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Vital Tooth Bleaching in Dental Practice: 3. Biological, Dental and Legal Issues

Abstract: The final section of this series examines both the evidence for the safety of external bleaching with hydrogen peroxide and related products and the legal position in the UK with regard to their sale and use in general dental practice. Potential side-effects are examined, including biological effects and dental effects, with a review of the current evidence. The EU Cosmetics and Medical Device Directive are both described and their impact on the provision of tooth bleaching in the UK is explained. The legal position in the UK renders the sale and supply of solutions containing >0.1% peroxide illegal, and practitioners must be aware of the underlying legislation and the basis upon which a prosecution may be pursued.

Clinical Relevance: Clinicians considering using hydrogen peroxide products must be aware of the safety issues surrounding their use and be able to explain to patients the nature of the risk and also the likelihood of any given patient experiencing them.

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It is essential that dental practitioners offering, or considering to offer, bleaching services to their patients, should be fully aware of any potential side-effects. This information should be assessed, the evidence for it evaluated, and then the pertinent facts related to the patient, preferably in a written format, as part of the informed consent process. The final article in this series examines the documented complications of vital tooth bleaching, its effects on biological and mineralized tissues and, in the final section, the current legal position in the UK.

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Safety of vital bleaching

Chemicals involved in vital bleaching and their proposed mode of action

As described previously, tooth bleaching is undertaken using hydrogen peroxide, either applied directly to the teeth, or via a chemical reaction from carbamide peroxide or sodium perborate. Hydrogen peroxide is a strong oxidizing agent that produces free radicals, hydrogen peroxide anions and reactive oxygen molecules.[1] It is proposed that these reactive molecules penetrate the tooth and reduce the long-chained, dark-coloured chromophore molecules into smaller, and hence less coloured, more diffusible variants. It is thought that the bleaching solutions reach, and enter-into the superficial dentine. The success of the bleaching process is, therefore, reliant upon the ability of the agent to reach the necessary chromophore molecules and the duration and frequency of the exposure to the agent.

Local side-effects

These include:

- Tooth sensitivity;
- Mucosal irritation;
- Effects on the dental hard tissues;
- Effects on restorative materials.

Tooth sensitivity

The commonest side-effect of vital tooth bleaching is sensitivity and all patients should be informed of this risk. A number of studies have assessed the occurrence of sensitivity and 11–93% of patients using 10% carbamide peroxide (CP) reported this as a problem.[1–4] A higher incidence, 67–78%, has been reported

Type of treatment	Bleaching regime	Duration	Number of active subjects	Control subjects	Incidence	Reference
At home	10% CP overnight	21 days	18	0	11%	(33)
At home	16% CP 10% CP 0% CP all overnight	14 days	20	20	16% CP–33% 10% CP–25% 0%–14%‡	(3)
At home	15% CP 3–4 hours daily	28 days	100	50	15% CP–37.5% 0% –25.5%†	(2)
At home	5% CP 10% CP overnight	7 days	60	0	5% CP–20% 10% CP–53%§	(34)
At home	10% CP 0% CP	14 days	24	24	10% CP–25% 0% CP–21%	(10)
At home	10% CP 15% CP Overnight	14 days	57	0	15% CP–93% 10% CP–93%	(35)
In office	30% HP + heat 3 x 30 mins	30 days	19	0	78%	(36)
In office	35% HP + heat 2–6 x 30 min	N/A	15	0	67%	(37)

† *Data calculated from publication; no significant difference between placebo and treatment group*
‡ *No significant difference between any of the groups*
§ *Significant difference detected at 0.05*

Table 1. Incidence of tooth sensitivity from a selection of clinical trials.

