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ORIGINAL ARTICLE

Efficacy of the additional use of subgingival air polishing with erythritol powder in the treatment of periodontitis patients: a randomized controlled clinical trial

Magda Mensi[1,2] · Eleonora Scotti[1,2] · Annamaria Sordillo[1] · Stefano Calza[3] · Maria Elena Guarnelli[4,5] · Chiara Fabbri[4,5] · Roberto Farina[4,5] · Leonardo Trombelli[4,5]

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Abstract

Objectives To date, scarce evidence exists around the application of subgingival air polishing during treatment of severe periodontitis. The aim of this study was to evaluate the benefits of subgingival air polishing during non-surgical treatment of deep bleeding pockets in stages III–IV periodontitis patients

Materials and methods Forty patients with stages III–IV periodontitis were selected, and pockets with probing depth (PD) 5–9 mm and bleeding on probing (BoP) were selected as experimental sites. All patients underwent a full-mouth session of erythritol powder supragingival air polishing and ultrasonic instrumentation. Test group received additional subgingival air polishing at experimental sites. The proportion of experimental sites shifting to PD ≤ 4 mm and no BoP at 3 months (i.e., non-bleeding closed pockets, NBCPs) was regarded as the primary outcome variable.

Results The proportion of NBCP was comparable between test and control group (47.9 and 44.7%, respectively). Baseline PD of 7–9 mm, multi-rooted teeth and the presence of plaque negatively influenced the probability of obtaining NBCP.

Conclusions The additional application of subgingival air polishing does not seem to provide any significant clinical advantage in achieving closure at moderate to deep bleeding pockets in treatment of stages III–IV periodontitis patients. The study was registered on Clinical Trials.gov (NCT04264624).

Clinical relevance While air polishing can play a role in biofilm removal at supragingival and shallow sites, ultrasonic root surface debridement alone is still the choice for initial treatment of deep bleeding periodontal pockets.

Keywords Non-surgical periodontal therapy · Clinical trial · Plaque control · Periodontitis

✉ Magda Mensi
magda.mensi@gmail.com

[1] Section of Periodontics, School of Dentistry, Department of Surgical Specialties, Radiological Science and Public Health, University of Brescia, P.le Spedali Civili 1, 25123 Brescia, Italy

[2] U.O.C. Odontostomatologia—ASST degli Spedali Civili di Brescia, Brescia, Italy

[3] Department of Molecular and Translational Medicine, University of Brescia, Brescia, Italy

[4] Research Centre for the Study of Periodontal and Peri-Implant Diseases, University of Ferrara, Ferrara, Italy

[5] Operative Unit of Dentistry, Azienda Unità Sanitaria Locale (AUSL), Ferrara, Italy

Introduction

With the introduction of low-abrasiveness powders, the range of applications of air polishing expanded from supragingival stain removal only to supra- and subgingival biofilm management [1, 2]. Air polishing with glycine or erythritol powder seems more effective than manual instrumentation at disrupting biofilm in both shallow and deep pockets [3–6], whilst safe on the root surface [7] and soft tissues [8], and allowing proper attachment of periodontal ligament fibroblasts [4].

Flemmig et al. (2012) [3] elaborated the concept of full mouth glycine powder air polishing (FM-GPAP), involving the application of air polishing followed by ultrasonic or manual removal of visible calculus. They concluded that the technique is more effective than manual SRP in biofilm removal

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and may result in a beneficial shift of the oral microbiota. When used to instrument pockets utilizing a specifically designed plastic nozzle, air polishing is proven a suitable option for maintenance therapy of periodontal patients [9–11] leading to similar clinical and microbiological results as traditional instrumentation [10] but in a more time-efficient and comfortable manner [9, 10].

To date, only three clinical trials have investigated the additional benefits of subgingival air polishing during treatment of periodontitis [12–14]. In these studies, erythritol or glycine powder was applied in selected pockets after ultrasonic and manual scaling and root planing (SRP). No additional clinical benefits could be demonstrated. However, the complete full mouth air polishing protocol [3] was not administered, limiting its application to the selected pockets and after traditional SRP.

