

Effect of a New Bleaching Gel on Tooth Whitening

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Clinical Relevance

The use of the novel tribarrel hydremide-peroxide bleaching system (KöR) did not offer any advantages in the lightening of bovine teeth compared with a traditional bleaching system (Opalescence) of hydrogen peroxide or carbamide peroxide.

SUMMARY

The purpose of this study was to compare the whitening efficacy of a novel bleaching agent containing a unique tribarrel hydremide-peroxide gel (KöR) with a traditional bleaching system of hydrogen peroxide or carbamide peroxide (Opalescence). Bovine incisors were mounted into a custom resin, arch-shaped mounting device. Four groups of 10 teeth were created using mounting devices containing five teeth each. The in-office and home bleaching gels of KöR and Opalescence were applied to the teeth alone and in trays to simulate a combination of in-office and home bleaching or home bleaching only. Spectrophotometer readings of L* a* b* were performed at baseline, the

end of active bleaching (immediate), and three and six months postbleaching. Immediately postbleaching, the use of Opalescence gel resulted in greater change in ΔE^* and Δb^* (less yellow) for combined and home bleaching techniques compared with KöR. After six months, Opalescence had significantly greater ΔE^* and Δb^* compared with KöR for home bleaching only. There was no significant difference in ΔL^* between Opalescence and KöR at any time period with either technique.

INTRODUCTION

Much emphasis is placed on outward appearance and often, a person's smile is what meets the eye first. Many people are enamored by whiter enamel, creating a high demand for esthetic bleaching. As such, home and in-office whitening products infiltrated the US marketplace in the late 1980s, and the bleaching empire has exploded ever since.¹ Whitening products include toothpastes, gels, and films, as well as in-office-based systems.¹ In 2005 alone, the in-office and home bleaching market generated \$2 billion in sales.² With such high demand and potential for profitability, there is a constant race for companies to create the latest and greatest whitening agents while adhering to the former American Dental Association (ADA) safety and efficacy guidelines.³

Vital bleaching is a relatively conservative way to achieve whiter teeth vs therapy such as micro-

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abrasion, veneers, or crowns. Generally there are two vital bleaching modalities: power bleaching (in-office) with 25%-35% hydrogen peroxide (HP) and home bleaching with 10%-20% carbamide peroxide (CP) or 2%-10% HP in a custom-made mouth guard over two to six weeks.^{4,5} The advantages of home whitening include ease of application, reduced chair time and cost, high success rate, and safety of materials.⁶ Furthermore, bleaching teeth with 10% CP in a custom-fitted tray has proven to be the safest, most cost-efficient whitening option for a large variety of tooth discoloration conditions.⁷ The degree of whitening may be similar for home bleaching and in-office bleaching, but in-office bleaching has more rapid regression.^{5,8} Home bleaching may be very successful for a compliant patient because it offers the safest, least expensive way to get whiter teeth with slower regression.

Although the outcomes seem revolutionary, the bleaching process and materials are not new. HP has been a dental workhorse for more than 70 years.⁴ Bleaching success is attributed to its ability to penetrate tooth structure and produce free radicals that oxidize organic stains within the tooth.⁹ During the bleaching process, CP breaks down into HP and urea, with the HP concentration being approximately one-third of the original CP concentration.⁶ Therefore, a 15% CP product is approximately 5% HP. Home bleaching with 10% CP was first reported by Haywood and Heymann¹⁰ in 1989, and although there are many different concentrations of bleaching agents, 10% CP seems to be the gold standard. In fact, 10% CP (specifically, 10% CP Opalescence, Ultradent Products, South Jordan, UT, USA) was the only bleaching product to have earned the ADA seal of approval. If a patient has the time, bleaching with 10% CP can be just as effective, if not more effective, than in-office bleaching with 35% HP. Bernardon and others,⁸ in 2010, illustrated such results with a clinical study involving 90 patients who found that home bleaching with 10% CP in a tray was comparable to in-office bleaching with 35% HP. Both home and in-office bleaching have been extremely successful. As such, several manufacturers have attempted to combine the two techniques to develop a more efficacious procedure.¹¹ Combination bleaching can be described as vital bleaching with 10%-20% CP or 2%-10% HP in a custom tray over two to six weeks with supplemental use of in-office vital bleaching with 25%-35% HP before or after home whitening.¹¹

Due to the prevalence of HP and CP in many bleaching products, the dental literature is saturated with research on their respective safety and efficacy.