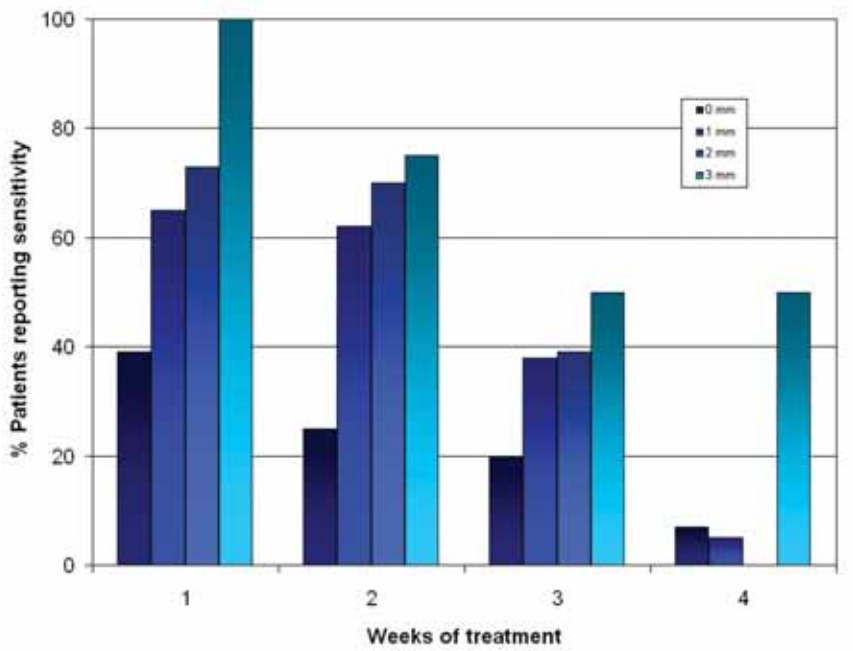

Figure 1. Percentage of patients reporting sensitivity based on gingival recession.

when in-office products containing hydrogen peroxide (HP) are used; but this study used heat activation, which is a technique largely abandoned in favour of light or chemical activation.[1–4]

Tooth sensitivity is an important issue in vital bleaching since it can affect patient compliance and should always be minimized.[5]

Table 1 provides a summary of the studies that have assessed tooth sensitivity following bleaching using a variety of therapeutic regimes. It is important to note that these represent only the incidence of sensitivity – there is no indication of severity. However, several studies reported severity and, in the main, the higher the concentration, the greater the sensitivity. None of the studies, however, shares a standardized method of sensitivity reporting and, therefore, it is difficult to present sound comparisons. It should also be noted that, in these trials,

Figure 2. Products recommended for TS pre- and post-vital bleaching.

subjects who dropped out of the study may have done so owing to unacceptably high levels of sensitivity. For example, in one study, 20% of those who experienced discomfort terminated the treatment.[6]

The onset of sensitivity also varies. Tam[7] observed that, using a 10% CP product, the average first report of sensitivity was after 4.8 days (±4.1 days) and lasted for 5.0 days (± 3.8 days). This is useful information to patients and should be included in a patient information sheet as part of the informed consent procedure.

The phenomenon of tooth sensitivity (TS) following bleaching is poorly understood, and likely to be multi-factorial. The data from controlled studies (see Table 1) illustrate this point; the placebo groups also reported sensitivity. In some trials, subjects reported that the nightguard itself caused TS. Although these subjects may have had some existing risk factors for TS, none admitted to TS prior to beginning the trial.[8-10] One study examined a number of factors that may contribute to patient susceptibility to TS during bleaching, namely, plaque index, gingival recession, caries, dentifrice used and tobacco use. The only factor that correlated to the incidence and severity of TS was gingival recession[2] (Figure 1). Further research has added pre-existing thermal sensitivity and treatment more than once per day, although actual duration did not seem to be a factor.[8]

At a histological level, teeth that were planned for orthodontic removal have been used to study pulpal changes. Evaluation of pulps after overnight bleaching with 10% CP for either 4 or 14 days demonstrated mild inflammatory changes in 4 out of 12 teeth, irrespective of treatment duration. However, in those teeth treated for 14 days, followed by a rest period of 14 days, no inflammation was detected.[11] Studies in dogs have demonstrated that HP alone, or in combination with heat, causes alteration in odontoblasts and the deposition of dentine. Both haemorrhage and inflammation were observed in teeth 3 and 15 days after bleaching, although all effects were reversed 60 days after completing treatment.[12]

