Opinion/Short Communication

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Title: Is it time to reconsider the use of vital teeth bleaching in children and adolescents in Europe?

Abstract: Enamel defects and opacities are relatively common in children's permanent teeth and can affect a young person's emotional and social wellbeing. Vital tooth bleaching with carbamide peroxide can be considered as one of the management options when treating discolouration caused by enamel hypomineralisation of permanent anterior teeth. In an era of social media and selfies, the appearance of teeth matters more and more to children and teenagers, and dentists are likely to be asked increasingly about such treatment options in the under 18-year-old patient. This article details the recent literature about the efficacy of carbamide peroxide in children. It discusses the indications, side effects and scrutinises the actual evidence available for its use in children.

Key Points

- Describes the evidence in the literature of using carbamide peroxide when bleaching vital permanent teeth in children
- Explains the law in the EU with regards to tooth bleaching
- Emphasises the need for better quality research including patient satisfaction, short-and-long term adverse effects and colour stability

Key Words

Carbamide peroxide, tooth whitening, tooth bleaching, child, adolescent, EU law

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Introduction

In the UK, 28% of 12-year-old children had an enamel opacity affecting one or more permanent teeth (Child Dental Health Survey 2013) and a recent study in Sweden found comparable prevalence with 30.2% of adolescents showing signs of demarcated or diffuse opacities of the enamel in the permanent dentition (Jälevik et al 2018). Opacities are due to enamel hypomineralisation, resulting in a tooth of normal size and shape, but affected by discolouration, which can range from white to yellow/brown. Main causes of enamel hypomineralisation in vital permanent teeth include molar incisor hypomineralisation (MIH), sequelae from localised trauma or infection in the primary dentition, fluorosis and amelogenesis imperfecta.

Some discolouration may be minor, and the child may not be concerned or happy to wait until adulthood for treatment. But some children with more visible opacities may be affected to such an extent that they may want to discuss treatment options earlier. Adolescents consider tooth colour to be associated with oral hygiene and can regard yellow or brown teeth to be a sign of a general lack of self-care and personal responsibility (Maida et al 2015). Enamel defects and opacities can have a significant effect on a young person's emotional and social wellbeing (Marshman et al 2014), and aesthetic problems in childhood and adolescence can have a significant effect on psychosocial development (Craig et al. 2015).

Vital tooth bleaching, microabrasion and resin infiltration can be used as a conservative first management options when treating discolouration and opacities in permanent teeth in children rather than resorting to more invasive options such or composite restorations or veneers, which require removal of enamel. Although case studies have shown success for these treatment modalities, difficulties in resin bonding and problems with cooperation in children pose considerable challenges. Conventional porcelain veneers are reserved for adult patients due to the immature gingival contour and risk of loss of pulp vitality in paediatric patients. Direct composite veneers and restorations can be used to mask severe defects in children when less invasive treatment methods have failed, but often require tooth preparation, and will have to be maintained, repaired and replaced in the future. Minimally invasive procedures such as resin infiltration and microabrasion in combination have recently shown to be successful in reducing the visibility of incisor enamel defects in children affected by MIH, consequently having a positive impact on the oral health- related quality of life (Hasmun et al. 2018). Tooth bleaching with carbamide peroxide has also been advocated as a tool for treating discolouration in children's vital permanent teeth and presently appears to be one of the least invasive interventions.

Carbamide peroxide ($CH_6N_2O_3$) is a complex crystalline solid that decomposes when it comes into contact with water and releases hydrogen peroxide (Carey 2014). Within minutes of application, hydrogen peroxide can penetrate through the enamel and leach through the dentinal tubules to the vicinity of the pulp. (Haywood 2003). Tooth whitening occurs when there is an interaction between the peroxide and the stain molecules, the so called chromaphores within the tooth. But the peroxide also changes the surface layer thereby altering the refractive index of the tooth. Tooth bleaching therefore results in complex changes to the surface layer and intrinsic structure of the tooth which in turn affects its optical properties (Kwon and Wertz 2015). Carbamide peroxide is most often used in a tray-based system. This method involves having a custom fitted tray made by the dentist and wearing the tray containing carbamide peroxide gel overnight or for several hours during the day. Tooth whitening is usually achieved by wearing the tray for 1-4 weeks but can take longer depending on the type of stain (Haywood 2003).