Just recently, a literature review concluded that when manufacturer's instructions are followed, HP- or CP-based tooth whitening is safe and effective.¹ But now there is a new type of bleaching gel. KöR Whitening (Evolve Dental Technology Inc, Irvine, CA, USA) contains a novel dual-activated hydremide-peroxide bleaching gel which the company claims¹² creates a whiteness that is unaffected by consumption of coffee, tea, or red wine with low to no sensitivity. The peroxide gel base is dispensed in a tribarrel system that allows the use of two distinctly different proprietary chemical accelerators. Three separate syringes are mixed together immediately before application. According to the company, KöR 34% hydremide peroxide gel is roughly equivalent to 30% HP and KöR 13% hydremide peroxide is roughly equivalent to 9% HP.¹² Refrigeration is provided throughout all phases of storage and shipping to reduce peroxide degradation. The KöR system also requires a proprietary tray (KöR-Seal trays) that reportedly provides a unique seal of the cervical 1- to 1.25-mm portion of teeth that functions to seal out both saliva and sulcular fluid. The KöR-Seal trays in combination with continuous refrigeration reportedly provide six to 10 hours of whitening activity compared with the typical 25-35 minutes.¹² Other than company articles provided by the inventor, Rod Kurthy, there is no independent research published on the KöR Whitening system.^{13,14}

The purpose of this *in vitro* study was to compare the tooth whitening capability of KöR bleaching gels with popular comparable Ultradent Products on bovine incisor crowns. Changes in color of the bovine teeth from the bleaching process were determined using the Commission Internationale de l'Eclairage (CIE) $L^*a^*b^*$ color space. L^* indicates lightness ($L^+ =$ lightness and $L^- =$ darkness), the a^* coordinate represents the red/green range ($a^+ =$ redness and $a^- =$ greenness), and the b^* coordinate represents for the yellow/blue range ($b^+ =$ yellowness and $b^- =$ blueness).¹⁵ The $L^*a^*b^*$ system allows the numeric definition of a color as well as the overall difference between two colors (ΔE). The null hypothesis was that there would be no difference in the change in L^* (ΔL), a^* , (Δa), b^* (Δb), and E^* (ΔE^*) on the basis of type of bleaching gel per technique over time.

METHODS AND MATERIALS

A total of four groups were created in this study to evaluate the whitening of crowns of bovine incisors using either a combined bleaching technique of in-office and home bleaching (Combined) or home

bleaching alone (Home) using KöR and Opalescence bleaching gels.

For the Combined bleaching, two groups were compared using the KöR Max Ultra Kit (Evolve Dental Technology) and Opalescence Boost 40% HP / Opalescence PF 15% CP bleaching gel (Ultradent Products). KöR bleaching kits are sold in three varieties: KöR Standard, KöR Max, and KöR Max Ultra. The KöR Max Ultra Kit was chosen for this study for combined bleaching because it is marketed for use with difficult cases and consists of 13% hydremide peroxide for three 20-minute chairside sessions, 16% CP home bleaching for 28 nights, and 34% hydremide peroxide for three 20-minute chairside sessions.

The Opalescence Boost 40% HP was used with Opalescence PF 15% CP home bleaching gel to create a combined bleaching technique. The Opalescence Boost 40% HP in-office bleaching gel is a dual-barrel system. Two separate syringes are mixed together immediately before application. Two additional groups were created to evaluate the home bleaching technique only. KöR 16% CP was compared with Opalescence PF 15% CP—two home bleaching gels with similar concentrations of CP. The four groups are outlined below:

- Group 1 (Combined): KöR 13% hydremide peroxide and 34% hydremide peroxide (KöR Max Ultra Kit) were used to simulate in-office bleaching, whereas KöR 16% CP was used in custom trays as a home bleaching agent.
- Group 2 (Combined): Opalescence Boost 40% HP was used as an in-office bleaching agent and Opalescence PF 15% CP was used in custom trays to simulate home bleaching.
- Group 3 (Home): KöR 16% CP was used in custom bleaching trays to simulate home bleaching.
- Group 4: (Home): Opalescence PF 15% CP was used in custom bleaching trays to simulate home bleaching.

