

# Assessment of efficacy and post-bleaching sensitivity of home bleaching using 10% carbamide peroxide in extended and non-extended bleaching trays

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## VERIFIABLE CPD PAPER

### IN BRIEF

- Considers the benefits of home bleaching as part of a patient's overall treatment plan.
- Describes the innovative use of a practice-based research project to answer a commonly asked question with respect to bleaching tray design.
- Discusses various bleaching tray designs and their indications.

**Aim** This study aimed to compare the effect of extended margin and conventional bleaching trays on tooth bleaching and tooth sensitivity. **Method and methods** Twenty subjects (18–56 years) were investigated in a split arch design clinical study that was conducted in a general dental practice. Each subject received a custom made bleaching tray and 10% carbamide peroxide gel. The bleaching trays had the borders extended 5 mm beyond the gingival margins on the right side and finished just at the gingival margin on the left side. Shade change and tooth sensitivity were the primary outcomes studied and analysed in this study. The shade of the six upper and lower anterior teeth was assessed using a value-ordered shade guide before, one week and two weeks after treatment. Sensitivity was self-assessed using a visual analogue scale (VAS) at the end of the first and second weeks of the study. **Results** At the end of week two, the mean shade change was 5.01 ( $\pm$  3.37) and 5.10 ( $\pm$  3.36) for teeth covered by extended and non-extended tray design, respectively. The mean VAS sensitivity scores for teeth covered by extended and non-extended tray design were 0.96 ( $\pm$  1.39) and 0.66 ( $\pm$  0.96), respectively. There was no significant statistical difference between the two designs at any assessment point with regard to shade change and sensitivity ( $p > 0.05$ ).

**Conclusions** It can be concluded that an extended tray design confers no superior effect in terms of the whitening outcome achieved or in reducing levels of sensitivity. Thus, both tray designs can be used depending on a dentist's personal preference.

## INTRODUCTION

In an era of minimally invasive and aesthetic dentistry, tooth discolouration is being treated more routinely using vital tooth bleaching techniques. Home bleaching using 10% carbamide peroxide is currently considered, by patient and dentist, as a preferred treatment option over in-office bleaching. This is attributed to the fact that colour improvement is similar upon using both techniques. Additionally, home bleaching results in long term shade retention,<sup>1</sup> reduced cost and chair-side time,<sup>2</sup> ease of application and higher patients' preference and satisfaction when compared with in-office bleaching techniques.<sup>3</sup>

Different bleaching tray designs have been advocated and studied for use with

at-home vital bleaching. Inclusion of reservoirs in the bleaching trays seems to help with retention of viscous bleaching gels yet the requirement for reservoirs has been questioned.<sup>4</sup> Furthermore, bleaching trays with reservoirs resulted in a higher degree of tooth lightening when the shade change was assessed using a colorimeter device.<sup>5</sup> However, several studies found no significant difference between trays with and without reservoirs as the shade difference is below the threshold of visual differentiation.<sup>5–7</sup>

Extension of a bleaching tray's border beyond the gingival margins (toward the mucogingival line) could theoretically allow prolonged retention of the bleaching agent, reduce salivary contamination of the bleaching gel and protect the soft tissues of the mouth. Thus, it can possibly increase the efficacy of a 10% carbamide peroxide bleaching agent, requiring a reduced treatment time. Sensitivity as a result of pulpal and/or gingival irritation induced by the bleaching agent is the most common side effect of vital tooth bleaching. It has been reported that risk and severity of sensitivity

increases with the time of exposure.<sup>8</sup> Thus, if the extended tray design conferred clinically acceptable results in a shorter time, the use of such design may also significantly reduce post-bleaching sensitivity. In addition, from a technical point of view, the construction of extended trays is much easier as careful trimming of the tray at the gingival margin levels is not required. Conversely, saliva may have an essential role in the breakdown and hence, activation of bleaching agent so it may as a consequence, have the reverse effect.<sup>9</sup>

The aim of this study was to establish whether extending the borders of bleaching trays by 5 mm would produce a clinically-superior result in comparison to a conventional tray design when used with a reduced exposure time (two hours per day for two weeks). Additionally, the study aimed to explore the effect of the reduced exposure time and tray design on post-bleaching sensitivity levels.

## MATERIALS AND METHODS

This study used a split mouth design where each patient acted as their own control.

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## Study design

The sample size calculation, which was based on previous similar studies, suggested that the sample size should be 20, giving the study a power of 95% at an alpha level of 5%. Twenty patients aged 18–56 years (mean  $31.7 \pm 10.72$  years) were recruited for the study. The sample had an equal number of male and female patients.

## Inclusion and exclusion criteria

The inclusion and exclusion criteria are summarised in Table 1.

## Methods

The study was conducted at Rossendale Dental Health Centre, a general dental practice in East Lancashire, UK. Ethical approval was obtained from The University of Leeds Dental Research and Ethics Committee (Reference no. 220,311/SM63). All participants were given information sheets in advance of consenting to their involvement in the study.

