Subgingival air-polishing with erythritol during periodontal maintenance

Randomized clinical trial of twelve months

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Abstract
Objectives: To evaluate repeated subgingival air-polishing in residual pockets with a new erythritol powder containing 0.3% chlorhexidine.
Material and Methods: Single-centre, examiner masked, randomized clinical trial of 12 months with a two-arm, within-subject parallel design. Fifty patients in periodontal maintenance were monitored in 3-month intervals. At months 0, 3, 6 and 9, all sites presenting with a probing depth (PD) >4 mm were subject to subgingival air-polishing (test side) or ultrasonic debridement (control side). The primary endpoint was presence/absence of PD >4 mm after 12 months.
Results: Totally 6918 sites were monitored at baseline, 457 of them had a PD >4 mm (range 5–9 mm). The number of pockets >4 mm per subject, PD and bleeding on probing were significantly lower at month 12. Differences between test and control were not significant. There was a significant difference in favour of air-polishing for the perception of pain/discomfort. Differences of frequencies at >1000 and >100,000 cells/ml of six microorganisms between baseline and month 12 were not significant. At month 12, test sites were less frequently positive for Aggregatibacter actinomycetemcomitans at >1000 cells/ml than controls, and counts never exceeded 100,000 cells/ml.
Conclusions: Repeated subgingival air-polishing reduced the number of pockets >4 mm similar to ultrasonic debridement. It was safe and induced less pain.

Accumulation of bacterial deposits on teeth is the primary cause of periodontitis, and thorough removal of such deposits has proven to be efficient in the treatment of this disease. Deep lesions may, however, not revert rapidly and fully to a sulcus with physiological probing depth (PD) (Heitz-Mayfield et al. 2002, van der Weijden & Timmerman 2002). As self-performed oral hygiene procedures have a limited capacity to remove newly formed bacterial deposits from residual pockets, regular debridement by professional intervention is necessary to prevent recurrence of disease. This absorbs a considerable amount of work time of qualified dental professionals, notably dental hygienists. As an example, 704 residual pockets with PD >4 mm were counted upon completion of active periodontal therapy in a cohort of 172 patients – on average 4.1 per patient (Matulienne et al. 2008). A total of 959 pockets, or 5.4 per patient, were present at a re-evaluation after a mean of 11 years in supportive periodontal therapy.

Conflict of interest and source of funding statement
RM has been asked to lecture for the sponsor. The authors report no other conflicts of interest related to this study.
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Traditionally, calcified and non-calcified bacterial deposits (i.e. calculus and biofilm) are removed from root surfaces by scraping with a steel curette, or using a steel tip activated by sonic or ultrasonic oscillation. Repeated instrumentation of this kind has unwanted effects that may cumulate over time. They include gingival recession and loss of tooth substance. As subgingival bacterial deposits may not mineralize between two maintenance visits to form hard and firmly attached calculus, methods less harmful than instrumentation with steel instruments may be more appropriate in this situation. Bacterial deposits can also be removed by “air-polishing”, a technology to clean or polish a surface with a jet of compressed air containing an abrasive powder (Petersilka et al. 2003). Using a low abrasive agent and a nozzle that can be introduced into a periodontal pocket, it is possible to remove subgingival biofilm from root surfaces in residual pockets. The safety, patient acceptance and short-term (7 days) microbiological effects of this method were evaluated in 50 patients with residual pockets >4 mm deep, by testing a newly designed nozzle that allowed the projection of the air-powder jet onto the root surface, and glycine powder with a grain size of 20 μm as the agent (Moëne et al. 2010). The results indicated that this procedure was safe, more acceptable and more time efficient than SRP. The clinical and microbiological effects in the longer term remained to be determined. A split-mouth study of two months duration in 20 recall patients confirmed these results, revealing no relevant differences in clinical or microbiological outcomes between subgingival air-polishing and ultrasonic debridement (Wennstrom et al. 2011). A subsequent study (Flemmig et al. 2012) examined the effects on bacterial biofilm in moderate-to-deep periodontal pockets over a period of 90 days and demonstrated beneficial shifts in the composition of the subgingival microbiota.