Attempts to reduce TS during vital bleaching, either by recommending additional products to use during the procedure, or by incorporating or removing items from the bleaching solutions, have been reported. Glycerin-based bleaching solutions have now been largely replaced, since they dehydrate the tooth, increasing the risk of TS. Less viscous solutions of HP and CP are now available that enable the tray to be worn for shorter time periods, but their low viscosity may lead to the material leaking and potentiate gingival irritation.[8] Conditioners and desensitizers can, as mentioned, either be used separately or combined with products, and generally are either potassium nitrate or neutral sodium fluoride. A study showed that 5% potassium nitrate-fluoride (1000 ppm) gel, when applied in trays, reduced sensitivity and therefore the number of subjects who were unable to complete the study owing to discomfort from TS.[13] Examples of products that may be recommended to patients for use are shown in Figure 2. A proprietary gel for use in bleaching trays and an at-home product in which a desensitizer has been incorporated into the bleaching solution are shown in Figure 3.

Mucosal irritation

Far less evidence on the incidence, severity and causes of gingival irritation exists. However, studies have shown that, in high concentrations, such as those used in power bleaching, HP is caustic to mucus membranes and can cause burns of the gingival and peri-gingival tissues, see Figure 11 from the first article in this series.[14,15] During such procedures the gingival tissues should be protected with either rubber dam or resin shield, as described in the first article in this series.[15] Concentrations of CP, such as those used in home bleaching, can cause gingival irritation (Girr). A study examining 0%, 10% and 16% CP, found that those quadrants receiving 16% CP experienced significantly more Girr than those on 0 or 10%, and, additionally, those on active treatment experienced Girr for more

a

b

Figure 3. (**a**) 10% CP solution containing anti-sensitivity agents incorporated within the gel. (**b**) A product designed to be used by patients within their trays should they experience sensitivity during their bleaching treatments. The product contains 3% potassium nitrate and 0.11% fluoride.

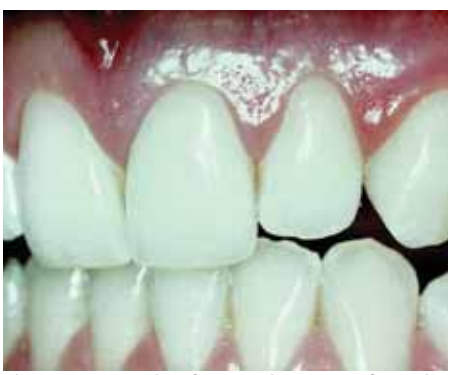

Figure 4. Example of gingival irritation from the use of night guard bleaching with 16% CP.

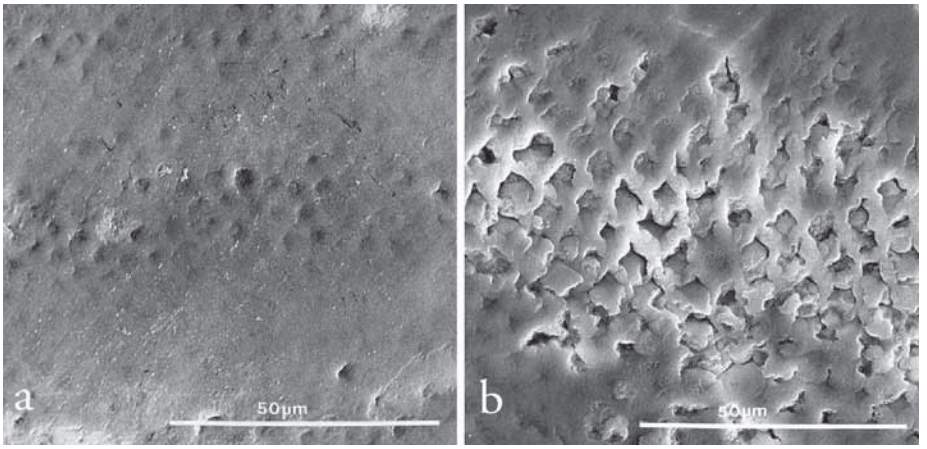

Figure 5. EM photomicrography of an enamel surface without (**a**) and with (**b**) exposure to 10% CP gel 1 hour, twice daily for three weeks.