After enrolment, each patient had coloured digital photographs taken of their upper and lower anterior sextants, and had the baseline shade of the six anterior teeth measured using the Vitapan classical shade guide with the shade guide tabs arranged from light to dark. This was done independently by two reviewers. Alginate impressions of both the upper and lower arches were taken to allow for the construction of custom made bleaching trays.

Custom bleaching trays with reservoirs were constructed via a vacuum formed technique using 0.9 mm thickness vinyl sheets. For all the participants, the tray margins on right side of the tray (extending from the upper and lower right central incisor to the most posterior tooth in the respective arch) were trimmed 5 mm above the gingival margins. Trays were trimmed just at the gingival margin level of teeth on the left side.

Each participant was given 4 × 1.2 ml tubes of bleaching gel (10% carbamide peroxide gel) along with the bleaching trays, which were checked for fit and adjusted accordingly. The dispensing and application of the bleaching gel was demonstrated and patients were asked to apply the gel in the presence of the examiner to ensure a complete understanding of the required procedure.

The participants were asked to wear the trays for two hours on a daily basis. A printed instruction sheet were given to all participants outlining the bleaching procedures, instructions of use, possible effects and complications in addition to advice on diet and a recommended oral hygiene regime.

Each participant was given a standard tube of 1,450 ppm toothpaste to use during the trial. Visual analogue scale (VAS) sheets were given to the patients along with

**Table 1** Inclusion and exclusion criteria of the study

| Inclusion criteria   | Exclusion criteria  |
|--|---|
| Adult, above 18 years  | Active caries or periodontal disease  |
| Available for the duration of the study and can attend recall visits                   | Allergies to bleaching agent or tray material   |
| Minimum of upper and lower six anterior teeth without restorations                     | Dentine hypersensitivity. Note, patients who complained of symptoms of dentine hypersensitivity and presented with exposed dentine on any of the teeth were excluded from the study. However, patients who had exposed dentine and did not complain of any symptoms were included in the study. |
| Teeth darker than Vita B1 shade at baseline examination                                | Smoking, pregnancy and breastfeeding during the trial   |
| Good general health and have the manual dexterity to apply bleaching agent to the tray | Using tooth bleaching products in the last 3 years  |

**Table 2** Mean shade difference values after week 1 and 2 for teeth covered with E and NE bleaching trays

| Tray design        | Mean shade difference: week one | Mean shade difference: week two |
|--------------------|---------------------------------|---------------------------------|
| Extended trays     | 3.3 (2.9)                       | 5.0(3.4)                        |
| Non-extended trays | 3.4 (2.9)                       | 5.1(3.4)                        |
| E vs NE (p value)  | >0.05                           | >0.05                           |

**Table 3** Mean VAS sensitivity scores after week 1 and 2 for teeth covered with E and NE bleaching trays

| Tray design        | Mean sensitivity score: week one | Mean sensitivity score: week two |
|--------------------|----------------------------------|----------------------------------|
| Extended trays     | 1.1(1.4)                         | 1.0 (1.4)                        |
| Non-extended trays | 1.0(1.2)                         | 0.7 (1.0)                        |
| E vs NE (p value)  | >0.05                            | >0.05                            |

appropriate instructions and they were asked to complete these on a daily basis throughout the study period in order to assess sensitivity levels. They were asked to rate their level of sensitivity on a scale from 1–10.

Training and calibration of the examiners involved in the study in the use the value-oriented Vitapan shade guide was undertaken at the dental practice where the trial was conducted. The training was carried out over a period of nine days (four subjects per clinical session) assessing 36 subjects. Kappa statistics were used to assess inter examiner agreement which showed a high degree of association between examiners (Kappa score 82%).

Changes in the shade of the teeth included in the study were assessed independently by two examiners at baseline, one and two week points. The assessments were carried out under natural daylight conditions as was the examiner calibration exercise to ensure a consistent approach. The shade was assessed at the mid third of the upper six anterior teeth and a score was given for each individual tooth and a mean score was calculated. Mean (VAS) sensitivity scores were also calculated from the data provided by the patients.

## Statistical analysis

The Mann-Whitney test was used to determine differences in the mean shade change and sensitivity scores for the groups of teeth covered by the extended and non-extended bleaching trays at the week one and two time points. Furthermore, the Wilcoxon signed ranks test was used to assess changes in shade within each group at the week one and two time points. SPSS (version 15) was used to perform data analysis and the statistical significance was set at the 5% level, or  $\alpha = 0.05$ .

## RESULTS

### Shade changes at week one and two

At the end of the first week, 51.3% and 50% of teeth covered by E and NE bleaching trays showed at least two shades change, respectively. At the end of the second week, 52.5% and 50% of teeth covered by E and NE bleaching trays showed at least 4.5 shades change, respectively.

