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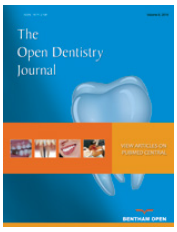

RESEARCH ARTICLE

Ozone Treatment on Dentin Hypersensitivity Surfaces – A Pilot Study

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Abstract:

Background:

Dentin hypersensitivity (DH) is a frequent condition in adults and difficult to treat. The aim of this single-blind, randomised controlled clinical trial was to investigate immediate and long-term effect of ozone treatment (Prozone, W&H NORDIC AB) for 12 seconds on hypersensitive teeth compared to placebo treatment, using a split-mouth design.

Methods:

26 patients (12 M, 14 F, mean age 44± 2) were included in the study having at least two teeth with confirmed DH in different quadrants of the dentition (each subject had one test and one control tooth). A visual analogue scale (VAS) was used to measure the patients´ pain perception immediately and at a long-term follow-up three months later.

Results:

Significant reduction in pain perception from DH surfaces was demonstrated from ozone treated test teeth as well as in placebo treated control teeth. We found a moderate (16.2%) but significant pain relief ($p < 0.012$) over time in 57.7% of all treated teeth.

Conclusion:

Results from this study confirm previously published results showing no significant effect of ozone treatment on hypersensitive teeth compared to placebo treatment.

Keywords: Dentin Hypersensitivity, Randomised Clinical Trial, Ozone, Placebo Treatment, Split-mouth Design.

INTRODUCTION

Dentin hypersensitivity (DH) is a common condition with a multifactorial cause and difficult to treat (Consensus-based recommendations for the diagnosis and management of dentin hypersensitivity 2003). Under unfavorable conditions, DH may develop and progress rapidly [1, 2], and DH is one of the most commonly encountered clinical problems [3, 4] . With the increasing number and proportion of dentate elderly in the community, the clinical management of sensitivity on exposed dentin surfaces is an unresolved issue in general dental practice. The therapy for management of DH is primarily aimed at occluding the dentinal tubules or making coagulates inside the tubules [3]. Even though there are various treatment modalities available, which can be used at home or professionally applied, the treatment used for DH often falls short of expectations [5 - 8] . In extreme cases, if the patient does not respond to the therapy and there are individual teeth exhibiting the symptoms, endodontic therapy can be initiated [3]. One interesting, novel approach may therefore be the use of ozone treatment in DH. In spite of promising results in the laboratory, where ozone has been suggested to enhance tubular occlusion and act as desensitizing agent [9], few clinical studies have been conducted to test the efficacy of this technology [10 - 12] . The aim of this single blind, randomised controlled clinical trial was therefore to investigate the effect of ozone treatment on DH. The null hypothesis was that

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the effect of ozone treatment on the subjective pain perception from DH after ozone treatment does not differ from placebo treatment. The immediate as well as the long term (three months) effect estimated on a self-rated pain scale, Visual Analogue Scale (VAS), was evaluated.

MATERIALS AND METHODS

Study Group

Subjects between 20-70 years of age, regular patients attending the dental student clinic at the Department of Dental Medicine, Karolinska Institutet, Sweden, were invited to participate in the study, mainly by the use of written information in social media, flyers sent to colleagues or posted on the dental schools' bulletin, or verbally asked while attending a regular dental appointment. Those who responded and met the inclusion criteria listed below were invited to a screening session. The research protocol and informed consent were approved by the regional ethical committee board at Karolinska Institutet, Stockholm, Sweden (2010/642-31/1**)**. Twenty-six healthy patients, 12 men and 14 women, 23-68 years of age (mean age 44±2), were recruited and enrolled after informed consent. The individual tooth was the unit of the study and a total of 52 teeth were included in this trial. The inclusion criteria were *i)* exposed dentin and a history of DH in at least 2 permanent teeth in different dental quadrants, *ii)* 20-70 years of age, *iii)* short, sharp pain, persisting no longer than 30 sec. arising from exposed dentin in the cervical area in response to an air of blast, *iv)* no use of any desensitizing agent during the trial. Exclusion criteria were *i)* on-going medication that could interfere with pain perception, *ii)* medical disorders affecting severe exposure of dentin; *e.g.* eating disorders and gastroesophageal reflux disease (GERD), *ii*) excessive intake of acidic diet, *ii)* any treatment for DH during the past 6 months, *iii)* periodontal disease and pocket depth < 4mm, *iv)* teeth with suspected pulpitis, caries, cracked enamel or dentin, cervical restoration, crowns, traumatic occlusion, or non-vital teeth.

