

Clinical and cost effectiveness of HealOzone for the treatment and management of dental caries

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19 August 2004

Declaration

The following submission was written on behalf of KaVo Dental Ltd., U.K. All information currently available to us has been included in the submission.

EXECUTIVE SUMMARY

Background

Tooth decay (dental caries) is the most frequent and widespread nutritional-related disease in industrialised countries, having affecting at least 80% of the developed world's population. It is a multi-stage, destructive disease of the tooth affecting us from birth and which occurs most commonly in pits and fissures on the occlusal surfaces and on exposed roots. Without treatment, decay can progress through the tooth's substance and ultimately lead to tooth extraction.

The initiation and progression of decay results from the interaction of cariogenic micro-organisms with dietary carbohydrates and tooth substance to produce plaque acids that cause tooth demineralisation and progression of decay through the tooth structure. Traditional approaches to the management of dental caries involve amputation of decaying tissue under anaesthetic and restoration with, most commonly, amalgam or composite resin, a process imposing a severe burden in terms of financial cost to the NHS and patient, as well as patient pain, discomfort and anxiety. In modern dental treatment, the strategy employed will depend on the severity and type of caries and other options include the use of sealants, fluoride and behavioural modification. However, until now no treatment has been available to allow the caries to remineralise predictably before a restoration is placed (if required), thereby minimising tissue loss and patient trauma.

The HealOzone device provides a novel method of treating dental caries by utilising ozone to destroy the micro-organisms and biomolecules associated with caries development, and promoting remineralisation of the tooth. Already, the HealOzone device has been used to treat well over 1 million patients in a number of dental surgeries across the UK.

Clinical effectiveness

The powerful anti-microbial activity of ozone is well known and has been used in commercial and medical applications for many years, while in dentistry ozone was first used in mouth rinses and following tooth extractions as a disinfectant. Clinical studies demonstrate that HealOzone has a significant anti-microbial effect, destroying greater than 99% of micro-organisms found in root caries.

The clinical safety and effectiveness of HealOzone in treating pit and fissure caries and root caries has been demonstrated in sixteen clinical studies, while many more studies are ongoing. These studies reported no adverse events associated with treatment with HealOzone. While a detailed comparison of clinical effectiveness between trials was problematic given the difference in treatment duration, treatment frequency, follow up time, initial severity of caries and the lack of detailed published data, the common outcome for the majority of studies is clear. HealOzone has been shown to have a stabilising or reversing effect in both root and pit and fissure caries of varying severity in permanent teeth. One study showed an improvement in non-cavitated pit and fissure caries in deciduous teeth.

The reversal of caries is associated with remineralisation of the tooth and this has been demonstrated based on ECM and DIAGNOdent measurements in many of the studies. In this way, HealOzone not only preserves tooth structure by avoiding the use of invasive techniques to remove decaying tissue, but also destroys the micro-

organisms responsible for the decay and promotes caries reversal and tooth remineralisation.

Many patients will find this less invasive treatment option appealing. Patient surveys reveal satisfaction with treatment incorporating HealOzone, to the extent that patients would be willing to pay more than for conventional treatment. Patient anxiety, commonly associated with 'drilling and filling' techniques and in some cases leading to patients missing dental appointments, were significantly reduced when patients underwent treatment with HealOzone.

Cost-effectiveness

An economic model was developed to compare costs and outcomes of HealOzone and current treatment. Clinical outcomes considered were caries progression and caries reversal; costs included treatment costs and the cost of re-restoration avoided. Univariate and multivariate analyses were used to examine data uncertainty.

It is estimated that HealOzone treatment will result in an average increase in dental fees of around £9,500 per 1,000 teeth treated. This equates to an incremental NHS cost of £6,200. The use of HealOzone is expected to result in a degree of caries reversal in approximately 850 teeth per 1,000 teeth treated and as a result, expert opinion suggests that HealOzone will reduce the requirement for initial restorative intervention by in excess of 50%.

By reducing the number of restorations, the long-term costs associated with re-intervention in restored teeth, are expected to fall. It is estimated that the avoidance of re-restorations alone will lead to a net incremental NHS cost saving of around £9,700 per 1,000 teeth treated at 10 years (discounted at 3.5% p.a.). This estimate is likely to be conservative, as it does not take into account other re-interventions associated with the lifecycle of a restored tooth such as root treatment, crown and extraction.

In the absence of quality of life data, the utility gains required to attain different cost per QALY thresholds were estimated for defined periods of future quality of life benefit. This analysis suggested that HealOzone would be cost-effective at a cost per QALY threshold of £30,000 if its use resulted in a utility gain of just 0.08 for a period of 1 day.

Wider implications to the NHS

It is estimated that HealOzone therapy would be suitable for the treatment of around 80% of NC-PFC, C-PFC and RC, which equates to approximately 9 million teeth in England and Wales each year. Current treatment in these teeth costs the NHS £60 million each year in England and Wales. If the NHS funded the cost of HealOzone treatment only and all suitable teeth were treated, the incremental cost of HealOzone would be approximately £56.7 million per annum.

If HealOzone were used to treat all suitable teeth, in excess of 4 million initial restorations could be avoided in England and Wales each year. The cost of re-restoration avoided in these teeth would reduce the net incremental cost of HealOzone treatment to £11.8 million within 5 years. Greater cost savings could result from the avoidance of other re-interventions associated with the life cycle of a restored tooth, including root treatment, crowns, extractions and dentures. These procedures currently cost the NHS an additional £190 million each year.

HealOzone provides a novel approach to the treatment of dental caries. Current treatments focus on the removal of decay, restoration of the tooth and prevention of caries progression, whilst HealOzone therapy facilitates the reversal of dental caries in the majority of teeth treated. If used in NC-PFC, HealOzone could prevent cavitation in the first instance and help patients maintain original dentition.

HealOzone offers patients with dental caries the possibility of a safe, effective and predictable treatment reducing the need for injections, drilling and restoration. It also offers the potential to avoid the anxiety, discomfort and cost associated with future invasive interventions such as root treatment and extraction. A number of studies have shown a correlation between deprivation and dental health, with caries experience increasing significantly in people living in deprived areas and yet at the moment, HealOzone is only available to those who can afford to pay for it.