MANAGEMENT OF ROOT CARIES USING OZONE

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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.
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 (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**
- **Group 1.** Application of O$_3$
- **Group 2.** No treatment of O$_3$ and sealant
- **Group 3.** Application of sealant only
  - ↓
- **1 month follow up**
- **Group 1.** No application of O$_3$
- **Group 2.** No treatment
- **Group 3.** Modified USPHS, possible re-application of sealant
  - ↓
- **3, 6 and 9 month follow up**
- **Group 4.** Modified USPHS, possible re-application of sealant
  - ECM and DIAGNOdent measurements and clinical indices
<table>
<thead>
<tr>
<th>Group 1</th>
<th>Group 2</th>
<th>Group 3</th>
<th>Group 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Re-application of (O_3)</td>
<td>No treatment</td>
<td>Re-application of (O_3) and possible sealant</td>
<td>Possible re-application of sealant only</td>
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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 (\(\Delta R\)), DIAGNOdent measurements (\(\Delta D\)), distance from the gingival margin (\(\Delta DGM\)), cavitation (\(\Delta C\)) and size (\(\Delta S\)) 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

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

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

<table>
<thead>
<tr>
<th></th>
<th>(O_3)</th>
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<th>Sealant only</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Baseline</strong></td>
<td>43.08 ± 3.22</td>
<td>42.14 ± 3.83</td>
<td>42.25 ± 3.34</td>
<td>41.13 ± 2.79</td>
</tr>
<tr>
<td><strong>1 month</strong></td>
<td>11.10 ± 2.18</td>
<td>45.29 ± 4.13</td>
<td>7.61 ± 2.11</td>
<td>12.46 ± 3.26</td>
</tr>
<tr>
<td><strong>3 months</strong></td>
<td>9.35 ± 1.71</td>
<td>45.95 ± 3.85</td>
<td>8.18 ± 1.88</td>
<td>11.53 ± 2.17</td>
</tr>
<tr>
<td><strong>6 months</strong></td>
<td>10.87 ± 2.35</td>
<td>46.36 ± 2.19</td>
<td>8.11 ± 1.96</td>
<td>10.92 ± 3.34</td>
</tr>
<tr>
<td><strong>9 months</strong></td>
<td>11.21 ± 3.11</td>
<td>49.24 ± 2.83</td>
<td>11.70 ± 3.55</td>
<td>13.49 ± 2.75</td>
</tr>
</tbody>
</table>
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 disintegration 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.
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