Superior Health Council

PUBLICATION OF THE SUPERIOR HEALTH COUNCIL No. 8782

Tooth bleaching – tooth whitening

In this science-policy advisory report, the Superior Health Council of Belgium provides an expert opinion on the safety of products such as hydrogen peroxide used for tooth bleaching/whitening in response to the publication of the new European regulation (Council Directive 2011/84/EU).
The Superior Health Council has some concerns about the usefulness of these treatments and considers some of them false advertising.

8 May 2013

1. INTRODUCTION AND ISSUES

Dental bleaching, also known as tooth whitening, is a common procedure in general dentistry. According to the US Food and Drug Administration (FDA), whitening restores natural tooth colour whereas bleaching whitens the teeth beyond their natural colour. In other words, whitening refers to the removal of stains at the surface of the teeth by means of cleansing and polishing agents, whereas bleaching is concerned with doing away with colorants and discolorations in tooth substance by means of oxygen radicals. Unfortunately, the terms “whitening” and “bleaching” are often used interchangeably.

The EU Council Directive 2011/84/EU of 20th September 2011[1] restricts the use of whitening and bleaching products: only dentists may use products for tooth whitening and bleaching that contain or release between 0,1 % and 6 % hydrogen peroxide (H_2O_2), products for tooth whitening and bleaching that contain or release up to 0,1 % H_2O_2 are available as over the counter products. Products with H_2O_2 concentrations over 6 % are prohibited as cosmetics. Tooth bleaching services may not be offered to anyone under the age of 18. The directive has been transposed into Belgian law by means of the Royal decree of 22.04.2012 (published on 27.04.2012)[2].

In this context the Superior Health Council has been asked for an advisory report on this subject by the Minister of Health taking into account the bleaching/whitening procedures performed in ‘bars à sourire’, performed by persons without any dental background and the amount of publicity on bleaching/whitening products. An *ad hoc* working group has been set up which includes experts in dentistry (oral diseases, conservative and restorative surgery) and toxicology**.** The standing working group “cosmetology and cosmetic devices including cosmetic surgery” read and approved the advisory report as well as the College does.

[1] Implementation of the Council Directive 2011/84/EU amending Directive 76/768/EEC, concerning cosmetic products, for the purpose of adapting Annex III thereto to technical progress
[2] Implementation of the Royal Decree of 22.04.2012 amending the Royal Decree of 15.10.1997 concerning cosmetic products

There is a wide range of bleaching techniques available. In many cases, though, such treatments are not necessary. Next to professional whitening and bleaching procedures performed in the dental office, some whitening and bleaching products are directly available to consumers as over-the-counter products and can be applied with custom-made or preformed trays, with a brush, or as a strip. It also appears that tooth whitening and bleaching procedures performed in non-dental settings (e.g. mall kiosks, spas, beauty centres, etc.) are on the rise.

The previously mentioned interchangeable use of the tems “whitening” and “bleaching” is also found in the translation of the Council Directive 2011/84/EU of 20 September 2011: Nl: tandbleekmiddelen – E: tooth whitening and bleaching – Fr: blanchiment et éclaircissement des dents. In order to avoid confusion in this advice, the English term ‘tooth whitener’ is used throughout these recommendations for all products resulting in tooth whitening. The process of restoring the colour of the tooth by way of cleansing or polishing but without actually changing it is referred to as a ‘whitening procedure’. Changing the intrinsic colour of the teeth is referred to as “bleaching”.

The Superior Health Council (SHC) agrees with the Council Directives. Nevertheless, a number of concerns are raised: (1) what can be expected from bleaching products with concentrations less than 0.1 %, (2) is there a potential damage by the free radicals needed for bleaching and/or by the light of the different lamps used to activate bleaching gels, (3) what about bleaching sclerotic teeth, teeth with tetracycline discolorations and non-vital teeth ?

2. CONCLUSIONS & RECOMMENDATIONS

Conclusions

Tooth bleaching and *whitening* are common procedures in general dentistry. *Whitening* procedures restore natural tooth colour and are based on the use of cleansing and polishing agents to remove stains at the surface of the teeth, whereas *bleaching* procedures whiten teeth beyond their natural colour and involve the use of oxygen radicals to do away with colorants and discolorations in tooth substance. These two terms are often used interchangeably.

In practically all techniques hydrogen peroxide (H_2O_2) is used as the whitening or bleaching agent either directly or via the decomposition of certain chemicals e.g. carbamide peroxide. In some cases light is used to enhance the bleaching process. At present, it remains a question if lamps (multi wavelength) may enhance the bleaching process be it that there is only heating of the gel. For as far as laser light is concerned (one wavelength) Argon and KTP-laser can be used to enhance the bleaching efficacy.

No adverse effects have been described for whitening products intended for oral hygiene that contain up to 0.1 % H_2O_2 (such as gels, chewing gums, rinses and toothpastes). There is no scientific evidence supporting the efficacy of whitening/bleaching products which release or contain H_2O_2 concentrations below 0.1%.

Tooth bleaching and whitening with products containing over 0.1 % H_2O_2 is not risk-free. Only limited long-term clinical data are available on their side effects. This accounts for both the lower concentrated formulations up to 6% H_2O_2 and the higher concentrated formulations up to 35% H_2O_2,although the current evidence base on tooth whitening and bleaching products suffers from methodological and publication biases.

