

Comparison of different maintenance strategies within supportive implant therapy for prevention of peri-implant inflammation during the first year after implant restoration. A randomized, dental hygiene practice-based multicenter study

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ABSTRACT: Purpose: This randomized clinical multicenter study compared different professional preventive approaches on peri-implant inflammation under supportive implant therapy (SIT). **Methods:** 105 participants (167 implants) were randomly allocated to four groups. All participants were under SIT with a 3-month recall interval. Plaque removal was performed by using manual curettes, a sonic-driven scaler, and a prophylaxis brush (Group A), supplemented by chlorhexidine (CHX) varnish on the implant surfaces (Group C) or by using manual curettes, air polishing with glycine powder, and a prophylaxis brush (Group B), supplemented by treatment with CHX varnish on the implant surfaces (Group D). The peri-implant probing depths (PPD), mucosal recession (MR), and bleeding on probing (BOP) on implants were determined at baseline. After 12 months, the final PPD, MR, and BOP on implants were assessed. The statistical evaluation consisted of Kruskal-Wallis-test, Wilcoxon-test and Chi-squared test modified according to McNemar ($P < 0.05$). **Results:** 62 subjects ($n = 101$ implants) were available for assessment. In Groups A, C, and D, no significant implant-related differences between baseline and follow-up were found in PPD, MR, and BOP. Group B showed a significant difference ($P = 0.022$) between baseline (1.77 ± 1.58 mm) and follow-up (2.31 ± 1.54 mm) in PPD. The location of implant ($P = 0.02$), the type of implant ($P = 0.01$), and the age of subject ($P = 0.04$) had significant influences on BOP. (*Am J Dent* 2017;30:190-196).

CLINICAL SIGNIFICANCE: All strategies were effective in preventing peri-implant inflammation. The supplemental application of chlorhexidine varnish had no significant additional benefit.

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Introduction

The placement of dental implants has become an essential therapy to replace missing teeth, given its wide variety of treatment applications in different clinical situations.^{1,2} Despite high success rates observed in clinical cases, there is an increasing number of studies reporting short- and long-term complications related to implant therapy in terms of biological and technical failures.²⁻⁸ Evaluating the prevalence of peri-implant diseases is difficult due to several reports with varying study designs and patient populations that were characterized by different risk factors.^{9,10} Based on the Consensus Report of the 11th European Workshop in Periodontology, the prevalence of mucositis was reported to be up to 43%, and the prevalence of peri-implantitis was weighted at 22%.²

Peri-implant mucositis and peri-implantitis appear as long-term biological complications that affect the health of both the soft and hard tissue surrounding the implant. Peri-implant mucositis is characterized by the presence of inflammation in the soft tissue surrounding an osseointegrated implant. While showing typical signs of inflammation such as erythema, swelling and bleeding upon probing, it is still a reversible inflammatory reaction; however, peri-implantitis, as a consequence of the permanent inflammatory process, is also associated with an irreversible loss of implant-surrounding crestal bone.¹¹ This inflammatory response is multifactorial but primarily caused by biofilm accumulation on dental implants and restorations, resulting from poor or inadequate oral hygiene

or initiated by iatrogenic conditions, such as cement remnants, over contoured restoration margins, implant malposition or technical complications.^{12,13}

Since the infection of the surrounding peri-implant tissues is most commonly caused by bacterial biofilm accumulation, anti-infective preventive protocols are based on professional mechanical plaque removal, individualized oral hygiene instructions and treating mucositis as a primary prevention of peri-implantitis.¹⁴⁻¹⁷ The pathogenesis of gingivitis and peri-implant mucositis bear a strong resemblance to each other; however, studies have indicated a stronger inflammatory reaction for peri-implant mucositis and, thus, a potentially higher resistance to therapy.^{11,12,18-21} Professional mechanical plaque control involves the removal of supra-gingival and sub-marginal plaque and calculus by using hand instruments or powered instruments; which then allows adequate patient-administered mechanical plaque removal.¹⁵

A systematic review¹⁴ revealed a correlation between the high long-term survival and success rates of dental implants and professional mechanical plaque control, including anti-infective preventive measures and peri-implant mucositis therapy; therefore, the efficacy of anti-infective prevention approaches must be investigated. In recent literature, the benefit and necessity of maintenance for preventing peri-implant inflammation have been clearly stated.^{17,22} To date, no clinical studies have compared different preventive approaches to avoid peri-implant inflammation under daily routines in a dental office.