Screening Procedure

The subjects were clinically examined and evaluated to confirm that they had DH, and once again checked for inclusion and exclusion criteria. To establish subjective pain perception from DH in two permanent teeth with exposed dentin in each subject, the following procedure was carried out: the test and control tooth were isolated using cotton rolls, and thermally stimulated by a blast of air from a dental syringe during one second with a distance of 10 mm to the buccal tooth surface in order to provoke a short, sharp pain that lasted no longer than 30 seconds (Consensus-based recommendations for the diagnosis and management of dentin hypersensitivity 2003). After 10 minutes, thermal stimulation was also carried out using Endo-Frost Spray (Roeko, Coltene, Schweiz), drowned in a small cotton pellet, applied for one second on the buccal tooth surface. Again, the provoked pain should not last longer than 30 seconds. To ensure vitality of the test and control tooth, an electric pulp tester was used (Vitality Scanner Model 2006, SybronEndo, Californien, USA) together with conducting paste, (Cefar Blågel, Cefar Compex, Malmö, Sweden). Prior to the electric pulp test, the test and control tooth were isolated using cotton rolls and dried by a blast of air from a dental syringe. To ensure inclusion criteria, response to all various pain stimuli described was assessed both on the test and control tooth, and as a safety measure, on adjacent teeth. The medical and dental history was screened thoroughly including medical condition, medication that affect the mouth, dietary habits, oral hygiene practice, drug, alcohol and tobacco use. Included teeth (n=52) were then randomly assigned to either ozone treatment or placebo treatment with the aid of a dice.

Study Design

The study was performed as a single blind, randomised controlled clinical trial with a split-mouth design, *i.e.* ozone- or placebo treatment was randomly assigned to different quadrats of the dentition, and the patient was blinded for treatment allocation. The effect of ozone and placebo treatment was assessed at Baseline and 3 months later, at Visit 1 (V1), using the participants' subjective pain perception from DH surfaces estimated on a self-rated pain scale (VAS). The study protocol was followed strictly throughout the study. The exact same procedure was carried out on the test tooth as well as on the control tooth, and each subject was treated and evaluated by the same investigator. Before treatment, the subjects were exposed to thermal stimulation by a blast of air from a dental syringe as previously described. The subjects measured the pain intensity according to VAS, in which the subject placed a mark on a 10 cm line labelled from no pain (0) to intolerable pain (10). Thereafter, a professional tooth cleaning of the full dentition was performed, using a rotating rubber cup and paste RDA 170 (CCS AB, Borlänge, Sweden). The test tooth was then treated with ozone for 12 seconds using the Prozone tip Coro according to the manufactures instruction (Prozone, W&H

NORDIC AB, Täby, Sweden), followed by a placebo treatment of the control tooth where the delivery cup was placed on the control tooth without activating the ozone. Pain perception, after thermal stimulation by a blast of air, were once again estimated by the subject on a self-rated pain scale VAS. The same procedure was carried out 3 months later (V1).

Statistical Methods

Wilcoxon rank sum test was used to compare differences between the two treatments groups before and after treatment at baseline, and at long-time evaluation three months later. The level of significance was 5% ($p< 0.05$). SPSS-22 (IBM Software; USA) was used for the statistical evaluation.

