Erythritol powder airflow for the treatment of peri-implant mucositis: a randomized controlled clinical trial

Stefano CORBELLA (1, 2, 3)

Katherine RADAELLI (1, 2)

Alice ALBERTI (1, 2)

Luca FRANCETTI (1, 2)

Silvio TASCHIERI (1, 2, 3)

Affiliations:

1: Dept. Of Biomedical, Surgical and Dental Sciences, Università degli Studi di Milano, Milan, Italy

2: IRCCS Istituto Ortopedico Galeazzi, Milan, Italy

3: Department of Oral Surgery, Institute of Dentistry, I. M. Sechenov First Moscow State Medical University, Moscow, Russian Federation

Corresponding author:

Dr. Stefano CORBELLA, PhD, DDS

IRCCS Istituto Ortopedico Galeazzi, Milan, Italy

Via R. Galeazzi, 4

20161 - Milan

Italy

Phone: +39 02 50319950 Fax: +39 02 50319960

E-mail: stefano.corbella@unimi.it

Author contributions: SC: conceptualization, methodology, formal analysis, investigation, Writing – original draft preparation, project administration; KR: conceptualization, formal analysis, investigation, data curation, Writing – original draft preparation; AA: conceptualization, formal analysis, investigation, data curation, Writing – review and editing; LF: conceptualization, methodology, investigation, Writing – review and editing, supervision, project administration, funding acquisition; ST: conceptualization, methodology, investigation, Writing – review and editing, supervision, project administration, funding acquisition.

Funding statement

The materials for the research, namely AIR-FLOW PROPHYLAXIS MASTER device, AIR-FLOW Erythritol powder (AF PLUS powder), AIR-FLOW handpiece, PERIO-FLOW handpiece, were provided by EMS, Switzerland.

Conflict of interest

The authors declare no conflict of interest.

Abstract

Objectives. Peri-implant mucositis is a biofilm-related, reversible inflammatory disease, which can evolve in peri-implantitis if not adequately treated. The aim of the present randomized controlled clinical trial was to evaluate the efficacy of air-abrasive powder as compared to chlorhexidine (CHX) for the treatment of peri-implant mucositis, in terms of clinical and patient-reported outcomes (PROMs) and occurrence of peri-implantitis up to 12 months after treatment.

Methods. In the control group, full-mouth calculus and plaque removal was performed with ultrasound and manual devices, and a 1.0% CHX gel was applied; in the test group, supra- and subgingival biofilm removal was performed using erythritol powder with a dedicated nozzle and calculus removal was performed with ultrasonic instruments if needed. Bleeding and plaque indexes, peri-implant probing depth and tissue level were measured at 1 week, one, three, six and 12 months after treatment, while PROMs were evaluated up to 7 days after treatment.

Results. Among 80 included implants, 70 were analyzed at 12 months follow-up (30 in the test group, 40 in the control group, 20 subjects). Success rates (implant-level) in terms of bleeding index were significantly different between test (96.7%) and control group (92.5%); as for PROMs, only taste sensation was significantly better in the test group. The test group was significantly correlated to smallest changes of peri-implant probing depth between baseline and three months.

Conclusions. The study showed that both treatment strategies are effective. This suggests that the use of air-abrasive powders could be used as an alternative biofilm removal method instead of adjunctive treatments with antiseptics.

Keywords

Air-polishing, dental implants, erythritol powder, mechanical plaque control, peri-implant mucositis, peri-implantitis.

Introduction

Peri-implant mucositis is a clinical condition affecting the peri-implant soft tissues whose diagnosis requires the presence of bleeding and / or suppuration after gentle probing with or without an increase in probing depth as compared to previous measurements, and no radiographic signs of crestal bone changes apart that ascribable to initial bone remodeling[1]. If not adequately treated, peri-implant mucositis could evolve in peri-implantitis, thus causing peri-implant bone resorption, implant mobility and, in the end, implant loss[2].

Peri-implant mucositis is a highly prevalent disease. One recently published systematic review of the literature that considered the prevalence of peri-implant mucositis in full-arch implant-supported rehabilitations, reported a prevalence of 57% patient level and 47% implant level in fully edentulous patients, while its prevalence among patients having at least one edentulous varied from 0 to 13.7% patient level, and from 0 to 20% implant level, with relative variability among the included studies[3]. A high heterogeneity among the included studies was found also by Lee and coworkers in their systematic review published in 2017[4]. Considering all type of implant-supported rehabilitations, the authors found a 29.48% implant level and 46.83% patient level prevalence of peri-implant mucositis[4]. The results of the paper by Lee substantially confirmed the ones considered in other previously published systematic reviews on similar topic[5,6].

