Systematic review of the effectiveness and cost-effectiveness of HealOzone® for the treatment of occlusal pit/fissure caries and root caries

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Executive summary

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Executive summary

Background

Dental caries is a chronic disease caused by the localised and progressive demineralisation of the hard tissues of the coronal and root surfaces of the teeth. Caries location, development and progression depend on a range of environmental, social and genetic factors, and vary greatly among individuals.

Despite the decline in the prevalence of dental caries observed in the high-income countries during the past few decades as a consequence of the increased availability of fluoride products and improved oral hygiene, dental caries is still a common disease experienced by almost 80% of children by the age of 18 years and by almost 90% of adults.

The current management of early non-cavitated occlusal and root caries, and cavitated root caries, which are still accessible to cleaning, is based on non-operative preventive strategies that include information on oral hygiene, dietary advice, use of topically applied fluorides and application of sealants. For cavitated occlusal caries and cavitated root caries that are not easily accessible to cleaning, restorative interventions are adopted (drilling and filling).

HealOzone® (CurOzone USA Inc., Ontario, Canada) has recently been proposed as a novel method for the treatment of dental caries. It is suggested that HealOzone may reverse, arrest or slow the progression of dental caries. The complete HealOzone procedure involves the direct application of ozone gas to the caries lesion on the tooth surface, the use of a remineralising solution immediately after application of ozone and the supply of a 'patient kit', which consists of toothpaste, oral rinse and oral spray all containing fluoride.

Objective

The review aims to assess the effectiveness and cost-effectiveness of HealOzone for the management of pit and fissure caries, and root caries.

Methods

Electronic searches were conducted to identify published and unpublished studies. The following databases were searched: MEDLINE (1966 to May 2004), EMBASE (1980 to May 2004), MEDLINE Extra (17 May 2004), Science Citation Index (1981 to May 2004), BIOSIS (1985 to May 2004), AMED (1985 to May 2004), Cochrane Library (Issue 2, 2004) National Research Register (Issue 2, 2004), Current Controlled Trials (18 May 2004), Clinical Trials (18 May 2004), SCI Proceedings (1991 to May 2004), Conference Papers Index (1982 to May 2002), ZETOC conferences (1993 to May 2004) and IADR meeting abstracts (2002 to 2004). Two reviewers independently assessed the methodological quality of included studies and extracted data. Criteria for assessment of study quality included method and unit of randomisation, concealment of allocation, comparability of groups at baseline, blinding procedures, number of withdrawals/dropouts and completeness of assessment at follow-up.

A systematic review of the effectiveness of HealOzone for the management of tooth decay was carried out. A systematic review of existing economic evaluations of ozone for dental caries was also planned but no suitable studies were identified. The economic evaluation included in the industry submission was critically appraised and summarised.

A Markov model was constructed to explore possible cost-effectiveness aspects of HealOzone in addition to current management of dental caries.

Results

Number and quality of studies, and direction of evidence

Five full-text reports and five studies published as abstracts met the inclusion criteria. Of these, only one was published in a refereed journal, but it lacked some study details. The remaining studies were PhD theses, unpublished reports or conference proceedings. The five full-text reports consisted of two randomised controlled trials (RCTs) assessing the use of HealOzone for the ▶

management of primary root caries and two PhD theses of three unpublished randomised trials assessing the use of HealOzone for the management of occlusal caries. Of the five studies published as abstracts, four assessed the effects of HealOzone for the management of occlusal caries and one the effects of HealOzone for the management of root caries.

Overall, the quality of the studies was modest, with many important methodological aspects not reported (e.g. concealment of allocation, blinding procedures, compliance of patients with home treatment). In particular, there were some concerns about the choice of statistical analyses. In most of the full-text studies analyses were undertaken at lesion level, ignoring the clustering of lesions within patients. The nature of the methodological concerns was sufficient to raise doubts about the validity of the included studies' findings. A quantitative synthesis of results was deemed inappropriate.

Summary of benefits

Root caries

Two studies (one published and one unpublished) assessing the use of HealOzone for the management of primary non-cavitated root caries reported high success rates for ozone-treated lesions and no significant changes in the control lesions, despite application of topical fluoride. This is puzzling, since topical fluoride is known to be effective. Results of cavitated root lesions were poorly defined and reported in one of these two studies. Cavitated lesions did not seem to benefit from ozone application.