The present randomized controlled trial aimed at evaluating the adjunctive clinical effect of subgingival air polishing with erythritol powder in the non-surgical treatment of deep bleeding pockets in stages III–IV periodontitis patients [15]. The hypothesis was that air polishing could improve biofilm removal in areas of the pocket normally difficult to reach with traditional mechanical instruments, leading to a better clinical outcome. The periodontal treatment was carried on according to the FM-GPAP protocol as outlined by Flemmig et al. [3] followed by ultrasonic pocket debridement.

Materials and methods

Study design and approval

This multicentre, single (examiner)-blinded, parallel arm randomized controlled clinical trial was conducted at the Section of Periodontics, School of Dentistry, Department of Surgical Specialties, Radiological Science and Public Health of the University of Brescia, within the ASST Spedali Civili di Brescia, Department of Odontostomatology, and at the Research Centre for the Study of Periodontal and Peri-implant Diseases, University of Ferrara. The protocol was reviewed and approved by the Ethics Committee of the University-Hospital of Brescia (CE: 2971) and the Ethics Committee of Area Vasta Emilia Centrale (protocol number: 83/2018/Disp/Unife) and the study conducted in accordance with the ethical principles of the Declaration of Helsinki. All participants signed written informed consent before the beginning of the study. The study was registered on Clinical Trials.gov (NCT04264624).

Patient selection and allocation

The inclusion criteria were as follows: ≥ 18 years and ≤ 75 years of age, good general health, diagnosis of stages III–IV periodontitis [15], at least 15 sites with probing depth (PD) 5–9 mm and positive to bleeding on probing (BoP) [16].

The exclusion criteria were as follows: pregnant or lactating patients, current or past (within 3 months of enrolment) medications that may influence periodontal conditions and/or interfere with healing following periodontal treatment (i.e., corticosteroids, calcium channel blockers), non-surgical and/or surgical periodontal debridement within 3 months of enrolment, the use of systemically administered antibiotics within 3 months of enrolment, tumours or significant pathology of the soft or hard tissues of the oral cavity, current radiotherapy or chemotherapy, chronic obstructive pulmonary disease and asthma, history of allergy to erythritol and the presence of orthodontic appliances.

Randomized patient allocation to either test or control intervention was performed centrally using ad hoc software [R version 3.6.1, R Core Team (2020). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL https://www.R-project.org/], using a blocked randomization scheme to achieve balanced treatment groups within centres.

Clinical parameters

At baseline (T0) and 3 months after treatment (T1), PD, clinical attachment level (CAL), gingival recession (REC), BoP and the presence of supragingival plaque (PII) were collected by a blinded examiner at 6 sites (mesio-buccal, mid-buccal, disto-buccal, mesio-lingual, mid-lingual, disto-lingual) for each tooth present. BoP and PII were expressed as % of positive sites on total examined sites. Probing measurements were performed using a UNC-15 periodontal probe (Hu Friedy®, Chicago, IL, USA) and rounded at the nearest mm. For each patient, all sites that showed PD 5–9 mm and were BoP-positive at T0 were identified as experimental sites.

Interventions

Interventions were performed by the same two experienced calibrated operators (ES and CF), responsible only for treatment delivery to ensure examiner blinding. In all subjects, after identification of the treatment group according to the generated randomization table, the entire dentition received the application of a disclosing agent (Mira-2-Ton®, Hager & Werken, Duisburg, Germany) to guide plaque removal and achieve better biofilm removal [17]. Supra- and juxtagingival areas were air polished (Airflow Prophylaxis Master, EMS, Nyon, Switzerland) with erythritol + chlorhexidine powder (PLUS powder, EMS, Nyon, Switzerland), followed by ultrasonic instrumentation for calculus removal with dedicated tip (PS tip, Airflow Prophylaxis Master, EMS, Nyon, Switzerland). This procedure is commonly known

by practitioners with the name of Guided Biofilm Therapy (GBT).

In patients allocated to test intervention, experimental sites received subgingival biofilm removal with erythritol + chlorhexidine powder delivered via a specifically designed nozzle (Perioflow, EMS, Nyon, Switzerland) followed by subgingival ultrasonic instrumentation. In patients allocated to control intervention, experimental sites received subgingival ultrasonic instrumentation only.