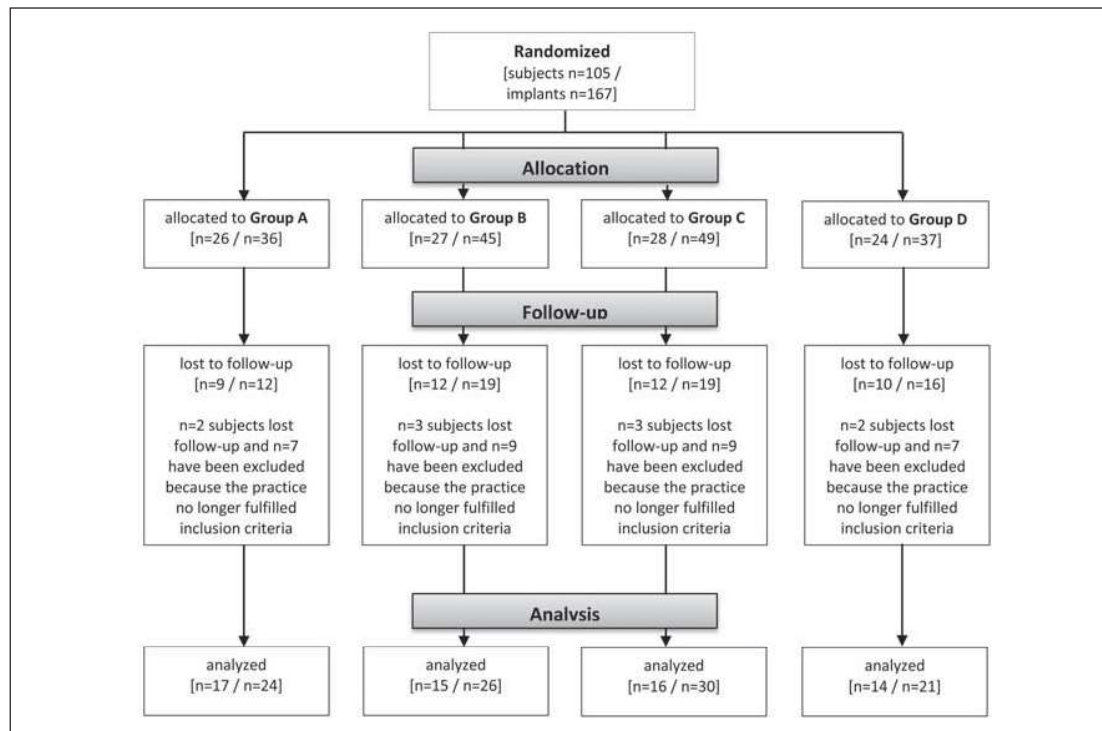


Fig. 1. Participant flow through the study according to the CONSORT guidelines.

Accordingly, this study compared different maintenance strategies for the prevention of peri-implant inflammation within supportive implant therapy during the first year after implant restoration in a randomized, dental hygiene practice-based multicenter study. It was hypothesized that the prevention of peri-implant inflammation is possible by maintenance, regardless of the chosen approach.

Material and Methods

Study design - This study was designed as a randomized clinical multicenter study and was performed in different dental practices in Germany. The study was assessed and approved by the Freiburg ethics committee, IRB/IEC Institutional Review Board/Independent Ethics Committee, Germany (application no. 012/1203). All subjects provided written informed consent, and guidelines for ethical approvals for human subjects were followed in accordance with the Declaration of Helsinki.

