

Danish Center for Evaluation and Health Technology Assessment HEALTH TECHNOLOGY ALERT

Ozone therapy for the treatment of dental caries

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Summary

- *Dental caries is a bacterial disease that can affect persons of all ages.*
 - *Traditional non-operative treatment of caries can consist of mechanical or chemical removal of plaque, home dental care, treatment with fluoride from toothpaste or other fluoride-containing substances, fissure sealing and dietary guidance.*
 - *Traditional operative treatment of caries consists of the removal of the demineralised dental tissue with a drill and subsequent replacement of the missing dental tissue.*
 - *Ozone therapy is a new method for the treatment of caries that is marketed as a treatment that acts by destroying the cariogenic bacteria.*
 - *Ozone therapy has been investigated in a few trials that do not fully meet the criteria that must be met before a treatment can be called evidence-based. There is therefore a fundamental need for more evidence before it is possible to determine whether ozone therapy can be included in the repertoire of dental care methods.*
 - *Future studies of ozone therapy should clarify the extent to which the treatment can replace non-operative and/or operative procedures, and the effect of this should be assessed through long-term studies.*
- *In view of the relatively limited knowledge available about the effect of ozone therapy, including uncertainty as to whether the treatment can replace operative and/or non-operative procedures, it is not possible to determine whether ozone therapy is more cost-effective than traditional caries treatment.*

The disease

Dental caries is the most common cause of toothache and if left untreated can lead to loss of the tooth [1]. The disease can affect children and adults of all ages. Studies show that caries affects both halves of the jaw symmetrically [2], but that not all teeth and tooth surfaces are equally vulnerable to caries [3].

Over the past 30-40 years the incidence of caries in the population of the industrialised world has declined considerably [4] as a result of prevention and treatment based on new research on the aetiology and progression of the disease. Fluoride, especially from toothpaste, has played an important role [5].

Caries can develop when the following factors are present concomitantly: a tooth, bacteria and substrate, including fermentable sugar for these bacteria. Certain bacteria form acid when they take up sugar, and the minerals in the tooth gradually dissolve when its environment becomes acidic (pH below approx. 5.5) [6].

Plaque (visible bacterial deposits) and fermentable sugar are necessary for the development of caries, but are not sufficient alone [6].

Further essential requirements are that conditions on the surface of the tooth remain undisturbed (for example through lack of brushing) and time. Popularly speaking, these factors comprise the »attack mechanism«. Other factors only affect the rate of progression of the caries. These factors, which are called determinants, include the occurrence of fluoride in the saliva, the saliva secretion rate and buffering capacity, and the diet and frequency of food intake [7].

The diet can increase the demineralisation rate, while the other determinants have an inhibitory effect and are considered to be »defence mechanisms«. In general, the risk of caries is also affected by social status and health attitudes [6].

Present methods for prevention and treatment of caries

The treatment of caries depends on how advanced the disease is on the individual teeth. The depth of the cavity relative to the nerve is the parameter most often used to subdivide caries in stages. The following three stages are used: superficial, median and deep (close to the tooth's nerve).

Treatment is traditionally subdivided into non-operative and operative treatment. The most important non-operative treatments are mechanical or chemical removal of plaque, home dental care (tooth brushing and cleaning with floss or tooth picks) and dietary guidance (restrictive use of carbohydrates), treatment with fluoride from toothpaste or other fluoride-containing substances such as fluoride chewing gum or fluoride gel, and fissure sealing. It has been shown quite clearly that fluoride reduces caries [8].

Fissure sealing is a treatment whereby fissures in the surface of the tooth are sealed with a resin-based fissure sealant to prevent the acid produced by the bacteria from dissolving the minerals in the tooth. This is particularly used in children and young people as the chewing surfaces of the rearmost molars can very rapidly develop the median and deep stages of caries [9,10]. The non-operative treatments are used with the early stages of caries.

Operative treatments are used in the median and deep stages of caries. The carious tissue is removed with a drill, and the cavity is filled. If the nerve and blood vessels of the tooth have been damaged, root treatment can be performed.

No drug treatment is presently able to eradicate the harmful bacteria - in this case cariogenic bacteria - without concomitantly eradicating the protective bacteria. The caries bacteria belong to the normal bacterial flora in the oral cavity and are important for our health in general.

New method for treating caries

Within the past few years, ozone therapy has been launched as a new method for treating caries. Ozone (O₃) is a gas with a characteristic, penetrating odour that is present in small amounts in atmospheric air. Ozone is an extremely strong oxidant that oxidises nearly all metals to the highest oxidation stage. Ozone reacts with numerous inorganic and organic compounds. It bleaches dyes and kills bacteria. Among other things, ozone is used to purify drinking water and water in dental equipment and for sterilising instruments for medical use. For many years, ozone has been used to treat infections (O₃ bagging). Ozone destroys the bacterial cell membrane, where after the bacteria die [11]. As bacteria cause caries, it was natural to investigate whether ozone could be used to treat caries.