At the end of the session, the patients received oral hygiene instructions on manual toothbrushing and the use of interdental cleaning devices.

Endpoints and statistical analysis

At 3 months (T1) after treatment, experimental sites were categorized as:

- Non-bleeding closed pockets (NBCP): PD ≤ 4mm and BoP-negative
- Bleeding closed pockets (BCP): PD ≤ 4mm and BoP-positive
- Non-bleeding residual pockets (NBRP): PD ≥ 5mm and BoP-negative
- Bleeding residual pockets (BRP): PD ≥ 5mm and BoP-positive

The proportion of experimental sites that shifted to NBCP at T1 was the primary outcome variable. Three-month values for CAL, PD, BoP and PlI were the secondary outcome variables. Sample size was estimated via Monte Carlo simulation. According to a previous study from Wennström et al. [18], we can expect 58% of periodontal pockets to be closed at 3 months after treatment with ultrasonic debridement. Given that the endpoint of the present study closed pockets with no bleeding, and given that Wennström et al. [18] reported a BoP score of 48% at 3 months, the authors assumed a proportion of NBCP at T1 of 40% in the control group. Being the present study the first applying the test protocol, a 1.7 odds ratio of test group versus control was arbitrarily set, based on evidence around air polishing efficacy in subgingival plaque removal [5, 6] and reduction of the red complex periodontal bacteria [19]. We used a fixed number of probed sites for every subject ($N = 120$, i.e. 6 sites for at least 20 teeth) and assumed a patient variance of 0.3. We simulated 1000 realizations of the event (PD < 5 mm and BoP-negative) at T1 using a binomial distribution and then modelled the simulated data using a GLMM logistic model with treatment (test vs control) as fixed effect and a single random component (patient intercept). The power is estimated as the proportion of simulations where the treatment effect was significant at the chosen 5% significant level. A sample size of 18 patients per group allowed for a power of at least 80%. Assuming a 10% attrition, we estimated a total sample size of 40 patients, equally randomized to the two treatment groups.

Data were described using standard summary statistics such as mean and standard deviations for quantitative variables and proportions for categorical variables. The overall percentage of NBCP were modelled using a logistic model fitted using Generalized Estimation Equations (GEE) with subject as clustering factor and binomial family, using a once-versus-all approach (i.e. estimating the percentage of one category versus all the others combined).

The probability to achieve at site level an NBCP at T1 was modelled using a logistic regression fitted using Generalized Linear Mixed Model (GLMM); this allowed to model the odds of pocket closure at site level accounting for within-subject measurement clustering.

Secondary continuous outcomes were modelled using longitudinal analysis of covariance (ANCOVA) [20] models fitted by Linear Mixed Model (LMM), adjusting for baseline values (baseline measurements added as covariate) based on Gaussian error distribution. All (G)LMM models accounted for a 2-level hierarchical structure (clustering level: patient and tooth within patient). Both PD and CAL were transformed on log scale prior to modelling. PII was modelled using a beta regression [21], while BoP was modelled using logistic regression.

Results were expressed as estimates and corresponding 95% confidence intervals. A significant level of 5% was assumed for all the comparisons, and all analyses were performed using R (version 3.6.1 or higher) and Stata (version 15).

Results

A total of 40 patients (20 for each centre) were allocated to either test ($n = 20$) and control ($n = 20$) group. During the study, 2 patients in each group were excluded due to failure to attend to the appointments ($n = 2$) and need for antibiotic treatment due to other unrelated health issues ($n = 2$).

Demographic data and baseline clinical parameters of the study population who completed the study are presented in Table 1. Groups were comparable for all considered variables. Table 2 describes the site characteristics as recorded full mouth and at experimental sites, respectively.

