

Comparison of the clinical efficacy and safety of carbamide peroxide and hydrogen peroxide in at-home bleaching gels

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Objective: The aim of this study was to evaluate the clinical efficacy of home-administered vital bleaching procedures and possible adverse effects derived from their use. One gel containing 3.5% hydrogen peroxide with a 5% potassium nitrate component (FKD, Kin Lab) was compared with a carbamide peroxide-based gel with a concentration of 10% (Opalescence, Ultradent). **Method and Materials:** Two sample groups were designed, each composed of 8 patients. All patients employed both bleaching products, 1 in the maxillary arch and the other in the mandibular arch on a random basis. The treatment was applied for 3 hours a day for 4 weeks. The degree of bleaching was evaluated using the Vita guide arranged by brightness. Dental sensitivity was measured with a specially designed 4-point scale. Gingival irritation was registered by the presence or absence of lesions in the marginal gingiva related to treatment. **Results:** The degree of bleaching was similar with both products (4.8 Vita shade tabs). The hydrogen peroxide product with potassium nitrate provoked less dental sensitivity, although the difference between the 2 products was insignificant ($P = .063$). Gingival irritation appeared in 6 subjects, but was unrelated to the applied product. **Conclusion:** Under the conditions of this study, no statistically significant differences were detected between 3.5% hydrogen peroxide containing 5% potassium nitrate (FKD) and the 10% carbamide peroxide-based product (Opalescence). (*Quintessence Int* 2006;37:551–556)

Key words: carbamide peroxide, home bleaching, hydrogen peroxide, potassium nitrate

Home-administered vital bleaching in customized trays was described by Haywood in 1989.¹ This procedure generally presents the same indications and prognosis as conventional in-clinic bleaching procedures, with the added advantage of lower cost and minor

adverse effects, such as oral tissue burns and dental sensitivity.² Because of the noninvasive nature of this treatment, at-home vital bleaching is probably the safest, most patient-pleasing method of obtaining effective tooth bleaching.³ The most commonly employed active ingredient is 10% carbamide peroxide (CP) gel, which has shown satisfactory clinical results.^{4–8} Different studies confirm no detrimental safety issues.^{9–11}

Hydrogen peroxide (HP) gel is also used as an at-home vital bleaching agent, with different concentrations and different application methods such as custom trays^{12,13} and whitening strips.¹⁴ Upon comparison of the clinical efficiency of CP and HP, depending

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Inclusion criteria

- Aged between 18 and 50 years
- Subject availability to attend the control visits
- Good overall general health
- A minimum of 24 natural teeth, including at least 4 molars (excluding third molars)
- Willingness to refrain from the use of any type of mouth rinse during participation in the study

Exclusion criteria

- Systemic disease or regular intake of any sort of medication; need of antibiotic prophylactic therapy to receive dental treatment
- Smoking habit
- Pregnant or breast-feeding
- Presence of active cavities; anterior sector restorations covering more than one sixth of the labial surface; anterior teeth with root canal treatment; crowns or veneers on anterior teeth
- A Löe-Silness Gingival Index²⁵ above 1
- Stains confirmed to be due to tetracycline
- Previous use of any sort of bleaching treatments in the past 5 years

Fig 1 Criteria of inclusion and exclusion (modification of the criteria suggested by Mokhalis et al¹⁷).

on the applied concentrations of these bleaching agents, many controversial results can be found.^{15–17}

The most common adverse effects of these bleaching gels are gingival irritation and dental sensitivity.^{5,6} Gingival irritations can be attributed either to the design of the tray or to the chemical bleaching agent. Interruption of treatment for 1 to 2 days along with minor adjustments to the application tray generally resolves the problem of gingival irritation.¹⁸ Dental sensitivity causes discomfort to the patient, but is reversible and rarely leads to suspension of treatment.¹⁹ The combination of the bleaching agent with potassium nitrate and fluoride can reduce this undesirable effect.^{20–22}

The 10% CP, upon contact with oral tissues and saliva, breaks down into 3% to 3.5% HP and 6.5% to 7.0% urea, HP being the active bleaching ingredient.^{2,23,24} The purpose of this study was to determine the clinical efficacy and possible adverse effects of a 10% CP gel versus a 3.5% HP gel containing a 5% potassium nitrate ingredient.