Long term effectiveness and adverse effects of this type of vital bleaching in adults have been studied for up to 17 years post bleaching (Boushell et al. 2012) and a review into safety aspects of tooth whitening using peroxide based materials by Li and Greenwall concluded that "Accumulated data indicate no significant, long-term health risks associated with professional at-home tooth bleaching using 10% carbamide peroxide gels, which is equivalent to 3.5% hydrogen peroxide" (2013). But is carbamide peroxide a safe and effective agent when bleaching vital permanent teeth in children?

Most research in children combines vital bleaching with carbamide peroxide and microabrasion (Croll, 1992; Killian, 1993; McEvoy, 1995; Croll and Segura, 1996; Croll, 1998; Croll, 2003; Sundfeld et al. 2007). This seems to be an effective method in improving the appearance of opacities, but it can sometimes be difficult to ascertain to which extent the bleaching with carbamide peroxide, the microabrasion or the combination of both has contributed to the improvement in appearance of the teeth. There are limited studies in children solely focussing on vital bleaching with carbamide peroxide, whereas permanent teeth have been bleached effectively with relatively few side effects (Haywood and Leonard, 1998; Donly et al 2003; Croll and Donly, 2014; Rogers et al., 2016). In 1994 Croll published a protocol on bleaching children's and adolescent's teeth (Croll, 1994) and in a more recent paper Greenwall-Cohen advocated the use of bleaching for discolourations in the under 18-year-old as a cornerstone of minimal intervention aesthetic dentistry (Greenwall-Cohen et al 2018). But what is the actual evidence in children and are there any barriers to carrying out this type of intervention?

Barriers - EU law

Ten percent carbamide peroxide, commonly used for vital bleaching, breaks down to 3.35% hydrogen peroxide and 6.65% urea (Fasanaro 1992). The EU Cosmetics Regulation. directive 2011/84/EU, restricted the use in children and specifies that products containing more than 0.1% hydrogen peroxide are not to be used on a person under 18 years of age (EU Council Directive 2011) This poses an ethical dilemma for dentists in the European Union who are, by law, prohibited from using concentrations greater than 0.1% hydrogen peroxide in children. Other countries such as the United States have a more liberal approach. The American Academy of Pediatric Dentistry has published a policy on the use of dental bleaching for child and adolescent patients (American Academy of Pediatric Dentistry Council on Clinical Affairs 2019) where it advocates the judicious use of bleaching of vital teeth in consultation with a dentist. However, there is with no restriction on hydrogen peroxide concentration and whitening products containing more than 6% hydrogen peroxide remain readily available for sale over the counter.

A recent European Academy of Paediatric Dentistry (EAPD) survey of its members showed that the majority (68%) did not provide vital bleaching for children and more than half (56%) did not know the regulations on bleaching for children in their country (Monteiro et al. 2019). These figures are likely to be significantly higher in the general dental population as the majority of the respondents were paediatric dental specialists. Of the dentists who did not provide bleaching, 58% said that their most likely treatment choice for a discoloured anterior tooth would be removal of the defect and a composite restoration. Reasons given for not bleaching children's teeth ranged from "no experience in bleaching" to it is "must be delayed until the age of 18". When respondents were willing to use vital bleaching in children, their main reasons for doing so were clinical presentation and concerns from the children and their parents. (Monteiro et al. 2019).

What is the evidence in children?

Despite this barrier to vital bleaching in children do we have any clinical trials which assess the use of carbamide peroxide solely in children? To answer this, a PICO structure was used to define the research question:

Population: Children with vital permanent teeth

Intervention: Vital bleaching with carbamide peroxide

Comparison: Any other vital bleaching technique

Outcome: Colour change, adverse effects and patient satisfaction

Selected databases were searched to find studies relevant to the investigation. The search was limited to articles concerning children under 18 years of age, to English language articles and human studies *in vivo*.

