

**NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE****Health Technology Appraisal****Tooth Decay - HealOzone****Draft scope****Objective:**

To appraise the clinical and cost effectiveness of the HealOzone procedure in comparison with conventional treatment for the treatment and management of occlusal pit caries, fissure caries and root caries, and to provide guidance to the NHS in England and Wales.<sup>1</sup>

**Background:**

Dental caries (tooth decay) is the localised destruction of the tissues of the tooth. It is a multifactorial, multistage process that extends from infection to demineralisation and cavitation. Bacteria adhere to the hard outer layer of a tooth (the enamel) and metabolise carbohydrates to produce acids that demineralise the tooth enamel (non-cavitated dental caries) and may create a 'cavity' (cavitated dental caries). If untreated, tooth decay progresses through the enamel to the dentine and then the pulp.

Cariou lesions tend to occur in areas that are difficult to clean: the margin between the tooth and the gum; the pits and fissures in the occlusal (biting) surfaces of premolars and molars and the approximal areas between adjacent teeth. Root caries generally occurs when the gum has receded exposing the dentine of the root; it can occur on the cemento-enamel junction, completely on the root surface or under the adjacent enamel. Dental caries in the margin between a restoration (filling) and the tooth tissue is termed 'secondary dental caries'.

The treatment strategy is dependent on the stage at which the caries is identified, the type of caries, and the assessment of risk and prognosis. Caries can be stopped or reversed if it is caught at an early stage. Strategies include application of fluorides, chlorhexidine, sealants, antimicrobials, salivary enhancers and patient education. Current management of cavitated dental caries consists of removing decayed tooth tissue and then filling the cavity.

In the 1998 Adult Dental Survey, 55% of adults in the UK had one or more decayed or unsound teeth, with an average of 1.5 teeth affected. In England and Wales 19.7 million permanent fillings were performed in the financial year 2001/02 in the NHS, at a cost of £223M. The results from the 2003 Dental Health Survey of Children and Young People are due to be published in the summer of 2004.

**The technology:**

HealOzone is a medical device which is CE marked for the treatment and management of occlusal pit caries, fissure caries and root caries.

The HealOzone device includes an ozone generator, hose and hand piece which delivers ozone at a concentration of 2,100ppm to the surface of the tooth. Ozone is a powerful antimicrobial agent that permeates the dental cavity killing the micro-organisms responsible for tooth decay. The tooth is then washed with a 'pH balancer'

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<sup>1</sup> The Department of Health and Welsh Assembly Government proposed remit to the Institute "To appraise the clinical and cost effectiveness of HealOzone for the treatment and prevention of tooth decay in comparison with conventional treatment."

and a mineral-permeable seal is applied. To remineralise the tooth, patients apply products containing fluoride, calcium, zinc, phosphate and xylitol for several weeks. The patient then returns to the dentist for assessment of the success of the treatment and need to undertake restorative repair.

HealOzone is currently available in a limited number of NHS and private dental practices. The initial cost of the device is £11,000 with annual maintenance costs in the region of £160 and £630 per annum (excluding VAT). The current cost of the HealOzone treatment is between £5 and £70 per treatment including the cost of the remineralisation kit (which lasts approximately one month). However many trial practices are charging the same price as a composite filling, approximately £13.

<b>Intervention(s)</b>	HealOzone
<b>Population(s)</b>	Children and adults with occlusal pit caries, fissure caries and/or root caries.
<b>Current standard treatments (comparators)</b>	<p>Non-cavitated caries: removal of plaque and application of fluorides, chlorhexidine, antimicrobials and sealants where appropriate.</p> <p>Cavitated caries: Current management strategies (removal of plaque and decayed tissue and restorative treatment or replacement of 'failed' restorations) without the HealOzone procedure.</p>
<b>Other considerations</b>	<p>The HealOzone procedure encompasses a package of care, including ozone treatment, use of a mineral-permeable sealant and remineralising products.</p> <p>The clinical and cost-effectiveness of the HealOzone procedure for non-cavitated and cavitated caries will be appraised separately.</p> <p>For cavitated caries, the addition of the HealOzone procedure to current management strategies (removal of plaque and decayed tissue and restorative treatment or replacement of 'failed' restorations) will be compared to the strategies excluding the HealOzone procedure.</p> <p>Outcomes include:</p> <ul style="list-style-type: none"> <li>• Progression of dental caries</li> <li>• Incidence of pulpal pathology</li> <li>• Time to filling replacement (re-restoration)</li> <li>• Adverse events</li> <li>• Quality of life</li> <li>• Suitability of treatment for children</li> </ul> <p>Where the evidence is available, separate consideration will be given to the clinical and cost-effectiveness of HealOzone for different severities of cavitated lesions.</p> <p>It is assumed that patients will be given education about improved dental hygiene and diet.</p>