Forty bovine incisors (Animal Technologies, Tyler, TX, USA) were stored and disinfected in 0.5% chloramine-T (Alfa Chemistry, Stony Brook, NY, USA). The teeth were then examined under a light microscope at 10× magnification (Nikon SMZ-1B, Melville, NY, USA) and discarded if any gaps, cracks, or pigmentation was found that would interfere with the bleaching evaluation. Custom arch-shaped mounting devices were created to provide a mechanism for bleaching tray fabrication and insertion as shown in Figure 1. The custom resin, arch-shaped mounting devices were created using a stereolithography printer

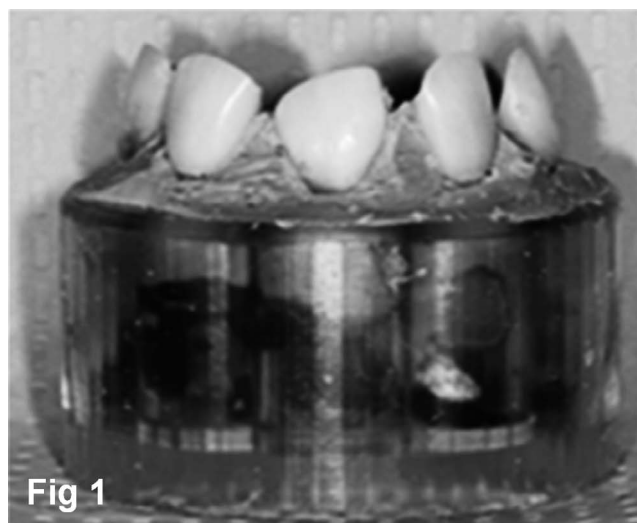


Fig 1



Fig 2

Figure 1. Teeth mounted in custom resin device.

Figure 2. Custom tray fabrication.

(Viper si2 SLA System, 3D Systems Inc, Darmstadt, Germany) with a clear resin material (Somos Water-Shed XC 11122, DMS Functional Materials, Elgin, IL, USA). Each device contained five mounting wells for the bovine teeth. Two mounting devices were printed per group, for a total of 10 teeth per group (n=10). Each tooth was mounted in the wells with vinyl polysiloxane (Regisil PB, Dentsply, York, PA, USA). After all the bovine teeth were mounted in the devices, custom trays were created per the manufacturer's guidelines using each company's proprietary block-out and tray materials, as shown in Figure 2.

KöR-Seal whitening trays were fabricated for use with KöR bleaching products. KöR-Seal trays require several steps and can be accomplished in-office or by mailing impressions to the KöR-Lab. All KöR-Seal trays for this study were fabricated by the research investigators following the manufacturer's instructions. Impressions of the mounted bovine teeth were made using KöR polycarbonate impres-

sion trays. After painting the impression trays with KöR Impression Tray Adhesive, the base impression was made with KöR-Seal VPS Putty. Evolve BLU-grinder burs were used to grind out the base impression. The wash impression was made with KöR Light Body Wash VPS. Impressions were allowed to degas 30-60 minutes, then were sprayed with debubbler (Smoothex, Whipmix Corporation, Louisville, KY, USA) and poured in dental stone (Denstone, Heraeus Kulzer, South Bend, IN, USA). The model bases were trimmed and blocked out with the same dental stone (0.5- to 1-mm thick, 1 to 1.25 mm from gingival line) per the manufacturer's recommendations. The KöR-Seal trays were made with a soft 0.40-inch ethylene vinyl acetate sheet via a positive-pressure, thermal-forming machine (Bio-star, Great Lakes Orthodontics, Tonawanda, NY, USA). To create bleaching trays for home bleaching with Opalescence PF 15% CP, an alginate impression was made of the mounted bovine teeth and poured in dental stone (Die Keen, Heraeus Kulzer, South Bend, IN). Model bases were trimmed and Ultradent LC Block-Out Resin was applied per manufacturer recommendations (0.5-mm thick, 1.5 mm from gingival line). Custom trays were made with 0.035-inch Sof-Tray with the positive-pressure, thermal-forming machine as before.