In terms of side effects, it has been shown that bleaching agents might have a negative effect on the surface morphology of enamel and dentine permeability. Tooth sensitivity caused by bleaching has been the most widely reported adverse reaction. Several cellular and tissue mechanisms underlying peroxide damage have been identified. At concentrations of 10 % or more, H_2O_2 is potentially corrosive to the mucous membranes or skin, causing a burning sensation and tissue damage. Studies have also reported that commercial peroxide-based gels induce cytotoxicity. Therefore, adequate barriers are necessary to protect the gingiva from mucosal damage. Gingival irritation is also common following at-home tooth bleaching. Finally, a specific attention is needed to be emphasized that bleaching products cannot change the colour of filling materials.

A typical course of bleaching can produce dramatic improvements in the appearance of most stained teeth; however, some stains do not respond to bleaching:

- Tetracycline staining may require prolonged bleaching, as it takes longer to bleach the dentine layer.
- Discoloration of inorganic origin (e.g. greyish discolorations as a result of metal release from amalgam restorations) cannot be bleached away.
- The whitening process may also result in white spots being highlighted and thus becoming more noticeable.
- Bleaching is not recommended in the event of tooth decay or infected gums.

Profound discolorations such as those found on sclerotic teeth, tetracycline-discoloured teeth and teeth that have had root canal treatment cannot be bleached away efficiently with bleaching gels containing H_2O_2 concentrations ≤ 6 %, or combinations of sodium perborate and water or 3 % H_2O_2. Higher concentrations of H_2O_2 have been shown to be effective for these indications – the question remains, taking into account the European directives, whether or not it is allowed to use bleaching products containing higher H_2O_2 concentrations for these specific indications to be delivered as prescription-only medication.

Recommendations

The SHC recommends that:

- tooth bleaching/whitening be performed by a professional dentist and following pre-treatment dental examination and diagnosis; with product of adequate concentration;

- product controls and controls on tooth bleaching/whitening practices be reinforced;

- the light sources used for the activation of tooth bleaching products and during bleaching treatments be marketed/delivered as medical devices only;

- the general public be informed by competent authorities about the fact that, at this time, there is no scientific evidence in support of the efficacy of whitening/bleaching products which release or contain H_2O_2 concentrations ≤ 0.1%. For this reason, the SHC is not totally in agreement with the European Council Directives based only on the absence of toxicity for products containing less than 0.1 % of H_2O_2 with no real attention to the efficacy; in this respect the utility of these products for obtaining any degree of whitening or bleaching can be questioned when these are applied as a gel for instant bleaching or whitening purposes.

- the various laws governing aesthetic practices include strict rules on advertising tooth bleaching treatments in order to protect the public against abusive practices for all products containing less than 0.1 % of H_2O_2;

- further research is needed:
    - with emphasis on pragmatic long-term and independent clinical studies that include participants from a variety of population groups, as many trials are limited to the short term effects and most studies are deemed to be at a high risk of bias and are either sponsored or conducted by the manufacturers;

    - to give an answer to the question whether the efficacy of whitening/bleaching prducts has at all anything to do with the H_2O_2 concentration;

    - to evaluate the long-term hazards;

    - to evaluate the re-use of bleaching agents in patients who have already had tooth bleaching treatments on previous occasions;

    - to investigate the safety and efficacy of alternative bleaching systems (not containing H_2O_2), as the latter have only received minor attention.

Keywords

Keywords	Mesh terms*	Sleutelwoorden	Mots clés	Stichwörter
	Tooth/teeth whitening	Tanden wit maken	Blanchiment/ éclaircissement dentaire	Zahnaufhellung
	Tooth/teeth bleaching	Tanden bleken	Blanchiment/ éclaircissement dentaire	Zahnbleichung/ Zahnbleaching
	Tooth/teeth colour	Tandkleur	Couleur dentaire	Zahnfarbe
	Laser tooth whitening	Tanden wit maken met Laser	Blanchiment dentaire au	Zahnaufhellung mit Laser

			laser	
	Home bleaching	Thuisbleken	Blanchiment chez soi	Zahnbleaching zu Hause

** MeSH (Medical Subject Headings) is the NLM controlled vocabulary thesaurus used for indexing articles for PubMed.*

3. FURTHER DETAILS AND ARGUMENTATION

List of abbreviations

ADA:	American Dental Association
CPO:	Carbamide peroxide
EDJ:	Enamel dental junction
FDA:	Food and Drug Administration
H_2O_2:	Hydrogen peroxide
KTP-laser:	Potassium Titanyl Phosphate
LED:	Light-Emitting Diode
OTC :	Over the counter
SHC:	Superior Health Council
SCCP:	Scientific Committee on Consumer Products
UV:	Ultraviolet
w/w:	Weight by weight

A. DENTAL BLEACHING

1. INTRODUCTION

Effective and safe tooth bleaching requires a correct diagnosis of the problems associated with tooth discolorations or stains (Ontiveros, 2011). Proper diagnosis can only be performed by a professional, i.e. a dentist.

