To Be Published September 2002

MANAGEMENT OF ROOT CARIES USING OZONE

A. BAYSAN*[1,2] and E. LYNCH[1]

[1]Division of Restorative Dentistry and Gerodontology,

Dental School, Royal Victoria Hospital, Queen's University, Belfast, Northern Ireland

[2]Department of Adult Oral Health,

Barts and the Royal London Queen Mary's School of Medicine and Dentistry, London, UK

Correspondence to:

Aylin Baysan BDS MSc

Barts and the Royal London

Queen Mary's School of Medicine and Dentistry,

Department of Adult Oral Health,

Turner Street, E1 2AD, London, UK

Tel: +44 20 7377 7000 ext. 2186

Fax +44 20 7377 7375

E-mail: abaysan@mds.qmw.ac.uk

BACKGROUND

Ozone can be considered as an alternative management strategy for root caries. Recently, Baysan *et al.,* (2000) reported that ozone application for either 10 or 20 s was effective to kill the great majority of micro-organisms in primary root carious lesions (PRCLs) *in vitro* and this application for a period of 10 s was also capable of reducing the numbers *of Streptococcus mutans* and *S. sobrinus in vitro*. Beighton *et al.,* (1993) have previously validated a root caries severity index and clinical diagnostic criteria for PRCLs. The Electrical Caries Monitor III (ECM III) has also been shown to correlate with PRCLs severity (Baysan *et al*., 2002).

AIM

The aim of this longitudinal study was to assess the safety and efficacy of a novel ozone delivery system (HealOzone, CurOzone USA) with or without a root sealant (Dentsply, Germany) for the management of PRCLs.

MATERIALS AND METHODS

Study population

Ethical approval was obtained by the District Ethics Committee of Queen's University Belfast. The data obtained from 220 PRCLs in 79 patients. A total of 49 (62%) male and 30 (38%) female participants with at least one PRCL, was selected. The mean (± SD) age of the subjects at baseline was 65 (± 14.76) years with a minimum of 30 and maximum of 72 years. Root caries in the middle severity category (leathery lesions with severity index 2) according to the perceived treatment needs (Beighton *et al.,* 1993) on at least two surfaces, which were accessible for the diagnostic procedure, were only chosen in this study (Figure 1).

Figure 1 Leathery root carious lesion with severity index 2

Equipment used

- Ozone delivery system

The ozone delivery system is a portable apparatus with an ozone generator for the treatment of caries and delivers ozone at a concentration of 2,100 ppm ± 10% (Figure 2). The vacuum pump pulls air through the generator at 615 cc/min to supply ozone to the lesion and purges the system of ozone after ozone treatment. A disposable removable silicone cup attached to the handpiece, is provided for receiving the gas and exposing a selected area of the tooth to the gas. The tightly fitting cup seals the selected area on the tooth to prevent escape of ozone (Figure 3). The ozone is drawn out of the sealing cup through an ozone neutraliser that converts the ozone to oxygen. A suction system then removes any possible remaining ozone whilst the cup is still adapted to the PRCLs (the suction system passed the gas from the delivery system through manganese (II) ions). The system then draws a liquid reductant through the sealing cup to neutralise any possible residual ozone.

Figure 2 Ozone delivery system

Figure 3 Handpiece with a cup

- The ECM III (Lode Diagnostics BV, Groningen, The Netherlands)

The electrical resistance was taken at the centre, mesial, distal, occlusal and gingival points of each PRCL (Baysan *et al.,* 2001a). The monitor recorded the value at the end of the drying period (end value) and the area under the curve during the drying period (integrated value).

- The DIAGNOdent

The DIAGNOdent (Kavo, Germany) was used to detect and quantify the severity of PRCLs. The instant reading indicates the real time value that the probe tip is measuring, whilst the peak value refers to the highest level scanned on the tooth. The peak value was subjected to statistical analyses.

Material used

- A root sealant

The root sealant (Seal & Protect, Dentsply, Germany) is self-adhesive and contains a mixture of dimethacrylate resins in acetone as a solvent, with triclosan and fluoride.

Study design

The study involved 79 patients with either 2 or 4 PRCLs who were randomly allocated to one of the 4 groups (Figure 4).

