available at www.sciencedirect.com

ScienceDirect

journal homepage: www.intl.elsevierhealth.com/journals/jden

Assessment of the safety of two ozone delivery devices

Brian J. Millar *, *Nicholas Hodson*

Primary Care Dentistry, King's College London Dental Institute at Guy's, King's College & St. Thomas' Hospitals, Caldecot Road, London SE5 9RW, UK

ARTICLE INFO

Article history:
Received 18 July 2006
Accepted 22 July 2006

Keywords:
Ozone
Dentistry
Safety

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

* *Corresponding author*. Tel.: +20 7346 3585; fax: +20 7346 3826.
E-mail address: brian.millar@kcl.ac.uk (B.J. Millar).
0300-5712/$ – see front matter
doi:10.1016/j.jdent.2006.07.010

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