Tooth whitening
An Update on Techniques and the New Legislation by Dr Trevor Bigg

The History
The bleaching of teeth has been practised from at least the 19th century utilizing many different chemicals, including chloride of lime, aluminium chloride, oxalic acid and carbamide peroxide amongst others.1

The birth of modern bleaching techniques started in the late 1960s with Klusmier devising a successful technique for home bleaching, which used 10% carbamide peroxide in a custom-made mouth tray. Initially, the carbamide peroxide was often placed in removable orthodontic retainers to reduce gingival inflammation following the removal of fixed orthodontic appliances. It quickly became apparent that a side effect of the treatment was that it whitened the teeth.

Although Dr Klusmier presented several table-clinics at the meetings of the Kansas State Dental and the Southwestern Orthodontic Societies, it wasn’t until the publication of Heywood and Heymann’s description of the technique in March 1989 that the dental profession became aware of a bleaching technique that was safe and relatively cheaper than previous options.2

Within a few years many products had appeared on the market, using carbamide or hydrogen peroxide and different modes of delivery that can be sub-divided into:

1. In-Office procedures
2. Nightguard vital bleaching using trays: Home Bleaching
3. ‘Over-the-counter’ (OTC) products

While OTC products proved popular throughout most of the world, they were never used greatly in the European Union (EU), as their purchase was easier to monitor and subsequent prosecution was a real possibility.

In-Office procedures were extensively advertised and proved popular as they continued in the tradition of dentistry being led by the dentist treating the patient in his/her surgery or office. In many cases, In-Office bleaching increased patient compliance, which could be poor if Home Bleaching alone was used. Many utilised ‘la-ser’ both to provide the ‘apparent’ and suggested modern, ‘state-of-the-art’ treatment modalities that appealed to the patient.

But wasn’t bleaching illegal? Until recently in the EU it was illegal to use hydrogen peroxide at a greater concentration than 0.1 per cent. However, the Dental Defence Societies were prepared to defend dentists who used bleaching techniques containing greater than 0.1 per cent hydrogen peroxide as their members were using a procedure that was safe, established and much less invasive than the alternatives. The General Dental Council (GDC) also recognised that the situation at that time was unsatisfactory for patients and dentists. Provided the dentists acted in the best interests of their patients and obtained fully informed consent, and that the dentist’s defence organisation gave indemnity for bleaching, the GDC stated that they would not act against a dentist unless they were prosecuted by Inspectors from the Department of Trade and Industry.

New regulations from 1st November 2012
This anomalous situation continued for many years in the EU until the publication of an amendment to the EU Directive 76/768/EEC concerning cosmetic products. The amendment Council Directive 2011/84/ EU was published in September 2011 requiring the UK Government to amend the law.

The Cosmetic Products (Safety) (Amendment) Regulations 2012 (the Regulations) amended all previous regulations relating to tooth whitening and subsequently, the practice of bleaching in this country altered overnight.

The new Regulations allow the use of hydrogen peroxide and carbamide peroxides that release hydrogen peroxide, including carbamide peroxide and zinc peroxide to be used for tooth whitening.

The Regulations have set out that products containing or re-leasing up to six per cent hydrogen peroxide can only be used, subject to the following conditions:

• To only be sold to dental practitioners

In practice this means that a dentist can only sell tooth-whitening products containing 6 per cent hydrogen peroxide to the public if they are patients at the practice.

For each cycle of use, the first bleaching system is used it must be applied by a dental practitioner. The dentist should show the patient how much material should be used and how to load and seat the tray. This procedure should be noted in the patient’s records.

• Under the dentist’s direct supervision, if an equivalent level of safety is ensured. Hygienists and therapists can administer the first use of the tooth-whitening product, under the prescription of the dentist, if they are trained and competent.

It’s uncertain at present, but a patient probably needs to be present on the premises.

No other member of the dental team can dispense whitening products, for example nurses and receptionists

• Afterwards the products may be provided to the consumer to complete the cycle of use. After the first in-surgery application the patient can be provided with tooth-whitening products for home use and additional products can be dispensed by the dentist, hygienist or therapist.

• They are not to be used on a person under 18 years of age.

