional bleaching with carbamide peroxide 20%.

In this study, we will evaluate:

- Tooth sensitivity.
- Bleaching efficacy.
- Color stability after 6 months follow-up.

Methods and Materials:

Study design:

Randomized clinical controlled trial.

Randomization: by dragging a paper showed the code of the bleaching system.

Study Sample:

In this study, 39 patients were randomly allocated into three experimental groups: (n=13) by dragging a paper showed the code of the bleaching system which will be used (either conventional at-home bleaching, whitelight system or dazzling white system). This step will be completed by a staff member who was not concerned in the experiment, so that, both the examiner and patients will be masked to the allocation assignment.

Place of study:

Damascus University, Faculty of dental medicine.
Endodontics and operative dentistry Department.

Inclusion criteria:

1- Good general health.

2- Adults (between 18 and 35).

3- No caries and restoration on the six maxillary anterior teeth.

4- Permanent teeth with a shade of A2 or darker.

5-no history of tooth sensitivity.

6-Availability for the follow-ups.

Exclusion criteria:

1- poor oral hygiene and general health,

2- Current or previous use of bleaching agents

3- A history of allergies to tooth bleaching products,

4- orthodontic treatment,

5- Having parafunctional habits such as bruxism,

6- pregnant or lactating women.

7- Advanced periodontal disease

8- active carious lesions

9-Tetracycline-stained teeth,

10- tooth hypersensitivity

11- deep cracks in the teeth

12- smoking.

Intervention:

A custom tray will be fabricated for each patient using soft vinyl sheets, 0.8 mm (Sof-Tray Classic, Ultradent, South Jordan, UT, USA) and trimmed 1 mm beyond the marginal gingiva based on a scalloped design.

each custom tray will be equipped with a hole in the middle of the vestibular surface of each of the right maxillary canine and the left maxillary central incisor in order to ensure that the color measurement will be taken in the same area of the tooth during the follow-up periods. another custom tray will be prepared for each patient of conventional at-home bleaching group. Each patient will be given a kit containing: (1) bleaching product (either bleaching gel syringe, WhiteLight^{TM} system or Dazzling white paint-on) in an opaque plastic coded container, (2) leaflet showed application's instructions, (3) oral hygiene kit containing

toothpaste without bleaching materials (Colgate Total Colgate-Palmolive Company, New York, USA). and medium toothbrush. Patients will be asked to use the oral hygiene kit to clean their teeth for 2 minutes twice per day.

every bleaching product will be applied according to the manufacturer's recommendations. The materials used, as well as their composition and application methods, are shown in Table 1.

Table 1 composition of the materials:

Group	Bleaching agent	Active ingredient	Other ingredients	Method of application
1	Opalescence 20%CP gel Ultradent, South Jordan, UT, USA (CAHB)	20% carpamide peroxide	Glycerin, Water, Xylitol, carbomer, PEG-300, Sodium Hydroxide, EDTA, Potassium Nitrate, Sodium Fluoride	once a day (4) hours for 14 days
2	The WhiteLight™ System (USA) (WL)	Carbamide peroxide	Water, Glyserin, Povidone, Silica, Sodium Hydroxide, Sodium Saccharin, Sorbitol, EDTA, K12.	once a day for 30 minutes with light transmitter
3	Dazzling white Grosvenor Consumer Products, Ontario, Canada	Hydrogen peroxide	purified water, denatured alcohol, polyvinyl pyrrolidone, polyethelene glycol	10 min twice daily for 14 days after brushing

Shade evaluation:

The color of the teeth will be assessed using a dental spectrophotometer Easy Shade Advance 4.0 (VITA Zahnfabrik, Bad Sackingen, Germany) on the middle third of the buccal surface of the maxillary right canine and maxillary left central incisor through the holes in the guide tray.

Digital spectrophotometer assesses tooth color according to the CIE L*a*b* colour space system and gives objective numerical values (10).

Color measurement will be performed at baseline, 7-day, 14-day of bleaching, 2 weeks and 6 months after bleaching

The total color difference ΔE^* will be calculated by the following equation: $\Delta E^*=[(\Delta a^*)^2+ (\Delta b^*)^2 + (\Delta L^*)^2]^{1/2}$

Tooth sensitivity evaluation:

Patients will be asked to evaluate tooth sensitivity for (1-day, 2-day, 3-day, 4-day, 5-day, 7-day and 14-day) of bleaching using visual analogue scale VAS graded from 0 which indicates 'no tooth sensitivity' to 10 which indicates 'unbearable tooth sensitivity'.

Data Analysis:

Statistical Analysis will be accomplished using SPSS ® statistical software V22 spss inc. Chicago il USA). To assess the normal distribution of the data, Kolmogorov- distributed test will be used using the same software. Differences in ΔE values will be analyzed by a one-way ANOVA. Differences in tooth sensitivity will be evaluated by the Mann Whitney U-test.

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