In the studies conducted thus far the procedure was applied only once and the benefit of the intervention was only evaluated short term. As it is customary in periodontal maintenance to clean subgingival root surfaces repeatedly, the objective of the present study was to evaluate the benefit of repeated subgingival cleaning with such an air-polishing device in residual pockets >4 mm over a period of 1 year.

Material and Methods

This was a single-centre, examiner masked, randomized clinical trial of 12 months duration with a two-arm, within-subject parallel design to compare the long-term effects of subgingival air-polishing (test group) with ultrasonic instrumentation (control group). The Ethical Committee of the University Hospitals of Geneva approved the protocol. Research was conducted according to the principles outlined in the Declaration of Helsinki on human medical experimentation. All participants were informed about the procedures and signed a consent form in advance of their inclusion in the study.

Subjects

Fifty systemically healthy patients were recruited between September 2011 and November 2012 from patients previously treated for periodontal disease at the School of Dental Medicine, University of Geneva. The clinical procedures and evaluations were carried out between October 2011 and November 2013.

The participants were included based on the following criteria: in maintenance care at least 3 month after completion of comprehensive periodontal therapy, aged 18 or over, and the presence of at least one residual pocket with PD >4 mm on the right and the left side of the dentition, absence of clinically detectable subgingival calculus, in the area between the distal aspect of the first incisor and the mesial aspect of the second molar. Exclusion criteria included chronic bronchitis or asthma and major systemic illnesses (i.e. diabetes mellitus, cancer, HIV, bone metabolic diseases or disorders that compromise wound healing, radiation or immunosuppressive therapy), antibiotics, anti-inflammatory drugs or other medication taken within the previous 28 days that may affect the outcome of the study, confirmed or suspected intolerance to the test products (erythritol or chlorhexidine), and any physical limitations or restrictions that might preclude normal oral hygiene procedures. The smoking history was recorded, but smoking was not an exclusion criterion. Dental professionals or dental students were not allowed to participate.

Test products and randomization

Subgingival air-polishing was carried out with erythritol powder (Air-Flow® Powder PLUS, mean grain size of 14 μm, Fig. 1) containing 0.3% chlorhexidine, using the air-polishing device of the Air-Flow® Master Piezon unit (all products from EMS Electro Medical System S.A., Nyon, Switzerland). A special disposable nozzle made from thermoplastic elastomer was utilized (Perio-Flow® Nozzle, EMS Electro Medical System S.A., Nyon, Switzerland). The air-powder mixture exits from this nozzle horizontally. The pocket is irrigated concurrently with water exiting from an outlet at the tip of the nozzle (Moëne et al. 2010). The test procedure consisted in inserting the tip into the pocket (Fig. 2) and activating the device for 5 s. The control treatment was subgingival instrumentation with the ultrasonic scaler (Piezon® LED, tip PS, EMS Electro Medical System S.A., Nyon, Switzerland) of the same unit for approximately 20 s per site. Treatments were carried out without anaesthesia.

In each patient, one side of the dentition was assigned to treatment with the test and the other with the control procedure. The sponsor allocated the treatments and specified the sequence of treatments, using a computer-generated randomization.
list. At baseline, month 3, 6 and 9, each site with PD >4 mm was treated.

Two clinicians performed all procedures involving a contact with the participants. The examiner (RM) enrolled the patients, recorded the data and took microbiological samples. Treatment allocation was concealed to the examiner. The operator (NM) opened a sealed envelope with concealed to the examiner. The operator selected the study teeth and the study sites. Two days before the first subgingival treatment (day −2) the examiner collected a subgingival plaque sample in the two study sites with one sterile paper point inserted to the bottom of each pocket and left in situ for 10 s. On the day of subgingival treatment the operator removed supragingival calculus, stain and plaque with hand instruments in the entire dentition and instructed the subjects in proper oral hygiene during 5–10 min (review of tooth brushing and inter-dental cleaning). Next, the randomization envelope for the subject number was opened to reveal the treatment assignment. On the test side, all pockets >4 mm were treated with the air-polishing device, on the control side with the ultrasonic device. Upon completion of either air-polishing or ultrasonic debridement in the first half of the dentition, the operator noted the time elapsed from picking-up the air-polishing or ultrasonic hand-piece to putting it back onto the instrument holder. The patient was asked to rate the pain experienced on a VAS. Any other comments were recorded. Then the second half of the dentition was treated with the other method. Time and pain were recorded once more.