Selection of dental practices - A total of 20 dental practices with experienced dental hygienists (all trained in the Center of Continuing Dental Education, Stuttgart, Germany) were asked for their collaboration. The requirement for inclusion in the study was to include at least eight subjects (two per/group) from each practice, all of whom were treated by the same professional dental hygienist within the practice. Eight practices did not fulfill these criteria; accordingly, only the remaining 12 practices were included in the study.

Study population - No previous power calculation was performed. However, the study aimed to include as many subjects as possible, with a minimum of 12 subjects and 20 implants in each group. The participants enrolled in the study were partially and fully edentulous subjects with at least one implant-supported restoration. They were asked to voluntarily

participate in the study. To ensure a caries-free and sufficiently, conservatively and prosthetically restored dentition during the study, dental and periodontal rehabilitation were performed beforehand.

The following inclusion criteria were required to participate in the study:

1. Regular appointments in a supportive post-implant therapy (SIT) program;
2. Age between 18 and 75 years;
3. Generally healthy;
4. Non-smoker;
5. Adequate self-performed oral hygiene;
6. Periodontally healthy; and
7. Current definitive implant restoration after previous implant insertion.

The following exclusion criteria were defined:

1. Existing infectious diseases (tuberculosis, hepatitis A/B/C, HIV);
2. Metabolic diseases (diabetes mellitus);
3. Seizures or neurological disorders;
4. Renal failure;
5. Addictions (alcohol, drugs); and
6. Required antibiotic prophylaxis.

The participants were informed about the course of the study and were consecutively included after signing the consent form. They were randomly allocated into four groups, upon which a matching according to age and gender was performed (Fig. 1). For all groups, a different prophylaxis approach was performed, beginning after the insertion of the implant prosthetic restoration (i.e., no signs of inflammation, no previous non-surgical or surgical therapy) every 3 months for a period of 1 year. The implants of participants allocated to Group A were treated using manual implant curettes (Barnhart 5-6,^a Langer 3-4,^a Nebraska 128/Langer 5,^a Scaler 204S^a), sonic-driven scalers (Sonicflex quick 2008 L^b including implant set) and a prophylaxis brush during SIT; in

Group C, these were supplemented with treatment using chlorhexidine (CHX) varnish (Cervitec plus^c) on the implant surfaces. Participants in Group B obtained therapy through the use of manual curettes, an air polishing system (Air-Flow Master^d) with glycine powder (Perio-Flow^e) and a prophylaxis brush during SIT; in Group D, these were supplemented with treatment using CHX varnish on the implant surface.

Data collection - The following parameters were evaluated using subject records: age and gender, medical history, type and number of implants, anatomical implant position, date of implant insertion and prosthetic treatment. Based on the available periodontal status, periodontal condition was classified as (1) healthy/mild periodontitis, (2) moderate periodontitis, or (3) severe periodontitis.²³

At the initial examination (baseline), the following parameters were assessed to determine the subjects' caries experience, quality of self-performed oral hygiene, and the level of mucosal inflammation in the peri-implant tissue (bleeding on probing: BOP).

DMF-T: The DMF-T was performed with a dental mirror and a dental probe to assess total dental caries experienced, determined based on the number of decayed (D), missing (M), and filled teeth (F), with a maximum value of 28, excluding third molars.²⁴

Papillary bleeding index (PBI): The PBI was performed to define gingival health by examining the bleeding tendency of the interdental gingiva. To score the bleeding, gentle movement of a periodontal probe (PCP 15^f) was applied to the gingival sulcus, from the base of the papilla to the top. The scores ranged from 0 (no bleeding; indication of inflammation free gingiva) to 4 (profuse bleeding; indication of severe inflammation).²⁵

