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Assessment of the safety of two ozone delivery devices

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ABSTRACT

Objectives: To evaluate the safety of an ozone gas device designed for use in dentistry.

Methods: Two commercially available ozone applicators, Ozi-cure and HealOzone were used in a clinical simulation using a phantom head while recordings of ozone levels were made in pharyngeal and nasal regions of the patient and near the mouth of the operator. Clinical simulations included ozone application for caries management and endodontic treatment. Recordings were made five times with different levels of suction to assess the effect on ozone levels.

Results: The results with Ozi-cure on caries mode resulted in a peak ozone level in the pharynx of 1.33 ± 0.52 ppm when no suction was used. The use of suction nearby reduced the ozone level to zero while suction on the opposite side of the mouth reduced the level to 0.22 ± 0.04 ppm. Used on endodontic mode the peak ozone level in the pharynx was 5.51 ± 1.63 ppm when no suction was used. The use of suction nearby reduced the ozone level to zero while suction on the opposite side of the mouth reduced the level to 0.84 ± 0.54 ppm. Recordings in the patient's nasal region gave a peak of 0.22 ppm when using the Ozi-cure on endodontic mode with no suction. At the operator's mouth the ozone level did not exceed 0.01 ppm although the characteristic smell of ozone was detectable. All recordings with HealOzone were zero. Concentrations of 15 ppm were recorded in a simulated tooth cavity with Ozi-cure and >20 ppm with HealOzone.

Conclusions: The Ozi-cure device when used without adequate suction allows ozone to be reach a concentration above permitted levels and therefore should not be used. The HealOzone was safe to use.

1. Introduction

Ozone has been recognized as a powerful sterilising agent which can destroy bacteria, viruses and odours. Ozone is present around us in small quantities as a natural material but is well-known for its presence above us in the outer atmosphere. When oxygen (O_2) rises to the upper atmosphere and is exposed to the sun's ultraviolet rays, that oxygen is naturally turned into ozone (O_3). This forms the protective "ozone layer" that filters out UV radiation but because ozone is heavier than air it naturally falls back to earth, where it is said to naturally purify air and water. Ozone also occurs commonly in nature as a result of lightning strikes during thunderstorms and waterfalls. Ozone has a recognisable smell, which we also associate with photocopiers and laser printers. The odour is generally detectable by the human nose at concentrations between 0.02 and 0.05 ppm or approximately 1% of the recommended 15 min exposure level.

Ozone is a respiratory irritant and following inhalation it can cause dryness in the mouth and throat, headache, chest

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restriction and coughing.[1] It acts as a hazardous air pollutant exacerbating asthma[2] as well as causing lung damage.[3] Ozone is a toxic gas at high concentrations and can be fatal (50 ppm for 60 min) with current recommended safety limits of 0.06 ppm for 8 h per day, 5 days a week or 0.3 ppm for 15 min (U.S. Occupational, Safety and Health Administration (OSHA)). While 120 ppb affects the airway[1] it has been suggested that there may be no safe threshold level for ozone.[4]

The application of ozone gas has been advocated for use in dentistry for the sterilising of cavities, root canals, periodontal pockets, herpetic lesions (for review, see Baysan and Lynch[5,6]). Much of the published work to date has been in relation to its antimicrobial effects[7] and caries[8–10] although some consider that there is a lack of evidence in support of the application of ozone gas to the surface of decayed teeth stopping or reversing the decay process.[11] Gaseous ozone has been shown to have an antibacterial effect on Enterococcus faecalis[12] although less effective than NaOCl. Ozonated water has also been shown to be useful.[13] Extra-oral use in dentistry has been promising and Murakami et al[14] has shown that ozone, when used as a denture cleaner, is effective against Methycillin Resistant Staphylococcus Aureus (MRSA) and viruses. However, some of the uses of ozone in medicine remain controversial.[15,16] Recent reports question its therapeutic effect although recent Department of Health advice[17] suggesting that ozone is of ''no benefit and do not use'' has been withdrawn. Current National Institute of Clinical Excellence (NICE) guidelines[18] advises against using ozone alone in the treatment of caries in general dental practice except as part of an approved clinical trial. As there is limited evidence of the benefits of gaseous ozone in its application in dentistry any therapeutic use of ozone must be coupled with an awareness of the risks. Evacuation of ozone from the oral cavity remains a key concern, both from the point of view of exposure received by patient and dentist alike.

