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.

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 Arkansas State Dental and the South-western 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.

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 being the most effective 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-ters’ 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, the EU 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, long-lasting 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.

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.

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/EC 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 other compounds or mixtures that release hydrogen peroxide, including carbamide peroxide and zinc peroxide to be used for tooth whitening.

However, the maximum concentration that may be used for tooth whitening under the Regulations is now six per cent hydrogen peroxide, which is approximately equivalent to 16 per cent to 18 per cent carbamide peroxide.

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

1. To only be sold to dental practitioners
2. In practice this means that a dentist can only sell tooth-whitening products containing six per cent hydrogen peroxide to the public if they are patients at the practice.
3. 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.
4. 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 dentist probably needs to be present on the premises.

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

A 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 Dentply contacted their clients to say that their high concentration whitening products, like Zoom and In Office Iluminite, 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.

References:
1. Fair R. Hygienists: are they fit to use tooth bleaching products? Br Dent J 2012; 212: 474-478
2. Goldstein FW: ‘Now “at home” bleaching techniques are ‘legal’’ Dent Mag 90:12, June 2012

Dr Bigg has been working in private practice in Woot Oxfordshire for nearly 40 years and treated up to four generations of some families. He takes referrals for cosmetic dentistry, the non-invasive restoration of the worn dentition and treatment of Temporomandibular Dysfunction. Dr Bigg has the Membership in General Dental Surgery at the Royal College of Surgeons, London and Fellowships from the College of Surgeons in Edinburgh
to the Royal College of Surgeons in Edinburgh and London. He is a past President of the British Society for General Dental Surgery. He lectures at home and abroad on crowns and bridge updates, posterior and anterior aesthetics, bleaching and Minimal Intervention Dentistry. He also runs hands-on courses on Contemporary Esthetic Dentistry and Posterior Composite and provides seminars on Bleaching and Posterior Composite Restorations.

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 different product options 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

About the author
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All you need to know about tooth whitening
Nick Torlot, DDU dento-legal adviser, looks at some questions from dental practitioners

I’ve 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.

ternally or internally eg on a root-canal treated tooth.

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 £3,000 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 Safety (Amendment) Regulations to amend the law.

The birth of modern bleaching and sodium peroxide amongst it included chloride of lime, alum and at least the 19th century utilised in the tradition of dentistry worldwide, they were never used.

The bleaching technique that was first time the tooth-whitening procedure that was safe, established was the use of 10% carbamide peroxide in a custom-made mouth tray. Initially, the first use of the tooth-whitening technique was illegal to use hydrogen peroxide, including carbamide peroxide, including carbamide peroxide and zinc peroxide to approximately equivalent to 16 per cent to 18 per cent carbamide peroxide.

The use of bleaching systems was prohibited, with the exception of the use of hydrogen peroxide at concentrations up to 6 per cent hydrogen peroxide. However, the good news was that higher bleach concentrations were permitted for the use of bleaching in this country although their patients requested.

In March 1989 that the dental society presented several table-clinics at the first time the bleaching system was used for tooth whitening.

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ciples of Dental Team Working (2006) requires a third person, trained to deal with medical emergencies, to be routinely present during planned treat-
ment by a hygienist. While the GDC does not specify that this has to be a dentist, the regula-
tions for tooth whitening pro-
cedures introduce a legal duty of direct personal supervision
by a dentist, which has been in-
terpreted to mean there must
be a dentist on the premises
during the first treatment cycle.

Do I need to warn patients
about the risk of relapse?
Yes, in seeking a patient’s con-
sent you need to warn them
about all the common risks and
complications of the procedure,
including relapse and sensitivi-
ty, along with the benefits. The
GDC also advises that before
starting any treatment, that you
must have the patient’s medi-
cal history. As part of effective
patient care and to ensure you
can provide evidence that you
have complied with both the
law and the GDC’s ethical guid-
ance, you should make a com-
plete 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 contin-
uide the treatment at home)
• any adverse outcome.

A patient is unhappy with the
shade of her teeth after
whitening even though I be-
lieve we have achieved a rea-
sonable 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 op-
tions with the patient, as well
as the potential risks, side ef-
fects 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 op-
tions 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 opin-
ion 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 aris-
ing from tooth bleaching

treatments. We encourage
our members to work within
the new regulations and to
use only compounds that con-
tain or release up to 6 per cent
hydrogen peroxide. In the
event of a criminal convic-
tion, the DDU would not pay
any fine.

Further information on the
legal position on tooth bleach-
ing is available from the DDU
at www.the-ddu.com

1 Cosmetic Products (Safety) (Amend-
ment) Regulations 2011, UK Govern-
ment, laid before Parliament 17 Septem-
ber 2011 http://www.legislation.gov.uk/
ukcis/2011/2467/introduction/quadra

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