However there are occasions where it’s in the best interests of a patient to use tooth whitening eg for a non-vital tooth.

In these cases Dental Protection suggests that the dentist discusses in detail with the patient (and their parents as they may be paying):

1. The risks and benefits of bleaching and more interventional alternatives
2. The legal status of tooth whitening for under 18s
3. Whether treatment could be delayed until after the age of 18

Document the consultation carefully in the patient’s notes and be aware that the dentist may be vulnerable to prosecution!

How does this change the way we bleach our patients?
During October 2012 many manufacturers, such as Philips and Dentiply contacted their clients to say that their high concentration whitening products, like Zoom and In Office Illumine, were being withdrawn from the market.

They were aware that, as up to 6 per cent hydrogen peroxide is now a legal, the Dental Societies would no longer defend their members who used higher concentrations.

Conversations with advisers from Dental Protection have confirmed that the Dental Societies would have difficulty justifying the use of greater than 6 per cent concentrations of hydrogen peroxide and its equivalent of carbamide peroxide when there is a viable legal alternative. Particularly, in these days of Evidence Based Dentistry, when research has shown that higher bleach concentrations did not quench the bleaching process and probably only increase tooth sensitivity and gum irritation.

The good news and the bad news!
So the bad news is that those dentists who favoured In-Office procedures with 25 to 50 per cent hydrogen peroxide would be unwise to continue, even though their patients requested the treatment.

However, the good news is that we can now offer many cheaper, safer and effective alternatives that we dare not use before. The use of bleaching systems utilizing whitening strips and pre-formed trays will help make the bleaching process cheaper and more accessible to our patients.

Conclusion
The recent changes in whitening legislation should be welcomed by the dental profession. By amending the EU Directive, dentists and their patients alike will benefit as:

1. The threat of prosecution has now been lifted and Dentists will be free to advertise, provided they follow GDC guidelines
2. Dentists will be encouraged to use lower, safer and effective concentrations of hydrogen peroxide
3. OTC preparations can now be sold by practitioners, providing a successful and cheaper whitening process

References:
5. 1 The threat of prosecution has now been lifted and Dentists will be free to advertise, provided they follow GDC guidelines
6. Dentists will be encouraged to use lower, safer and effective concentrations of hydrogen peroxide
7. OTC preparations can now be sold by practitioners, providing a successful and cheaper whitening process
All you need to know about tooth whitening
Nick Torlot, DDU dento-legal adviser, looks at some questions from dental practitioners

I have heard the law on tooth whitening has changed, what is the latest legal position?

Under new regulations which came into effect on 31 October 2012, dental professionals can legally treat patients over 18 years of age with tooth whitening treatments which contain or release up to six per cent hydrogen peroxide. This is provided that:

- The treatments are sold to dental practitioners
- For each cycle, the treatment is first administered by a dental practitioner or under their direct supervision. It can then be completed by the patient at home.

There are times when I think a patient would benefit from a product containing 10 per cent hydrogen peroxide. Is it legal to provide the patient with a bleaching kit containing a higher level of hydrogen peroxide than six per cent to use at home?

No, it is illegal to use tooth bleaching compounds containing or releasing more than six per cent hydrogen peroxide. The new regulations make no distinction between in-surgery bleaching and at-home bleaching products provided by dental professionals, in terms of the permitted concentration of hydrogen peroxide. This means patients can only be provided with bleaching kits containing up to six per cent hydrogen peroxide after they have been examined by a dentist and have received their first cycle of treatment in the surgery.

The new regulations are informed by scientific advice that compounds containing or releasing up to six per cent hydrogen peroxide are safe.

If you were to use or supply a bleaching compound containing 10 per cent hydrogen peroxide, you could face a criminal prosecution by Trading Standards and a GDC investigation. In the worst case scenario, you may be imprisoned and/or fined up to £5,000 under the Consumer Protection Act 1987.

I am a dental hygienist, can I offer tooth whitening treatments to my patients?

Yes, provided a dentist has examined the patient, prescribed the treatment and is present on the premises during the first treatment cycle. As with any treatment you must be trained and competent to carry out the treatment, so the level of safety is equivalent to a dentist carrying out the treatment.

The GDC’s guidance, Prin-
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