The outcome of a tooth bleaching procedure is influenced by the type of stain, initial tooth colour and age of the subject. In a number of cases, the original colour can be restored simply by thoroughly cleaning the teeth (Suliemann, 2008).

2. MATERIALS AND METHODS

Studies published up to December 2012 on the issue of tooth whitening and tooth bleaching were retrieved by searching the PubMed database and the Cochrane Central register of Controlled Trials. This search was not restricted as regards publication date and language.

The following terms and keywords were used: (bleaching or whitening or brightening or colour) and (tooth or teeth) and/without (agent) or (light or lamp or activation or heath or radiation or ultraviolet (UV) or laser) as well as bleaching lamp, tooth bleaching heat, tooth/teeth brightening, tooth bleaching activation, tooth bleaching radiation, ultraviolet tooth bleaching, laser tooth whitening, tooth/teeth whitening/bleaching/brightening agents, tooth bleaching/whitening light,

brightening, tooth/teeth colo(u)r, whitening toothpaste, whitening dentifrice, vital bleaching, dental bleaching review en tooth whitening review.

In addition to recent studies on this issue, a number of recent reviews were also used to provide the information on the basis of which this expert opinion report was finally drawn up.

3. RESULTS

3.1. Dental bleaching – working mechanisms

Most **colourations** on teeth (extrinsic colourations) or in the hard tissues (intrinsic colourations) are of organic origin. The colour producing materials in solution or on a surface possess extended conjugated chains of alternating single or double bonds. They often include heteroatoms, carbonyl, and phenyl rings in the conjugated system and are frequently referred to as chromophores. Bleaching and decolourisation of the chromophore is caused by the destruction of one or more of the double bonds in the conjugated chain, by conjugated chain cleaving, or by oxidation of other chemical moieties in the conjugated chain (Joiner, 2006).

The chemical reaction of the two reagents with the organic extracellular matrix components, including pigments and chromophores, constitutes the chemical basis of tooth bleaching. In order to change the intrinsic colour of a tooth, bleaching agents have to diffuse into and through the enamel, reach and cross the enamel dental junction (EDJ) and interact in the subjacent dentine with the chromophores, pigments and ions that caused the change in tooth colour.

Hydrogen peroxide (H_2O_2**)** can act as a powerful oxidising agent and can give rise to agents known to be effective bleaching agents : its corresponding mono-anion HO_2^- and hydroxyl radical •OH. Most current bleaching techniques are based on the effects of carbamide peroxide (CPO) containing agents, which release about 33 % of their content as H_2O_2. In addition, CPO also releases urea, which rapidly decomposes into carbon dioxide and ammonia.

Other hydrogen peroxide–separating agents such as sodium percarbonate as well as sodium perborate in the form of mono-, tri- or tetrahydrate can be used to bleach discoloured teeth. Suspensions consisting of sodium percarbonate and water or 30 % hydrogen peroxide have a good bleaching effect on teeth that were artificially stained in vitro by iron sulphide (Attin et al., 2003; Plotino et al., 2008). However, there have been no reports to date on clinical studies with sodium percarbonate.

Mixtures of sodium perborate mono-, tri- or tetrahydrate and water or hydrogen peroxide have the same whitening efficacy. H_2O_2 is released during the decomposition of perborate. The released H_2O_2 can generate different radicals or ions depending on pH value, light influence, temperature, existence of co-catalysts and metallic reaction partners (Attin et al., 2003). These products are formed after the cleavage of H_2O_2 and are responsible for its oxidative and reductive properties, thus accounting for its bleaching effects. The radicals can crack unsaturated double bonds of long, coloured molecules or reduce coloured metallic oxides like Fe_2O_3 (Fe^{3+}) to colourless FeO(Fe^{2+}).

It has to be emphasized, however, that **the mechanism of bleaching with H_2O_2 is still not well understood**. Depending on the substrate, the reaction environment and catalysis (e.g. reaction conditions, including temperature, pH, light and presence of transition metals), there has been argued that H_2O_2 can form a number of different oxygen species (Buchalla & Attin, 2007; De Moor & Vanderstricht, 2009).

- Under alkaline conditions, the formation of perhydroxyl ions (HO_2^-) is favoured.

- Other conditions can give rise to free radical formation such as H• and •OOH, an 2•OH.
- Photochemical reactions initiated by light and lasers increase the formation of hydroxyl radicals from H_2O_2.
- Heating the bleaching gel may enhance the ionisation of H_2O_2 .

Moreover, further research is needed on the nature and chemical composition of the coloured materials naturally found within the dental hard tissues as well as the mechanistic effects of peroxide on these structures.

3.2. Dental whitening and bleaching: products and techniques

3.2.1. Types of bleaching techniques

A distinction is made between the bleaching of vital and non-vital teeth (in general, teeth that have had root canal treatment).

There are three bleaching approaches: (1) in-office bleaching (gels applied at the dental office); (2) at-home bleaching (gel is applied by the patient at home – also called supervised nightguard bleaching) and (3) the use of mass market bleaching products (Buchalla & Attin, 2007; Suliemann, 2008).