CurOzone USA Inc. (Ontario, Canada) developed the HealOzone which is now distributed by Kavo Dental (Kavo GmbH, Biberach, Germany) for use in dentistry which can deliver relatively high concentrations of ozone (2100 ppm as 0.052%, v/v in air at a rate of 13.33 ml/s). The system has a built-in suction scavenging system designed to create a seal around the applicator tip. This permits ozone application only when coupled with a scavenging system. This makes it readily useable on occlusal, buccal and lingual/palatal cavities. However, if a seal cannot be achieved then the HealOzone will not operate and this can limit its use. For example, applying ozone to interproximal lesions or into a periodontal pocket is difficult and there are anecdotal reports that clinicians are modifying the applicator to extend its use into other areas of the mouth.

More recently the Ozi-cure (PO Box 68992, Centurion, South Africa) has been launched in some markets (South Africa), which uses lower concentrations of ozone with no apparent need for scavenging. While this increases its clinical application due to a simple delivery system there are concerns about the safety of patients and clinical staff. The absence of a built-in evacuation system makes it essential that high volume aspiration is used appropriately to provide this function. Nevertheless, there remains concern regarding the safety of such a device. The aim of this study was to compare the safety of the two systems regarding the amount of ozone escaping during the delivery of ozone. The hypothesis was that the use of the Ozi-cure device would not result in significantly higher ozone levels in the oral cavity when compared with the HealOzone device.

2. Methods

The ozone generator under evaluation was the Ozi-cure device which is not available, or licensed for use, in Europe. This device was compared to the readily available HealOzone. The Ozi-cure was evaluated on a manekin (phantom head unit) in clinical setting as it does not have a CE mark for clinical use and to avoid safety concerns.

Ozone was detected using an ozone meter (OS-3 Eco-Sensor, Switzerland). The ozone meter was accurate in detection of ozone between 0 and 20 ppm. Ozone recordings were made at three sites: ''patient's'' pharynx, ''patient's'' nasal orifice and near the clinical operator's mouth. One author acted as clinician using the device and was unaware of the recorded ozone levels.

Two of the four ozone modes on Ozi-cure were used: caries (setting 1; 10 s ozone application) and endodontics (setting 4; 30 s ozone application) to represent the two possible extremes. The ozone was applied to the lower right second molar as stated in each experiment below. Vacuum aspiration (suction) was applied to the region immediately adjacent to the same side (immediately adjacent to the lingual surface of the lower right second molar) or to the opposite side of the mouth to the ozone application by the lower left second molar tooth. The ozone levels without any suction were also recorded.

Ozone levels and time were recorded and stored on video for later analysis. Measurements of ozone levels were made every 5 s until the levels had dropped below 0.01 ppm. For Experiment 4, measurements were made every second for the first 25 s then every 5 s for the remaining recording time due to the rapid change in ozone levels. The time to peak ozone level was also measured. Five recordings were made for each test parameter and the graphs below show the mean data for the five sets of data.

In Experiment 1, ozone level recordings were made in the pharyngeal region of the manekin head while the Ozi-cure was running on caries mode. The ozone tip was held close to the lower right 2nd molar tooth while suction was either not used, used with the tip close to the lower right molar, or applied lingual to the lower left 2nd molar on the opposite side to the applicator. The HealOzone was used as a control set to a 10 s ozone application on the same tooth. The readings were recorded every 5 s and the mean of 5 readings calculated. The 1 min average ozone level with the Ozi-cure was determined by calculating the average value of the period. In Experiment 2, the above procedure was repeated with the Ozi-cure on endodontic mode compared with the HealOzone on 40 s.