The mean shade change after first week of the teeth covered by E and NE bleaching trays was 3.33 (2.86) and 3.35 (2.89) respectively. There was no statistically

significant difference between these two groups ( $p > 0.05$ ). The mean shade change after the second week of the teeth covered by E and NE bleaching trays was 5.01 (3.37) and 5.10 (3.36) respectively. There was no statistically significant difference between the two groups ( $p > 0.05$ ). Mean shade change was significantly higher at week two in comparison to week one,  $p > 0.05$  for both groups. These results are summarised in Table 2.

### VAS sensitivity scores

The most frequently occurring sensitivity score of both E and NE trays was zero. Thirteen participants reported mean sensitivity ranging from 0–1. Seven participants reported mean sensitivity ranging from 1–6. None of the participants reported mean sensitivity ranging from 6–10. None of the participants experienced pain which they felt required a clinical intervention.

At the end of week one, mean sensitivity VAS scores for teeth covered by E and NE were 1.08 (1.44) and 0.99 (1.21) respectively (almost no sensitivity). There was no significant statistical difference between the two groups ( $p > 0.05$ ). Similarly, there was no significant statistical difference between VAS scores for teeth covered by the E and NE bleaching trays after week two (0.96 (1.39) versus 0.66 (0.96),  $p > 0.05$ ). These results are summarised in Table 3.

### DISCUSSION

The null hypothesis was that there would be no difference in terms of shade change and VAS sensitivity scores for teeth covered by E and NE bleaching trays. The results of this study have shown that there is no significant statistical difference and thus, the null hypothesis cannot be rejected. The split-arch design of this trial reduced significantly the scope for inter patient error and confounding factors.

Teeth covered by either tray design showed shade change more than four steps on a value ordered shade guide which conforms to the ADA efficacy limits for home bleaching products.<sup>9</sup> The visual assessment of shade change using value-ordered shade guide has been widely used in tooth whitening clinical studies and it was shown to be clinically relevant and valid.<sup>10–15</sup> However, this method is highly subjective, not fully reproducible and may be susceptible to inconsistencies and operator bias.<sup>16,17</sup> In fact, it is affected by several factors such as, lighting conditions, background and surrounding colours physiological condition and eye's tiredness and operator's experience.<sup>11,18</sup>

Shade guides are still used by the majority of GDPs during the course of bleaching treatment for patient's records and

medico-legal purposes. Despite the fact that it is a subjective technique, it is generally, cheap and accessible by the majority of GDPs who might be interested. Moreover, research findings have shown that colour measurement and perception can be improved with training and experience.<sup>19,20</sup> In addition, reliability of shade matching process is quite high when value-ordered the shade guide is used.<sup>21</sup> The two assessors in this study have received thorough training on colour measurement using the Vitapan classical shade guide and the inter-examiner agreement was found to be high. In addition, the shade assessment at; baseline, week one and week two was done independently and under consistent, natural daylight conditions similar to those present in the shade assessment trainings.

The use of a colorimeters and spectrophotometers can potentially overcome some of the above problems and give more objective results.<sup>11,22,23</sup> However, colour measurements of these devices can be largely influenced by contour, translucency and texture of teeth. Also, there is difficulty with attaining reproducible positioning on the tooth surface which can affect the accuracy and reliability of these devices unless custom-made, windowed stents are used to ensure measuring the shade of the same area.<sup>24</sup> Computer analysis of digital photographs can also be used to objectively assess shade difference. Though, this technique requires accurate reproduction of lighting conditions and positioning of the subject in addition to the use of robust mathematical transformation algorithms.<sup>25</sup> In addition it would be difficult to provide this equipment in a practice setting.

The post-bleaching sensitivity in this study as a result of gingival and pulpal irritation was assessed. Despite exclusion of subjects with symptomatic dentine hypersensitivity from this study, sensitivity of pulpal origin was assessed as some of the studied subjects had asymptomatic exposed dentine. Exclusion of patients with symptoms of dentine hypersensitivity may contribute to the very low sensitivity rates reported in this study. However, such subjects need thorough desensitising treatment before, during and after bleaching which was not planned for this investigation.

The shortened exposure time to the bleaching agent may be the most important factor of achieving low sensitivity rates. Many studies reported higher incidence and severity of post-bleaching sensitivity upon over-night exposure to bleaching agent.<sup>8</sup> Additionally, the use of high fluoride concentration toothpaste may also help to alleviate and/or prevent sensitivity induced by pulpal irritation.

### CONCLUSIONS

Within the limitations of this clinical investigation, it can be concluded that a reservoir-containing extended bleaching tray design offers no advantage over a reservoir-containing conventional (non-extended) design in terms of efficacy and reducing tooth sensitivity. The results of this study therefore suggest that tray design selection with the 10% carbamide peroxide bleaching gel can be decided on the basis of personal preference and convenience of the dentist.

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