Figure 4 Schematic diagram of the study

Patient recruitment

⇓ (1 month)

Baseline

ECM and DIAGNOdent measurements and clinical indices

Group 1. Application of O_3

Group 2. No treatment O_3 and sealant

Group 3. Application of sealant only

Group 4. Application of

⇓

1 month follow up

ECM and DIAGNOdent measurements and clinical indices

Group 1. No application of O_3

Group 2. No treatment

Group 3. Modified USPHS, possible re-application of sealant

Group 4. Modified USPHS, possible re-application of sealant

⇓

3, 6 and 9 month follow up

ECM and DIAGNOdent measurements and clinical indices

Group 1.	**Group 2.**	**Group 3.**	**Group 4.**
Re-application of O_3	No treatment	Modified USPHS, Re-application of O_3 and possible sealant	Modified USPHS, Possible re-application of sealant only

⇓

Statistical analyses

If patients presented any form of discomfort, PRCLs for each group were immediately treated with conventional drilling and filling procedures. Patients in all the above groups used a standard dentifrice containing 1,100 ppm sodium fluoride (Advanced whitening toothpaste with soft polish, Natural White, U.S.A) and soft toothbrushes (Natural White, U.S.A). Dentifrices and toothbrushes were provided during the study period i.e., after 1, 3, 6 and 9 months, or earlier by post if required.

Statistical analyses

The means of the resistance and DIAGNOdent readings recorded at baseline and after 1, 3, 6 and 9 months were used for data analyses. Subsequently, the ECM readings were transformed using the $\log_{10}$ function to normalise variance for all groups. Means and standard errors for each variable (cavitation, size, distance from gingival margin, and severity index) were then recorded. When statistical analyses were carried out, the ozone only group was compared to the control group, whilst the sealant and ozone group was compared to the sealant only group. In the ozone and control groups, the primary outcome variable was reversal of severity index, whilst the marginal adaptation of the root sealant was the primary outcome for the sealant and ozone and sealant only groups.

- Hardness and severity index

The differences in the number of lesions becoming hard and reversed into a less severe index were tested.

- ECM and DIAGNOdent readings, distance from the gingival margin, cavitation, and size

The differences in ECM resistance (ΔR), DIAGNOdent measurements (ΔD), distance from the gingival margin (ΔDGM), cavitation (ΔC) and size (ΔS) measurements between baseline examination, 1, 3, 6 and 9 months were calculated by subtracting the 1, 3, 6 and 9 month values from the baseline.

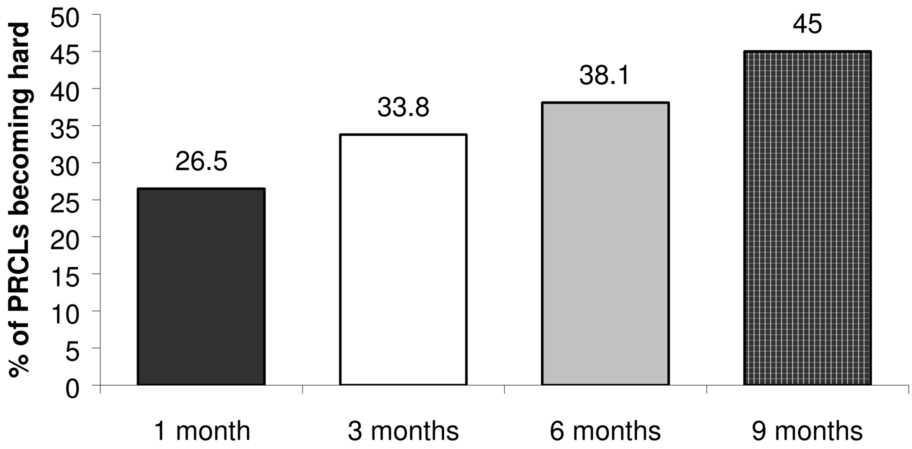
All statistical tests were performed using the SPSS statistical package for MS Windows version 6.1. and the threshold of significance was 0.05.

RESULTS

Hardness

At baseline, all lesions were of a leathery consistency. Percentages of hardness of PRCLs in the ozone only group are shown in Figure 5 ($p < 0.001$).