Bacterial biofilm is the most relevant etiologic factor for peri-implant mucositis, being the main cause of peri-implant tissue inflammation [7]. The prevention of plaque accumulation at implant level could be obtained by proper oral hygiene practices and by an effective supportive care protocol, which consists of regular clinical examination, radiographic evaluation, oral hygiene instructions, professional plaque control, and mechanical debridement, and it was demonstrated to reduce the risk of development of peri-implant mucositis[8]. Considering the role of bacterial biofilm in the development of peri-implant mucositis, all the treatment strategies were based on the need of removal such biofilm from the implant and prosthetic surfaces, preserving the soft tissues. Indeed, after adequate nonsurgical treatment, peri-implant mucositis could be considered a reversible condition[9]. Several treatment options were proposed and studied for the treatment of peri-implant mucositis, such as the use of air abrasive powders[10,11], antiseptics[12], antibiotics[13], lasers and photodynamic therapy[14,15], and probiotics[16]. Despite the results of a recent meta-analysis[17] did not support fully the use of adjunctive measures to the ‘standard’ treatment of peri-implant mucositis, the application of such measures could have an effect also on the stability of the peri-implant soft tissue over time and on the durability of the results. Moreover, in most studies, patient reported outcomes were not considered.

Differently from the other studies performed on this topic, in the present protocol we used erythritol powder, which has low granulometry, while maintaining the biofilm removal and anti-microbial activity [18].

Therefore, the aim of the present study was to determine whether the application of a biofilm removal treatment strategy (by using air-abrasive powder) for peri-implant mucositis could lead to significantly improved clinical parameters as compared to standard antiseptic treatment.

Materials and methods

Trial design and ethical considerations

The present study was conducted following a predetermined research protocol (Clinicaltrials.gov registration number NCT03915665) that was approved by the Ethics Committee of the IRCCS Istituto San Raffaele in 2018, before the beginning of the recruitment (133/int/2018). The research was performed in accordance with the recommendations of the Helsinki Declaration on human studies[19] and the results are here presented in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines[20].

The present was a randomized controlled clinical trial on human subjects, with an allocation ratio between control and test group of 1:1. The allocation sequence was computer-generated and given to an external operator, who communicated group allocation after participants recruitment.

Participants

For the purposes of the study, the following inclusion criteria were applied:

(I) Subjects should have at least one implant with bleeding on probing or spontaneous bleeding with local swelling (code 1, 2 or 3 as described in Corbella et al. 2011[21]); (II) and with bone resorption of no more than 1 mm (preferably no bone loss visible on radiographs) as evaluated through the use of standardized radiographs, taken with the use of an individualized radiograph holder in comparison with findings from radiographs taken immediately following placement of the implant prosthesis (similar to Renvert et al. 2009[22]); (III) full mouth bleeding score % lower than 20%.

The exclusion criteria were:

(I) systemic diseases that could affect the immune response or that could condition the bacterial colonization (II) use of anti-inflammatory prescription medications, or antibiotics within the preceding respectively 1 week and 3 months or during the study, (III) full-mouth plaque score (FMPS) >20%; (IV) full-mouth bleeding score (FMBS) >20%, (V) smokers of more than 5 cigarettes a day, (VI) documented allergy or intolerance towards the components of the products used in the study, (VII) presence of active infection with suppuration, (VIII) absence of diagnosis of periodontitis, (IX) pregnancy (certified by auto-declaration), (X) patients suffering from upper respiratory tract infections, from chronic bronchitis, (XI) endocarditis, breast feeding, contagious

disease, immune deficiency (neutropenia, angranulocytosis, diabetes, hemophilia), patients under treatment (radiotherapy, chemotherapy, antibiotics).

The subjects were all recruited among those attending the Dental Clinic of the IRCCS Istituto Ortopedico Galeazzi in Milan, Italy between 2018 and 2020, and the data were collected and analyzed in the same location.

Interventions

During the baseline visit all subjects were checked for inclusion based on the above-mentioned criteria. After the initial checking and signing the informed consent form, a full-mouth clinical evaluation was performed, and medical history collected. Considering only the included implants, one operator performed a periapical radiograph and collected baseline clinical data. The patients were then randomized in two groups (control and test), following the methods described in the paragraph below.

In the control group, an operator provided personalized oral hygiene instruction, together with full-mouth supra- and submucosal calculus and plaque removal from teeth and implant surfaces using dedicated ultrasonic and manual instruments (Hu-Friedy, Titanium Implant Scalers, Implacare II curettes, Chicago, IL)[22,23], and polishing[22,23]. After that, a gel containing CHX 1.0% (Corsodyl gel, GSK, London, England) was applied in the sulcus and circumferentially in the site affected after the professional oral hygiene phase[24]. The patients were then instructed not to wash or drink for at least 5 minutes after the CHX gel application.