METHOD AND MATERIALS

The study group was made up of 16 subjects, 11 women and 5 men, with a mean age of 31.8 years (SD \pm 4.49). All the subjects volunteered for the study and expressed an interest in bleaching their teeth. Each patient was handed a consent form as well as a brief written explanation of the indications and contraindications of the bleaching procedure they were about to undergo. Inclusion and exclusion criteria were applied based on a modification of the criteria suggested by Mokhalis et al¹⁷ (Fig 1).

Fast-setting alginate (Cavex ColorChange, Cavex) impressions of both arches of each patient were made. Hard plaster (Rubinit, Protechno) casts were cut into horseshoe shapes. Bleaching trays were made with 1-mm mouthguard sheets (Buffalo Dental). An Econo-Vac (Buffalo Dental) machine was used to customize the individual trays. Trays were trimmed 1 mm above the gingival margin, avoiding a possible coverage of the interdental papilla.

The compared bleaching products were (1) FKD (Kin Lab), composed of 3.5% hydrogen peroxide, 5% potassium nitrate, and carbopol, with a pH of 5.0 to 5.5, and (2) Opalescence (Ultradent), composed of 10% carbamide peroxide with carbopol and a pH of 6.5.

At the first stage of the study, patients were instructed on the application method, and initial photographs of each patient were taken (Nikon camera F601 and Medical-Nikkor 120-mm lens) in a slide format (Elite, Kodak) that included anterior teeth of both arches and incorporated a tooth from the Vita Classic Shade Guide (Vita Zahnfabrik) as a reference.

Patients were instructed to apply the gel for a total of 3 hours a day on each arch, and to renew the gel every hour. All patients employed both bleaching products, 1 in the maxillary arch and the other in the mandibular arch. Eight patients used Opalescence in the maxillary arch and FKD in the mandibular arch, and the other 8 patients employed FKD in the maxillary arch and Opalescence in the mandibular arch. Both groups applied the



Fig 2a Bleaching of the maxillary arch with Opalescence and the mandibular arch with FKD (initial stage).



Fig 2b After 4 weeks of treatment.



Fig 3a Bleaching of the maxillary arch with FKD and the mandibular arch with Opalescence (initial stage).



Fig 3b After 4 weeks of treatment.

products on a random basis. The duration of the treatment was 4 weeks.

Bleaching efficacy and adverse effect controls were obtained on days 7, 14, 21, and 28 of the study. Using the central incisor as the reference, the degree of bleaching was estimated by comparing photographs taken at the 4 control visits, using the Vita Lumin-Vacuum color guide arranged by brightness (B1, A1, B2, D2, A2, C1, C2, D4, A3, D3, A3, B4, C3, A4, C4). The shade changes were evaluated by Vita shade tabs. To evaluate dental sensitivity, a scale of 4 levels was applied: absence of sensitivity (grade 0), slight sensitivity not necessitating suspension of treatment (grade 1), sensitivity that forced suspension of treatment for 1 day (grade 2), sensitivity that led to suspension of treatment for more than 1 day (grade 3). Gingival irritation related to the treatment was registered as present or absent.

Analysis of variance of repeated measurements and McNemar test were applied to compare the efficacy of the bleaching agent in both arches. The level of significance was set at $P < .05$.

RESULTS

All 16 patients completed the study. At the end of the treatment, significant bleaching was obtained with both products (maxillary arch, $P = .020$; mandibular arch, $P = .027$). The final degree of lightening obtained with the 2 products was not significantly different (maxillary arch, $P = .213$; mandibular arch, $P = .121$). With both gels an average lightening of 4.8 shades of the Vita Lumin-Vacuum arranged by brightness was accomplished (Figs 2 and 3).

