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Ozone safety

The question of safety for dental uses of ozone is one that has been studied independently of the suppliers, manufacturers and inventors so there is objective information about the topic.

As pointed out by **Johansson** et al (*see below*), during daily life, humans are continually exposed to low concentrations of ozone in the air. In heavily polluted cities, ozone can be found in elevated concentrations during summertime in photochemical smog.

As noted by Millar (* see below*), 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

There have been some very good studies of safety looking at negative pressure systems (such as the KaVo Healozone), positive pressure systems (such as the Ozicure/Ozotop), and comparisons of both.

In 2006, Millar & Hodson (see below) compared the safety of two ozone delivery systems, the Ozi-cure and the HealOzone, in regard to leakage, however they did not test the scenario where the delivery cycles were not completed.

Johansson E, Andersson-Wenckert I, Hagenbjörk-Gustafsson A, Van Dijken JW. Ozone air levels adjacent to a dental ozone gas delivery system. Acta Odontol Scand. 2007 Nov;65(6):324-30.
This study investigated the sealing capacity of the (Healozone) delivery system and its re-suction capacity during accidental displacement of the cup at different stages of ozone delivery. The rationale for the study was that there were "claims that it removes any remaining ozone during covering and sealing of the tooth, but there are areas where it is difficult to apply, or to obtain a good seal, and this limits its clinical use. It is important that no repeat leakage of any remaining ozone occurs during the application in tooth treatment or during accidental displacement of the delivery system, thus exposing patient and operator to harm." The HealOzone Biberach, Germany) delivers ozone at concentrations of 4,200 mg m7 3910%. Removable single-use silicone sealing cups, diameters ranging between 3 and 8 mm, are attached on a hand-piece to a console with a multi-lumen hose. The ozone gas can be delivered when a tight fit is achieved. The apparatus delivers ozone under vacuum only and has a re-suction system which the manufacturer claims removes any remaining ozone during the 10 sec re-suction period that follows the ozone delivery period, while the cup still covers and seals the selected tooth. Ozone leakage was studied in vitro after application on a flat metal surface and on buccal and occlusal tooth surfaces. An ozone analyzer was used to measure ozone gas concentrations adjacent to the delivering cups when adapted to the target surfaces during and after 10-20 second application cycles. Measurements were performed 1) after complete ozone application cycles, 2) within the cycle before the start of the suction

period, and 3) after displacements of the cup during the cycles. Ozone air values varied between 8 and 166 microgram/meter-3 for the flat metal surface and between 0 and 108 microgram/meter-3 for the tooth surfaces. Ozone leakage levels were 7.6 microgram/m-3 for the flat and and 7.4 microgram/meter-3 and 5.6 microgram/meter-3 for the buccal and occlusal surfaces, respectively, and 5.2 microgram/meter-3 and 9.8 microgram/meter-3 for the premolar and molar surfaces, respectively. Cycles with displacement showed significantly higher leakage levels than continuous complete cycles (p=0.03). Ozone application cycles with displacements showed significantly higher leakage levels than continuous complete cycles. The largest ozone delivery cups showed the highest leakage values. The overall measured ozone leakage values were low after normally functioning delivery cycles and after repeated displacements. It was concluded that the delivery system can be considered safe.

They also observed "*possible leakage of ozone during application periods with a tightly fitted cup and after displacement of the cups during the delivery cycles*" and commented that "*Owing to limited accessibility of the target tooth or to noncooperating patients, slippage of the resin cup from the teeth can easily occur during different clinical situations.*"

Overall, this study points out leakage issues with the Healozone silicone caps/cups which sometimes are hard to get a seal with.

The second study emphasizes the importance of high velocity evacuation when using the Ozicure/Ozotop device. Millar points out that the Ozi-cure 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 .

Millar BJ, Hodson N. Assessment of the safety of two ozone delivery devices. J Dent. 2007 Mar;35(3):195-200.
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. 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.

The study confirmed that Ozi-cure will deliver ozone at concentrations of up to 15 ppm within a tooth. 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.

Note the second study explains why the unit is safe when HVE is in use, and emphasizes why one would use that.

So taken together these two studies show that both negative and positive pressure systems are safe when used according to the manufacturer's instructions.

At UQ we have used many different ozone systems including the negative pressure system from KaVo as well as various designs of positive pressure systems (e.g. Ozicure-Ozotop, W&H) for dental clinical use, as well as various water treatment systems. We published a paper on endodontic disinfection using ozone earlier this year in the Journal of Endodontics which showed excellent results on thick biofilms of E faecalis in root canals, a very tough test, for the positive pressure system. The research project was not sponsored financially by any company but was truly independent.

Case PD, Bird PS, Kahler WA, George R, Walsh LJ. Treatment of root canal biofilms of Enterococcus faecalis with ozone gas and passive ultrasound activation. J Endod. 2012 Apr;38(4):523-6.
Biofilms of resistant species such as Enterococcus faecalis pose a major challenge in the treatment of root canals with established periapical disease. This study examined the effects of gaseous ozone delivered into saline on biofilms of E. faecalis in root canals of extracted teeth with and without the use of passive ultrasonic agitation. Biofilms of E. faecalis were established over 14 days in 70 single roots that had undergone biomechanical preparation followed by gamma irradiation. The presence and purity of biofilms were confirmed using scanning electron microscopy and culture. Biofilms were treated with saline (negative control), 1% sodium hypochlorite for 120 seconds (positive control), ozone (140 ppm ozone in air at 2 L/min delivered into saline using a cannula for 120 seconds), saline with passive ultrasonic activation (70 kHz and 200 mW/cm(2) applied to an ISO 15 file held passively within the canal, for 120 seconds), and ozone followed immediately by ultrasonic agitation. After treatment, samples were taken from the biofilm and serially diluted for plate counting. Analysis revealed that 1% sodium hypochlorite was the most effective disinfecting agent followed by ozone combined with ultrasonic agitation, ozone alone, and finally ultrasonic alone. Although none of the treatment regimes were able to reliably render canals sterile under the conditions used, ozone gas delivered into irrigating fluids in the root canal may be useful as an adjunct for endodontic disinfection.

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