Experiment 3 was designed to record the levels of ozone in the nasal orifice of the ''patient'' (Fig. 1) and close to the mouth of the operator while using Ozi-cure on caries and endodontic modes. HealOzone was used as a control. In Experiment 4, records ozone concentration was determined inside a simulated tooth cavity with Ozi-cure on caries mode. Measurements were made to evaluate the effect of suction on the levels

Fig. 1 – Recording set-up for detecting nasal concentration of ozone.

of ozone within a tooth cavity by embedding the Ozone sensor within a temporary crown sealed around the periphery with light-body silicone impression material and with a "cavity" cut through the occlusal surface. The effect of no suction, application of suction adjacent to the "tooth" for the time of application and for 2 min on level of ozone within the "cavity" were evaluated and compared to the levels seen with HealOzone.

The results had a non-normal distribution and so statistical analysis was carried out using Kruskal–Wallis One Way Analysis of Variation on Ranks (Anova on Ranks) and Mann–Whitney Rank Sums. Multiple pairwise analysis was by Dunn's method within Anova on Ranks.

3. Results

3.1. *Experiment 1. Recording pharyngeal levels of ozone with Ozi-cure on caries mode*

A reading of the ozone concentration was recorded every 5 s and this was repeated five times. The Ozi-cure was used in caries mode. The mean ozone concentration over time is shown in Fig. 2.

The absence of suction when using the Ozi-cure device allows a high level of ozone to build-up in the pharynx, with a peak level of 1.33 ± 0.52 ppm. Suction on same side as application is highly effective in preventing build-up of ozone levels with no ozone being detected in the pharyngeal area. Suction on the opposite site of the mouth results in a peak level of 0.22 ± 0.04 ppm. No ozone levels were detected in the pharynx when using the HealOzone machine. Ozone levels were significantly different between the groups ($P < 0.001$, Anova on Ranks). Pairwise comparison for ozone levels between no suction and suction either on the same or opposite side and between the two suction conditions were all significantly different ($P < 0.05$, Dunn's test). No significant difference was detected between pharyngeal levels for the HealOzone and Ozi-cure when suction was applied on the same side ($P = 1$, Mann–Whitney Rank Sums). Pairwise comparison showed ozone levels for no suction and suction on the opposite side, for the Ozi-cure were significantly higher than HealOzone ($P < 0.05$, Dunn's test).

The average ozone level was determined by calculating the area under the curve, and dividing this by the time base for the area in minutes. In the absence of suction for the caries setting when using the Ozi-cure device the average ozone exposure was 0.39 ppm over 1 min, and 0.07 ppm over 1 min in the presence of suction on the opposite side. The area under the curve, which represents the ozone exposure and possible inhaled volume was calculated to be 4.3 ppm when suction was used and 23.2 ppm without the use of suction.

During the course of the experiments, it was noted that with repeated use of ozone treatments from the Ozi-cure there

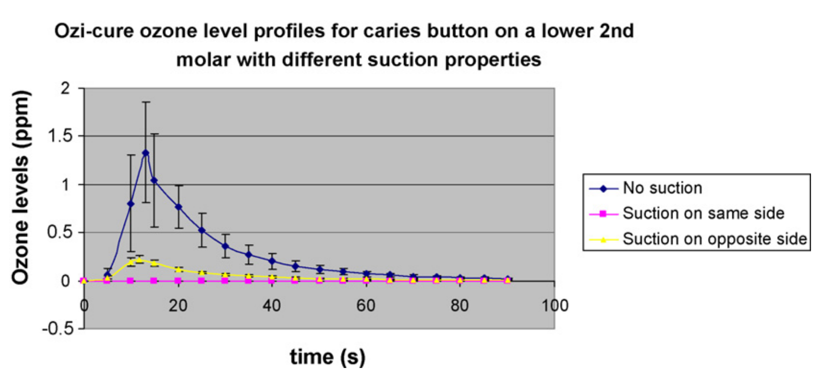

Fig. 2 – Ozone concentration over time while using Ozi-cure on caries mode. The effect of suction near the point of application, on the opposite side and no suction is demonstrated.