(1) In-office bleaching generally uses relatively high levels of whitening agent-O (i.e. gels that contain or release > 20 % hydrogen peroxide) applied directly to the teeth (trayless bleaching) or with a custom-made mouth guard, which is worn at night for at least two weeks. Another alternative is for the gel to be activated by means of heat or light (halogen lamps, LED (Light-Emitting Diode), laser, etc.). In each case, it is necessary to protect the soft tissues.

(2) Nightguard bleaching uses a gel with a relatively low H_2O_2 or CPO concentration. The gel is applied on the teeth via a custom-made mouth guard and is worn at night for at least 2 weeks.

(3) The mass market products available in the European Union may only contain very low levels of whitening agent (gels containing or releasing < 0,1 % hydrogen peroxide) and are self-applied to the teeth via gum shields, strips and paint-on product formats. They need to be applied twice a day for at least 2 weeks.

3.2.2. Toothpastes and other products for whiter teeth

Commercial whitening products intended for home use include gels, chewing gums, rinses, and toothpastes.

In general, toothpastes that are specifically manufactured for tooth whitening purposes achieve this goal by removing and preventing the formation of extrinsic stains. One of the key functional ingredients is the abrasive substance to which other chemical or optical ingredients have been added (abrasives: hydrated silica, calcium carbonate, dicalcium phosphate dehydrate, calcium pyrophosphate, alumina, perlite, sodium bicarbonate / chemical approaches: hydrogen peroxide, calcium peroxide, sodium citrate, sodium pyrophosphate, sodium tripolyphosphate, sodium hexametaphosphate, papain / optical approach: blue covarine). In general, whitening toothpastes have become complex formulations with multiple combinations of these ingredients (Joiner, 2010). These formulations also contain a source of fluoride, which can be beneficial for enamel health (CSH 6103, 2002; CSS 8309, 2009; CSS 8520, 2009; CSS 8671, 2011).

As previously mentioned, the role of the abrasive ingredient is essential. It is well documented that if a very low-abrasive toothpaste is used, stains usually accumulate to form a pellicle film on the surface of the teeth. It is now widely accepted that toothpastes require a certain amount of abrasive substances to remove extrinsic stains or prevent them from forming. It has to be emphasized that the evidence to date still suggests that the primary stain-removing ingredient in the toothpaste remains the abrasive substance.

Unfortunately, most stain removal/prevention studies are conducted over a period of time that ranges between 2-6 weeks, with a few studies measuring whitening effects for up to 12 weeks or longer. There is little information on the longer-term maintenance and stability of the tooth whitening effects and there are no studies that evaluate the stain levels in the event of a non-whitening toothpaste being switched to following the use of a whitening toothpaste. There is also limited information available on the subjectivity with which the improvements achieved by whitening toothpastes are perceived.

The efficacy of the toothpastes used also depends on the use, type and hardness of the toothbrush.

Chewing gums and rinses marketed for dental whitening or bleaching only received minor attention in dental research so that no conclusions can be drawn for these products.

3.3. Efficacy of bleaching gels

Concentration and time

The key factors that affect the efficacy of peroxide-containing products used for tooth whitening purposes are concentration and time (Buchalla & Attin, 2004). Higher concentrations lead to faster results than lower ones. However, after extended treatment times, the efficacy of products containing lower concentrations is expected to be similar to that of products with higher concentrations (Matis et al., 2009).

Light-activation is only based on thermal heating

Power or light-accelerated bleaching uses light energy to accelerate the process of bleaching in the dental office. Different types of energy have been proposed for this procedure, the most common of which are halogen, LED, or plasma arc light (Buchalla & Attin, 2007; He et al., 2012). The lights used are typically within the blue light spectrum, as this has been found to contain the most effective wavelengths for initiating the hydrogen peroxide reaction. Recent technical improvements are expected to minimize heat and ultraviolet emissions, allowing for shorter patient preparation procedures. Most currently available power tooth bleaching treatments are carried out within approximately 30 minutes to one hour.

Research has demonstrated that the use of light during in-office bleaching procedures may not improve the efficacy of bleaching when it is combined with very high concentrations of H_2O_2 (25 – 35 %) (Buchalla & Attin, 2007). The high concentration of bleach itself can quickly produce enough radicals that react with pigments.

Because the light-activated systems increase the risk of tooth sensitivity, this system should be used with great caution (He et al., 2012). It should be emphasized that there is no evidence that 'light' itself may activate the bleaching gel. In fact, activation by means of light is solely based on heating because of the absence of photosentizers in present-day marketed bleaching products (Bruzell et al., 2009).

The arch form of a number of light sources does not coincide with the arch form of the jaws. This discrepancy and the fact that the intensity of the light coming from the arch of the light source or the lamp at the level of canines and the posterior region is far lower and most of the times insufficient (to low the intensity) to activate the bleaching gel also explains the lack of efficacy of light-activated bleaching procedures.

Real light activation following the addition of photosensitizers

Light-activation of the bleaching gel can only be induced by incorporating photosensitizers (De Moor & Vanderstricht, 2009). Except for a number of gels containing a photo-activator for laser light activated bleaching, not a single form of light-induced catalysis of the H_2O_2 has been shown to occur to date using conventional light sources (multi wavelength) and low power LEDs.