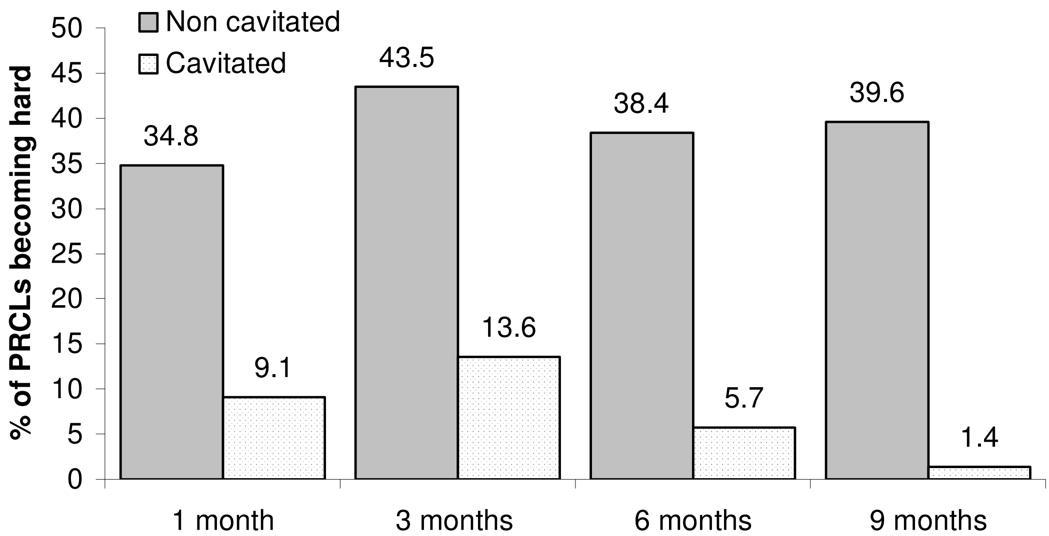
Figure 5 Percentages of hardness of PRCLs in ozone only group after 1, 3, 6 and 9 months



Cavitation

Non-cavitated lesions (<0.5 mm) at baseline were more likely to become hard after 1, 3, 6 and 9 months in the ozone group ($p < 0.05$) (Figure 6).

Figure 6 Percentage of lesions becoming hard after 1, 3, 6 and 9 months for non cavitated and cavitated lesions



Values obtained from the ECM

The mean ECM scores are shown in Table 1. At baseline, the ECM readings were similar for all groups. The mean ECM readings for the control group tended to decrease at all examinations ($p < 0.05$). In contrast, the mean ECM readings of the lesions in the ozone only, ozone and sealant and sealant only groups increased when compared to baseline readings during the study. There were statistically significant differences in the changes in ECM readings between the ozone only and control groups at 1, 3, 6 and 9 month examinations in the regression models ($p < 0.001$).

Table 1 Mean (± SE) $\log_{10}$ ECM scores in all groups

	O_3	No treatment	O_3 + Sealant	Sealant only
Baseline	5.24 ± 0.04	5.20 ± 0.04	5.24 ± 0.31	5.25 ± 0.34
1 month	5.78 ± 0.07	5.18 ± 0.03	6.30 ± 0.77	5.95 ± 0.93
3 months	5.63 ± 0.08	5.13 ± 0.03	5.75 ± 0.66	5.60 ± 0.71
6 months	5.62 ± 0.12	4.92 ± 0.21	5.56 ± 0.14	5.45 ± 0.16
9 months	5.56 ± 0.11	4.47 ± 0.22	5.58 ± 0.16	5.38 ± 0.24

Values obtained from the DIAGNOdent

The mean DIAGNOdent scores are shown in Table 2. At baseline, the DIAGNOdent readings were similar for all groups. The mean DIAGNOdent readings for the control group tended to increase after 1, 3, 6 and 9 months when compared to baseline ($p < 0.05$). In contrast, the mean DIAGNOdent readings in the ozone only, ozone and sealant and sealant only group tended to decrease when compared to baseline measurements during study ($p < 0.001$). There were statistically significant differences in the changes in DIAGNOdent readings between ozone only and control groups at 1, 3, 6 and 9 month examinations in the regression models ($p < 0.0001$).

Table 2 Mean (± SE) DIAGNOdent scores in all groups

	O_3	No treatment	O_3 + Sealant	Sealant only
Baseline	43.08 ± 3.22	42.14 ± 3.83	42.25 ± 3.34	41.13 ± 2.79
1 month	11.10 ± 2.18	45.29 ± 4.13	7.61 ± 2.11	12.46 ± 3.26
3 months	9.35 ± 1.71	45.95 ± 3.85	8.18 ± 1.88	11.53 ± 2.17
6 months	10.87 ± 2.35	46.36 ± 2.19	8.11 ± 1.96	10.92 ± 3.34
9 months	11.21 ± 3.11	49.24 ± 2.83	11.70 ± 3.55	13.49 ± 2.75