The superficial enamel of the bovine teeth was cleaned with prophy paste (Nupro, Dentsply, York, PA, USA) using a disposable prophy angle (Nupro Revolv, Dentsply) to remove extrinsic stains. Due to a higher inherent value of bovine teeth, a tea-staining protocol was used as described by D'Arce and others,¹⁶ after mounting the teeth and prior to Home or Combined bleaching. The mounting devices with the bovine teeth were immersed in a solution of black tea for six consecutive days at room temperature in order to create a standardized, stained surface of the enamel.¹⁷ The tea solution was created by soaking one filter bag (Starbucks Awake English Breakfast Tea, Starbucks, Seattle, WA) in eight ounces of boiling water for five minutes. The tea solution was changed every 24 hours. Then, the teeth were stored in synthetic saliva at oral temperature at 37°C for seven days in a laboratory incubator (Model 20GC, Quincy Lab, Chicago, IL, USA) to stabilize the stained surfaces. The synthetic saliva was prepared as described by Lata,¹⁸ using Na_3PO_4 , 3.90 mM; NaCl_2 , 4.29 mM; KCl , 17.98 mM; CaCl_2 , 1.10 mM; MgCl_2 , 0.08 mM; H_2SO_4 , 0.50 mM; NaHCO_3 , 3.27 mM; and distilled water, with a pH set to a level of 7.2. A pH meter (Accumet XL50, Fisher Scientific, Waltham, MA, USA) was used to measure pH.



Figure 3. Clear custom stent to standardize placement of spectrophotometer tip.

A customized, resin insert was printed using stereolithography and sprayed with white paint. The insert was placed in the mounting device during spectrophotometer readings (Easyshade Compact, VITA, Bad Säckingen, Germany). Teeth were positioned so that the lingual surfaces were parallel to the white insert. A baseline reading was performed using the spectrophotometer. The tip of the spectrophotometer was placed into a customized clear vinyl polysiloxane stent that rested on the teeth to create a standardized position for recording, as shown in Figure 3.

After the baseline reading, the bleaching procedures were performed according to the following four protocols. All bleaching agents were stored in a refrigerator at 1.5°C when not in use (Model HB27AW, Hamilton Beach, Glen Allen, VA, USA), verified with a thermometer (No. 5295, Taylor, North Mankato, MN, USA). KöR bleaching gels arrived from the manufacturer in a refrigerated container.

Group 1 (Kör, Combined)

- Day 1: To simulate in-office bleaching, a 1-mm layer of KöR 13% hydremide-peroxide gel was applied to the teeth using a custom tray for 20 minutes. Bleaching gel was suctioned off the teeth, and a new mix of KöR 13% hydremide-peroxide gel was again applied to the teeth using a custom tray for another 20-minute session. The bleaching gel was suctioned off once again and the teeth were thoroughly rinsed, dried, and stored in synthetic saliva at 37°C.

- Days 1-28: To simulate home bleaching, KöR 16% CP was applied to the teeth for eight hours using a custom tray. The first eight-hour session of home bleaching was the same day as the in-office bleaching. After each daily eight-hour tray bleaching session, the teeth were thoroughly rinsed and dried and stored in synthetic saliva at oral temperature at 37°C. The home bleaching process was repeated every day for 28 days.
- Day 29: To simulate in-office bleaching once again, 1 mm of KöR 34% hydremide-peroxide gel (instead of KöR 13% hydremide-peroxide gel) was applied to the enamel surfaces. The teeth were bleached for three 20-minute sessions instead of two, as recommended by the manufacturer.

Group 2 (Opalescence, Combined)

- Day 1: To simulate in-office bleaching, 1 mm of Opalescence Boost 40% HP gel was applied to the teeth for 20 minutes. The bleaching gel was suctioned off the teeth, and a second 1-mm layer of Opalescence Boost 40% HP gel was applied to the teeth for another 20-minute session. The bleaching gel was suctioned off teeth once again, and a third and final 1-mm layer of Opalescence Boost 40% HP gel was applied to the teeth for the last 20-minute session. At the end of the third bleaching session, bleaching gel was suctioned off and the teeth thoroughly rinsed, dried, and stored in synthetic saliva at 37°C.
- Days 1-4: A four-day resting period was allowed between in-office treatments per manufacturer recommendations.
- Day 5: To simulate in-office bleaching, the Opalescence Boost 40% HP gel was applied to the teeth in the same manner as on Day 1.
- Days 5-8: Resting period. A second four-day resting period was allowed, as after the first in-office treatment. No in-office bleaching gel was applied again until day 9.
- Days 9-30: To simulate home bleaching, 1 mm of Opalescence PF 15% CP was applied to the teeth for six hours using a custom tray following the manufacturer's instructions. After each daily six-hour tray bleaching session, the teeth were thoroughly rinsed, dried, and stored in synthetic saliva at oral temperature at 37°C. The bleaching process was repeated every day for 21 days.

