A short-term study of the effects of ozone irrigation in an orthodontic population with fixed appliances

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Abstract

Aim The aim of the present study was to compare the clinical efficacy of chlorhexidine and ozonised water in the oral hygiene maintenance of orthodontic patients.

Materials and methods Study design: This is a prospective clinical study. Thirty patients with orthodontic brackets were selected at the Versilia General Hospital (Lido di Camaiore, Italy). Patients were randomly allocated to one of two groups: standard oral hygiene session followed by prescription of either chlorhexidine mouth-rinse or ozonated water. At each moment of the follow-up, the following parameters were recorded: pocket probing depth (PPD), full-mouth plaque index (FMPI), and full mouth bleeding score (FMBS). Statistics: Sample size was computed according to previously published data. Significance level was set at 0.05 for all analyses, and non-parametric Wilcoxon signed rank test was used for comparisons.

Results At baseline, mean PPD was 1.89 ± 0.13 mm for the control group and 1.95 ± 0.10 mm for the test group. Mean FMPI was 63.9 ± 16.5% and 68.7 ± 10.33% respectively. Mean FMBS was 31.5 ± 15.6% and 32.8 ± 8.85 respectively. One month after treatment (T2), both groups showed a significant improvement of FMPI and FMBS. Mean FMPI was 42.8 ± 14.3% and 24.3 ± 6.41% respectively. Mean FMBS was 19.5 ±12.6% and 4.70 ± 3.56% respectively. The test group treated with ozone exhibited a greater improvement of FMPI and FMBS.

Conclusions Ozone yielded better outcomes than chlorhexidine in the management of gingivitis in orthodontic patients. Ozone should be further investigated in longitudinal studies with larger samples.

KEYWORD Gingival inflammation; Orthodontic therapy; Ozone.

Introduction

Orthodontic fixed appliances increase the surfaces available for bacterial biofilm formation, enhancing the risk of plaque-related pathologies, especially caries and periodontal disease [Bollen et al., 2008; Vinh and Embil, 2005].

Orthodontic patients are often young with irregular eating habits and irregular home oral hygiene. Orthodontic therapy might lead to the vestibular inclination of teeth, eventually causing dehiscence in the bone resulting in an acquired anatomy that may favour the development of periodontal problems [Wishney, 2017]. Furthermore, orthodontic therapy is a long-span treatment, so that there is plenty of time for pathogenic risk factors to set in [Ruf, Hansen, and Pancherz, 1998]. In patients undergoing orthodontic treatment, plaque retention is increased [Pender, 1986]. Dental plaque is a structured biofilm providing microbial species with different niches where to differentiate, with enhanced resistance to immunological response and to antimicrobial agents [Bortolaia and Sbordone, 2002]. The mechanical removal of the biofilm is the most effective procedure to reduce the bacterial load. However, the number of studies about alternative approaches is increasing [Donlan, 2002]. Different protocols have been introduced to increase the efficacy of mechanical debridement when treating oral conditions. Powered tooth-brushes and subgingival irrigations with different chemical agents have been promoted [Burch, Lanese, and Ngan, 1994; Babay and Jasser, 1996; Mettraux, Gusberti, and Graf, 1984].

Ozone has a high oxidation potential and an antimicrobial activity which is 1.5 times greater than that of chloride versus bacteria, viruses, fungi, and protozoa. It has analgesic capacity; it stimulates blood circulation and the immune response towards healing [Nogales et al., 2008]. Ozonated water, in particular, has the capacity to entrap and then release oxygen and ozone in oral tissues [Saini, 2012].

Ozone has already been tested in orthodontics as a measure

of caries prevention and for its positive effect on shear bond strength of orthodontic brackets to enamel [Kronenberg, Lussi, and Ruf, 2009; Cossellu et al., 2017]. Lately, given its promising results in periodontal patients, the use of medical ozone has been extended to the management of orthodontic gingivitis as well [Pires et al., 2013; Kshitish and Laxman, 2013; Al Habashneh, Alsalma, and Khader, 2015].

The aim of the present clinical study was to compare two different types of home plaque control systems in young orthodontic patients: the delivery of ozonated water via an oral domiciliary device and chlorhexidine mouthwashes.

Material and methods

The present randomised clinical study took place at the Istituto Stomatologico Toscano (Versilia General Hospital, Camaiore, Italy).

The design and the implementation of the study followed the updated guidelines of the CONSORT 2010 Statement for parallel group clinical trials. Each patient, or his/her parents when minors, had to sign an informed written consent before entering the experimental part of the study. All participants were screened according to the following inclusion and exclusion criteria.

