The History

The bleaching of teeth has been practised from at least the 19th century utilizing many different chemicals, including chloride of lime, alumino-magnesium 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 safe effect of the treatment was that it whitened the teeth.

Although Dr Klusmier presented several table-clinics at the meetings of the Arkansas 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 promoted as the way to go with the ‘hands on’ improvement technique 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 for their ‘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 amending 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 at very high concentrations that release hydrogen peroxide, including carbamide peroxide and zinc peroxide to be used for tooth whitening.

Within the new Regulations, the patient can be provided with 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 interventionist 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 dentists to say that their high concentration whitening products, like Zoom and In-Office Ilumine, 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.

‘The new Regulations allow the use of hydrogen peroxide and other compounds or mixtures that release hydrogen peroxide, including carbamide peroxide and zinc peroxide to be used for tooth whitening’

Conversations with advisors 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 for tooth whitening 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.

1. 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 other bleaching products 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:

3. ‘UK Position Statement’ Tooth Whitening 17 October 2012

About the author

Dr Bigg has been working in private practice in Woot Oxwich for nearly 40 years and treated up to four generations of some families. He has been involved in the delivery of education of dentists in the European Union, and has taken roles in the delivery of Postgraduate Dental Education. He has been president of the British Society for General Dental Surgery and has been a faculty member and chair of many courses on Bleaching and Minimal Intervention Dentistry. He has published and read papers on bleaching, minimal intervention dentistry, and the use of composite resins.
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, Principles of Clinical Governance, states 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.

A new regulation states that the legal status of tooth bleaching has now been lifted and Dentists and their patients alike can now benefit from a treatment that was safe, established and much less invasive.

Until recently in the EU it was illegal to sell tooth-whitening products containing hydrogen peroxide for tooth whitening. However, in 2012, a new directive was introduced allowing ‘over-the-counter’ products to be sold in EU member states.

The recent changes in whitening products have improved and expanded the range of options for patients. Dentists and their patients alike can now benefit from a treatment that was safe, established and much less invasive.

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Do I need to warn patients about the risk of relapse?
Yes, in seeking a patient’s consent you need to warn them about all the common risks and complications of the procedure, including relapse and sensitivity, along with the benefits. The GDC also advises that before starting any treatment, that you must have the patient’s medical history. As part of effective patient care and to ensure you can provide evidence that you have compiled with both the law and the GDC’s ethical guidance, you should make a complete and clear record, at the time of the consultation, of the following:
- the treatment plan,
- the consent discussion
- any instructions given to the patient (such as how to continue the treatment at home)
- any adverse outcome

A patient is unhappy with the shade of her teeth after whitening even though I believe we have achieved a reasonable result. She smokes, and drinks black coffee and red wine, and seems unwilling to change her lifestyle, despite my advice. She wants further whitening treatment, which I don’t believe is in her best interests. Can I refuse to provide it?

It is important that before any procedure is carried out, you discuss the treatment options with the patient, as well as the potential risks, side effects and complications that could occur. The patient should be given the opportunity to ask questions and you should make sure they have a realistic idea of the likely results, given their oral health and lifestyle. It may be wise to allow the patient a ‘cooling off period’ so they can go away and consider their options more fully.

Any dental treatment that you carry out should be in the best interests of the patient and if you do not feel that is the case, then you should explain this to the patient and not carry it out. You may decide to refer the patient for a second opinion or to a colleague, such as a dental hygienist, for alternative treatment.

Whatever your decision, it is important that accurate and detailed notes are kept of any consultations. That way, if a complaint is made, it will be easy to refer back to the notes and recall the course of events leading up to the complaint.

Will you indemnify me for tooth bleaching treatments?
DDU members can seek our assistance with complaints, claims, disciplinary actions or criminal prosecutions arising from tooth bleaching treatments. We encourage our members to work within the new regulations and to use only compounds that contain or release up to 6 per cent hydrogen peroxide. In the event of a criminal conviction, the DDU would not pay any fine.

Further information on the legal position on tooth bleaching is available from the DDU at www.theddu.com

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About the author

Nick qualified from University College Hospital in 1985. After starting his career in hospital dentistry, he has spent the past 10 years as assistant and then clinical director of salaried dental services in Hampshire, while continuing to practise dentistry. He has also been involved in dental education as an adviser and vocational trainer with the London Deanery and as a trainer with the Winchester scheme. He joined the DDU in 2008.

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