In the test group, the same operator, trained specifically for the use of the tested devices, provided individual oral hygiene instructions including re-education and motivation if needed. Then, full-mouth biofilm and calculus removal was performed using AIR-FLOW PROPHYLAXIS MASTER device from EMS, Switzerland, following the protocol described here:

(I) Full mouth biofilm removal:

(a) Supragingival biofilm removal using AIR-FLOW Erythritol powder (AF PLUS powder, AIR-FLOW handpiece, AIR-FLOW PROPHYLAXIS MASTER device from EMS, Switzerland). Device is to be used as per recommendations: power set at 30-60% and water set at maximum.

(b) Depending on probing depth, sub gingival biofilm removal using AIR-FLOW Erythritol powder (AF PLUS powder, AIR-FLOW handpiece (up to depth of 3-4 mm, PERIO-FLOW nozzle, PERIO-FLOW Handpiece for probing depth more than 4 mm, AIR-FLOW PROPHYLAXIS MASTER device from EMS, Switzerland). Device is to be used as per recommendations: power set at 30-60% and water set at maximum. The PERIO-FLOW handpiece should be used in a vertical direction with intermittent repetitive movements towards the

occlusal or incisal surface. The instrumentation time at each aspect (i.e. mesial, distal, vestibular, and oral) was limited to 5 s per site (four to six sites per implant), as recommended by the manufacturer.

(II) Full mouth calculus removal: supra and sub-gingival calculus removal around teeth using PS instrument (EMS, Switzerland), around implants using PI (EMS, Switzerland). The device was AIR-FLOW PROPHYLAXIS MASTER (EMS, Switzerland) set at 30-60% power and maximum water for both tips.

Outcomes

The main outcome of the study was to evaluate the difference in bleeding index (BI) as a clinical parameter of inflammation between the two groups after 3 months of treatment. The secondary outcomes were the changes of other clinical parameters from baseline, namely: peri-implant probing depth (PPD) changes, tissue level (TL) changes, BI changes in follow-up visits other than the 3-month visit, plaque index (PI) changes. Moreover, the occurrence of peri-implantitis in the included implants, the occurrence of adverse events, and patient-reported outcomes (PROMs) after the treatment were evaluated.

The clinical parameters were defined as follows:

(I) PPD as the distance between the mucosal margin and the most apical extent of the peri-implant pocket (II) TL, measured as the distance between a reference point on an occlusal personalized stent, made with vinyl polysiloxane impression material, and the mucosal margin (III) BI and (IV) PI measured as described in Corbella et al. 2011[21], (BI: 0) no bleeding; 1) bleeding on probing without redness and swelling; 2) bleeding on probing, redness and swelling; and 3) spontaneous bleeding; PI: 0) no plaque accumulation; 1) plaque accumulation only detectable using a probe; 2) moderate accumulation of visible plaque/ calculus; 3) high accumulation of visible plaque/calculus.)

All measurements were performed at six aspects per implant: mesiovestibular (mv), midvestibular (v), distovestibular (dv), mesio-oral (mo), midoral (o) and disto-oral (do) by one blinded operator with a periodontal probe (Hu-Friedy, Colorvue UNC15 Oxford, Chicago, IL). The investigator was previously calibrated with a specific force-controlled probe.

Regarding the PROMs, the following evaluations were made immediately after the intervention and in each of the seven days after the treatment: (I) Pain perception measured with a 10-cm long VAS scale being 0 equal to no pain; (II) limitation in daily activity measured with a 10-cm long VAS scale being 0 equal to no limitation; (III) taste alteration measured with a 10-cm long VAS scale being 0 equal to no alteration; (IV) taste sensation measured with a 10-cm long VAS scale being 0 equal to good taste.

Fourteen days after the treatment, during the visit, patients were asked if they would repeat the treatment if required, asking them to respond dichotomously yes or no. The follow-up visits were planned and performed after 1, 3, 6, and 12 months from the treatment.

Sample size

The study was planned to detect a difference between groups in terms of proportion of implants showing bleeding in the site of intervention of 20% in the 3-month follow-up visit. The value was chosen based on authors' judgement, to identify a clinically significant difference between the two groups. The minimum number of implants for each group was calculated to be 32. The number was increased of 25% for dropouts. A total of 80 implants were included.

Randomization

Block randomization was performed by one external operator by means of computer-generated tables and the allocation sequence was masked to the operators before the treatment session.

Blinding

Both the operator that measured the clinical parameters and the statistician were not aware of the allocation.

Statistical methods

Descriptive statistics was performed in terms of mean and standard deviations for continuous variables.

The Shapiro-Wilk test was applied to test normality of distributions of primary and secondary outcome variables. Differences between group for normally distributed variables was tested by means of Student's t test. Mann-Whitney test was used to test differences between group for non-normally distributed continuous variables. Moreover, a regression analysis was performed to detect factors affecting the outcome. Intention-to-treat analysis was performed accounting from dropouts.