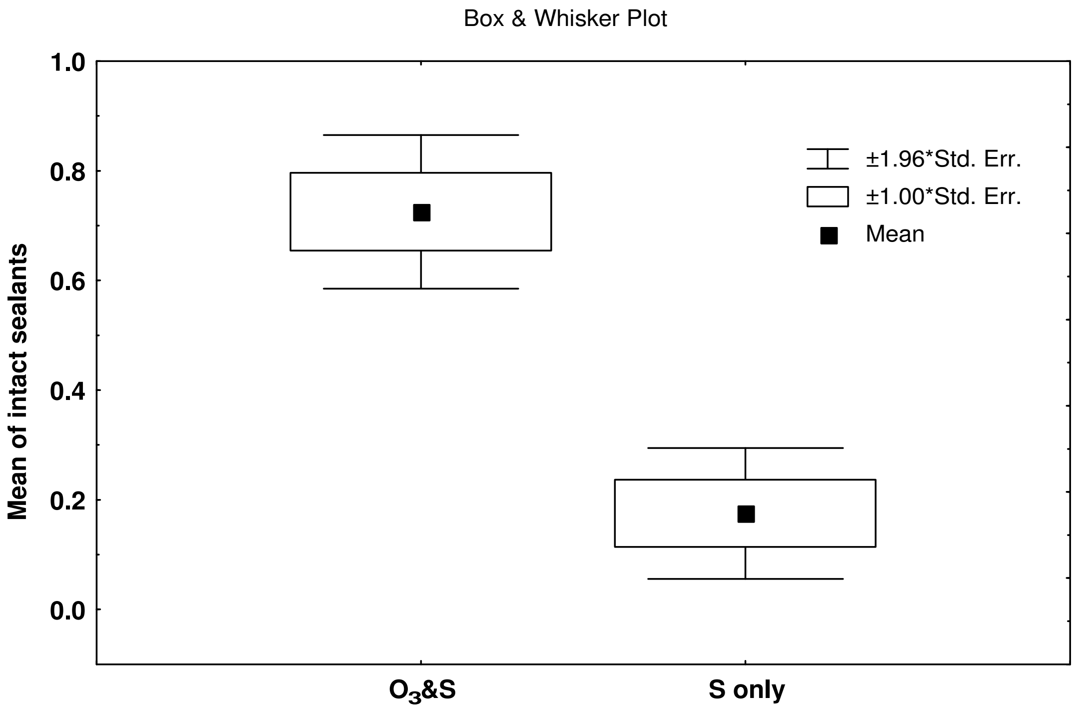
Severity index

At 1 month recall, 26.5% of PRCLs had become hard in the ozone group, whilst in the control group, 1.5% of PRCLs got worse ($p < 0.001$), and 54.4% of lesions reversed from severity index 2 to 1 in the ozone group, when compared to the control group ($p < 0.001$). Between 1 and 3 months, 13.5% of PRCLs in the ozone group reversed from severity index 1 to 0 (i.e., hard), whilst none of the lesions in the control group reversed ($p < 0.001$), and 23.1% of lesions reversed from severity index 2 to 1 in the ozone group, compared to only 5.9% in the control group ($p < 0.001$). At 6 months, 38.1% of PRCLs had become hard in the ozone group, whilst in the control group 2% of lesions got worse and 50% of lesions reversed from severity index 2 to 1 in the ozone group compared to only 5% in the control group. After 9 months, 45% of PRCLs reversed from severity index 2 to 0 (i.e., hard) in the ozone only group, whilst none of the lesions became hard in the control group ($p < 0.001$) and 51% of lesions reversed from severity index 2 to 1 in the ozone group compared to only 8% in the control group ($p < 0.001$).

Sealant retention

After 1, 3, 6 and 9 months, modified USPHS criteria revealed a number of debonds, marginal disintegrity and anatomic failures for both the ozone and sealant, and the sealant only group. Modified USPHS criteria after 9 months revealed that there were 61% of intact sealants in the ozone and sealant group and 42% of intact sealants in the sealant only group ($p < 0.05$) (Figure 7).