HealOzone® is a CE-labelled apparatus for clinical ozone therapy of caries. HealOzone, which has been developed by Curozone Inc., Canada and is distributed by KaVo Dental Ltd., converts oxygen to ozone. The ozone is thereafter led to a hand piece fitted with a silicone cup. Differently shaped silicone cups are available that correspond to the form of various teeth and their surfaces. This ensures close contact between the silicone cup and the carious area of the tooth so that the ozone does not escape. The ozone is led through the silicone cup over the tooth for a minimum of 10 seconds. The ozone in the silicone cup is collected again and reconverted to oxygen by the apparatus. Ozone treatment of the caries lesion is completed after 2-3 minutes. Thereafter a solution containing 2% sodium fluoride and 5% xylitol is applied [12] to promote healing (remineralisation) of the caries lesion.

Use in Denmark

According to KaVo (DK), HealOzone has only been tested by a small number of dentists in Denmark. In other EU countries such as Germany and England, HealOzone is already in use in many private dental practices [13].

Evidence

Ozone has been used to treat established carious lesions of various stages [12,14], but has not been used for prevention.

A number of studies have investigated the effect of ozone on caries. A recent Cochrane Review identified 3 randomised controlled trials (RCTs) and a further 42 conference papers, abstracts and posters, etc. (from an unknown number of studies) [12]. Only the three RCTs were included; the remaining articles were excluded for reasons such as a lack of blinding, randomisation or controls, less than six months follow-up or a lack of investigation of extracted teeth. Two of the three RCTs included in the analysis investigated the effect of ozone therapy on crown lesions, while the third investigated the effect on root lesions [12]. The Cochrane Review concluded that these trials provide no evidence that the application of ozone arrests or reverses the de-cay process [12].

A further two studies concerning the effect of ozone therapy on carious root lesions have been published [15,16].

One of these studies demonstrated a significant reduction in the number of bacteria in ozone-treated lesions compared with placebo-treated lesions immediately after the treatment [16]. The study showed that 20 sec of ozone therapy resulted in harder dentine in 81% of the ozone-treated teeth, while 10 sec of ozone therapy resulted in harder dentine in just 22% of the ozone-treated teeth [16]. This indicates that the number of bacteria in carious root lesions is considerably reduced by ozone therapy, and that the lesions clinically change to stages in which progression of the caries can be considered to have ceased.

The objective of the other trial [15] was to assess the effect of ozone therapy in combination with the daily use of remineralising products. The control period was up to 18 months, and the patients were

recalled for examination and repeat treatment after 3, 6, 12 and 18 months. The trial showed that 69-100% of the ozone-treated lesions (duration of treatment 40 sec) became harder during the 18-month trial and none became softer. In the placebo group only 1% of the caries lesions became harder, while 4-37% became softer (worsening). The regained hardness of the dental tissue could indicate that caries can be arrested. The change could also be partly attributable to the uptake of minerals from the saliva, the daily influence of remineralisation products or the effect of the solution applied after the ozone treatment, but this is uncertain. It is also unclear to what extent the caries had been removed by the subjects themselves through tooth brushing between examinations.

Neither of the studies determined the degree of caries prior to initiation of treatment (baseline). Whether the ozone-treated lesions remineralise is not sufficiently clarified. Neither is it clear whether one or two ozone treatments are sufficient to arrest future progression of the lesion, although the preliminary results seem to indicate that ozone treatment should be repeated at regular intervals. In these studies the patients did not report any adverse side effects of the treatments [15,16].

Ozone therapy is a non-operative treatment and should also be compared with other non-operative treatments for controlling caries. In the two above-mentioned trials the ozone therapy was used to treat root caries, which is normally treated both non-operatively and operatively depending on to what extent and how rapidly the patient develops caries, the stage of progression and the location of the caries lesion on the tooth. Lesions that are difficult to access such as those between two teeth will not be amenable to ozone treatment, as the silicone cup cannot penetrate into the gap. Thus ozone therapy of caries is only suitable for easily accessible surfaces where the caries can also be removed with a toothbrush or other non-operative procedures [3].

Ongoing studies

The School of Dentistry, University of Copenhagen, is currently conducting a randomised trial of the efficacy of ozone therapy in preventing caries, and whether the effect lasts for a long time. The

results can be expected in 2-3 years. Among other things, the trial will investigate whether the effect is attributable to the ozone treatment per se, the solutions applied after treatment or to a combination of both [17].

Costs

The HealOzone apparatus costs DKK 160,000 - to which must be added running costs for silicone cups and solutions. One of the users states that ozone therapy costs the patient around DKK 200 per caries lesion. KaVo recommends that the procedure should be repeated after approx. four weeks, but the reason for this is not stated, and its necessity remains to be clarified. This cost should be compared with the cost of other non-operative procedures such as the patient brushing away the caries attack himself or also having it »brushed« away by a professional, possibly in combination with mechanical and/or chemical plaque removal and fluoride treatment. Such a comparison of costs should be based on long-term studies [3].

No health economics analyses comparing ozone therapy with traditional treatment have been found.

Implementation

At the present time, evidence for the efficacy of the treatment is lacking. There is a need to document an effect over and above that provided by ordinary tooth brushing before it is possible to determine whether ozone therapy can be included in the repertoire of dental care methods. If an effect of ozone therapy on dental caries can be demonstrated it might be possible to use the method in dental care as a supplement to home dental care and professional tooth cleaning/brushing.

There is no evidence that ozone therapy offers any advantage compared with current preventative measures such as regular tooth brushing, rinsing with fluoride or fissure sealing [3,12].

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