The participants returned to the clinic after 3, 6, 9 and 12 month. At months 3, 6 and 12 the examiner collected subgingival plaque samples from the study sites. At all time points he inspected the oral tissues, assessed root hypersensitivity at the study sites and recorded, PlI, PD, BOP, REC at six sites of all teeth. Then the operator took over, giving instructions for improvement of oral hygiene and removing supragingival soft and hard deposits. All sites with a PD >4 mm were treated subgingivally, on the test side with air-polishing and on the control side with the ultrasonic device. Each time the operator noted the time spent for the subgingival debridement and asked the patient to rate the pain. At 12 month the participants were only seen by the examiner who collected the final subgingival plaque samples and recorded the clinical data.

Microbiological procedures

Genomic DNA was extracted using the GenElute Bacterial Genomic DNA Kit (Sigma-Aldrich Co., St. Louis, MO, USA) in accordance with the manufacturer’s instructions. Quantitative real-time PCR was performed to detect and quantify six specific bacteria (Porphyromonas gingivalis, Aggregatibacter actinomyces- tecomitans, Tannerella forsythia, Treponema denticola, Prevotella intermedia, Parvimonas micra) using species-specific primers (Shelburne et al. 2000, Kozarov et al. 2006). SYBR Green (Life Technologies, Carlsbad, CA, USA) was used as nucleic acid stain. Real-time PCR was carried out using an ABI Prism® 7900HT Sequence detection system (Applied Biosystems, Foster City, CA, USA). Bacterial counts were calculated by comparison with homologous reference. The detection limit was 1000 cells/ml.

Statistical analysis

Average scores were generated of the test and control side of each patient, at each examination, by summing the scores and dividing by the number of sites graded on that side. The primary endpoint was presence or absence of PD >4 after 12 months (persisting pockets >4 mm are commonly perceived as needing continuous subgingi-
gival maintenance care in clinical practice). Secondary clinical outcomes included changes in PD, BOP+, REC (clinical attachment level CAL = PD + REC), presence or absence of target microorganisms above \( >1000 \) (detection threshold) and \( >100,000 \) cells/ml before and after 3, 6, and 12 months. The sample size was chosen based on the clinical considerations. After 12 months of supportive periodontal care with subgingival debridement mean PD changes of \( 0.37 \pm 0.15 \) mm have been reported (Heasman et al. 2002). Assuming that the common standard deviation of PD is 1 mm, a sample of 50 per group would provide 80% power to detect a true difference of 0.4 mm between groups. The \( t \)-test was used to determine differences between test and control. Longitudinal changes were analysed in all patients completing the trial using the Wilcoxon matched-pairs signed-ranks test. Adverse events and observations concerning oral hard and soft tissues were summarized by treatment group for all evaluable subjects. One statistical program package (IBM SPSS Statistics 22; IBM Corporation, Somers, NY, USA) was used for all statistical analyses. Adjusting for multiple comparisons, \( p \) values <0.01 were accepted for statistical significance.

### Results

Fifty persons gave informed consent, were enrolled in the study and received treatment as allocated. The mean age was 58.5 years. There were 21 (42%) males and 29 (58%) females; 31 (62%) were non-smokers and 19 (38%) were smokers. A total of 49 subjects completed the study. One participant was not willing to continue participating at month 3 and withdrew. A total of 6918 sites (six on a total of 1153 teeth) were clinically monitored. A total of 457 (7%) sites had a PD \( >4 \) mm: 328 were 5 mm deep, 99 were 6 mm deep, 24 were 7 mm deep and 3 were 9 mm deep. Table 1 displays the baseline characteristics, given as patient means per treatment protocol. The overall mean PD was 2.8 ± 0.3 mm.

Table 2 shows the baseline characteristics of the study sites – one site per participant on the test and one on the control side. By definition, all these 100 sites had a PD \( >4 \) mm and 53% of them were BOP+.