Photosensitizers are also used in the bleaching gel for laser bleaching and are chosen on the basis of the wavelength used (e.g. Argon laser – 488 nm, Diode laser - range from 790 to 960 nm, KTP laser – 532 nm) (KTP-laser - Potassium Titanyl Phosphate). This means that wavelength specificity for photosensitizers is mandatory.

In this respect it has to be mentioned that the highest bleaching efficacy with laser light is seen with KTP (532 nm) and a red coloured photosensitizer with an absorption peak at a wavelength of around 532 nm.

Photobleaching

Only specific wavelengths have been shown to lead to photobleaching, i.e. direct photo-oxidation of tetracyclines and grey discolorations. Efficient wavelengths in this respect are 290 nm, 365 nm and 532 nm (De Moor & Vanderstricht, 2009).

Light-induced dehydration

There is limited evidence that light is able to produce better immediate bleaching effects when H_2O_2 concentrations of 15-20 % are applied (He et al., 2012). There is, however, some evidence in support of the occurrence of light-induced H_2O_2 photolysis, which results in a rise in hydroxyl radicals that compensates for the low concentrations of H_2O_2. Light-induced dehydration (heating of the tooth surface by light heated gels results in dehydration) may play a significant part in bleaching processes that lead to immediate results, which are, however, of temporary duration.

Regardless of the heat or photolysis mechanism used, the dehydration effect has been frequently mentioned as an important factor in light-activated systems (He et al., 2012). Hence, the bleaching effect is temporary.

3.4. Limitations of bleaching gels

A typical course of bleaching can produce dramatic improvements in the appearance of most stained teeth; however, some stains do not respond to bleaching.

Tetracycline staining may require prolonged bleaching, as it takes longer for the bleach to reach the dentine layer. Discoloration of inorganic origin (e.g. greyish discolorations as a result of metal release from amalgam restorations) cannot be bleached away.

The whitening process may also result in white spots being highlighted and thus becoming more noticeable.

Bleaching is not recommended in the event of tooth decay or infected gums.

3.5. Side-effects of bleaching gels

The toxicity of peroxide containing products

Products with a H_2O_2 concentration below 3.6 % (w/w) (10 % (w/w) carbamide peroxide) that are used under the adequate supervision of a dentist are not believed to entail any toxic or sub-toxic risk. The ingestion of peroxide, which is mostly caused by poorly adapted trays, should be avoided : bleaching gels may have a laxative effect.

Dental hard tissues

It has been shown that bleaching agents might have a negative influence on the surface morphology of enamel, such as loss of mineral substance, erosion and porosity. Also, enamel demineralization can occur when the bleaching agent has a pH below 5.2 to 5.8. This means that small defects can be found at the enamel surface and subsurface (Joiner, 2007; Attin et al., 2009).

There can also be alterations in dentine permeability (Joiner, 2007).

Cervical resorption has been observed after non-vital tooth bleaching and intracoronal placement of the bleaching gel. It occurs in an unpredictable manner (Goldberg et al., 2010).

There is currently no evidence that bleaching has any long-term effect on the development of carious decay.

Tooth sensitivity

Tooth sensitivity caused by bleaching has been the most widely reported adverse reaction (Sulieman, 2008; Goldberg et al., 2010).

Transient dentinal hypersensitivity can be observed after the treatment, which alters dentine permeability. In clinical research studies, the number of patients affected by tooth sensitivity during bleaching ranges between 18 % and 78 %, either as a result of at-home tray bleaching or in-office procedures. In this respect, it should also be pointed out that the same tooth sensitivity rates were found to occur with the use of trays containing a placebo. Hence, the design of the trays is an important factor.

In this respect, it is also necessary to carry out a proper case selection: care has to be taken with dentinal surfaces exposed to the oral environment, such as abrasion and/or erosion lesions, dental necks or exposed root surfaces in the event of gingival retraction.

Light-activated systems are likely to increase the occurrence or severity of tooth sensitivity. This sensitivity is explained by the fact that light sources can cause a rise in pulp temperature and may accelerate the permeability of the enamel and dentine, thus allowing the peroxide to reach the pulp after easily passing through the enamel and dentine.

Soft tissues

Cellular and tissue mechanisms underlying peroxide damage have been identified. At concentrations of 10 % or more, H_2O_2 is potentially corrosive to the mucous membranes or skin,

causing a burning sensation and tissue damage. Studies have also reported that commercial peroxide-based gels induce cytotoxicity (Goldberg et al., 2010).

Therefore, adequate barriers are necessary to protect the gingiva from mucosal damage.

Gingival irritation is also common following at-home tooth bleaching. The data indicate that the risk of gingival irritation as a result of at-home bleaching is linked to the H_2O_2 concentration in the bleaching gel, i.e. there is a higher prevalence of gingival irritation when bleaching gels with higher peroxide concentrations are used (Li, 2011; Goldberg et al., 2010).

It is clear that long-term gingival tissue damage has to be avoided.

The effects on the pulp are the most contradictory and may therefore be inconsistent.