The distribution of the experimental sites into the 4 categories at 3 months (T1) is illustrated in Table 3. 47.9% and 44.7% of experimental sites shifted to NBCP at T in test and control group, respectively, with no significant inter-group difference ($p = 0.64$). The average overall pocket closure

Table 1 Patients characteristics in test and control group

	Control ($N = 18$)	Test ($N = 18$)
Number of elements		
Mean (SD)	24.98 (3.16)	24.94 (2.41)
Median (Q1, Q3)	26.00 (23.00, 27.75)	25.50 (23.25, 26.75)
Smoker	3 (16.7%)	4 (22.2%)
Male	7 (38.9%)	11 (61.1%)
Age		
Mean (SD)	48.44 (9.31)	52.06 (10.17)
Median (Q1, Q3)	49.50 (42.50, 54.25)	53.00 (46.25, 60.00)
N° anaesthetic doses (1.8mL)		
Mean (SD)	1.28 (2.40)	1.67 (2.83)
Median (Q1, Q3)	0.00 (0.00, 0.75)	0.00 (0.00, 3.00)
BoP index (%)		
Mean (SD)	84.08 (16.91)	83.88 (14.28)
Median (Q1, Q3)	86.01 (69.58, 100.00)	86.51 (71.90, 98.61)
Plaque index (%)		
Mean (SD)	81.17 (21.36)	92.53 (7.63)
Median (Q1, Q3)	84.66 (75.22, 96.34)	93.29 (87.45, 100.00)
Number of experimental sites		
Mean (SD)	59.89 (17.61)	49.56 (16.96)
Median (Q1, Q3)	60.00 (45.50, 76.25)	45.50 (38.00, 58.25)

BoP bleeding on probing

(NBCP + BCP) was 80% for test group and 77.6% for control group.

Analysis of the patient- and site-level factors influencing the probability to achieve a NBCP at T1 is displayed in Table 4. For continuous predictors, such as % of experimental sites, the OR corresponds to variation in probability as a consequence of a one-unit increase in the predictor values: an OR> 1 indicates that when the variable grows the probability of NBCP increases and an OR< 1 indicates that when the variable grows the probability of NBCP decreases. Test treatment seemed to influence positively the probability to achieve NBCP (OR 1.23 [0.70–2.16]) but failed to reach statistical significance ($p = 0.476$). Factors positively affecting primary outcome were treatment at BS centre (OR 0.27 [0.15 – 0.49]), absence of plaque at T1 (OR 0.66 [0.51–0.84]) and single-rooted tooth (OR 0.66 [0.51–0.86]) ($p < 0{,}001$). Smoking status did not significantly influence the outcome ($p = 0.701$). For both treatments, the higher the PD at T0, the lower the probability to get NCBP at T1. Test treatment seemed to perform slightly better than control, especially at shallower sites (Fig. 1).

A further analysis investigating the impact of different combinations of treatment, type of tooth and baseline PD on

Table 2 Sites characteristics in treatment and control group— all sites and experimental sites only (PD = 5–9 mm and BoP+)

	Control		Test	
	All sites ($N = 2688$)	Experimental sites (N=1078, 40.1%)	All sites (N=2694)	Experimental sites (N=892, 33.1%)
PD (mm)				
Mean (SD)	4.16 (2.14)	6.04 (1.12)	3.89 (1.97)	5.85 (1.06)
Median (Q1, Q3)	4.00 (2.00, 6.00)	6.00 (5.00, 7.00)	4.00 (2.00, 5.00)	5.00 (5.00, 6.00)
Recession (mm)				
Mean (SD)	0.60 (1.24)	0.66 (1.28)	0.58 (1.16)	0.48 (1.00)
Median (Q1, Q3)	0.00 (0.00, 1.00)	0.00 (0.00, 1.00)	0.00 (0.00, 1.00)	0.00 (0.00, 0.00)
Range		0.00 - 10.00		0.00 - 6.00
CAL (mm)				
Mean (SD)	4.76 (2.51)	6.70 (1.72)	4.47 (2.19)	6.33 (1.49)
Median (Q1, Q3)	4.00 (3.00, 6.00)	6.00 (5.00, 8.00)	4.00 (3.00, 6.00)	6.00 (5.00, 7.00)
Range		5.00 - 19.00		5.00 - 13.00
Plaque				
Yes	81.17%	88.4%	92.53%	98.4%
PD (cat)				
< 5 mm	1548 (57.6%)	-	1736 (64.4%)	-
5–6 mm	783 (29.1%)	763 (70.8%)	707 (26.2%)	679 (76.1%)
7–9 mm	315 (11.7%)	315 (29.2%)	216 (8.0%)	213 (23.9%)
> 9 mm	42 (1.6%)	-	35 (1.3%)	-
Type of tooth				
Monorooted	-	625 (58.0%)	-	508 (57.0%)
Multirooted	-	453 (42.0%)	-	384 (43.0%)