### Table 1. Clinical baseline characteristics of all 6918 monitored sites by treatment

| Test side | Control side | \( p \) Value |
|-----------|--------------|--------------|
| \( n \) sites per patient | 70.9 (11.7) | 72.5 (11.2) | n.s. |
| \( n \) sites with PD \( >4 \) mm | 4.6 (5.6) | 4.8 (5.2) | n.s. |
| PI, score 0–3 | 0.4 (0.2) | 0.4 (0.2) | n.s. |
| PD, mm | 2.8 (0.3) | 2.8 (0.3) | n.s. |
| BOP+, % | 22 (10) | 21 (10) | n.s. |
| REC, mm | 0.9 (0.7) | 0.9 (0.7) | n.s. |

Data are means (SD) per patient (\( n = 50 \)).

### Table 2. Baseline characteristics of the study sites (in each participant the site with the deepest PD on the test and control side, \( n = 50 \) sites on each side)

| Test site | Control site | \( p \) Value |
|-----------|--------------|--------------|
| PD, mm | 5.2 (0.4) | 5.4 (0.6) | 0.003 |
| BOP+, % | 58 (50) | 48 (50) | n.s. |
| REC, mm | 1.0 (0.9) | 0.9 (1.0) | n.s. |
| Root hypersensitivity, mm VAS | 22.2 (27.4) | 21.2 (21.2) | n.s. |
| AA >1000; >100,000 | 7; 1 | 7; 0 | n.s.; n.s. |
| BF >1000; >100,000 | 37; 20 | 39; 15 | n.s.; n.s. |
| PG >1000; >100,000 | 37; 14 | 37; 12 | n.s.; n.s. |
| TD >1000; >100,000 | 42; 22 | 42; 27 | n.s.; n.s. |
| PI >1000; >100,000 | 20; 8 | 14; 6 | n.s.; n.s. |
| PM >1000; >100,000 | 44; 19 | 49; 23 | n.s.; n.s. |

Clinical data are means (SD), microbiological data are numbers of sites positive with counts >1000 and >100,000.

PD, probing pocket depth; BOP+, bleeding on probing; AA, Aggregatibacter actinomycetemcomitans; BF, Tannerella forsythia; PG, Porphyromonas gingivalis; TD, Treponema denticola; PI, Prevotella intermedia; PM, Parvimonas micra.
received two, 60 sites had received three and 39 sites had received four rounds of air-polishing. During the same period, 290 sites were subjected to ultrasonic instrumentation: 116 sites had received one, 69 sites had received two, 50 sites had received three and 55 sites had received four rounds of ultrasonic instrumentation. Table 3 shows the status at 12 months of all 6750 sites that were clinically monitored over 1 year as means per patient. The total number of pockets remaining with PD >4 mm was 176 on the test sides and 164 on the control sides, corresponding to 3.6 residual pockets with a PD >4 mm per participant in the area treated using air-polishing and 3.9 residual pockets with a PD >4 mm in the area maintained using ultrasonic instrumentation. The majority of these residual pockets were 5 mm deep. A total of 36 and 32 sites had a PD of 6 mm, respectively, 5 and 2 sites had a PD of 7 mm, and none were deeper. Compared to baseline the mean number of pockets >4 mm per subject was significantly lower with both protocols ($p < 0.001$); the difference between groups was not significant (primary outcome).

Table 4 shows the clinical and microbiologic status of 49 test and 49 control study sites after 12 months. From baseline to month 12 there were significant improvements of PD and BOP+ in the test sites (PD $p < 0.001$, BOP+ $p = 0.007$) and of PD in the control sites ($p < 0.001$). The differences between test and control did not reach a level of statistical significance.

The detection frequencies of the studied microorganisms at >1000 and >100,000 cells/ml were not significantly different before and after 12 months. However, at the final examination the frequency of sites with counts of A. actinomycetemcomitans >1000 cells/ml was lower in the test compared to the control group, and no sample contained >100,000 cells/ml, compared to two in the control group.