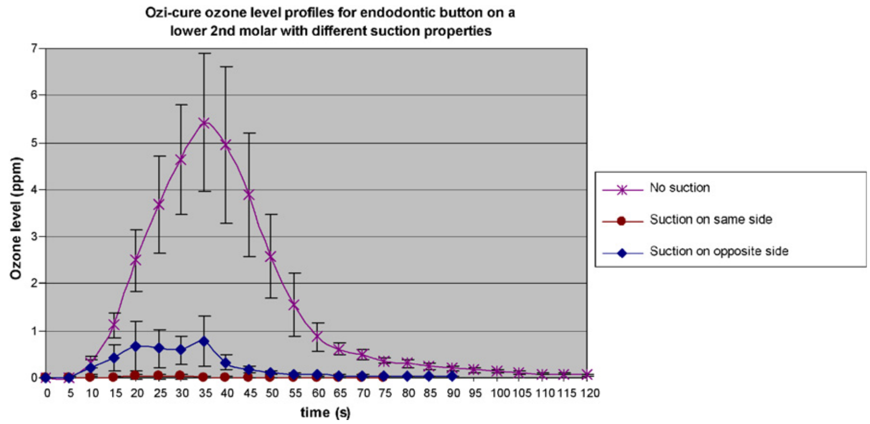

Fig. 3 – Ozone concentration over time while using Ozi-cure on endodontic mode. The effect of suction near the point of application, on the opposite side and no suction is demonstrated.

was an increase in recordable ozone levels with increased use. There was a significant difference between the last two repeats of a series of five compared to the two initial repeats ($P < 0.05$; Dunn's method within repeated measures ANOVA on Ranks).

3.2. *Experiment 2. Recording pharyngeal levels of ozone with Ozi-cure on endodontic mode*

A reading of the ozone concentration was recorded every 5 s and this was repeated five times. The Ozi-cure was used in endodontic mode. The mean ozone concentration over time is shown in Fig. 3.

Ozone levels between no suction and suction either on the same or opposite side for the period of measurement were significantly different ($P < 0.001$, ANOVA on Ranks). Pairwise comparison for ozone levels between no suction and suction either on the same or opposite side, and between the two suction conditions were all significantly different ($P < 0.05$, Dunn's method within ANOVA on Ranks). Absence of suction allows a high level of ozone to build-up in the pharynx, with a peak level of 5.51 ± 1.63 ppm. Suction on same side as application still appears to be highly effective in preventing build-up of ozone levels with only 0.02 ± 0.05 ppm ozone being detected in the pharyngeal area. Suction on the opposite site of the mouth results in a peak level of 0.84 ± 0.54 ppm.

A comparison of the rate of rise in pharyngeal levels without suction showed a mean rate of rise for the first 15 s of 0.1 ppm/s for the caries mode and 0.08 ppm for the endodontic mode. No significant differences could be found for pharyngeal ozone levels at 15 s for comparisons between the caries and endodontic setting of the Ozi-cure ($P > 0.1$, *t*-test).

3.3. *Experiment 3. Recording nasal and operator levels of ozone with Ozi-cure on caries and endodontic modes*

Ozone concentrations were recorded in the "patient's" nasal orifice and near to the mouth of the operator. A reading of the ozone concentration was recorded every 5 s and this was