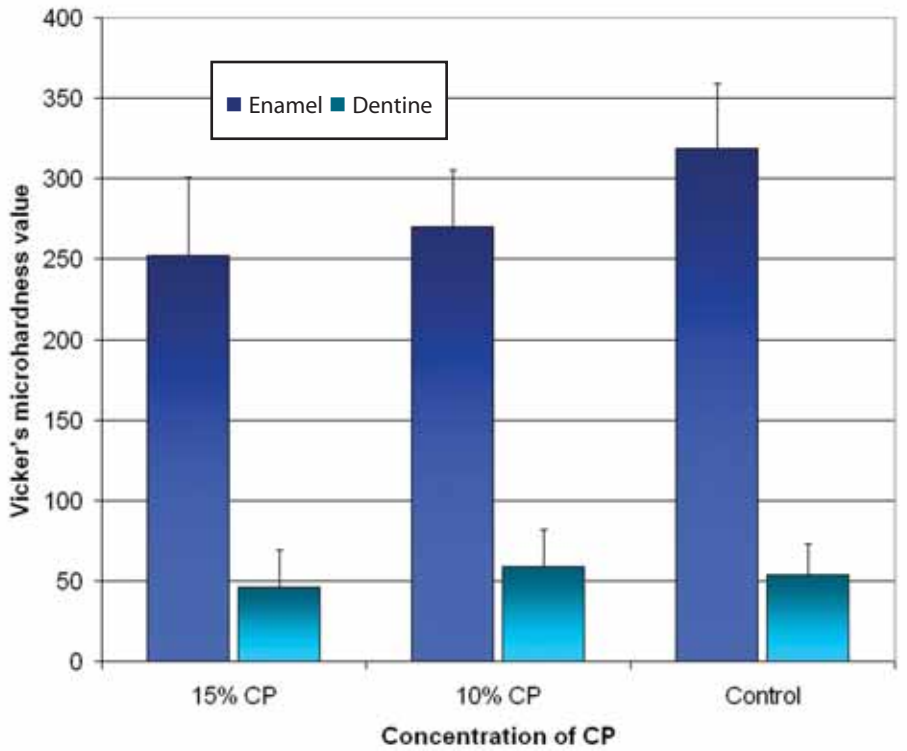

Figure 6. Effect of CP on the microhardness of enamel and dentine *in vitro*; none of these differences was significant.

days than those on a placebo. However, it should be noted that 36% of the placebo group reported Girr.[3] These results may suggest that the tray itself is responsible, in some part, for the irritation and so care should always be taken to ensure that the tray is scalloped and free from sharp edges or flashes of resin. Figure 4 demonstrates an example of the gingival irritation seen in this study.

Effects on the dental hard tissues

Several authors have described the effect of bleaching solutions on enamel morphology. In enamel samples exposed to 10% CP for 15 hours per day, for two- and four-week periods, those exposed for four weeks demonstrated significant surface effects[16] Briefly, the enamel appears to lose its aprismatic layer and this was not repaired after 90 days (Figure 5). *In vitro*, 35% CP was found to change the inorganic composition of the enamel, whereas the lower concentrations of 10 and 16% had no such effect.[17] A recent study examined enamel and dentine samples, again bleached and examined *in vitro*, using surface microhardness. At concentrations of 10 and 15% CP, there was no significant difference in microhardness of either dentine or enamel when compared to a distilled water control[18] (Figure 6). These results were confirmed by an *in situ* study examining the effect of 10% CP on enamel samples[19] and a further study examining 6% HP.[20]