The most notable shade lightening was achieved mainly in the first 3 weeks of the study, with no considerable progress observed during the final week with either product (maxillary arch, $P = .118$; mandibular arch, $P = .227$) (Fig 4).

Dental sensitivity associated with the bleaching agent was of a slight nature in all recorded cases and did not lead to suspension of treatment in any of the patients. In the first week, 8 patients had sensitivity in the arch where CP (Opalescence) was applied, and 7 patients experienced sensitivity in the

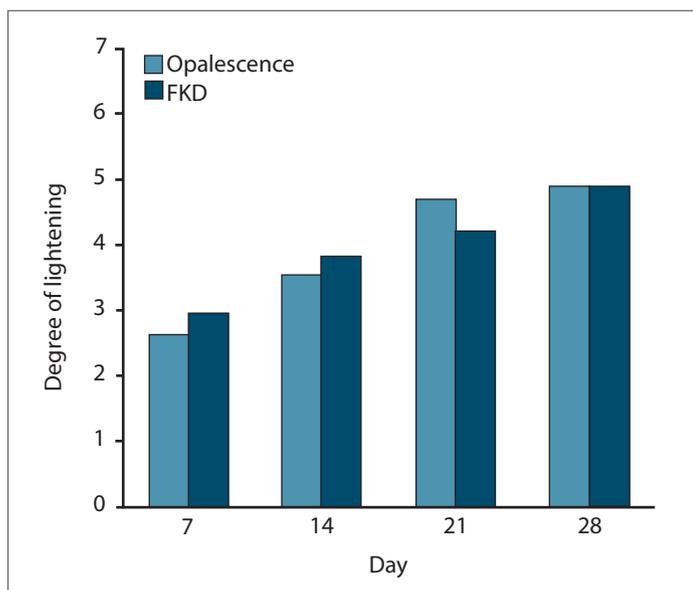


Fig 4 Degree of lightening by product (number of lightened shades according to the Vita Lumin-Vacuum arranged by brightness).

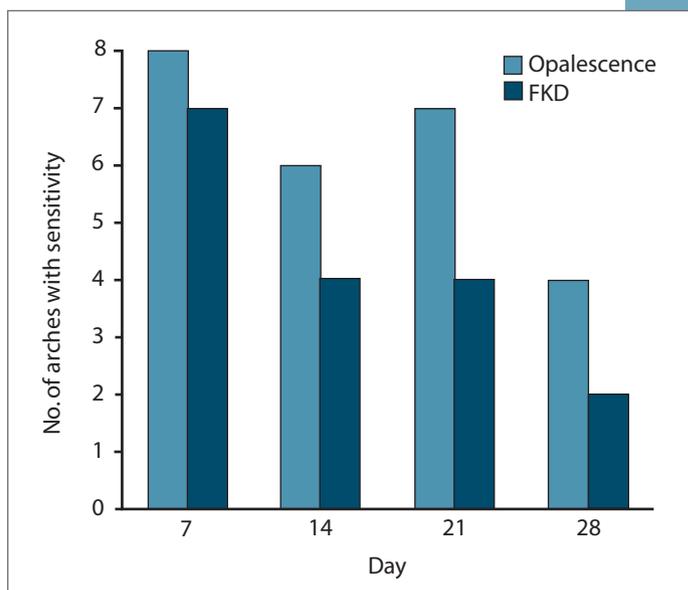


Fig 5 Evaluation of dental sensitivity by product. All cases of sensitivity were mild (degree 1).

arch where they applied HP (FKD). In the final week of treatment, 4 patients had sensitivity in the arch treated with CP and 2 with HP (Fig 5). Where dental sensitivity did not occur in the first week, it was not observed in the following 3 weeks.

During the first week gingival irritation was observed in 5 patients, 3 with CP and 2 with HP, with no occurrence in the final week. All cases were resolved with proper trimming of the trays in the lesion area, and in none of the cases was there recurrence of discomfort.