Approximal plaque index (API): The API was performed using erythrosine to measure dental plaque that occurs in the approximal areas to assess the quality of self-performed oral hygiene. The presence (with 1) or absence (with 0) of plaque was noted. The scores ranged from < 30% (appropriate oral hygiene) to 70-100% (inappropriate oral hygiene).²⁵

Peri-implant probing depths (PPD) and bleeding on probing (BOP): The probing depths were evaluated around implants by applying gentle movement of a periodontal probe (PCP 15) in the mucosal sulcus with a probing force of 0.25 N. They were measured from the peri-implant mucosal margin to the bottom of the probable pocket at six measurement points per implant and tooth: mesio-buccal, mid-buccal, disto-buccal and respective lingual/palatal sites.

Bleeding on probing (BOP) was assessed as a sign of inflammation of the mucosa. Gentle probing in the gingival sulcus was performed to review possible sulcular bleeding at six aspects per implant and tooth and to simultaneously measure the PPD. The PPD and BOP were also assessed on all remaining teeth of the subjects and in the implants.

Mucosal recession (MR): Mucosal recession, referring to gingival recession, describes the apical displacement of marginal mucosa. The distance between the mucosal margin and the margin of the prosthetic restoration was measured using a periodontal probe (PCP 15).²⁶

Course of study - The study period began after the prosthetic

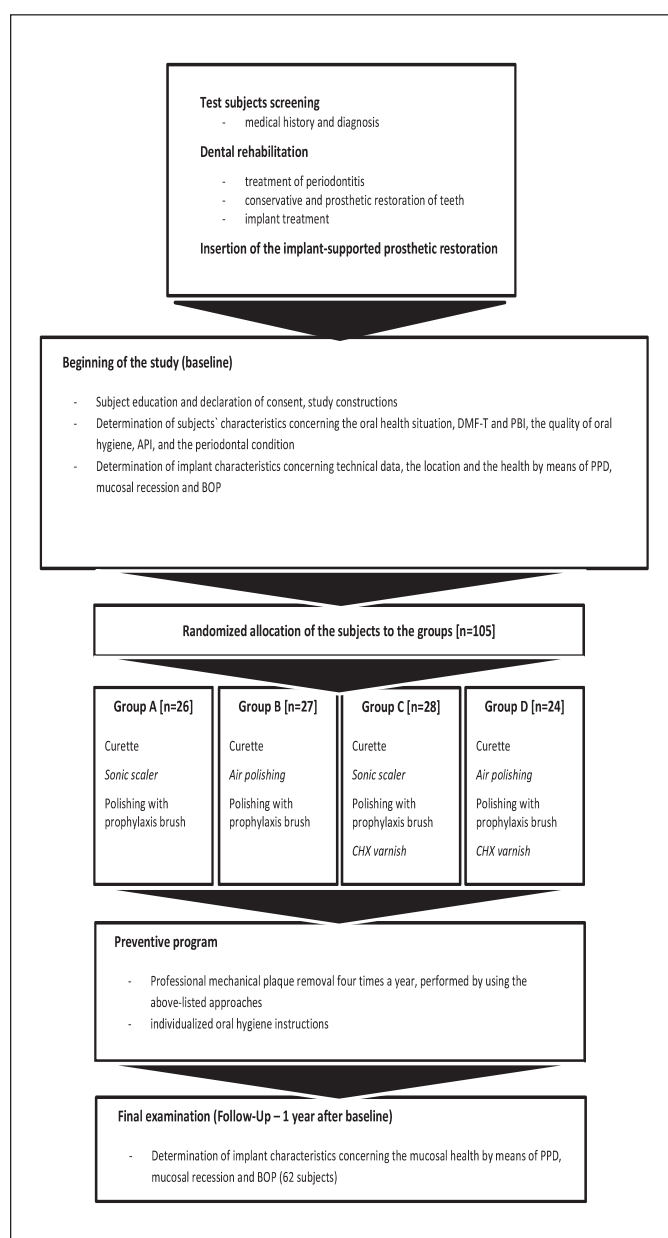


Fig. 2. Study timeline.