Group 3 (KöR, Home)

- Days 1-21: To simulate home bleaching, KöR 16% CP was applied to the teeth for eight hours with a

custom tray following the same technique as described previously with the KöR Combined group.

Group 4 (Opalescence, Home)

- Days 1-21: To simulate home bleaching, Opalescence PF 15% CP was applied to the teeth for six hours using a custom tray using the same technique as described previously with the Opalescence Combined group.

All teeth specimens were stored in artificial saliva at 37°C between active bleaching. The bovine teeth were measured immediately after completion of bleaching and at three and six months postbleaching using a spectrophotometer. $L^*a^*b^*$ values were recorded for each tooth at each time interval. ΔL^* , Δa^* , and Δb^* were calculated by subtracting each reading from baseline per time interval. Baseline values were similar but not the same for all groups. ΔE^* was determined using the following formula: $\Delta E^* = [(\Delta L^*)^2 + (\Delta a^*)^2 + (\Delta b^*)^2]^{1/2}$. Data were analyzed with a repeated-measures analysis of variance (ANOVA) examining the effects of type of bleaching (Home vs Combined) or type of bleaching agent (KöR vs Opalescence) on ΔE^* or Δb^* over time ($\alpha=0.05$). However, significant interactions were found ($p<0.05$). The ΔE^* and Δb^* data were evaluated with a one-way ANOVA per bleaching gel and treatment type and unpaired t -tests between bleaching gels and treatment type. A Bonferroni correction was applied because multiple comparison tests were completed ($\alpha=0.01$). Due to the large variability of the data, ΔL^* was analyzed with Kruskal-Wallis and Mann-Whitney U-tests with a Bonferroni correction ($\alpha=0.01$).

RESULTS

Immediately postbleaching, the use of Opalescence gel resulted in greater change in ΔE^* and Δb^* for Combined and Home bleaching techniques compared with KöR ($p<0.01$). After six months, Opalescence had significantly greater ΔE^* and Δb^* compared with KöR for Home bleaching only ($p<0.01$). There was no significant difference in ΔL^* between Opalescence and KöR at any time with either technique ($p>0.01$). Also, there was no significant difference in ΔE^* , b^* , or L^* for either material or technique on the basis of time ($p>0.01$), as shown in Table 1.

DISCUSSION

The purpose of this *in vitro* study was to evaluate the tooth whitening capability of a new bleaching gel

Table 1: ΔE^* , Δb^* , and ΔL^* Values for Combined and Home Bleaching Techniques for both Opalescence and KöR Bleaching Gels^a

	Combined Bleaching			Home Bleaching		
	Immediate	3 mo	6 mo	Immediate	3 mo	6 mo
ΔE^*						
Opalescence	14.5 (5.5) Aa	13.2 (5.2) Aa	13.8 (4.6) Aa	20.4 (7.9) Aa	19.9 (5.5) Aa	20.7 (6.6) Aa
KöR	8.5 (4.0) Ab	11.3 (3.2) Aa	10.4 (3.3) Aa	10.9 (3.2) Ab	14.5 (3.2) Aa	14.0 (3.5) Ab
Δb^*						
Opalescence	-11.4 (3.9) Aa	-7.1 (3.1) Aa	-9.5 (3.3) Aa	-17.8 (5.0) Aa	-17.4 (3.0) Aa	-18.7 (4.9) Aa
KöR	-4.7 (3.9) Ab	-6.0 (2.8) Aa	-6.5 (2.1) Aa	-9.6 (3.0) Ab	-12.9 (3.0) Ab	-13.2 (3.2) Ab
ΔL^*						
Opalescence	7.9 (4.1) Aa	10.8 (4.0) Aa	9.4 (3.4) Aa	6.9 (8.8) Aa	8.1 (6.3) Aa	6.3 (7.1) Aa
KöR	6.3 (2.9) Aa	9.5 (2.2) Aa	7.9 (2.4) Aa	4.6 (2.6) Aa	5.3 (3.5) Aa	3.5 (3.3) Aa

^a Groups with the same uppercase letter per row and treatment or same lowercase letter per column and treatment are not significantly different ($p > 0.01$).

system (KöR) containing a unique hydremide-peroxide formulation. KöR bleaching gels were compared with popular bleaching gels from Ultradent Products on bovine incisor crowns using the CIE $L^* a^* b^*$ color space system.