The significance was posed to $P<0.05$.

Results

A total of 80 implants were included in the study, 40 for each group. In the study we included 3.5 implants per patient on average. The flowchart of patients' recruitment, treatment and analysis is presented in Figure 1. Ten implants in the test group did not reach the 3 months follow-up for the following reasons: six implants belonging

to one subject because the patient moved away in another country, three belonging to one patient that refused to attend the follow-up visits, one in one patient because he failed to attend the second visit (i.e., 14 days after the treatment).

Table 1 presents the characteristics of the analyzed implants at baseline. Overall, the general level of oral hygiene was good and remained stable over time being FMPS% less or equal than 20% in all follow-up visits. The clinical results are represented in Table 2: a statistically significant difference was present in terms of PPD values between groups throughout the study, but without any significant difference in PPD changes from baseline between groups. Changes of PI showed a significant difference between test and control group only one year after non-surgical treatment. BI mean scores over time are presented in online appendix 1; considering the primary outcome, that is BI at 3 months, in the test group all the implants but one out of 30 (one patient out of eight) showed complete healing of the peri-implant tissues (96.7% success rate implant-level, 87.5% patient-level), while in the control group three implants out of 40 (two patients out of 12) presented still signs of peri-implant mucositis (92.5% implant-level, 83.3% patient-level) and the difference is statistically significant.

BI decreased significantly in both groups from baseline after 3 months ($P<0.05$). There is no evidence of a statistical difference between mean PI levels at 3 months as compared to baseline.

About PROMS, pain sensation was extremely low in both groups (online appendix 2), without any significant difference between test and control (Table 3); the taste sensation was significantly better in the test group than in control one during every follow-up except day 7, although, generally, the size of the effect was small for both groups (online appendix 3). The other parameters (limitation in daily activities and taste alteration) resulted to be not affected by the allocated treatment.

No adverse events were recorded.

A multilevel linear regression analysis found no effect of group allocation on the primary outcome, whilst the decrease of BI between baseline and 3 months visit was strictly correlated to baseline BI value. Moreover, belonging to test group is significantly correlated to smallest changes of PPD between baseline and three months.

Discussion

The study here presented found that both the treatment strategies (standard approach with the use of antiseptic gel and use of air-abrasive powders) are effective for treating peri-implant mucositis, leading to complete healing, considered as the absence of bleeding on probing at implant sites, after 3 months from the

treatment in most of the cases in both groups. Focusing on the differences between test and control group, a higher percentage of implants showed healing of the peri-implant soft tissues in the test group as compared to control one and, in general, PROMs were substantially the same, although a positive taste sensation was associated to test treatment. The difference in PPD at baseline between the two groups did not influence the outcomes over time and, in any case, it does not represent the presence of a site with pathological probing depth since none of the sites presented peri-implantitis.

To understand the validity of the results of the study they should be read in the light of the existing literature on the topic. First, the control group was treated with a standard non-surgical treatment protocol including the use of chlorhexidine for the decontamination of the implant site, based on scientific evidence that a certain adjunctive effect may be exerted by antiseptics. In fact, a recent systematic review confirmed significant better clinical results of adjunctive chemical approaches for implant surface decontamination, as compared to sub-marginal instrumentation alone in the non-surgical treatment of peri-implantitis [25]. Moreover, the meta-analysis by Ramanauskaite et al. [17] investigated the adjunctive effect of local antiseptics specifically for the non-surgical treatment of peri-mucositis, finding a beneficial effect in terms of PD. The same systematic review of the literature [17] included three studies about the use of air-polishing devices with glycine powder[10,11,26]. The results of the meta-analysis, performed on just two studies, did not show statistically significant adjunctive effect of the use of abrasive powder, in terms of clinical outcomes, as compared to standard mechanical debridement. However, analyzing the results in more details, in the paper published in 2015 by our research group[11] the clinical results associated to the use of glycine powder were significantly better than the control group that, differently from the present study, was treated only with professional oral hygiene, without the adjunct of chlorhexidine gel. In this perspective, the use of abrasive powder as an alternative biofilm removal method could limit the need of further antiseptic agents use. Moreover, some authors found a superior effect even as compared to chlorhexidine 0.1% irrigation for the maintenance of peri-implant health status [27]. It must be highlighted that the heterogeneity of the results reported in literature may vary also because of the application of different definitions of peri-mucositis for case selection and inclusion.