restoration of a previously inserted implant. At the beginning of the study, all included subjects were examined under standardized conditions in a dental unit with light, using a dental mirror and a dental probe. The examinations were performed in dental practices by calibrated, skilled dental hygienists, who were trained in the Center of Continuing Dental Education, Stuttgart, Germany and members of the German Society of Dental Hygienists (DGDH). Only one dental hygienist per dental practice was authorized for SIT to ensure the standardized acquisition of data. Initial examinations included collecting anamnestic and implant-specific data and dental findings, determining the oral health and periodontal situation by performing the DMF-T, API, PBI, and evaluating the PPD and BOP as well as MR.

The participants were instructed to attend the SIT program in a 3-month interval. During SIT, the hygienists applied the approaches in accordance with the group allocation (A-D).

Table 1. Subjects' characteristics at baseline.

General	Total (n=62)	Group A (n=17)	Group B (n=15)	Group C (n=16)	Group D (n=14)
Age in years (mv ± sd)	55.21 ± 11.3	51.86 ± 11.3	57.06 ± 12.58	56.01 ± 11.92	56.38 ± 9.33
Gender [n(%)]					
Male	35 (56.5)	8 (47.1)	8 (53.3)	10 (62.5)	9 (64.3)
Female	27 (43.5)	9 (52.9)	7 (46.7)	6 (37.5)	5 (35.7)
Number of implants [n (%)]	101 (100)	24 (23.76)	26 (25.74)	30 (29.7)	21 (20.8)
Oral health condition					
DMF-T (mv ± sd)	11.47 ± 6.8	10.18 ± 6.8	12.07 ± 7.37	12.19 ± 7.5	11.57 ± 5.84
API (%) (mv ± sd; median)	17.1 ± 23.15 (12.29)	12.65 ± 12.28 (13.04)	32.7 ± 37.12 (21.05)	16.66 ± 16.34 (13.19)	6.29 ± 10.17 (0)
PBI (%) (mv ± sd; median)	12.15 ± 19.88 (6.65)	9.44 ± 11.03 (8.33)	14.18 ± 16.83 (8.33)	12.34 ± 25.07 (2.18)	13.04 ± 25.66 (6.55)
Periodontal condition					
[n (%)]					
Healthy/mild	13 (21)	5 (29.4)	4 (26.7)	3 (18.8)	1 (7.1)
Moderate	36 (58.1)	9 (52.9)	7 (46.7)	11 (68.8)	9 (64.3)
Severe	13 (21)	3 (17.6)	4 (26.7)	2 (12.5)	4 (28.6)

mv = mean value; sd = standard deviation.

Table 2. Implant-related results concerning the clinical parameters PPD, MR, and BOP.

Parameters	Total (101)			Group A (n=24)			Group B (n=26)			Group C (n=30)			Group D (n=21)		
	T0	T1	P value	T0	T1	P value	T0	T1	P value	T0	T1	P value	T0	T1	P value
PPD (mm) (mv ± sd)	2.08 (±1.51)	2.21 (±1.35)	0.2	1.75 (±1.23)	2.21 (±1.32)	0.6	1.77 (±1.58)	2.31 (±1.54)	0.02	2.67 (±1.63)	2.23 (±1.28)	0.38	2 (±1.38)	2.05 (±1.32)	0.93
MR (mm) (mv ± sd)	1.3 (±0.94)	1.18 (±0.96)	0.19	1.5 (±0.89)	1.5 (±0.89)	1	0.88 (±1.14)	0.77 (±1.07)	0.63	1.23 (±0.86)	1 (±0.91)	0.15	1.67 (±0.66)	1.57 (±0.75)	0.56
BOP (%)	4	7.9	0.22	0	4.2	1	11.5	11.5	1	0	100.25	4.8	4.8	1	

mv = mean value; sd = standard deviation.

