

PERSONAL STATEMENT ON THE ROLE OF HEALOZONE IN THE PREVENTION AND TREATMENT OF DENTAL CARIES

by

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I have been nominated by the Faculty of General Dental Practitioners to provide expert advice on their behalf on the appraisal of HealOzone in tooth decay. My expertise in the field arises through my doctorate studies focussing on caries preventive strategies. In this submission I wish to explore the potential role of HealOzone in caries prevention and treatment by posing a series of key questions and providing answers to them based on current scientific thinking. As highlighted in the scoping document, dental caries is a dynamic process – the condition can progress, regress or be arrested.

The Cochrane review¹ on HealOzone concluded that the evidence of effectiveness of HealOzone was poor. Most of the studies that were included in the review were carried out in Belfast by someone paid by HealOzone. The methodologies of the trials used to provide data to support the adoption of HealOzone are weak and in my opinion cannot be used to support the adoption of it as a care modality. The study designs and sample sizes are very inadequate; there are flaws in recording techniques, and a failure to take into account the natural history of the caries process when reporting outcomes. The length of any trial would need to be far longer than currently reported.

Below are some reasons for doubting whether HealOzone is a reasonable preventive technology.

1. What is the natural history of caries and why is this important?

Caries is a process. It arises through the action of bacteria on the tooth surface interacting with sugars. While treatments with HealOzone may reduce the numbers of bacteria for a period of time, unless the causes of the increased numbers of bacteria are dealt with, bacteria will recolonise the tooth site. Consequently, treatments based on HealOzone would need to be repeated for an indeterminate number of years. The cost of repeated treatments will need to be considered when estimating the cost-effectiveness of the product, if it does work.

2. Why is the rate of caries progression important and what do we know about?

The rate of progression of caries is important for two main reasons:

First, it will determine the appropriateness of any form of intervention: the slower the rate of progression the lower the need to intervene. Indeed, the rate may be so slow that there is no need whatsoever for any intervention. Furthermore, the caries process is dynamic. While a lesion may progress as further mineral content is lost, it can also remineralise and

the lesion repair. Inappropriate intervention may indeed lead to irreparable damage to the tooth and prevent remineralisation.

The recent guidelines on the periodicity of routine recall intervals produced by NICE² highlighted the above issues. Of particular importance was the finding from reviewed studies that it can take up to 6 years for a lesion to reach dentine from enamel. The addition of fluoride to the oral environment leads to a reduction in rates of caries progression and helps remineralisation. Given that approximately 95% of the population use fluoridated toothpaste, the time necessary to establish whether HealOzone offers any benefits over current care modalities would be considerable and the sample size large. Current published data on the trials involving HealOzone fall far short of these requirements.

Second, the rate of progression will determine the length of any trial. As we know that caries is a slow process in Western populations who currently have low rates of caries, any trial to alter or arrest the rate will need to be of a longer duration than the reported period of the HealOzone trials³.

3. How is caries diagnosed and how does this impact on any findings?

The Cochrane systematic review of HealOzone highlighted the poor description of the methodology used in the published work to diagnose caries: the information in the papers is vague. The importance of accurate diagnosis is critical in establishing the correct rates of progression. First, clinical diagnosis of caries is very variable. Second, research has highlighted that radiographic measures of caries progression require standardised radiographic methods. A small change in the angulation of the radiographic tube and x-ray film, make considerable differences in the apparent extent of the carious lesion. For example, a very early lesion in the outer enamel can appear as a deep lesion near dentine by changing the angulation of the radiographic tube. Unless highly standardized methods are used in any study, any claimed changes in the extent of caries lesion and in consequence, the progression of lesions, are unreliable. Such methods were not used in the trials of HealOzone.

4. Are other elements of the HealOzone treatment contributing to the effects on caries?

HealOzone is not the only element involved in the treatment used in the trials. Fluoride and chlorhexidine were also used. It is difficult to identify the additional role of the unique element of HealOzone, namely O₃, from the other caries reducing elements. Atraumatic Restorative Treatment (ART) where caries is removed atraumatically and lesions restored with a fluoride containing glass ionomer cement is a recognised intervention of proven success in the treatment of the lesion types that HealOzone is claimed to address. Most of the steps used in the HealOzone studies were used in ART. The findings supporting the effectiveness of ART have been widely published in refereed scientific journals. So the non-HealOzone aspects of the studies have been shown to work. The HealOzone studies were not designed to isolate the additional effect of HealOzone except in the non-cavitated lesion studies where the enamel was intact.

Furthermore, for ART the non-labour costs of the treatments are far lower than for HealOzone.

Summary

Population approaches to reduce the levels of caries are very effective as evidenced by the substantial declines of caries that have occurred since the 1970s. Although there are arguments to support preventive regimes for specific sub-groups of a population, the inability to accurately identify and predict individuals who will get caries, provides little support for an individualistic, apparently expensive, approach to the prevention of caries.

The trials and rationale used to provide data to support the adoption of HealOzone are weak and in my opinion cannot be used to support the adoption of it as a dental care modality. The study design and sample sizes reported are very weak; there are flaws in recording techniques, and; a failure to recognise the natural history of the caries process when reporting outcomes. The length of any trial would need to be far longer than those used in the HealOzone studies.

If references besides those listed below are required to substantiate the statements made I shall be happy to provide them.

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References

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