In order to put these surface changes into perspective, it has been shown that, while high concentrations of CP can alter the enamel structure, it is significantly less than that seen with acid etching.[21]

Effects on restorative materials

Many patients presenting for tooth bleaching will have composite or glass ionomer anterior restorations. As described in the first article, such restorations should be repaired prior to bleaching if there are gross discrepancies between restorative margin and tooth, or replaced if terminally compromised.[15] However, definitive restorations should not be placed until the degree of shade change has been established. The bleaching process will have no effect on the colour of the restorative material, although it may remove extrinsic stain from the margins of a poorly polished restoration.

While this advice is sound, several studies[4] have shown that the bleaching with 10–35% CP adversely affects the subsequent bond strength of composite to etched enamel.[22] This reduction was more pronounced when using acetone-based (such as *Prime & Bond NT*, Dentsply, Weybridge, UK) rather than ethanol-based (such as *Scotchbond*, 3M ESPE, St Paul, USA)[23] adhesives immediately after bleaching. The suggested mechanism for this reduction is inhibition of the polymerization of the adhesive resins. The resin-enamel bond strength returns to normal within three weeks of treatment cessation and so definitive restorations should be delayed.[4] This time period will

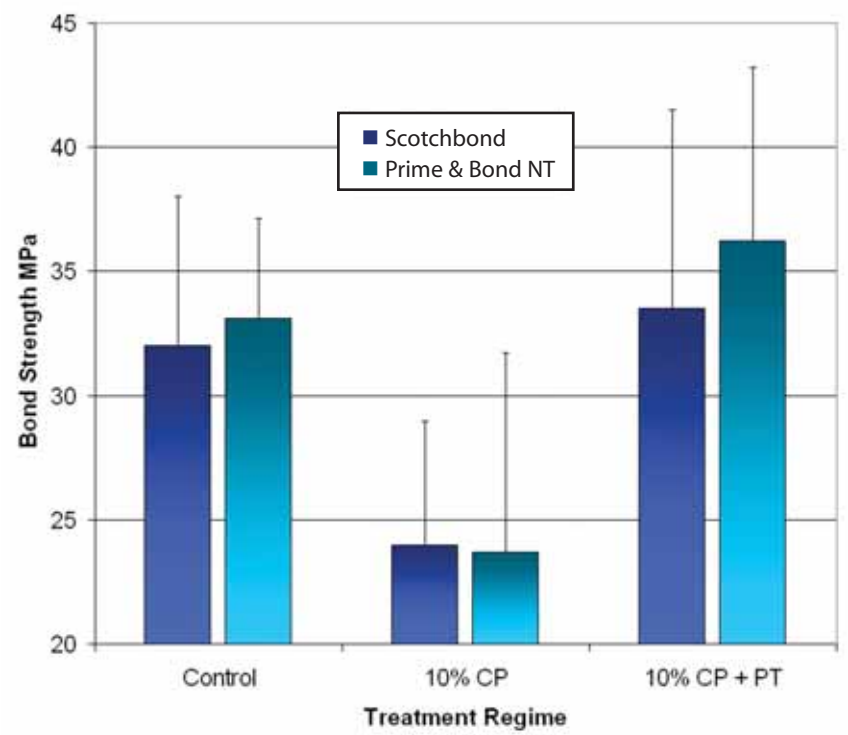

Figure 7. Demonstrating the effect of bleaching on bond strength, and the reversal of this with pre-treatment (PT) sodium ascorbate.