It must be noticed that the possibility of removing bacterial biofilm from implant-supported prosthesis could also depend on the characteristics of the prosthesis itself [28-30]. However, the use of air-polishing devices could help in particularly complex situation, when the characteristics of the prosthesis provide a limitation to the possibility of accessing the peri-implant tissues, without removing the prosthesis itself [31]. Moreover, in subjects with full-arch implant-supported rehabilitations, it was found that the use of air polishing led to significantly lower level of discomfort and better clinical outcomes over time, as compared to hand instrumentation alone

[32]. In the present study the sample size was not sufficient to evaluate the effect of implant / prosthesis characteristics on the outcomes, but, based on the existing literature, we can assume that they have a role. The present study included mostly implants belonging to fixed partial dentures (mostly cemented) and a lower number of implants being support of full-arch fixed restoration. Since the characteristics of the prosthetic design may influence the accessibility for cleansing, this aspect should be further explored in clinical studies.

The medium term (1 year) stability of the results confirmed the reversibility of the disease and the correctness of the maintenance protocol. It is known that an effective oral hygiene and maintenance protocol is very important to preserve peri-implant soft tissue health over time, reducing the occurrence of peri-implant mucositis and peri-implantitis [21,30]. Once obtained the resolution of the disease, the importance of the maintenance protocol is paramount, since one-year results are mostly related to the maintenance protocol than on the treatment performed at baseline [33].

In the present study PROMs were analytically examined. In general, partially in contrast with what found by Menini and coworkers [32], the subjects appreciated both treatments, without any significant difference between groups regarding pain values, and most cases reported no pain during or after the treatment. Interestingly taste sensation was slightly better in test group, but the effect size is too small to make any inference on this data.

Although no significant advantage of using test treatment versus control one was found, it can be highlighted that, in scientific literature, air flow showed beneficial effect on soft tissue stability as compared to other treatment options, also favoring the surgical intervention in cases of peri-implantitis [34]. Although this aspect is not perfectly appliable to the aims of the present investigation, the findings related to soft tissue stability after treatment with abrasive powders should be explored more.

The findings of the studies should be evaluated considering the limitations of the study, that may affect the validity of the results. First, the number of implants in the test group available for final analysis was lower than control group because of the ten dropouts, and this aspect lowered the statistical power of the analysis. However, an intention-to-treat analysis was performed to consider this aspect, limiting the risk of bias. Then, initial disease evaluation as performed also by using periapical radiographs that may be subject to a certain extent of distortion of the images. Another limitation could be the fact that multiple implants of the same subject were included, which could reduce the external validity of the results. However, multilevel analysis served to take in account the (random) factor, related to patients' variability. Finally, two aspects that can affect the hygienic maintenance around implants were not considered, namely the prosthetic characteristics and the peri-implant soft tissue phenotype, which include keratinized mucosa width, mucosal thickness, and supracrestal

tissue height. As for peri-implant phenotype, recent literature confirmed that an inadequate keratinized mucosa width is associated with local discomfort upon oral hygiene performance, increasing the risk of peri-implant diseases [35]. Even though we analyzed the presence of plaque, which was reported recently to influence bleeding on probing regardless of brushing discomfort in implant sites with reduced keratinized mucosa[36], it would be interesting to evaluate the effect of phenotype on the clinical success of non-surgical treatment of peri-implant mucositis. Prosthetic characteristics were also not considered, as discussed before, but the same was done in other published studies with the same topic, and this issue provided a partial confirmation that the treatments are effective in all the prosthetic configurations.

Conclusion

The results of our study revealed that both test and control treatments were effective for the treatment of peri-implant mucositis, although a small advantage in the proportion of healed implants could be found in the test group. This suggests that the use of air-abrasive powders could be used as an alternative biofilm removal method instead of adjunctive treatments with antiseptics.

Clinical relevance

Scientific rationale for study: The aim of the study was to investigate the efficacy of air-abrasive powders for biofilm removal, together with ultrasonic instruments, as a strategy for the early treatment of peri-implant mucositis.

Principal findings: The tested treatment was proven to be as effective as antiseptic treatment with CHX gel in the present study, with a slightly higher success rate in terms of bleeding.

Practical implications: This treatment strategy may provide similar clinical outcomes as compared to the use of antiseptics such as CHX gel, and it may be useful in complex situations when the characteristics of the prosthesis limit the access to the peri-implant tissues.