Restorative materials

A number of effects on dental materials have been acknowledged. In vitro studies suggest that dental restorative materials may be affected by tooth bleaching agents. These findings relate to possible physical and/or chemical changes in the materials, such as increased surface roughness, crack development, marginal breakdown, and decreases in tooth-to-restoration bond strength (Attin et al., 2004). Mercury and silver ions may be released from amalgam fillings, though the maximum acceptable daily intake (ADI) of mercury to be 40 µg as recommended by the World Health organization is not exceeded (an amount of 37 to 38 amalgam restorations is needed to exceed the recommended ADI for mercury) (Al-Salehi, 2009). Such findings have not appeared in clinical reports or studies. There are, however, no reports in the literature indicating that bleaching may exert a negative impact on existing restorations that would result in the need to renew restorative materials and restorations (Attin et al., 2004). Recent investigations reporting on present-day resin composite formulations/restorations (microhybrid composites, nanofilled composites) exposed to bleaching gels demonstrate that the effect of bleaching gels on the surface characteristics and physical properties is 'limited' to 'not significant' (Mourouzis et al., 2013; Varanada et at., 2013). Care, however, has to be taken when combining a bleaching agent, even at low concentration, with abrasive dentifrices (Ozkan et al., 2013).

It needs to be emphasized that bleaching products cannot change the colour of filling materials.

B. SPECIAL CONCERNS TAKEN INTO CONSIDERATION

1. SAFETY AND ADVERSE EFFECTS OF BLEACHING PRODUCTS

It is reasonable to assume that when individuals purchase and use bleaching products that contain or release over 0.1 % hydrogen peroxide, some adverse effects may go unnoticed (e.g. changes in enamel surface).

Safety issues have been raised regarding the effects of bleaching on the tooth structure, pulp tissues, and the mucosal tissues of the mouth, as well as systemic ingestion. Regarding mucosal tissues, safety concerns relate to the potential toxicological effects of free radicals produced by the peroxides used in bleaching products. Free radicals are known to be capable of reacting with proteins, lipids and nucleic acids, causing cellular damage. Because of the potential of hydrogen peroxide to interact with DNA, concerns with carcinogenicity and co-carcinogenicity of hydrogen peroxide have been raised, although these concerns so far have not been substantiated through research (Li ,1996; Munro et al., 2006a & b).

Hydrogen peroxide and carbamide peroxide are mutagenic *in vitro.* No mutagenic effects have been found in *in vivo* studies. Hydrogen peroxide has a weak potential to induce local carcinogenic effects. The mechanism is unclear, but a genotoxic mechanism cannot be excluded. As regards to tumour promotion, several mechanisms might be operative; direct genotoxicity, impairment of DNA repair, and chronic inflammation. Due to degradation of hydrogen peroxide in the oral cavity, it is unlikely that the use of tooth whitener will represent a cancer risk in persons that do not have an increased risk of oral cancer due to tobacco use, alcohol abuse, or genetic predisposition. The risk of oral cancer such groups may increase with repeated treatments with tooth whiteners. On the basis of a case report it has been suggested that users of tooth whiteners should be further studied with regard to oral cancer (Burningham et al., 2004).

Tooth sensitivity is the most frequently reported side-effect after vital tooth bleaching. Gingival irritation can occur in a significant portion of the patients, although in most cases it is mild to moderate and transient.

Potential adverse effects are possible as a result of improper application, abuse, or the use of inappropriate at-home bleaching products. Moreover, concerns have remained about the long-term safety of unsupervised bleaching procedures, not only due to abuse but also because of undiagnosed or underlying oral health problems. As regards the use of mouth guards, it has to be emphasized that these devices are custom-made and that care has to be taken not to overextend the gingival margins over the cemento-enamel junction.

There is a risk that a patient who has not had appropriate instruction on loading a home tooth whitening tray with the tooth whitening product and who has not received instruction on fitting the tray in the mouth could be at risk of swallowing excess material. The requirement that the first use of each cycle is by a dental practitioner (or under their direct supervision), helps to allay these concerns as it allows the dental professional to demonstrate the amount of material to be used and how to load and seat the tray. This would therefore decrease the risk of the patient inadvertently using an excess of the product, which would increase the risk of the product being swallowed.

The SHC also refers to the European Scientific Committee on Consumer Products (SCCP), which draws the following conclusion in its opinion SCCP/1129/07 on hydrogen peroxide (in its free form or released) in oral hygiene products and tooth whitening/bleaching products:

> **“Oral hygiene and tooth whitening/bleaching products containing up to 0.1 % hydrogen peroxide**
>
> • The use of oral hygiene and tooth whitening/bleaching products containing up to 0.1 % hydrogen peroxide does not pose any risk to the health of the consumer.
>
> **Tooth whitening/bleaching products containing > 0.1 % and ≤ 6 % hydrogen peroxide**
>
> • Based on the available data, the SCCP is not in a position to define a level of hydrogen peroxide and a frequency of application that would result in exposure which would be considered safe for the consumer.
>
> • With increasing concentration of hydrogen peroxide and frequency of application there will be an increasing risk associated with the use of these products. It cannot be anticipated what the exposure would be if the products were to be freely and directly available to consumers.
>
> • Potential risks associated with the use of products containing more than 0.1 % and up to 6 % hydrogen peroxide may be reduced if:

a) they are used only after clinical examination to ensure the absence of risk factors identified below or any other oral pathology of concern.