PD probing depth, *BoP* bleeding on probing, *CAL* clinical attachment level

Table 3 Distribution of experimental sites at T1 according to PD (closed/residual pocket) and BoP (+/-)

	CTRL	TEST	OR (CI 95%)	*p value*
Closed pocket BoP- (NBCP)	44.7% *(36.0%; 53.7%)*	47.9% *(38.1%; 57.8%)*	1.14 *(0.66; 1.95)*	0.64
Closed pocket BoP+ (BCP)	32.9% *(26.1%; 40.6%)*	32.1% *(24.9%; 40.2%)*	0.96 *(0.59; 1.56)*	0.87
Residual pocket BoP– (NBRP)	6.9% *(4.1%; 11.2%)*	4.6% *(3.0%; 7.0%)*	0.65 *(0.32; 1.32)*	0.24
Residual pocket BoP+ (BRP)	15.5% *(9.8%; 23.7%)*	15.5% *(10.6%; 22.1%)*	1.00 *(0.50; 1.98)*	1

OR odds ratio

the probability of obtaining NBCP at T1 is shown in Table 5. Test treatment seemed to give a higher probability of pocket closure at sites with initial PD of 5–6 mm at multi-rooted teeth compared with control (56.4 vs 40.8%).

Table 6 shows the comparison of estimated periodontal parameters at T1 adjusted for baseline levels. No significant difference was found between the two treatment groups.

No adverse effects with probable or certain association with experimental treatment were registered during the study or reported by the patients.

Discussion

This study was performed to evaluate the clinical outcome of the adjunctive use of subgingival air polishing with erythritol powder at deep bleeding pockets in the treatment of stages III–IV periodontitis patients.

The periodontal treatment was carried out in both groups via full mouth air polishing, followed by ultrasonic calculus removal and pocket debridement. Full mouth air polishing and ultrasonic pocket debridement can be considered an alternative option to traditional SRP for biofilm and calculus management [3, 4, 7, 11, 20] and are the chosen techniques in the centres where the study took place. The Test and Control groups differed only in the additional application of a subgingival nozzle for air polishing, intending to highlight the possible benefits of this adjunctive measure.

The outcome analysis revolved around the 3-month clinical healing of baseline BoP-positive sites with PD≥ 5mm (experimental sites). The results were comparable in test and control group, failing to prove any significant difference between treatment protocols.

To date, three other clinical trials have investigated the effects of subgingival air polishing during treatment of periodontal disease. However, the difference in study design and the lack of details about the selected experimental sites make comparison difficult. Tsang et al. [14] utilized glycine powder air polishing subsequently to ultrasonic and manual SRP ("within one week"); Park et al. [13] performed supragingival calculus removal first, followed by SRP of all periodontal pockets with Gracey curettes and application of erythritol + chlorhexidine powder in the test group; finally, Caygur et al. [12] applied glycine powder in pockets after manual and ultrasonic SRP. While these studies failed to prove any additional clinical effect over standard SRP, Tsang et al. [14]

Table 4 Patient-level and site-level factors influencing the probability of obtaining Non-Bleeding Closed Pocket (NBCP) at experimental sites at T1