One unpublished study showed that fissure sealants preceded by the application of ozone for the preventive treatment of non-cavitated root lesions were more likely to remain intact (61% versus 42%, $p < 0.05$).

Pit and fissure caries

One unpublished study did not show any significant benefits of HealOzone for the management of non-cavitated pit and fissure lesions in the permanent dentition. Similarly, a small unpublished pilot study did not show any significant differences between cavitated occlusal lesions treated with or without ozone, apart from an improvement in the hardness and visual clinical indices. In contrast, findings from conference proceedings (which provide little detail for the assessment of their methodological quality and therefore are of little use in systematic reviews) reported very high success rates (from 86.6% to 99% of reversal of caries).

Adding ozone to a fissure sealant did not seem to produce better sealant retention in occlusal lesions extending 2–4 mm into dentine.

Data on the use of HealOzone for the treatment of occlusal lesion in the deciduous dentition were available from only one unpublished study. An overall reduction in clinical severity scores was reported for non-cavitated occlusal lesions in primary molars treated with ozone.

On the whole, there is not enough evidence from published RCTs on which to judge the effectiveness of ozone for the management of both occlusal and root caries.

Costs

The perspective adopted for the study was that of the NHS and Personal Social Services. The analysis, carried out over a 5-year period, indicated that treatment using current management plus HealOzone cost more than current management alone for non-cavitated pit and fissure caries (£40.49 versus £24.78), but cost less for non-cavitated root caries (£14.63 versus £21.45). Given the limitations of the calculations these figures should be regarded as illustrative, not definitive.

Cost per quality-adjusted life-year

It was not possible to measure health benefits in terms of quality-adjusted life-years. This was mainly due to uncertainties around the evidence of clinical effectiveness, and to the fact that the adverse events avoided are transient (e.g. pain from injection of local anaesthetic, fear the drill).

Sensitivity analyses

One-way sensitivity analysis was applied to the model. However, owing to the limitations of the economic analysis, this should be regarded as merely speculative. For non-cavitated pit and fissure caries, the HealOzone option was always more expensive than current management when the probability of cure using the HealOzone option was 70% or lower. For non-cavitated root caries the costs of the HealOzone comparator were lower than those of current management only when cure rates from HealOzone were at least 80%. The costs of current management were higher than those of the HealOzone option when the cure rate for current management was 40% or lower.

One-way sensitivity analysis was also performed using similar NHS Statement of Dental Remuneration codes to those that are used in the industry submission. This did not alter the results for non-cavitated pit fissure caries as ▶

the discounted net present value of current management remained lower than that of the HealOzone comparator (£22.65 versus £33.39).

Conclusions

Any treatment that preserves teeth and avoids fillings is welcome. However, the current evidence base for HealOzone is insufficient to conclude that it is a cost-effective addition to the management and treatment of occlusal and root caries.

Limitations of the calculations

The economic analysis was severely constrained by the uncertainty over clinical effectiveness, and it could be argued that such analysis was inappropriate. It was done merely to illustrate the key factors involved in economic modelling. The long-term effects of HealOzone are unknown and the assumption that reversed caries remains inactive may not be reliable.

Recommendations for research

To make a decision on whether HealOzone is a cost-effective alternative to current preventive methods for the management of dental caries, further research into its clinical effectiveness is required. Independent RCTs of the effectiveness and cost-effectiveness of HealOzone for the management of occlusal caries and root caries need to be properly conducted with adequate design, outcome measures and methods for statistical analyses.

Publication

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The HTA Programme commissions research only on topics where it has identified key gaps in the evidence needed by the NHS. Suggestions for topics are actively sought from people working in the NHS, the public, service-users groups and professional bodies such as Royal Colleges and NHS Trusts.

Research suggestions are carefully considered by panels of independent experts (including service users) whose advice results in a ranked list of recommended research priorities. The HTA Programme then commissions the research team best suited to undertake the work, in the manner most appropriate to find the relevant answers. Some projects may take only months, others need several years to answer the research questions adequately. They may involve synthesising existing evidence or conducting a trial to produce new evidence where none currently exists.

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Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search, appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

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