- Particular care in using them should be taken by persons with gingivitis and other periodontal diseases or defective restorations. Conditions such as pre-existing oral tissue injury or concurrent use of tobacco and/or alcohol may excacerbate the possible toxic effects of hydrogen peroxide.
- Their use is not recommended prior to or immediately after dental restoration.

b) exposure to tooth whitening/bleaching products containing 0.1 to 6 % hydrogen peroxide is limited in a manner that ensures that the products are used only as intended in terms of frequency and duration of application in order to avoid reasonably foreseeable misuse." (SCCP, 2007)

c) It should be emphasized that a critical oral examination is needed before bleaching and/or whitening procedures are installed. A typical dental examination begins with a health and dental history. Intra-oral examination of the hard and soft tissues of the mouth and extra-oral examination of the head and neck are also conducted to assess the patient for oral health problems as well as lumps, sores, or other signs of disease such as cancer or infection. Seminal to decisions regarding tooth bleaching, the patient history would include the patient's opinions regarding the cause of tooth discoloration, a history of allergies (which may include ingredients in bleaching materials; no allergenic effects were detected with hydrogen peroxide), and information regarding any past problems with tooth sensitivity. Some tooth discolorations may be the result of a disease or condition that requires endodontic therapy, restorations or dental surgery. Such diagnoses can only be made by a dentist or another licensed health care professional, depending on local licensing regulations. In light of these and additional factors noted below, a dental examination with appropriate radiographs or other screening or diagnostic tests is recommended prior to considering tooth bleaching. It has also to be emphasized that a good oral hygiene may contribute to the absence or to limited superficial tooth discolorations by means of pigments coming from tea, coffee, wine, tobacco, a number of rinsing solutions with chlorhexidine or liquid medication. The stains can be easily removed by professional cleaning or polishing.

"• There is an absence of good clinical data and long-term epidemiological studies that assess the possible adverse effects within the oral cavity (see SCCP/0974/06). The SCCP recommends that, in consideration of public health, independent long-term safety evaluations be performed (see SCCP/0974/06).

• In the absence of specific data on the safety of tooth whitening/bleaching products in children/adolescents, the SCCP is not in a position to assess the potential health risks associated with their use in this population subgroup.

Tooth whitening/bleaching products containing > 6 % hydrogen peroxide

Because of the increasing risks of acute and long-term effects, tooth whitening/bleaching products containing > 6.0 % hydrogen peroxide are not considered safe for use by the consumer (SCCP, 2007; Lima et al., 2013)".

2. ALTERNATIVE, NON-HYDROGEN PEROXIDE CONTAINING BLEACHING SYSTEMS

Alternative bleaching systems to those based on peroxide have received only minor attention. Hence, their efficacy and safety still needs to be investigated (Li, 2011). The free radicals needed for tooth bleaching can also be formed by light-activating different types of nanoparticles. A number of concerns have been raised regarding the biocompatibility of nanoparticles. Future research in this area has to take into account this specific concern.

3. LIGHT ACTIVATION

There is limited and conflicting evidence in support of the efficacy of light-activated systems versus non-light activated controls in clinical studies. Nevertheless, it can be concluded that light (broad spectrum i.e. non-laser light) may not improve the efficacy of in-office bleaching procedures using high concentrations of hydrogen peroxide (H_2O_2 - 25-35 %) (Buchalla & Attin, 2007; Bruzell et al., 2009; He et al., 2012). Because the conventional light-activated systems increase the risk of tooth sensitivity, dentists should exert great caution when using this system or avoid it altogether.

There is limited evidence that light activation leads to better immediate bleaching effects for H_2O_2 concentrations of 15-20 % (Buchalla & Attin, 2007). Extensive research is needed into the advantages of the light-activated systems for lower concentrations of H_2O_2.

As previously mentioned, the activation by multi-wavelength light is solely based on heating, unless photosensitizers are used to catalyse the ionisation of the H_2O_2.

4. CONCERNS

At the moment, there is still a need for long-term clinical studies to demonstrate the effects of tooth bleaching practices using lower H_2O_2 concentrations, i.e. concentrations between 0.1 and 6 %, and especially those below 0.1 %. To the SHC's knowledge, no evidence-based protocol for the use of concentrations below 0.1 % has ever been published.

There is also a need for studies that evaluate the re-use of bleaching agents in patients who have already had tooth bleaching treatments on previous occasions.

Profound discolorations such as those found on sclerotic teeth, tetracycline-discoloured teeth and teeth that have had root canal treatment cannot be bleached away efficiently with bleaching gels containing H_2O_2 concentrations ≤ 6 %, or combinations of sodium perborate and water or 3 % H_2O_2. Higher concentrations of H_2O_2 have been shown to be effective for these indications – the question is whether or not it would be advisable for products containing such concentrations to be delivered as prescription-only medication.

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5. RECOMMENDATIONS FOR FURTHER RESEARCH

- As there is no evidence in support of the efficacy of whitening/bleaching products that contain or release H_2O_2 concentrations < 0.1 %, studies are needed to show whether their efficacy is related to the H_2O_2 they contain;

- With many trials focussing on the short term effects of tooth bleaching/whitening and most studies either sponsored or conducted by the manufacturers themselves and therefore deemed to be at a high risk of bias, there is a need for pragmatic long-term and independent clinical studies that include participants representing diverse population groups;

- There is also a need to evaluate the long-term hazards of these practices.