RESULTS

All recruited subjects, 26 healthy patients, 12 men and 14 women, 23-68 years of age (mean age 44±2) fulfilled the study. In each subject, 2 teeth with confirmed dentin hypersensitivity (n=52) were included in the study. The tooth type distribution is described in Table **1** and was very similar in the two treatment groups. As shown in Table **2**, an immediate pain relief was demonstrated after both procedures in the majority of the patients. Significant reduction in pain perception (VAS) from DH surfaces on the ozone treated test teeth as well as on the placebo treated control teeth was demonstrated, both during treatment-session Baseline (51.9% reduction in VAS in the test-teeth and 40.1% in the control-teeth) and during treatment-session V1 (43.7% reduction of pain intensity in the test-teeth and 31.0% in the control-teeth). No significant difference in treatment effect was demonstrated between ozone and placebo. Compared to the initial levels, the pretreatment pain perception was reduced at follow-up 3 months later. We found no significant difference in treatment effect between ozone- and placebo treatment. Therefore, as shown in Table **3**, all 52 treated teeth were summarized. We found a moderate (16.2%) but significant pain relief ($p<0.012$) over time in 57.7% of all treated teeth. The subjects' sex, mean age and the included tooth distribution with DH were considered to be well balanced. No side- or adverse effects were reported during the study period and no drop-outs were experienced.

Table 1. Distribution of tooth type in ozone and placebo treatment groups. (%) of teeth within tooth type.

Type of tooth		n	(%)		n	%
Incisors		3	(12)		4	(15)
Canines		4	(15)		2	(8)
Premolars		11	(42)		12	(46)
Molars		8	(31)		8	(31)
Total		26	(100)		26	(100)

Table 2. Visual Analogue Scale (VAS) scores of 26 pairs of teeth expressed in median, lower (25% percentile) and upper (75% percentile) before and after treatment with ozone (test) and air (control) at baseline and at follow up after three months (V1).

	VAS	Median	25e percentile	75e percentile
Baseline	Before ozone treatment	6.00	3.00	7.00
	After ozone treatment	2.00	1.00	5.00
	Before air treatment	4.50	2.75	7.00
	After air treatment	2.00	0.75	4.00
V1	Before ozone treatment	4.00	2.00	6.125
	After ozone treatment	2.00	0.75	3.50
	Before air treatment	3.00	2.00	5.00
	After air treatment	2.25	0.75	4.00

Table 3. Visual Analogue Scale (VAS) scores of 52 teeth expressed in median, lower (25% percentile) and upper (75% percentile) before and after treatment with ozone and air at Baseline, and at follow up after three months (V1).

	VAS	Median	25e percentile	75e percentile
Baseline	**Before treatment ozone and air**	5.0	3.0	7.0
	After treatment ozone and air	2.0	1.0	4.0
V1 (3-months control)	**Before treatment ozone and air**	4.0	2.0	6.0
	After treatment ozone and air	2.0	1.0	3.5

DISCUSSION

The present study was undertaken to investigate and evaluate the effect of ozone treatment on dentin hypersensitivity surfaces in adult patients. The subjective pain perception from DH surfaces was estimated on a self-rated pain scale (VAS). The main finding of this pilot study was that pain relief was seen in both ozone and air treated teeth. Our results are in agreement with the few previously published clinical trials, conducted to test the efficacy of ozone technology on DH. Azarpazhooh *et al.* [10], evaluated the effect of ozone treatment on DH. All participants reported a clinically significant reduction of pain in DH teeth, regardless of ozone or placebo treatment. However, the difference between the study groups was not statistically significant, and the authors concluded a large placebo effect that narrowed the range over which to detect treatment differences. Dahnhardt *et al.* [11], also aimed in their study to determine whether the treatment of DH with ozone reduced pain immediately after treatment and in the longer term. Again, the pain level decreased significantly in both ozone and placebo treated teeth, both immediately after treatment and over time. No statistically significant difference in pain reduction was reported when comparing test and placebo teeth. A third, and to our knowledge, latest published study on ozone treatment on hypersensitive teeth, conducted by Elgalaid [12], confirmed the previously described studies and their results. All participants reported a clinically significant reduction in pain, relative to baseline, at each follow-up visit. The difference between the study groups was not statistically significant, however, and also here the author concluded a large placebo effect that narrowed the range over which treatment differences might be detected.