References

1. Berglundh T, Armitage G, Araujo MG, et al. Peri-implant diseases and conditions: Consensus report of workgroup 4 of the 2017 World Workshop on the Classification of Periodontal and Peri-Implant Diseases and Conditions. *J Clin Periodontol.* 2018;45 Suppl 20:S286-S291.
2. Schwarz F, Derks J, Monje A, Wang HL. Peri-implantitis. *J Clin Periodontol.* 2018;45 Suppl 20:S246-S266.
3. Ramanauskaite A, Galarraga-Vinueza ME, Obreja K, Sader R, Schwarz F. Prevalence of Peri-implant Diseases in Patients with Full-Arch Implant-Supported Restorations: A Systematic Review. *Int J Prosthodont.* 2021;34:s27-s45.
4. Lee CT, Huang YW, Zhu L, Weltman R. Prevalences of peri-implantitis and peri-implant mucositis: systematic review and meta-analysis. *J Dent.* 2017;62:1-12.
5. Derks J, Tomasi C. Peri-implant health and disease. A systematic review of current epidemiology. *J Clin Periodontol.* 2015;42 Suppl 16:S158-171.
6. Atieh MA, Alsabeeha NH, Faggion CM, Jr., Duncan WJ. The frequency of peri-implant diseases: a systematic review and meta-analysis. *J Periodontol.* 2013;84(11):1586-1598.
7. Renvert S, Polyzois I. Risk indicators for peri-implant mucositis: a systematic literature review. *J Clin Periodontol.* 2015;42 Suppl 16:S172-186.
8. Lin CY, Chen Z, Pan WL, Wang HL. The effect of supportive care in preventing peri-implant diseases and implant loss: A systematic review and meta-analysis. *Clin Oral Implants Res.* 2019;30(8):714-724.
9. Salvi GE, Aglietta M, Eick S, Sculean A, Lang NP, Ramseier CA. Reversibility of experimental peri-implant mucositis compared with experimental gingivitis in humans. *Clin Oral Implants Res.* 2012;23(2):182-190.
10. Ji YJ, Tang ZH, Wang R, Cao J, Cao CF, Jin LJ. Effect of glycine powder air-polishing as an adjunct in the treatment of peri-implant mucositis: a pilot clinical trial. *Clin Oral Implants Res.* 2014;25(6):683-689.
11. De Siena F, Corbella S, Taschieri S, Del Fabbro M, Francetti L. Adjunctive glycine powder air-polishing for the treatment of peri-implant mucositis: an observational clinical trial. *Int J Dent Hyg.* 2015;13(3):170-176.

12. Menezes KM, Fernandes-Costa AN, Silva-Neto RD, Calderon PS, Gurgel BC. Efficacy of 0.12% Chlorhexidine Gluconate for Non-Surgical Treatment of Peri-Implant Mucositis. *J Periodontol.* 2016;87(11):1305-1313.
13. Hallstrom H, Persson GR, Lindgren S, Olofsson M, Renvert S. Systemic antibiotics and debridement of peri-implant mucositis. A randomized clinical trial. *J Clin Periodontol.* 2012;39(6):574-581.
14. Aimetti M, Mariani GM, Ferrarotti F, Ercoli E, Liu CC, Romano F. Adjunctive efficacy of diode laser in the treatment of peri-implant mucositis with mechanical therapy: A randomized clinical trial. *Clin Oral Implants Res.* 2019;30(5):429-438.
15. Deeb MA, Alsahhaf A, Mubaraki SA, Alhamoudi N, Al-Aali KA, Abduljabbar T. Clinical and microbiological outcomes of photodynamic and systemic antimicrobial therapy in smokers with peri-implant inflammation. *Photodiagnosis Photodyn Ther.* 2020;29:101587.
16. Galofre M, Palao D, Vicario M, Nart J, Violant D. Clinical and microbiological evaluation of the effect of Lactobacillus reuteri in the treatment of mucositis and peri-implantitis: A triple-blind randomized clinical trial. *J Periodontal Res.* 2018;53(3):378-390.
17. Ramanauskaite A, Fretwurst T, Schwarz F. Efficacy of alternative or adjunctive measures to conventional non-surgical and surgical treatment of peri-implant mucositis and peri-implantitis: a systematic review and meta-analysis. *Int J Implant Dent.* 2021;7(1):112.
18. Drago L, Del Fabbro M, Bortolin M, Vassena C, De Vecchi E, Taschieri S. Biofilm Removal and Antimicrobial Activity of Two Different Air-Polishing Powders: An In Vitro Study. *J Periodontol.* 2014;85(11):e363-e369.
19. World Medical Association. Declaration of Helsinki. *Jama.* 2013;310(20).
20. Schulz KF, Altman DG, Moher D, Group C. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. *PLoS Med.* 2010;7(3):e1000251.
21. Corbella S, Del Fabbro M, Taschieri S, De Siena F, Francetti L. Clinical evaluation of an implant maintenance protocol for the prevention of peri-implant diseases in patients treated with immediately loaded full-arch rehabilitations. *Int J Dent Hyg.* 2011;9(3):216-222.
22. Renvert S, Samuelsson E, Lindahl C, Persson GR. Mechanical non-surgical treatment of peri-implantitis: a double-blind randomized longitudinal clinical study. I: clinical results. *J Clin Periodontol.* 2009;36(7):604-609.