- There is also a need for studies that evaluate the re-use of bleaching agents in patients who have already had tooth bleaching treatments on previous occasions.

- Further research is needed into alternatives to hydrogen peroxide as bleaching and whitening agents.

6. COMPOSITION OF THE WORKING GROUP

All experts joined the working group ***in a private capacity.*** The names of the members and experts of the Superior Health Council are indicated with an asterisk*.

The following experts were involved in drawing up the advisory report :

ADANG Dirk	Non-ionizing radiation	UCL
BEUN Sebastien	Restorative Dentistry,	UCL - Département de Médecine Dentaire et Stomatologie
DE MOOR Roeland	Restorative Dentistry, Endodontics, Dental Traumatology, Lasers in dentistry	UGhent – UZ Ghent Ghent Dental Laser Centre, Ghent Dental Photonics Research Clustre
DEVRIESE Michel	Dentistry	Société de médecine dentaire asbl Vice-president Conseil de l'Art Dentaire
GEERTS Sabine	Conservative Dentistry, Endodontics	ULiège
HANSON Stefaan	Dentitry	Verbond der Vlaamse Tandartsen Ondervoorzitter Raad voor Tandheelkunde
PEUMANS Marleen	Dentistry, Oral Diseases and Oral Surgery	K.U.Leuven
TYTGAT Jan	Toxicology	K.U.Leuven- labo toxicology and bromatology
VAN HAECKE Tamara	Toxicology	VUB – Vrije Universiteit

		Brussel
VLEMINCKX Christiane	Toxicology	ISP

The administration was represented by:

DE CLOCK Dominique	staff member cosmetics and nutrition	DG4 – nutrition and cosmetics
MEUNIER Joëlle	Expert in cosmetics	DG4 – nutrition and cosmetics
PASTEELS Karine	Technical expert	DG2 - Inspectiedienst
VRINDTS Els	Inspector-coordinator	DG4 Inspectie Consumptieproducten

The working group was chaired by Roeland DE MOOR, the scientific secretary was Anne-Madeleine PIRONNET.

The following experts of the standing group "cosmetology and cosmetic devices including cosmetic surgery" read and approved the advisory report:

BEELE Hilde	Medicine, dermatology	UZ Gent
BORIES Yvon	Art of nursing, hospital hygiene	AZ Nikolaas, Sint Niklaas
De CUYPER Christa	Medicine, dermatology	AZ Sint-Jan, Brugge
HAUSDÖRFER Suzanne	Medicine, dermatology	Private practice

The following individuals were heard:

BOECKX John	Chairman	BESKO – Beroepsvereniging voor Bio-esthetiek en Kosmetologie
DELGOFFE Daniel	Engineer, Technical advisor at UNEB-NUBE	Union Nationale des Esthéticiennes de Belgique
GYS Francine	Honorary chairwoman	BESKO - Beroepsvereniging voor Bio-esthetiek en Kosmetologie
SALEMBIER Nadine	Chairwomen	UNEB-NUBE - Union Nationale des Esthéticiennes de Belgique

The administration was represented by:

The standing group was chaired by Hilde BEELE and the scientific secretary was Anne-Madeleine PIRONNET.

About the Superior Health Council (SHC)

The Superior Health Council is a federal body that is part of the Federal Public Service Health, Food Chain Safety and Environment. It was founded in 1849 and provides scientific advisory reports on public health issues to the Ministers of Public Health and the Environment, their administration, and a few agencies. These advisory reports are drawn up on request or on the SHC's own initiative. The SHC takes no decisions on the policies to follow, nor does it implement them. It does, however, aim at giving guidance to political decision-makers on public health matters. It does this on the basis of the most recent scientific knowledge

Apart from its 25-member internal secretariat, the Council draws upon a vast network of over 500 experts (university professors, members of scientific institutions), 200 of whom are appointed experts of the Council. These experts meet in multidisciplinary working groups in order to write the advisory reports.

As an official body, the Superior Health Council takes the view that it is of key importance to guarantee that the scientific advisory reports it issues are neutral and impartial. In order to do so, it has provided itself with a structure, rules and procedures with which these requirements can be met efficiently at each stage of the coming into being of the advisory reports. The key stages in the latter process are: 1) the preliminary analysis of the request, 2) the appointing of the experts within the working groups, 3) the implementation of the procedures for managing potential conflicts of interest (based on the declaration of interest, the analysis of possible conflicts of interest, and a referring committee) and 4) the final endorsement of the advisory reports by the Board (ultimate decision-making body). This coherent set of procedures aims at allowing the SHC to issue advisory reports based on the highest level of scientific expertise available whilst maintaining all possible impartiality.

The advisory reports drawn up by the working groups are submitted to the Board. Once they have been endorsed, they are sent to those who requested them as well as to the Minister of Public Health and are subsequently published on the SHC website (www.css-hgr.be), except as regards confidential advisory reports. Some of them are also communicated to the press and to target groups among healthcare professionals.

The SHC is also an active partner in developing the EuSANH network (European Science Advisory Network for Health), which aims at drawing up advisory reports at the European level.

In order to receive notification about the activities and publications of the SHC, you can send a mail to info.hgr-css@health.belgium.be .