The treatment of DH is based on the assumption that therapeutic agents can either reduce or interrupt the transmission of stimuli by sealing the tubular apertures or by penetrating the dentinal tubules to modify neural responses at the pulp. Current clinical desensitising procedures attempt to inhibit painful stimuli either by sealing off the dentinal tubules with a surface coating, or by altering the contents of the tubules by coagulation, protein precipitation or the creation of insoluble calcium complexes [3]. Despite the great variety of available therapeutic agents and desensitising procedures, DH remains an increasing and difficult-to-solve problem with uncertain prognosis [4]. Consequently, there is need for other clinical modalities, and ozone has therefore been suggested as a novel approach that could aid in treatment of DH [13] . A weakness with our pilot study is the limited numbers of included subjects, but the study design using the patient as his own control eliminates common confounding factors related to differences between the treatment groups. We applied essentially the same methods and have overall recorded similar results as the previously published studies regarding ozone and treatment of DH [10 - 12]. Response to treatment is based on the patients' subjective assessments of the severity of the condition. This has obvious drawbacks, particularly in relation to emotional effects on the patient's perception of pain at any given time, which can differ from person to person, between sex, gender and age, and also, from one day to another. In spite of this scattered effect in the patients' perception of pain, and therefore a weakness when comparing similar clinical trials, we were able to report similar results as previously published studies. In our pilot study, we consider the included subjects' sex, mean age and tooth distribution with DH to be well balanced. We have in general used the same methods as previous published clinical trials when provoking and recording the subjects´ pain perception, and the use of a self-rated pain scale (VAS) is considered to be a well-documented method [14] .

All included subjects described a significant pain reduction in both ozone and placebo treated teeth. A possible placebo effect may mask and overshadow any therapeutic effect of ozone and a number of reasons could influence the outcome of the present study, such as doctor-patient relationship, spontaneous improvement, fluctuation of symptoms, regression to the mean, answers of politeness, conditioned answers, *etc.* [15] .

The ozone mode of action in DH is still debated. The beneficial effects have commonly been explained such that ozone has a strong oxidation potential on calcium covered surfaces forming calcium oxalate [11]. Calcium oxalate is a traditional applied substance in desensitising agents, aimed at occluding dentinal tubules or making coagulates inside the tubules [6]. Despite the somewhat negative findings in our and previous studies regarding ozone treatment on DH, the powerful oxidising property of ozone might contribute to the treatment of DH, but with a different mode of action. Abdelaziz *et al.* [9], suggested that ozone treatment of exposed dentin removes smear layers, opens up the dentinal tubules, broadens their diameter and facilitates the entrance of minerals. Mineral and substance both from saliva or from other desensitising agents, for example calcium and fluoride ions, enter the tubules easily and deeply effectively plugging the dentinal tubules and preventing the fluid exchange through these tubules. It has also been suggested that ozone application should not be used alone for the treatment of dentinal hypersensitivity, but could be considered a viable adjunct to fluoride-containing desensitizers in enhancing tubular occlusion [16].

The need for consensus recommendations and the lack of clear and robust evidence regarding management of DH,

makes ozone treatment as a novel, non-invasive and relatively inexpensive preventive method with an immediately effect after treatment, interesting to evaluate. The Canadian Advisory Board on Dentin Hypersensitivity [17] and several authorities within the field [10, 18], as well as dentists and dental hygienists from general dental practice, emphasize the need for more clinical and scientific evidence on whether ozone treatment is effective on DH or not. The Swedish National Board of Health and Welfare [2] has selected a number of recommendations that may be particularly important for the dental care sector from a management perspective. The Board bases its decision to draw up guidelines on the fact that there is a great demand for direction and guidance in the sector of dental care, and has listed ozone treatment in dentistry as interesting but insufficiently evaluated, and suggests that ongoing and future research may provide new knowledge. Even though it included a limited numbers of subjects, we consider that our pilot study has contributed to the evidence regarding ozone treatment on DH, and strengthens previously acquired knowledge.

The conclusion drawn from the basis of our findings, which are in agreement with similar previous conducted and published clinical trials, is that no effect of ozone treatment was observed on dental hypersensitivity compared to placebo treatment.

LIST OF ABBREVIATIONS

DH	=	Dentin hypersensitivity
VAS	=	Visual Analogue Scale

CONFLICT OF INTEREST

The authors confirm that this article content has no conflict of interest.

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LK and MK have contributed to the clinical part of the study, as well as acquisition and interpretation of data. LK and MK have made substantial contributions to conception and design, analysis and interpretation of data, drafting the manuscript and revising it critically for important intellectual content.

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