Inclusion criteria:

- Patients aged from 15 to 30 years
- Orthodontic patients with brackets and arch wires both in maxilla and mandible for a minimum of 6 months in place;
- Orthodontic patients in maintenance therapy with periodical control by the dentist or the hygienist;
- Compliance to the study protocol and willingness to adhere to the hygienist instructions.

Exclusion criteria were:

- Pregnancy;
- Patients who had been administered antibiotics, FANS or steroids in the previous 3 months;
- Severe systemic diseases;
- Uncompensated diabetes;
- Chronic or aggressive periodontitis;
- Smoking more than 5 cigarettes daily;
- Alcohol or other drugs abuse.

Sample size was computed with the estimated sample size for two-sample comparison of means test. Power was set at .90 and significance level at 0.05. Means and relative standard deviations were obtained from a previous study with a similar setting [Martin et al., 2016]. The minimum required sample to detect a significant difference in bleeding score between test and control group was 28 patients (14 per group). At the end of the screening procedure, 30 orthodontic patients were enrolled in the present study and randomised into two groups of treatment. Randomisation was obtained with a computer software and the allocation file was included in thirty consecutive closed envelopes:

1. Control group: patients underwent a traditional professional oral hygiene session; afterwards, patients received general instructions for oral hygiene and were prescribed with a domiciliary chlorhexidine mouthwash to be used twice a day after tooth-brushing.
2. Test group: patients underwent a traditional professional oral hygiene session and received general instructions for proper oral hygiene. At the end of the session, a trained hygienist delivered a calibrated amount of ozonated water with a professional ozone delivery device (Aquolab®, EB2C; Milano, Italy). Patients were given a domiciliary version of the same ozone-delivery device which is characteristic for its safer settings (bigger nozzle and lower jet pressure). Patients were instructed to use the device twice a day, after tooth-brushing.

Demographic data, anamnesis and clinical parameters were collected for each patient. All subjects were instructed to clean the interproximal spaces between teeth, the brackets and the arch-wire using interdental brushes. Brushing procedures were shown directly in the mouth of the patient in front of a mirror. The participants were asked to reproduce the correct brushing technique under the supervision of a dental hygienist.

The clinical parameters measured on each patient included the following.

- Probing pocket depth (PPD), measuring the mean value of vestibular, palatal/lingual, mesial and distal sites.
- Full-mouth plaque index (FMPI), measuring 6 surfaces for teeth and reporting the global percentage of the mouth;
- Full-mouth bleeding score (FMBS), measuring 6 surfaces for teeth and reporting the global percentage of the mouth.

Computational outcome measures were measured subtracting the baseline values to follow-up values for each parameter as follows.

- Change in pocket probing depth (ΔPPD = PPDX-PPD0).
- Change in full-mouth plaque index (ΔFMPI = FMPIX-FMPI0).
- Change in full-mouth bleeding score (ΔFMBS = FMBSX-FMBS0).

At T1 (1 week) and T2 (4 weeks), the same operator repeated each clinical measurement. In order to increase compliance, all patients were motivated by an expert dental hygienist showing the patients the results of a plaque disclosing system and giving oral hygiene instructions at each time point of the follow-up.

Chlorhexidine was used at a concentration of 0.05% in a mouth-rinse with ADS (Anti Discoloration System, Curasept; Curaden Healthcare, Saronno, Italy), while for the test group the ozone/water delivery system was used with ozone release of 50 mg/h (20 °C) and a mass flow rate of 0.2 l/min.

Statistical analysis

Data were enetered in a software for statistical analysis computing descriptive statistics (mean, median, standard deviation) and longitudinal pairwise analysis. The Shapiro-Wilk test was used to confirm normal distribution of the data related to each numerical variable for each follow-up time point. Pairwise comparisons were performed using the Wilcoxon signed-rank test for matched samples, in order to compare the time effects. The control and the test group were compared with the Wilcoxon sign rank test. The level of statistical significance was set at 0.05 for all analyses. The statistical software used was Stata 12.0 (StataCorp LLC 4905 Lakeway Drive College Station, Texas 77845-4512 USA).