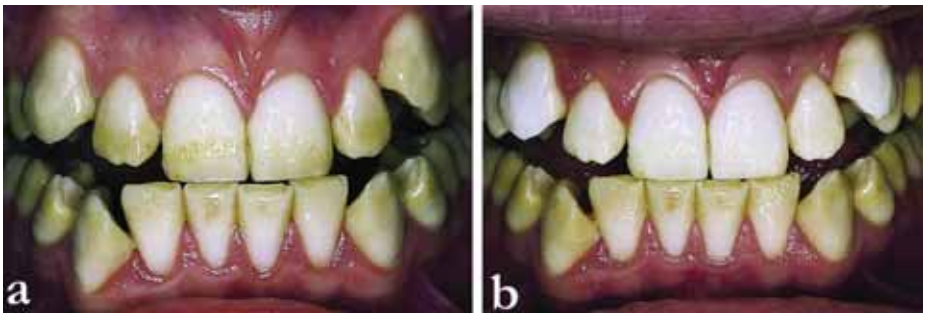

Figure 8. Example of the successful treatment (Mx arch) of discoloration associated with amelogenesis imperfecta using 10% CP for 2 hours daily over a two-week period. The use of higher concentrations of CP or HP may not be justified given the evidence of efficacy for 10% solutions.

also allow the clinician to observe any re-bound effect and thus enable a more aesthetic shade match.

If, for example in the case of tetracycline staining, a decision has been made to bleach veneer or resin-bonded crown preparations, then a further temporizing period of three weeks should be allowed before definitive restorations. If this is not possible, for example extensive veneer preparations into dentine, then bleaching can be undertaken from the palatal aspect, thus enabling immediate bonding to the buccal surface.[15]

Researchers have also suggested that the application of 10% sodium ascorbate (an anti-oxidant) will reverse the inhibitory effect of bleaching. This is simply applied before etching and then the composite bonding process continues as per normal. Results of this system are encouraging[4] (Figure 7). There is no suggestion that bleaching adversely affects the bond strength of existing bonded restorations.

The effect of bleaching on restorative materials themselves has also been studied. Laboratory work demonstrated an increased mercury release from amalgam when exposed to CP. This release varied with the amalgam type and concentration of CP from 4–30 times more than in saline controls.[24,25] Further work suggests that the solubility of glass ionomers and other cements may also be increased.[26] Careful application of the block-out resin should ensure that, for example, occlusal amalgams in premolars are not exposed to large amounts of bleaching solution. Palatal access cavities restored with amalgam can be replaced with composite, both to ensure reduction of mercury exposure and reduce any potential 'shine-through' that may compromise the aesthetic result.

Summary of side-effects

Bleaching teeth appears to be safe, although readers are again referred to the excellent review of the toxicity of HP and CP by Dahl and Pallesen,[1] who describe the dose responses and risk assessments of the procedures. HP and CP can be dangerous; a child died after swallowing 600 mg of a 3% HP solution[27] and so strict instructions on storage should be provided.

Many of the side-effects are exacerbated by increasing the concentration of either CP or HP.[28,29] These are minimized by the use of 10% CP.[5] The commercial availability of higher concentrations, and media presentation of these, tend to suggest that higher concentrations are superior in terms of end result and speed. However, while high concentrations will certainly achieve results faster, there is no evidence that the end results (ie degrees of shade change) is superior to 10% CP, and any decrease in treatment time must be balanced against the increased severity and duration of common side-effects.

A study at Indiana University compared eight of the most commonly used 'in-office' products (ie CP > 22%) with 10% CP.[30] They found that none of the in-office products was as effective as a 10% CP at-home product used overnight for two weeks. Surveys that assessed patient's satisfaction with bleaching procedures found that 73% of those who had at-home treatments were 'very satisfied' with the post-treatment results compared to only 40% of the in-office group.[30]

These data tend to suggest that a recommendation of 10% CP for a duration determined by the severity of the presentation is the safest, and possibly most effective, means to bleach teeth (see Figure 8).

Legal aspects of the provision of peroxide bleaching services in the UK

The UK 1996 Cosmetic Products (Safety) Regulations 1996 derive from EU Directive (76/768/EEC) in 1976 and its subsequent amendments, controlling cosmetic products, principally from a standpoint of safeguarding public health.[31] A cosmetic product was defined as any solution or preparation that was intended for contact with various external body parts and, of interest to us, the teeth and the oral mucosa, for the principle (or exclusive) purpose of 'cleaning them, perfuming them or protecting them in order to keep them in good condition, change their appearance or correct body odours'.