23. Persson GR, Samuelsson E, Lindahl C, Renvert S. Mechanical non-surgical treatment of peri-implantitis: a single-blinded randomized longitudinal clinical study. II. Microbiological results. *J Clin Periodontol.* 2010;37(6):563-573.
24. Mombelli A, Lang NP. The diagnosis and treatment of peri-implantitis. *Periodontol 2000.* 1998;17(1):63-76.
25. de Waal YCM, Winning L, Stavropoulos A, Polyzois I. Efficacy of chemical approaches for implant surface decontamination in conjunction with sub-marginal instrumentation, in the non-surgical treatment of peri-implantitis: A systematic review. *J Clin Periodontol.* 2022.
26. Riben-Grundstrom C, Norderyd O, Andre U, Renvert S. Treatment of peri-implant mucositis using a glycine powder air-polishing or ultrasonic device: a randomized clinical trial. *J Clin Periodontol.* 2015;42(5):462-469.
27. Lupi SM, Granati M, Butera A, Collesano V, Rodriguez YBR. Air-abrasive debridement with glycine powder versus manual debridement and chlorhexidine administration for the maintenance of peri-implant health status: a six-month randomized clinical trial. *Int J Dent Hyg.* 2017;15(4):287-294.
28. Yi Y, Koo KT, Schwarz F, Ben Amara H, Heo SJ. Association of prosthetic features and peri-implantitis: A cross-sectional study. *J Clin Periodontol.* 2020;47(3):392-403.
29. Serino G, Hultin K. Periimplant Disease and Prosthetic Risk Indicators: A Literature Review. *Implant Dent.* 2019;28(2):125-137.
30. Serino G, Strom C. Peri-implantitis in partially edentulous patients: association with inadequate plaque control. *Clin Oral Implants Res.* 2009;20(2):169-174.
31. Menini M, Delucchi F, Bagnasco F, Pera F, Di Tullio N, Pesce P. Efficacy of air-polishing devices without removal of implant-supported full-arch prostheses. *Int J Oral Implantol (Berl).* 2021;14(4):401-416.
32. Menini M, Setti P, Dellepiane E, Zunino P, Pera P, Pesce P. Comparison of biofilm removal using glycine air polishing versus sodium bicarbonate air polishing or hand instrumentation on full-arch fixed implant rehabilitations: a split-mouth study. *Quintessence Int.* 2019;50(9):722-730.
33. Schwarz F, Alcoforado G, Guerrero A, et al. Peri-implantitis: Summary and consensus statements of group 3. The 6th EAO Consensus Conference 2021. *Clin Oral Implants Res.* 2021;32 Suppl 21:245-253.

34. Atieh MA, Almatrooshi A, Shah M, Hannawi H, Tawse-Smith A, Alsabeeha NHM. Airflow for initial nonsurgical treatment of peri-implantitis: A systematic review and meta-analysis. *Clin Implant Dent Relat Res.* 2022.

35. Monje A, González-Martín O, Ávila-Ortiz G. Impact of peri-implant soft tissue characteristics on health and esthetics. *Journal of Esthetic and Restorative Dentistry.* 2023;35(1):183-196.

36. Perussolo J, Matarazzo F, Dias DR, Oliveira Ricardo P, Araújo MG. The effect of brushing discomfort on peri-implant health in sites exhibiting inadequate keratinized mucosa width: A cross-sectional study. *Clin Oral Implants Res.* 2022;33(12):1212-1223.

Tables

Table 1. Characteristics of the analyzed sample at baseline.

	Test group	Control group	Total	Diff T vs C
Subjects	8	12	20	NS
History of periodontal disease (number of subjects)	3 / 7 History of periodontitis 1 not assessable	3 / 10 History of periodontitis 2 not assessable	6 / 17 History of periodontitis 3 not assessable	-
Implants	30	40	70	NS
Mandibular / maxillary	14 / 16	22 / 18	36 / 34	NS
M/F	5/3	5/7	10/10	NS
Mean age at treatment visit	72	67	69,5	NS
Type of prosthetic restoration (number of implants)	Single-tooth: 3 Fixed partial dentures: 20 Full-arch restorations: 7	Single-tooth: 6 Fixed partial dentures: 30 Full-arch restorations: 4	Single-tooth: 9 Fixed partial dentures: 50 Full-arch restorations: 11	NS
Retention (number of implants)	Screwed: 9 Cemented: 21	Screwed: 10 Cemented: 30	Screwed: 19 Cemented: 51	NS
PPD (Vm ± SD)	2.61 ± 0.69	3.38 ± 0.68	3.05 ± 0.78	< 0.001
TL (Vm ± SD)	0.02 ± 0.12	0.23 ± 0.79	0.14 ± 0.61	NS
BI (Vm ± SD)	0.67 ± 0.55	0.74 ± 0.63	0.71 ± 0.59	NS
PI (Vm ± SD)	0.69 ± 0.78	0.53 ± 0.53	0.60 ± 0.65	NS

BI: bleeding index, C: control, F: female, M: male, PI: plaque index, PPD: probing pocket depth, T: test, TL: tissue level.