DISCUSSION

Taking into account the results obtained in previous studies that suggest that the activity of the component is reduced to 50% in the first 20 to 30 minutes,²⁶ it was recommended that participants in the present study renew the bleaching gel on an hourly basis to obtain the maximum bleaching effect.

In the present study, the bleaching efficacy obtained with a 10% CP gel and with a 3.5% HP gel was similar, confirming the results obtained by Kowitz et al²⁷ in their comparison of 10% CP and 3% HP. This can be explained by the fact that a 10% CP is transformed into 3.5% HP and 6.5% urea, HP being the active whitening component.^{2,23,24} The degree of lightening obtained in this study with both products (4.8 Vita shade tabs arranged by brightness) is similar to the results described by Myers et al,¹³ who applied a 3% HP with similar methodology.

In recent literature, few studies are encountered covering the topic of velocity of bleaching agents, and among these, there are diverse results. Mokhlis et al¹⁷ commented that 20% CP bleaches faster than 7.5% HP in a 14-day treatment period, although in 12-week controls there were no observable differences. On the other hand, Greenwall²⁸ suggested that HP needs less time for bleaching, although this theory is not supported by many studies.²⁹

Sensitivity occurred less frequently in the arches where FKD was administered. Many publications associate the use of potassium nitrate with a reduction of dental sensitivity during bleaching treatment.^{20,21} Tam²¹ compared 2 10% CP-based products, 1 containing potassium nitrate and fluoride and the other only the bleaching agent. In 2 weeks, the group that used the whitening gel containing the desensitizing agents developed less sensitivity and similar shade whitening. Consequently, the inclusion of a desensitizing agent with the bleaching gel would reduce this frequently occurring adverse effect. Gingival irritations as a result of at-home bleaching procedures can be considered infrequent, even with the application of higher concentrations of bleaching agents.⁹

CONCLUSION

In the application of 3.5% hydrogen peroxide or 10% carbamide peroxide, at the end of the active phase of treatment, no appreciable differences were observed in the degree of bleaching. It is reasonable to consider the final, fourth week of treatment as unnecessary, as no significant color change was achieved.