Determinant	Odds Ratio (OR) † (CI 95%)	*p value*
Test/Control	1.23 (0.70–2.16)	0.476
Centre (FE/BS)	0.27 (0.15–0.49)	< 0.001*
PD at baseline (7–9/5–6 mm)	0.30 (0.23–0.40)	< 0.001*
Age (years)	0.99 (0.96–1.02)	0.38
Gender (M/F)	1.53 (0.88–2.67)	0.131
Smoke (yes/no)	0.87 (0.43–1.77)	0.701
Multi/single-rooted	0.66 (0.51–0.86)	0.002*
Plaque (yes/no)	0.66 (0.51–0.84)	0.001*
% Experimental sites at baseline	0.99 (0.97–1.01)	0.504

† OR > 1 indicates an increased probability of NBCP at the numerator, whereas OR < 1 indicates an increased probability of NBCP at the denominator

PD probing depth, *FE* Ferrara, *BS* Brescia

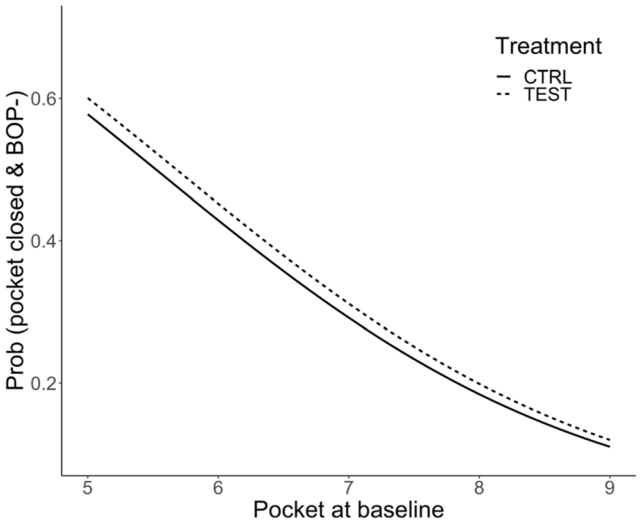

Fig. 1 Probability of obtaining a Non-Bleeding Closed Pocket (NBCP) at T1 at experimental sites per each treatment, based on the initial Probing Depth

observed a reduced volume of crevicular fluid, indicating a lower level of subclinical gingival inflammation, and Park et al. [13] detected a lower relative level of *P. gingivalis*, probably due to the reported antimicrobial effects of the powder [22].

In our study design, the two treatment groups differed only for subgingival air polishing at experimental sites, whereas both groups received full mouth supra- and juxta-gingival air polishing and ultrasonic debridement. In the clinical protocol, the application of subgingival ultrasonic instrumentation is performed as last operative step to avoid the occurrence of air emphysema. Based on our findings, air polishing seems to provide no additional clinical benefit over ultrasonic instrumentation in moderate to deep bleeding pockets. It may be speculated that, although proven effective for dental biofilm removal in both in vitro [4] and clinical [5, 6] studies, the clinical effect of subgingival air polishing (in terms of pocket closure and elimination of periodontal inflammation) could have been masked by the well-established effectiveness of subgingival ultrasonic instrumentation, particularly when performed with thin, dedicated tips [18]. In our study, post-treatment changes in subgingival microbiome were not assessed. A previous study [11] has shown a beneficial shift in the subgingival microflora at 6 months following subgingival air polishing with erythritol powder (EPAP). Whether and to what extent the impact of EPAP on subgingival periopathogens may translate in improved clinical outcomes at observation intervals longer than 3 months needs be fully understood.

Table 5 Probability of probability of obtaining Non-bleeding Closed Pocket (NBCP) at T1 at experimental site based on initial Probing Depth and type of tooth (Single/Multi-rooted)

Treatment	Single/multi-rooted	PD (mm)	Probability (%)
Test	Single	5–6	59.4
	Multi	5–6	56.4
Control	Single	5–6	53.6
	Multi	5–6	40.8
Test	Single	7–9	28.6
	Multi	7–9	19.7
Control	Single	7–9	34.8
	Multi	7–9	17.8

PD probing depth

Both treatments led to pocket closure and elimination of BoP (NBCP) in more than 40% of the experimental sites, plus an additional ~ 32% of sites reaching PD ≤ 4 mm and persistent BoP (BCP) (Table 3). The overall pocket closure, defined by PD reduction to ≤ 4mm regardless of the BoP status (NBCP + BCP), was 80% for test group and 77.6% for control group. These results can be considered positive when compared with the data available in literature. In a study by Wënnstrom et al. [18], 41 patients with chronic periodontitis underwent either full mouth ultrasonic debridement (Fm-UD) or quadrant SRP (Q-SRP). At the 3-month re-evaluation, the percentage of pocket closure for the Q-SRP group was 66. Therefore, the outcome suggests that full mouth air polishing followed by ultrasonic removal of calculus and pocket debridement can be a suitable option for periodontal treatment.