Given the description above, bleaching agents are defined as cosmetics and cannot contain, amongst other things, 'hydrogen peroxide and other compounds or mixtures that release hydrogen peroxide, including hydrogen-peroxide urea (carbamide) and zinc peroxide for the purpose of 'oral hygiene products' unless the maximum concentration of hydrogen peroxide in that product is 0.1% present or released.'

Any breach of the Cosmetic Product Regulations would be prosecuted under the Consumer Protection Act of 1987, and therefore anyone supplying, or possessing, goods with the intention to supply, is liable, upon conviction, to pay a fine of £5000 and/or up to 6 months imprisonment.[32]

One legal argument that has been proffered is that bleaching systems are a medical device and therefore do not fall under the Cosmetic Regulations described. *Optident* (Ilkley, West Yorkshire, UK) and *Ultradent* (South Joran, Utah, USA) manufacturers and suppliers of the Opalescence range of peroxide products, took the matter to Court and, in 1998, it was held that *Opalescence Gel* (10% CP) was a medical device and hence covered under the Medical Device Directive. [32] The Cosmetic Regulations were, therefore, not applicable and the Departments of both Trade and Industry and Health had been incorrectly applying them in order to prevent distribution of the gel.[31]

This decision was repealed in 1999 by those government departments and overturned, leading to a further, and final, appeal by *Optident/Ultradent* to the House of Lords. Here it was decided that the purpose of the bleaching gel was contact with teeth exclusively or mainly to change their appearance, placing the product firmly within the cosmetic category and therefore controlled by cosmetic legislation.[32]

The future

Given that the House of Lords has ruled that tooth bleaching products are cosmetics, then a change to the EU Cosmetics Directive must be made in order to allow higher concentrations of peroxide within cosmetic products. Such amendments are possible, requiring an appropriate scientific opinion to be presented. Such an opinion has been sought and is now under consideration. If accepted, this would still require a subsequent change in the relevant UK law, namely the 1996 Cosmetic Regulations, before products could be legally supplied.

The medical defence organizations, in conjunction with the BDA, are working to lobby the DTI and DoH to bring these changes expeditiously. However, practitioners must be reminded that the supply of products containing concentrations of peroxide over 0.1% is illegal and liable to prosecution. Should a claim be made by a patient, the medical defence organizations believe that, in the current legal climate, defence would be difficult. Practitioners considering offering tooth bleaching should contact their defence organization for the most current advice, and those working for corporate bodies should understand that the legal ramifications of supply may well involve them as individuals rather than the corporate group, especially if they are self-employed.

Summary

It seems likely that the UK law will eventually change and, when it does, the market is likely to be quickly invaded with consumer products such as *Crest White Strips* and *Colgate ExtraWhite*. These products are supported by sound research and will undoubtedly appeal to consumers.

The research on safety, effectiveness and acceptability tends to suggest that, in terms of professional bleaching, a 10% carbamide peroxide gel, held in reservoir trays, for daily overnight use, is to be recommended. Higher concentrations cannot be recommended at present and there is insufficient research on assisted and power bleaching for informed recommendations to be made. The duration of treatment with the 10% solution should be altered, depending on the severity and underlying cause of the staining.

Practitioners who choose to offer this service to their patients, often saving them from more aggressive restorative interventions, must ensure careful case selection, good consent and careful monitoring and review. Are we saying that dentists might be offering 'illegal' treatment here?

Affiliations
Professor RM Davies and Dr RP Ellwood are employees of Colgate Palmolive.

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CPD ANSWERS

JULY/AUGUST 2006

1. A, B, D
2. A, C, D
3. A, B
4. B, C, D
5. A, B, D
6. B, C
7. A, D
8. A, C, D
9. C, D
10. C, D