Figure 7 Box plots of intact sealant according to the groups after 9 months



DISCUSSION

The main clinical problem with pharmaceutical approaches to the management of root caries is the difficulty in suppressing or eliminating micro-organisms for extended periods of time. After treatment with selected pharmaceuticals, organisms may proliferate and re-colonise in PRCLs. Interestingly, 45% of the lesions had become hard after 9 months in this study. It can be speculated as to why most of the lesions reversed. This is associated with several factors including the level of microbial reduction and the oxidant effects on PRCLs. The dramatic reduction in microbial flora will have eradicated the ecological niche of the acidogenic and aciduric micro-organisms. This shifting of microbial flora to the normal oral commensals would predominantly allow remineralisation to occur within the carious process. In addition, an oxidant (sodium hypochlorite) has previously been shown to improve the remineralisation potential of demineralised dentine. Inaba *et al.,* (1995) found that the use of an oxidant (10% sodium hypochlorite) on demineralised root dentine lesions improved their potential to remineralise since sodium hypochlorite is a non-specific proteolytic agent and was effective in removing organic components in the lesions. Subsequently, Inaba *et al.,* (1996) showed that when root dentine samples were treated with this oxidant for 2 min, the permeability of fluoride ions increased and concluded that removal of organic materials from dentine lesions was an acceptable approach to enhance remineralisation. This may partly account for the dramatic remineralisation results shown after ozone application in this study. It may also indicate that ozone has the ability to remove proteins in carious lesions, and to enable calcium and phosphate ions to diffuse through the lesions, a phenomenon resulting in remineralisation of some of the PRCLs after ozone application in this study.

After the initial suppression of the numbers of total micro-organisms, recolonisation of the micro-organisms may be retarded by a resistance of the normal commensal oral flora against intruding organisms into lesions. In addition, the ecological niche of these acidogenic and aciduric micro-organisms would be severely disrupted, which in turn could interfere with recolonisation and re-growth by this specific microflora. This may result in long-term suppression of acidogenic and aciduric micro-organisms in PRCLs. Emilson (1981) also reported that after a short-term intensive treatment of the dentition with 1% chlorhexidine, *S mutans* was suppressed *in vivo* for a significant length of time (14 weeks).

It is possible that hypermineralisation is less likely to occur following the application of ozone. Since ozone is a strong oxidant, it will undoubtedly oxidise PRCL biomolecules and hence open dentine channels in the lesions. Ozone may also have prepared a base for the lesion to allow the diffusion of calcium and phosphate ions through the depth of the lesion. Moreover, it should be noted that the patients used a dentifrice containing a standard amount of fluoride. Martens and Verbeeck (1998) reported that low concentrations of fluoride have the capacity to remineralise carious lesions to their full depth. In this respect, future studies are required to determine the significance of these postulates.

Results acquired from the ozone study were very promising. The use of ozone is safe, cost-effective, cost-efficient, and time-efficient. Oral self and professional care become more difficult for elderly people since compromising somatic and mental conditions affect this growing population. These compromising situations can be overcome using early intervention strategies. In this respect, the use of ozone can be considered especially for medically compromised patients, domiciliary care patients and home-bound elderly people (Baysan *et al.,* 2001b). There is no injection involved in ozone treatment and the ozone delivery system is portable. Therefore, elderly patients who have limited access to the dental services can highly benefit from this treatment.

In conclusion, this novel treatment regime using ozone is capable of clinically reversing leathery PRCLs and can be considered to be revolutionary alternative to conventional "drilling and filling". In addition, the root sealant can be retained better on ozone treated leathery PRCLs.

REFERENCES

Baysan A, R. Whiley, Lynch E:
Anti-microbial effects of a novel ozone generating device on micro-organisms associated with primary root carious lesions *in vitro*.
Caries Res 2000; 34: 498-501.

Baysan A, Lynch E, Ellwood R, Davies R, Petersson L, Borsboom P:
Reversal of primary root caries using dentifrices containing 5,000 and 1,100 ppm fluoride.
Caries Res 2001a; 35: 41-46.

Baysan A, Lynch E, Grootveld M:
The use of ozone for the management of primary root carious lesions.
Tissue Preservation and Caries Treatment. Quintessence Book 2001b, Chapter 3, p. 49-67.

Baysan A, Prinz J, Lynch E:
Relationships between clinical criteria used to detect primary root caries with electrical and mechanical measurements.
Submitted to Amer J Dent 2002.

Beighton D, Lynch E, Heath MR:
A microbiological study of primary root caries lesions with different treatment needs.
J Dent Res 1993; 73: 623-629.

Emilson CG:
Effects of chlorhexidine gel treatment on *Streptococcus mutans* population in human saliva and dental plaque.
Scand J Dent Res 1981; 89: 239-246.

Inaba D, Duscher H, Jongebloed W, Odelius H, Takagi O, Arends J:
The effects of a sodium hypochlorite treatment on demineralized root dentin.
Eur J Oral Sci 1995; 103: 368-374.

Inaba D, Ruben J, Takagi O, Arends J:
Effects of sodium hypochlorite treatment on remineralization of human root dentine *in vitro*.
Caries Res 1996; 30: 214-218.

Martens LC, Verbeeck RM:
Mechanism of action of fluorides in local/topical application
Rev Belge Med Dent 1998; 53: 295-308.