For articles to be included in the investigation the study had to exclusively involve children and the intervention had to involve bleaching with carbamide peroxide without any accompanying treatment such as microabrasion, resin infiltration or restorative work. Case studies were not included.

The final articles were screened by abstract to exclude irrelevant studies and then the remaining articles were analysed by full text to identify relevant studies which fitted the inclusion criteria. The literature review revealed only three clinical trials assessing the use of carbamide peroxide in children's vital permanent teeth (Donley et al. 2002; Donley et al. 2004; Donley et al. 2007).

All three studies compared the efficacy of 10% carbamide peroxide at-home bleaching to whitening strips containing 14%, 10% and 6.5% respectively. Outcomes deemed important to be analysed were:

- Colour change
- Patient satisfaction
- Patient-reported tooth sensitivity
- Patient-reported oral irritation

A GRADE (Grading of Recommendations, Assessment, Development and Evaluations) analysis was used to rate the certainty of evidence for the outcomes measured in the three clinical trial.

Results from all three articles showed that both systems, 10% carbamide peroxide in a custom- made tray and hydrogen peroxide strips of varying concentrations significantly whitened teeth ($p < 0.0001$) relative to baseline.

Although the authors mentioned potential indications for using vital bleaching techniques in children such as white spot lesions, fluorosis and significant yellowing of teeth, no teeth bleached in the three articles had enamel opacities. Therefore, no assessment could be made with regards to the visual improvement of tooth opacities.

Common local side effects of bleaching with 10% carbamide peroxide were investigated and discussed in the three articles. Tooth sensitivity was the most common side effect ranging from 27%-35% in the three studies. This is comparable to adult studies where a range of 15%-

65% has been reported (Tredwin et al 2006). Only one study assessed patient-reported oral irritation as a separate outcome (Donley et al. 2007) and found it to be 6.7%. This falls within the range of 5 – 50% reported in adult studies (Li and Greenwall 2013). As there was no follow up in the articles assessed by GRADE, no assessment of colour stability in children post treatment could be made with regards to carbamide peroxide.

Even though patient satisfaction was deemed to be an important outcome, it could not be analysed, as none of the three trials assessed this outcome. All three articles had a high risk of bias and suffered from significant errors of imprecision and inconsistency, so it was difficult to make valid recommendations. The following deductions can be made very tentatively from the analysis, keeping in mind the very low certainty of the evidence

It appears that tooth bleaching with 10% carbamide peroxide appears to be a long studied, safe and efficacious method in bleaching permanent teeth in adults, but the evidence for children alone is limited. Its low concentration of peroxide probably makes it a suitable bleaching material when considering tooth bleaching for a child. The use of the product in a custom-made tray means that the tray can be adapted so that the bleaching agent can specifically target the areas of concern. This is particularly important if only one or a few teeth are to be treated, there are gaps between the teeth, or the child has a malocclusion.

Vital tooth bleaching is an aesthetic procedure and careful patient selection for this treatment is paramount, especially in children. The correct diagnosis of the defect should be discussed with the child and parent and documented in the clinical notes. Many opacities are mild, and the child may not be concerned. In these instances, treatment is not indicated. However, if a child is unhappy about the appearance of the opacities then treatment options should be discussed and, in some instances, bleaching with carbamide peroxide may well be the most appropriate treatment method of choice. Better quality research is required to assess the efficacy of carbamide peroxide in children's permanent teeth including patient satisfaction, short- and long-term adverse effects and colour stability. Well-designed trials which compare bleaching with carbamide peroxide in children to other bleaching techniques and management options such as microabrasion, resin infiltration or the 'bleach, etch and seal technique' would also be helpful in the quest to find the most effective method to improve the appearance of opacities and discolouration in children's permanent teeth.

If concerns of children and teenagers are not taken seriously, and dentists are not willing to consider the provision of minimally invasive intervention, there is a risk that children may look at questionable over-the-counter whitening kits or do-it-yourself protocols on the internet. It is

important that paediatric dental societies represent their patients appropriately and provide the best care.

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