Results

The initial enrolment included 34 orthodontic patients. After screening procedure, 4 patients did not satisfy all of the inclusion criteria so that they were excluded from the experimental part of the study. Thirty consecutive patients were recruited from October 2016 to April 2017. Fifteen patients were assigned to the control group (chlorhexidine) and fifteen to the test group (ozone). All of the patients completed the follow-up. The entire cohort of patients included 14 males and 16 females with no systemic diseases and a mean age of 16.4 ± 1.6 years. The treatment group included eight males and seven females (16.1 ± 1.1 years of age); the control group included 6 males and 9

females (16.8 ± 2.1 years of age).

Complete descriptive and analytic statistics of outcome measures is reported in Table 1. At baseline (T0), all of the periodontal indexes (PPD, FMPS, FMBS) were comparable between the two groups. Mean PPD was 1.89 ± 0.13 mm for the control group and 1.95 ± 0.10 mm for the test group. Mean FMPI was 63.9 ± 16.5% and 68.7 ± 10.33%, respectively. Mean FMBS was 31.5 ± 15.6% and 32.8 ± 8.85, respectively. Fifteen days after treatment (T1), PPD was 1.87 ± 0.14 mm for the chlorhexidine group, and 1.92 ± 0.09 mm for the ozone group. Mean FMPI was 38.6 ± 10.9%, and 31.0 ± 11.1%, respectively. Mean FMBS was 12.7 ± 10.6% for the control group, and 5.93 ± 3.80 % for the test group. One month after treatment (T2), both groups showed a significant improvement of FMPI and FMBS within each subject (intragroup or within patient analysis) with a p-value <0.05. Mean PPD was 1.86 ± 0.13 mm for the control group, and 1.90 ± 0.10 mm for the test group. Mean FMPI was 42.8 ± 14.3%, and 24.3 ± 6.41%, respectively. Mean FMBS was 19.5 ±12.6%, and 4.70 ± 3.56%, respectively. The computation of deltas on each parameter (ΔPPD, ΔFMPI, ΔFMBS) allowed the comparison in efficacy between groups (inter-group analysis) by means of the Wilcoxon rank sum test. The test group treated with ozone exhibited a greater improvement of FMPI and FMBS both at a 15-day and at a 30-day evaluation (p-value < 0.05) as shown in Figure 1 and 2. No differences in change of PPD could be recorded between the two groups.

Variable	Time point	Treatment Group		Differences between groups
		Chlorhexidine Mean ± SD	Ozone Mean ± SD	
PPD	T0	1.89 ± 0.13	1.95 ± 0.10	
	T1	1.87 ± 0.14	1.92 ± 0.09	
	T2	1.86 ± 0.13	1.90 ± 0.10	
ΔPPD	T0-T1	0.02 ± 0.02	0.03 ± 0.04	0.89
	T0-T2	0.02 ± 0.03	0.05 ± 0.04	0.39
	T1-T2	0.01± 0.01	0.01 ±0.02	0.51
FMPI	T0	63.9 ± 16.5	68.7 ± 10.3	
	T1	38.6 ±10.9	31.0 ± 11.1	
	T2	42.8 ± 14.3	24.3 ± 6.41	
ΔFMPI	T0-T1	25.2 ± 13.2	37.6 ± 9.63	0.07
	T0-T2	21.0 ± 5.18	44.3 ± 9.05	0.0001
	T1-T2	-4.20 ± 9.9	6.53 ± 5.59	0.03
FMBS	T0	31.5 ± 15.6	32.8 ± 8.85	
	T1	12.7 ± 10.6	5.93 ± 3.80	
	T2	19.5 ±12.6	4.70 ± 3.56	
ΔFMBS	T0-T1	18.8 ± 10.0	26.9 ± 8.43	0.12
	T0-T2	11.9 ± 7.21	28.1 ± 8.82	0.006
	T1-T2	-6.84 ± 4.00	1.22 ± 4.00	0.004

TABLE 1 Mean ± Standard Deviation of outcome variables. The right column shows the p-values for inter-group comparisons.

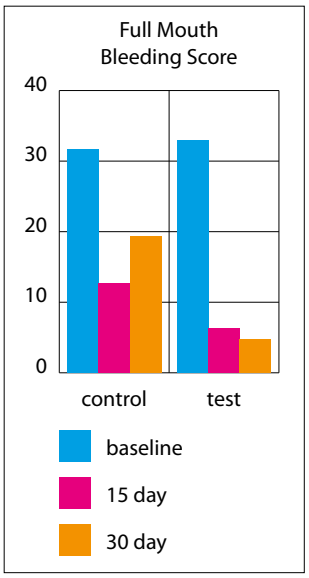

FIG. 1 Mean values for full-mouth bleeding scores in the control group (left) and in the test group (right) at each moment of the follow-up.