A multilevel analysis showed that a PD of 7–9 mm, location of the pocket at a multi-rooted tooth and presence of plaque at the site reduce the probability of obtaining a NBCP. These findings are in agreement with the results reported by Tomasi et al. [23]. Conversely, in the present study, the smoking status did not seem to affect the outcome negatively. The magnitude of treatment effect in terms of pocket closure observed in both groups may have masked the detrimental effect of smoking on non-surgical treatment of deep pockets as reported in previous [24, 25]. Figure 1 confirms that the probability of obtaining an NBCP is inversely proportional to the baseline PD: the deeper the pocket, the less probable the shift to NBCP, with test protocol performing slightly (but not significantly) better at shallow pockets. A further statistical analysis was performed on single- or multi-rooted with different initial PD. Test protocol seems to increase the chance of obtaining a NBCP at multi-rooted teeth with sites with 5–6 mm PD compared with control (56.4 vs 40.8%). Nevertheless, further clinical trials with larger sample size are required to draw any conclusion.

Possible limitations of the present study are the small sample size and the patients' allocation in the study groups at the beginning of the intervention rather than just before the subgingival treatment.

Table 6 Estimated periodontal parameters at T1. Probing Depth (PD), Clinical Attachment Level (CAL) and Bleeding on Probing (BoP) and Plaque Index (PI) values at T1 were estimated via analysis of covariance (ANCOVA) and adjusted on the mean baseline values

Variable	T0	T1|control	T1|test	Between-treatment effect ratio† (test/control)	*p* value
PD (mm)	5.86	3.24 (2.88 ; 3.65)	3.29 (2.92 ; 3.70)	1.01 (0.86 ; 1.20)	0.875
CAL (mm)	6.35	3.79 (3.36 ; 4.29)	3.73 (3.30 ; 4.21)	0.98 (0.83 ; 1.17)	0.839
BoP (%)	100	48 (37; 60)	47 (35 ; 58)	0.93 (0.48; 1.81)	0.834
PI (%)	86	40 (31 ; 50)	46 (36; 56)	1.25 (0.71; 2.22)	0.439

† OR for BoP, PI

PD, CAL, BoP and PII values at T1 were estimated via analysis of covariance (ANCOVA) adjusted on the mean baseline values. PD and CAL were modelled on a log scale; therefore, between-treatment effect (T1 estimates in TEST compared to T1 estimate in Control) is reported as a ratio. BoP and PII were modelled on logit scale (log odds); therefore estimate is an odds ratio (OR)

Conclusions

The additional application of subgingival air polishing does not seem to provide any significant additional advantage in achieving closure at moderate to deep bleeding pockets during treatment of stages III–IV periodontitis patients.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00784-020-03648-z.

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Compliance with ethical standards

Conflict of Interest M. Mensi reports grants, personal fees and non-financial support from EMS—Electro Medical Systems; E. Scotti reports grants, personal fees and non-financial support from EMS—Electro Medical Systems; A. Sordillo reports personal fees from EMS—Electro Medical Systems; S. Calza declares that he has no conflict of interest; M.E. Guarnelli declares that she has no conflict of interest; C. Fabbri declares that she has no conflict of interest; R. Farina declares that he has no conflict of interest; and L. Trombelli reports grants and non-financial support from EMS—Electro Medical Systems.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the Ethics Committee of the University-Hospital of Brescia (CE: 2971) and the Ethics Committee of Area Vasta Emilia Centrale (protocol number: 83/2018/Disp/Unife) and with the 1964 Helsinki declaration and its later amendments.

Informed consent Informed consent was obtained from all individual participants included in the study.

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