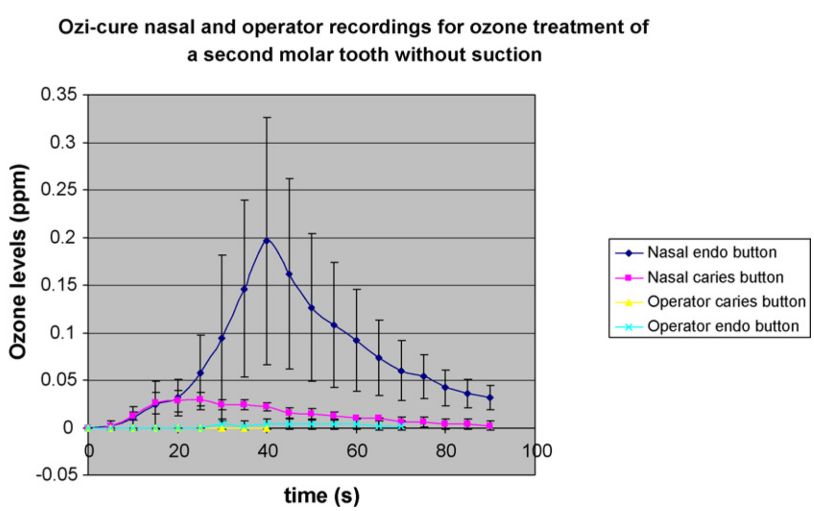

Fig. 4 – Ozone concentrations recorded in the "patient's" nasal orifice and near to the mouth of the operator. A reading of the ozone concentration was recorded every 5 s and this was repeated five times. The Ozi-cure was used in caries and endodontic modes. No suction was used.

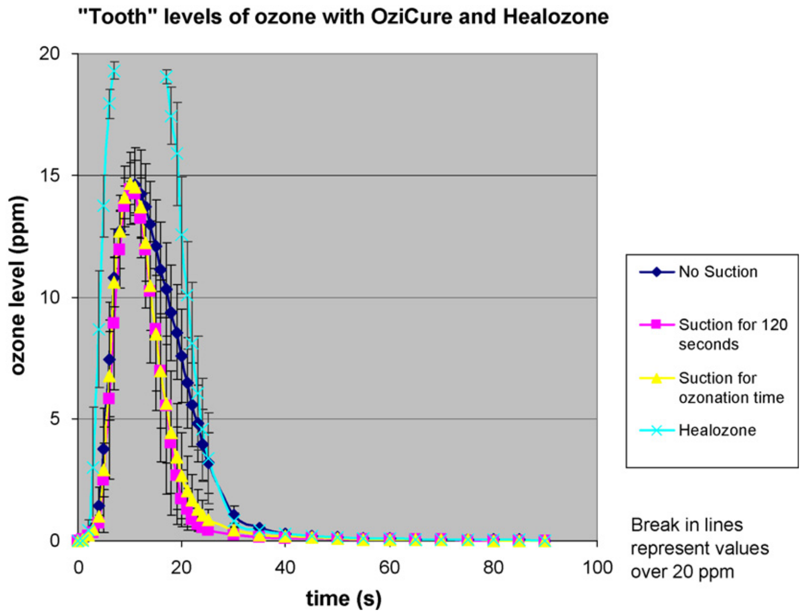

Fig. 5 – Ozone concentrations were recorded in a simulated cavity every second for the first 25 s then every 5 s for the remaining recording time and this was repeated five times. The Ozi-cure was used in caries mode and suction was applied for the period of ozonation, for 120 s as well as no suction. The mean ozone concentration over time is shown.

repeated five times. The Ozi-cure was used in caries and endodontic modes. The mean ozone concentration over time is shown in Fig. 4.

No ozone was detected when suction was used either on the same or opposite side to ozone treatment. Ozone levels were only detected in the region corresponding to the patient's nasal orifice when the Ozi-cure was used without suction. However, in the absence of suction, a peak ozone level of 0.03 ppm at 25 s for the "caries" setting and 0.22 ppm at 40 s for the "endo" setting and these levels was detected which was significantly different from all other conditions ($P < 0.05$, Dunn's Method). The ozone levels were significantly higher in the nasal region when the "endodontic" setting was used compared to the "caries" setting ($P < 0.05$, Dunn's Method). A slight rise in ozone level was detected to 0.01 ppm at the "operator" level on two repeats when the "endodontic" setting was used without suction.

3.4. *Experiment 4. Recording levels of ozone inside the tooth with Ozi-cure on caries mode*

Ozone concentrations were recorded in a simulated cavity. A reading of the ozone concentration was recorded every 5 s and this was repeated five times. The Ozi-cure was used in caries mode and suction was applied as before on the same side, and the opposite side as well as no suction. The mean ozone concentration over time is shown in Fig. 5.