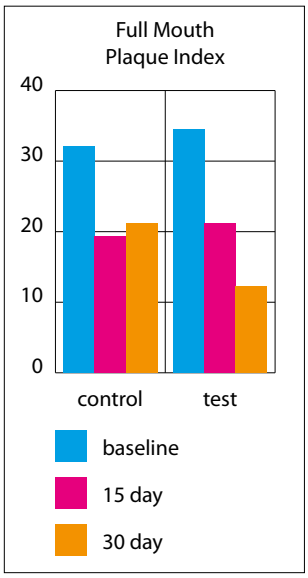

FIG. 2 Mean values for full-mouth plaque index in the control group (left) and in the test group (right) at each moment of the follow-up.

Discussion

The present study was designed as a randomised prospective clinical study to evaluate the clinical effect of the delivery of ozonised water compared to that of 0.20 % chlorhexidine mouth-rinse in patients under orthodontic therapy with fixed appliances.

The findings of this clinical short-term study demonstrated that the application of ozonised water resulted in improved values of full-mouth plaque index and full-mouth bleeding score, better than the values obtained with the adjunctive use of chlorhexidine mouth-rinse. The established chemical anti-microbial agent for periodontal treatment is chlorhexidine gluconate (CHX, 0.2-2%) [Gartenmann et al., 2016]. However, chlorhexidine may cause oral mucosa desquamation, fibroblast attachment to the tooth surfaces, tooth staining, and altered taste sensation [Groppo et al., 2002]. Ozone has been lately proposed as a possible alternative to standard oral antiseptic agents [Gupta et al., 2012]. It has a high antimicrobial power, it is not allergenic and it is safe [Saini, 2011]. Ozonated oils and water showed good outcomes in terms of biocompatibility, substantivity, and antimicrobial potential [Stübinger, Sader, and Filippi, 2006].

The ozone delivery device was used in the present study, both in its professional and in its domiciliary version according to the manufacturers' instructions. The ozonised water jet was directly applied to the oral mucosa and did not cause any negative tissue effect. This was coherent with findings of previous *in vitro* studies which concluded that ozone is safer on human oral epithelium and gingival fibroblast cells when compared to chlorhexidine use [Huth et al., 2006]. Both treatment groups exhibited a significant improvement of active inflammation at a 1-month evaluation. Ozonised water performed better than chlorhexidine mouth-rinse in reducing FMPI and FMBS. This finding was in line with a previous clinical study from Kshitish and Laxman [2010]. The authors compared chlorhexidine and ozone irrigation and reported better results for the latter with a 12% reduction in plaque index for the ozonated water and a 4% reduction for the chlorhexidine. Positive outcomes for the ozonised-water irrigation in the management of gingival inflammation in orthodontic patients have been shown by Dhingra and Vandana [2011] as well. The authors reported a significant reduction for plaque index, bleeding index, and probing depth at a 15- and a 28-day evaluation.

The extra information provided by the results of the present randomized clinical study is that ozone could perform better than chlorhexidine in the management of gingival inflammation. The clinical outcomes showed ozone therapy to be significantly (p-value < 0.05) more efficient than chlorhexidine in reducing the FMPI and the FMBS both at a 15- and at a 30-day evaluation. Patients treated with chlorhexidine showed the highest rate of relapse from the 15-day to the 30-day evaluation, thus suggesting that ozonised water is capable to maintain a healthier environment for a longer period. It is possible that the recommendation of a domiciliary device could strongly motivate young patients to adhere a daily routine in order to preserve a positive homeostasis of the oral microbiome [McCambridge, Witton, and Elbournec, 2014].

The authors belief is that the ozone delivery system could have shown better results because of the healing property of ozone, in addition to its antimicrobial effect. Ozone enters the tissues and stimulates local blood circulation and immune response. Therefore, it is indicated in the management of oral conditions because of the fast substances' absorption potential of the oral mucosa [Zhang, Zhang, and Streisand, 2002]. Ozonised water might replace the use of traditional chemical antimicrobial agents in maintaining oral health in orthodontic patients.

Conclusion

The ozone oral delivery device showed better results than the domiciliary use of chlorhexidine mouth-rinse in reducing plaque and bleeding on probing at a 1-month evaluation. Further studies with larger samples and longer follow-up are required to support the results of the present pilot study.

Conflict of interest

The authors report no conflicts of interest, and are alone responsible for the content and writing of the paper.

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