Table 2. Clinical results. Differences are calculated between the follow-up and baseline (Table 1). A negative value represents a decrease over time. Highlighted cells represent a statistically significant difference between test and control group, and p values are indicated for each parameter as follows: A <0.0001; B <0.0001; C <0.0001; D =<0.0001; E = 0.001; F = 0.040; G = 0.019; H = 0.009; I = 0.013.

		1 week	1 month	3 months	6 months	1 year
PPD (mm)	*test*	2.36 ± 0.63	2.31 ± 0.74	2.39 ± 0.78	2.21 ± 0.60	2.24 ± 0.59
	ctrl	3.40 ± 0.59 [A]	3.18 ± 0.71 [B]	3.40 ± 0.65 [C]	2.92 ± 0.75 [D]	2.83 ± 0.79 [E]
Δ PPD (mm)	*test*	-0.24 ± 0.53	-0.42 ± 0.48	-0.22 ± 0.55	-0.25 ± 0.57	-0.36 ± 0.64
	ctrl	-0.10 ± 0.55	-0.16 ± 0.58	-0.11 ± 0.68	-0.38 ± 0.72	-0.51 ± 0.74
TL (mm)	*test*	0.01 ± 0.06	0.08 ± 0.23	0.17 ± 0.72	0.09 ± 0.24	0.04 ± 0.15
	ctrl	0.22 ± 0.65	0.21 ± 0.69	0.28 ± 0.92	0.17 ± 0.29	0.22 ± 0.75
Δ TL (mm)	*test*	-0.01 ± 0.14	0.05 ± 0.28	0.15 ± 0.73	0.09 ± 0.25	0.02 ± 0.20
	ctrl	0.01 ± 0.28	0.02 ± 0.28	0.03 ± 0.18	0.12 ± 0.27	0.02 ± 0.18
BI	*test*	0.46 ± 0.31	0.29 ± 0.31	0.44 ± 0.38	0.50 ± 0.62	0.34 ± 0.37
	ctrl	0.46 ± 0.44	0.42 ± 0.43	0.37 ± 0.32	0.27 ± 0.28	0.45 ± 0.43
Δ BI	*test*	-0.21 ± 0.60	-0.45 ± 0.59	-0.22 ± 0.66	0.02 ± 0.78	-0.32 ± 0.71
	ctrl	-0.31 ± 0.59	-0.29 ± 0.57	-0.33 ± 0.68	-0.42 ± 0.57 [F]	-0.26 ± 0.66
PI	*test*	0.48 ± 0.49	0.30 ± 0.34	0.41 ± 0.53	0.82 ± 0.71	0.41 ± 0.40
	ctrl	0.56 ± 0.52	0.56 ± 0.52 [G]	0.54 ± 0.69	0.52 ± 0.58	0.71 ± 0.54 [H]
Δ PI	*test*	-0.21 ± 0.85	-0.23 ± 0.75	-0.28 ± 0.69	0.06 ± 0.62	-0.28 ± 0.81
	ctrl	-0.05 ± 0.73	0.03 ± 0.61	-0.03 ± 0.70	0.14 ± 0.65	0.18 ± 0.62 [I]

BI: bleeding index, ctrl: control, PI: plaque index, PPD: probing pocket depth, TL: tissue level.

Table 3. Results of patient-reported outcomes. Highlighted cells represent a statistically significant difference between test and control group.

		Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Pain (mean ± SD)	*test*	0.33 ± 0.80	0.28 ± 0.78	0.28 +- 0.78	0.20 ±0.55	0.21 ± 0.56	0.20 ±0.55	0.17 ± 0.53
	ctrl	0.19 ± 0.75	0.81 ± 0.37	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00
Daily activities impairment (mean ± SD)	*test*	0.27 ± 0.79	0.20 ±0.55	0.20 ±0.55	0.13 ± 0.35	0.13 ± 0.35	0.13 ± 0.35	0.10 ± 0.31
	ctrl	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00
Taste alteration (mean ± SD)	*test*	0.22 ± 0.55	0.20 ± 0.55	0.20 ± 0.55	0.13 ± 0.35	0.13 ± 0.35	0.13 ± 0.35	0.10 ± 0.31
	ctrl	0.52 ± 1.36	0.53 ± 1.38	0.39 ± 1.02	0.26 ± 0.68	0.06 ± 0.36	0.00 ± 0.00	0.00 ± 0.00
Taste sensation (mean ± SD)	*test*	0.35 ± 0.88	0.33 ± 0.88	0.33 ± 0.88	0.13 ± 0.35	0.13 ± 0.35	0.13 ± 0.35	0.10 ± 0.31
	ctrl	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00

Figure

Figure 1. Patients' flow diagram.