



Title	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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Aim

To assess the effectiveness and cost effectiveness of HealOzone® (CurOzone USA Inc, Ontario, Canada) in managing pit and fissure caries, and root caries.

Conclusions and results

The complete HealOzone procedure involves direct application of ozone gas to the caries lesion on the tooth surface, the use of a remineralizing 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. Five full-text reports and 5 studies published as abstracts met the inclusion criteria. The 5 full-text reports consisted of 2 randomized controlled trials (RCTs) assessing the use of HealOzone in managing primary root caries, of which only 1 was published in a journal, and 2 doctoral theses of 3 unpublished randomized trials assessing the use of HealOzone in managing occlusal caries. Of the abstracts, 4 assessed the effects of HealOzone in managing occlusal caries and 1 the effects of HealOzone in managing root caries. Overall, the quality of the studies was modest. In particular, there were concerns about the choice of statistical analyses. In most of the full-text studies, analyses were at the lesion level, ignoring the clustering of lesions within patients. The methodological concerns were sufficient to raise doubts about the validity of the findings. Evidence from RCTs was insufficient to judge the effectiveness of ozone in managing both occlusal and root caries. It was not possible to measure health benefits in terms of quality-adjusted life-years, due to uncertainties about the evidence of clinical effectiveness and the transient nature of the adverse events avoided. A model was designed, but owing to the limitations of the economic analysis, results are regarded as speculative.

Recommendations

Any treatment that preserves teeth and avoids fillings is welcome. However, the evidence on HealOzone is insufficient to conclude that it is an effective addition to the management and treatment of occlusal and root caries.

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

Methods

A systematic review studied the effectiveness of HealOzone in managing tooth decay. A systematic review of 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 summarized. An economic model was constructed to illustrate the possible cost-effectiveness aspects of HealOzone when used in addition to current management of dental caries.

Further research/reviews required

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