There was a significant difference between the levels of ozone measured at the tooth level with HealOzone and Ozi-cure for the different suction patterns ($P < 0.001$, Anova by Ranks). Ozone levels with HealOzone were significantly higher than when using the Ozi-cure ($P < 0.05$, Dunn's Method), and the ozone levels in the tooth for Ozi-cure without suction were significantly higher over the observation period compared to Ozi-cure with suction during all the time of observation ($P < 0.05$, Dunn's method).

The ozone levels took longer to fall for the Ozi-cure measurements when suction was not applied, however the peak ozone levels for Ozi-cure with or without suction were virtually identical at 14.59 ± 1.56, 14.39 ± 0.34 and 14.66 ± 0.85 ppm for no suction, suction at all times and suction during ozone application, respectively.

4. Discussion

The study confirmed that Ozi-cure will deliver ozone at concentrations of up to 15 ppm within a tooth. Recording pharyngeal levels of ozone with Ozi-cure on caries mode showed that in the absence of suction the ozone level in the pharynx could reach 1.33 ± 0.52 ppm, which is above the 15 min safety threshold of 0.3 ppm. The 1 min average of 0.39 ppm is at this level and there is a potential for multiple applications creating a cumulative effect of ozone build-up. The effect of the patient breathing and, in particular, inhaling during the procedure was not evaluated in this study. The total exposure from a single application or "treatment" was 23.2 ppm if suction was not applied nearby. When suction was applied nearby, the ozone level in the pharynx was reduced to zero and with suction on the opposite side, considered to be likely scenario in the clinical environment, the ozone peak was 0.22 ppm (significantly reduced). In comparison, HealOzone did not create a detectable ozone level in the pharynx even without additional suction. Recording pharyngeal levels of ozone with Ozi-cure on endodontic mode gave similar results but with a peak ozone level of 5.5 ppm. Suction was effective in reducing the levels.

If it was assumed that rubber dam was applied with the additional advantage in protecting the oral airway from ozone then it could be assumed that the nasal level would be relevant for patient safety. Recording nasal concentration of ozone with the Ozi-cure on endodontic mode indicated that 0.2 ppm could be detected. On caries mode the level was much lower. Suction reduced the nasal levels to zero. With regard to the safety of the clinician the ozone concentration in the region of the operator's mouth was almost zero in all cases.

The ozone concentration in the tooth was determined as 15 ppm for the Ozi-cure, which was less than the Healozone. The use of suction reduced the intra-cavity levels slightly. Also repeated applications may increase the overall ozone build-up. It was noted that ozone levels tended to rise during the experiment.

This study suggests that the use of suction would be essential and as it is not built-in to the Ozi-cure design, unlike HealOzone, the operator and support staff would need to be aware of its importance for patient safety. This remains a safety issue.

This report shows safety concerns with the use of the Ozi-cure device and the authors feel that proper training of the dentists and chairside assistant would be essential. The suction system would need to be used correctly and this is difficult to legislate. Ensuring evacuation from the suction outside the clinical area and safely outside the building would also be important.

The results confirm that the Ozi-cure will deliver ozone up to 15 ppm within a tooth but this study has not investigated if this would achieve a therapeutic dose. In comparison with HealOzone, the ozone concentration is considerably less. However, there are controversies about the efficacy of the HealOzone in caries management[11] and the advice from NICE[18] must be considered. In view of this, the caution would need to be observed with the Ozi-cure device, particularly as it provides a lower concentration of ozone, the effect of which is unproven, and there are serious safety concerns with its potential for misuse as identified in the present study.

The hypothesis that the use of the Ozi-cure does not result in significantly higher ozone levels in the oral cavity when compared with the HealOzone is therefore rejected.

The Ozi-cure device when used without adequate suction allows ozone to be reach a concentration above permitted levels and therefore should not be used. The HealOzone was safe to use.

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