The null hypothesis was rejected. There was a difference in Δb^* and ΔE^* on the basis of type of bleaching gel per technique. However, the differences varied over time. For both Combined and Home bleaching, the use of Opalescence gel resulted in a greater change in ΔE^* compared with KöR immediately after bleaching. A greater change in ΔE^* is associated with an overall greater change in color. However, ΔE^* does not provide specific information as to the direction of the color change. Previous literature has shown that whitening from bleaching agents is manifested mainly by a reduction in yellowness (lower b^*) and an increase in lightness (higher L^*) and to a minor extent, a reduction in redness (lower a^*).¹⁹⁻²⁴ Whereas all values ($L^* a^* b^*$) were obtained at all intervals of this study, ultimately only ΔE^* , Δb^* , and ΔL^* were reported. Due to the variability and fluctuation of a^* , the Δa^* values were not analyzed and were deemed singularly noncontributory.²⁰ These findings are consistent with a study by Lenhard²⁵ that found that the variance in a^* values had only a minor influence on color change.

The use of Opalescence gel resulted in a greater change in Δb^* (ie, less yellow) compared with KöR immediately after bleaching for both Combined and Home bleaching. However, after six months post-bleaching, Opalescence had significantly greater Δb^* compared with KöR for Home bleaching only. Home bleaching was associated with a greater reduction in yellowness (Δb^*) than Combined bleaching; however, there was a tendency for

Combined bleaching to result in greater lightness (ΔL^*) than Home bleaching, suggesting no overall benefit from either technique. Two recent clinical studies found no statistically significant difference between combined and home bleaching.^{11,26} However, more sensitivity was reported with combined bleaching compared with home bleaching.²⁶ In this study, there was no statistically significant difference in ΔL^* between Opalescence and KöR at any time with either technique. Although the use of Opalescence gel may have initially resulted in a greater reduction in yellowness compared with KöR with either Combined or Home bleaching, the difference became less significant over time with Combined bleaching. Although not statistically significant, ΔE^* and b^* values had a tendency to improve with KöR over the first three months after bleaching and remain more stable with Opalescence. In all groups, bleaching treatment resulted in a significant overall color change (ΔE^*) above the limit of visible detectability, which has been reported to be greater than 3.3 units.^{27,28} Wiegand and others²⁰ evaluated the effects of bleaching agents using enamel and dentin bovine segments. After 12 months of storage in artificial saliva, the researchers found no difference in color retention between the different bleaching techniques (home, in-office and walking) using the CIE $L^* a^* b^*$ color system. However, the color change was not stable, with the greatest regression with ΔL^* .²⁰ These results differ from this study, however, where after six months of storage in artificial saliva there was no significant change in ΔE^* , b^* or L^* for either material or technique based on time. Longer storage time may be necessary to demonstrate regression of the whitening effect. Also, in the study by Wiegand and others,²⁰ the authors did not use artificial

staining prior to the bleaching procedure. Although superficial prestaining of bovine teeth has been used in multiple *in vitro* bleaching studies, it is uncertain to what extent the tea-staining protocol augmented the natural organic discoloration of the bovine teeth.²⁹⁻³² Bovine teeth are much more readily available than human anterior teeth, have similar physical chemistry to human teeth, and provide similar results when staining or whitening procedures are evaluated in the laboratory.^{16,33-36}

CONCLUSIONS

Within the limitations of this study, the following statements can be made. Immediately after bleaching, the use of Opalescence gel resulted in greater change in ΔE^* and Δb^* (less yellow) compared with K  r for both bleaching techniques. After six months, Opalescence had significantly greater ΔE^* and Δb^* for Home bleaching only. The use of the novel tribarrel hydremide-peroxide bleaching system (K  r) did not offer any advantages in the lightening of bovine teeth compared with a traditional bleaching system (Opalescence) of HP or CP.

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Regulatory Statement

This study was conducted in accordance with all the provisions of the local human subjects oversight committee guidelines and policies of Wilford Hall Ambulatory Surgical Center IACUC. The approval code for this study is FWH20150018A.

Disclaimer

The views expressed in this article are those of the authors and do not reflect the official policy of the United States Air Force, the Department of Defense, Uniformed Services University of the Health Sciences, or the United States government.

Conflict of Interest

The authors do not have any financial interest in the companies or products mentioned in this article.

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