REFERENCES

- Haywood VB, Heymann HO. Nightguard vital bleaching. *Quintessence Int* 1989;20:173–176.
- Haywood VB. History, safety, and effectiveness of current bleaching techniques and applications of the nightguard vital bleaching technique. *Quintessence Int* 1992;23:471–488.
- Haywood VB. Current status of nightguard vital bleaching. *Compend Contin Educ Dent Suppl* 2000;28:S10–17.
- Niedermaier R, Tantraphol MC, Slinin P, Hayes C, Conway S. Effectiveness of dentist-prescribed, home-applied tooth whitening. A meta analysis. *J Contemp Dent Pract* 2000;15:20–36.
- Cibirka RM, Myers M, Downey MC, et al. Clinical study of tooth shade lightening from dentist-supervised, patient-applied treatment with two 10% carbamide peroxide gels. *J Esthet Dent* 1999;11:325–331.
- Barnes DM, Kihn PW, Romberg E, George D, DePaola L, Medina E. Clinical evaluation of a new 10% carbamide peroxide tooth-whitening agent. *Compend Contin Educ Dent* 1998;19:968–972, 977–978.
- Matis BA, Cochran MA, Eckert G, Carlson TJ. The efficacy and safety of a 10% carbamide peroxide bleaching gel. *Quintessence Int* 1998;29:555–563.
- Kowitz GM, Nathoo SA, Wong R. Comparative clinical evaluation of two professional tooth-whitening products. *Compend Suppl* 1994;17:S635–639.
- Collins LZ, Maggio B, Gallagher A, York M, Schafer F. Safety evaluation of a novel whitening gel, containing 6% hydrogen peroxide and a commercially available whitening gel containing 18% carbamide peroxide in an exaggerated use clinical study. *J Dent* 2004;32(suppl 1):47–50.
- Ritter AV, Leonard RH Jr, St Georges AJ, Caplan DJ, Haywood VB. Safety and stability of nightguard vital bleaching: 9 to 12 years post-treatment. *J Esthet Restor Dent* 2002;14:275–285.
- Dahl JE, Pallesen U. Tooth bleaching—A critical review of the biological aspects. *Crit Rev Oral Biol Med* 2003;14:292–304.
- Collins LZ, Maggio B, Liebman J, Blanck M, Lefort S, Waterfield P. Clinical evaluation of a novel whitening gel, containing 6% hydrogen peroxide and a standard fluoride toothpaste. *J Dent* 2004;32(suppl 1):13–17.
- Myers ML, Browning WD, Downey MC, Hackman ST. Clinical evaluation of a 3% hydrogen peroxide tooth-whitening gel. *J Esthet Restor Dent* 2003;15:50–56.
- Gerlach RW, Barker ML. Professional vital bleaching using a thin and concentrated peroxide gel on whitening strips: An integrated clinical summary. *J Contemp Dent Pract* 2004;15:1–17.
- Li Y, Lee SS, Cartwright SL, Wilson AC. Comparison of clinical efficacy and safety of three professional at-home tooth whitening systems. *Compend Contin Educ Dent* 2003;24:357–360, 362, 364.
- Nathoo S, Stewart B, Petrone ME, et al. Comparative clinical investigation of the tooth whitening efficacy of two tooth whitening gels. *J Clin Dent* 2003;14:64–69.
- Mokhlis GR, Matis BA, Cochran MA, Eckert GJ. A clinical evaluation of carbamide peroxide and hydrogen peroxide whitening agents during daytime use. *J Am Dent Assoc* 2000;131:1269–1277.
- Haywood VB, Heymann HO. Nightguard vital bleaching: How safe is it? *Quintessence Int* 1991;22:515–523.
- Heymann HO, Swift EJ Jr, Bayne SC, et al. Clinical evaluation of two carbamide peroxide tooth-whitening agents. *Compend Contin Educ Dent* 1998;19:359–362, 364–366.
- Haywood VB, Caughman WF, Frazier KB, Myers ML. Tray delivery of potassium nitrate-fluoride to reduce bleaching sensitivity. *Quintessence Int* 2001;32:105–109.

21. Tam L. Effect of potassium nitrate and fluoride on carbamide peroxide bleaching. *Quintessence Int* 2001;32:766–770.
22. Jacobsen PL, Bruce G. Clinical dentin hypersensitivity: Understanding the causes and prescribing a treatment. *J Contemp Dent Pract* 2001;2:1–12.
23. Crispin BJ. Procedimientos estéticos no restauradores. In: Crispin BJ (ed). *Bases Prácticas de la Odontología Estética*. Barcelona: Masson, 211998: 6–46.
24. Fasanaro TS. Bleaching teeth: History, chemicals, and methods used for common tooth discolorations. *J Esthet Dent* 1992;4:71–78.
25. Silness J, Löe H. Periodontal disease in pregnancy. II. Correlation between oral hygiene and periodontal condition. *Acta Odontol Scand* 1964;22:121–135.
26. Pruebas clínicas y de laboratorio de CRA sobre 23 productos de blanqueamientos populares realizables en casa. *CRA Newsletter (Spain edition)* 2001;15(3):2–4.
27. Kowitz GM, Rustogi KN, Wong R, Curtis JP, Wieckowski SE. In vivo effects of peroxides on tooth coloration [abstract 1268]. *J Dent Res* 1991;70:424.
28. Greenwall L. Bleaching materials. In: Dunitz M (ed). *Bleaching Techniques in Restorative Dentistry: An Illustrated Guide*. London: T&F STM, 2001:31–47.
29. Frysh H, Baker FL, Wagner MJ. Patients' perception of effectiveness of 3 vital tooth bleaching systems [abstract 2430]. *J Dent Res* 1991;70:570.