NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

Health Technology Appraisal

Tooth Decay - HealOzone

Final scope

Objective:
To appraise the clinical and cost effectiveness of the HealOzone procedure, in comparison to 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.[1]

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. Commensal 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). If untreated this process may create a 'cavity' (cavitated dental caries) by further progression through the enamel to the dentine and then the pulp. Under the right conditions, the development of a cavity may occur rapidly over a period of months and without effective treatment, cavitated dental caries commonly leads to the loss of the tooth. Deciduous (milk) teeth are more susceptible to decay than permanent teeth because the enamel and dentine is less well mineralised and the enamel is thinner.

Carious lesions tend to occur in 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 is more common in older people and 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'; this may contribute to failure of the filling and necessitate its replacement (re-restoration).

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. If it is caught at an early stage, it is possible to stop or reverse caries with use of fluoride to remineralise the tooth, and a change of diet. Additional strategies include clorhexidine, sealants, antimicrobials, salivary enhancers and patient education. Current management of cavitated dental caries consists of removal of decayed tooth tissue and then filling the cavity. For root caries, the root is debrided and fluorides, glass ionomers, chlorhexidine and sealants are applied.

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.

[1] 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."

The technology:
HealOzone is a medical device that 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 that delivers ozone at a concentration of 2,100ppm to the surface of the tooth. Ozone is a powerful antimicrobial agent that kills the microorganisms responsible for tooth decay. The ozone-treated tooth is then flushed with a 'mineral reductant' containing fluoride, calcium, zinc, phosphate and xylitol. After HealOzone treatment, patients are supplied with an 'at home' kit of toothpaste and mouth rinse. These products must be applied for several weeks to remineralise the tooth.

In pre-cavitated dental caries no further intervention is generally required as, with correct after-care, the lesion should arrest and reverse in approximately 6 to 8 weeks. In cavitated dental lesions that would be prone to food impaction, any necrotic carious tissue is removed, and the lesion is sealed with a fluoride-releasing glass ionomer. The patient then returns to the dentist for assessment of the success of the treatment and the need to undertake repetition of treatment or restorative repair.

HealOzone is currently available in a limited number of dental practices. The initial cost of the device is £12,000 (excluding VAT) with annual maintenance costs in the region of £160 or £630 per annum (excluding VAT), depending upon level of Maintenance Contract purchased. The current cost of the HealOzone treatment to the patient, is between £10 and £90 per lesion including the cost of the remineralisation kit (which lasts for approximately one month). However many HealOzone practices are charging the same price as a composite filling, approximately £35 to £45 for the first tooth and £25 to £30 for subsequent teeth.

Intervention(s)	HealOzone (application of ozone and mineral reductant).
Population(s)	Children and adults with permanent teeth with occlusal pit caries, fissure caries and/or root caries. Children with deciduous teeth with occlusal pit caries, fissure caries and/or root caries.
Current standard treatments (comparators)	**Non-cavitated fissure/occlusal pit caries:** Current management strategies (removal of plaque and application of re-mineralising fluorides, chlorhexidine, antimicrobials and sealants where appropriate) without ozone treatment using HealOzone. **Cavitated fissure/occlusal pit caries:** Current management strategies (removal of plaque and decayed tissue and restorative treatment or replacement of 'failed' restorations where appropriate) without ozone treatment using HealOzone. **Root caries:** Current management strategies (root debridement in conjunction with the application of re-mineralising fluorides, glass ionomers, chlorhexidine and sealants) without ozone treatment using HealOzone.
Other considerations	The addition of the HealOzone to current management strategies will be compared to the strategies excluding the HealOzone. HealOzone is intended to be used as part of a package of care that includes treatment with ozone and reductant, application of a

	fluoride-containing sealant, appropriate use of remineralising products and the provision of education about improved dental hygiene and diet. Where the evidence permits, the appraisal will attempt to determine the incremental cost-effectiveness associated with each component of the package of care. For both permanent and deciduous teeth, separate consideration will be given to the clinical and cost-effectiveness of the use of HealOzone for non-cavitated and cavitated caries of both the fissures/occlusal pits and roots. Where the evidence is available, separate consideration will be given to the clinical and cost-effectiveness of HealOzone for different severities of lesions. Outcomes to be considered include: • Progression of dental caries • Incidence of symptoms associated with pulpal pathology (cavitated caries only) • Time to filling replacement (re-restoration) (cavitated caries only) • Adverse effects of treatment • Patient-centred outcome measures (i.e. relief and prevention of pain, retention of functional dentition and patient satisfaction) • Health-related quality of life Where the evidence permits, consideration will be given to the suitability of treatment for different groups of individuals. The time horizon for the economic evaluation should reflect the necessity for longer-term follow up to evaluate the impact of HealOzone on both progression of caries and need for (re-) restoration.