### Discussion

The aim of this study was to evaluate the benefit of repeated subgingival air-polishing in residual pockets >4 mm over a period of 1 year. A within-subject parallel design was chosen. This method has repeatedly been used in studies evaluating local treatments (Wennstrom et al. 2011). However, intra-individual comparisons have their limitations as local therapy may have systemic effects and hereby influence outcomes in other sites in the same dentition (Antczak-Bouckoms et al. 1990). Even if the risk for crossover effects appears minimal, as treatment was provided to only a restricted number of sites, the design of the study needs to be considered in the interpretation of the data. The primary endpoint, i.e. the reduction of sites with PD >4 mm, was achieved to a similar degree by treatment according to both protocols: On the test side the average number of sites decreased from 4.6 to 3.6 per person, and on the control side from 4.8 to 3.9. To achieve this goal, sites were retreated variable numbers of times. Due to the continued presence of PD>4 mm, 55 sites assigned to ultrasonic instrumentation were instrumented at all four treatment visits, whereas only 39 sites received four rounds of air-polishing. The sample size for the study was chosen considering that mean PD changes in the order of 0.4 mm may be expected in 12 months of supportive periodontal care with subgingival debridement (Heasman et al. 2002). Although this is the largest trial on subgingival air-polishing conducted so far, the size of the sample may still be insufficient to detect a difference in presence or absence of PD >4 after 12 months. However, the findings suggest that repeated subgingival air-polishing in residual pockets was beneficial since the mean number of pockets >4 mm per subject was significantly reduced after 12 months ($p < 0.001$).

In comparing these results with results from other trials it is important to note that the treated sites had previously been subject to comprehensive periodontal therapy and subsequently may have been exposed numerous times to mechanical debridement in the context of periodontal maintenance. Conceptually,
The effects of air-polishing with erythritol powder on dentine have been compared to sodium bicarbonate and glycine powder in vitro (Tocha 2013). Erythritol induced the lowest volume loss and defect depth and produced the smoothest surface. In a two-species biofilm model erythritol showed inhibitory effects on oral streptococci and P. gingivalis (Hashino et al. 2013). The effect of one round of subgingival air-polishing with erythritol powder on BOP+ has been evaluated in 91 residual pockets in 40 patients (Häggi et al. 2013). After 3 months, the bleeding tendency was significantly lower, however, with no difference to the control treatment (SRP). No adverse events were recorded and the patients tolerated the test better than the control treatment.

Detection frequencies of the studied microorganisms at >1000 and >100,000 cells/ml were not markedly different at the beginning and at the end of our study. It has been shown in the past that bacterial biofilms can grow back rapidly after subgingival instrumentation (Sharawy et al. 1966) and that the composition of the microbiota may reach pretreatment levels within months (Haffajee et al. 1997). The microbiological findings of our study, derived from samples taken 3 months after previous treatment, may essentially mirror re-colonization. The lower frequency of sites with counts of A. actinomycescomitans >1000 cells/ml and the absence of sites with counts >100,000 cells/ml in the test group may warrant further attention in future trials. Several studies have shown that traditional mechanical debridement alone seems to have a limited effect especially on A. actinomycetemcomitans (Slots & Rosling 1983, Sato et al. 1993, Mombelli et al. 1994a, b). It is unclear to what extent this potential advantage may be attributed to the addition of 0.3% chlorhexidine to the polishing powder. The manufacturer actually adds chlorhexidine for the purpose of conserving the powder, not with the intention to have a therapeutic effect.

Time efficiency, high patient acceptance and minimal tissue damage are essential requirements for treatments that are repeated many times in periodontal maintenance care. An additional aspect, not evaluated here but that would merit a comprehensive comparative evaluation, is cost-efficiency. Repeated subgingival cleaning of residual pockets with a new air-polishing device over a period of 12 month was safe, induced less pain and reduced the number of pockets >4 mm. The findings regarding safety are limited to clinical examination and thus, to overt clinical adverse events. Long-term effects of protocols for periodontal maintenance should be studied further with a focus on hard tissue safety.

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Clinical Relevance

Scientific rationale for the study: As subgingival bacterial deposits may not mineralize between two maintenance visits to form calculus, methods less aggressive than debridement with steel instruments may be more appropriate for residual pockets.

Principal findings: We compared repeated subgingival air-polishing of residual pockets using a new erythritol powder containing 0.3% chlorhexidine to conventional ultrasonic debridement. Subgingival air-polishing of residual pockets was safe and induced less pain than ultrasonic instrumentation. Outcomes at month 12 were not significantly different.

Practical implications: For maintenance of residual pockets air-polishing is a valid alternative to conventional debridement.