The treatment encompassed the following elements for all subjects at each appointment: assessment of PBI and API, re-instruction and re-motivation of effective individual plaque control, professional tooth and implant cleaning and polishing according to groups (A-D), and application of a fluoride gel on the teeth. The following general guidelines regarding self-performed oral hygiene were made: the participants were instructed to use an oscillating-rotating power toothbrush (Oral-B Professional Care 3000[®]) or sonic-active toothbrush (Philips Diamond^h), to floss or use interdental brushes (GUM Trav-ler^l) to use the sodium-fluoride containing toothpaste (Dentagard^d) and to practice oral hygiene twice a day. After a repeated diagnosis (two times) of peri-implant mucositis, 1% CHX gel (Chlorhexamed^k) was applied to the tissue surrounding the implant and in the mucosal sulcus.

The final examinations, including the recording of the PPD, MR, and BOP, were completed 12 months after baseline. The timeline of the study can be found in Fig. 2.

Statistical analysis - All subject data (personal data, clinical parameters, and implemented measures) were recorded with a computer program (ParoStatus^l). Statistical analysis was performed using SPSS^m Version 24. The testing for normal distribution of the metric variables was performed using the Kolmogorov-Smirnov Test. This resulted in a non-normal distribution of the three test parameters. Accordingly, the Kruskal-Wallis test was used as a non-parametric procedure for more than two independent parameters, followed by a Bonferroni correction in case of statistical significance. Moreover, two dependent samples were analyzed using the Wilcoxon-test. In comparison of dichotomized data before vs.

after intervention, the Chi-squared test with McNemar modification was applied. The significance level was set at $\alpha = 5\%$.

Results

Subjects and implants - A total of 105 subjects with 167 implants (62% maxilla, 91% posterior region) were included in the study. The dropout rate was 40.95% due to a loss of 43 participants to follow-up (Fig. 1); one reason was the loss of subjects during follow-up ($n = 10$), and another was that the practices did not fulfill the inclusion criteria (at least 8 subjects in each practice) at the time of analysis ($n = 33$ from five practices). Therefore, 62 subjects (from seven practices) with a mean age of 55.21 ± 11.3 years were analyzed after 1 year of SIT; 35 were males (56.5%), and 27 (43.5%) were females. The mean oral health situation was described as follows: DMF-T 11.47 ± 6.8 , API $12.15 \pm 19.88\%$, and PBI $17.1 \pm 23.15\%$. The mean periodontal condition was mild in 13 (21%), moderate in 36 (58.1%), and severe in 13 (21%) of the subjects. Table 1 summarizes pertinent subject characteristics. In total, 101 implants were included in the final analysis (Table 1). None of the implants were lost during the observation period (implant survival rate: 100%).

Examination parameters - In implant-based analysis, no statistically significant differences were found for PPD between baseline and t1 for Groups A, C and D. However, a significant difference of PPD between baseline (1.77 ± 1.58 mm) and t1 (2.31 ± 1.54 mm) was detected for Group B ($P = 0.022$). Furthermore, no statistically significant differences were found between t0 and t1 in MR and BOP for all groups (Table 2). In subject-based analysis, no statistically significant

Table 3. Patient-related results concerning the clinical parameters PPD, MR and BOP.

Parameters	Total (n=62)		Group A (n=17)		Group B (n=15)		Group C (n=16)		Group D (n=14)	
	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1
PPD (mm)										
(mv ± sd)	1.94 ± 1.5	2.27 ± 1.36	1.76 ± 1.15	2.35 ± 1.27	1.93 ± 1.67	2.47 ± 1.6	2.25 ± 1.77	2.06 ± 1.29	1.79 ± 1.48	2.21 ± 1.37
MR (mm)										
(mv ± sd)	1.29 ± 0.98	1.21 ± 0.99	1.29 ± 0.99	1.29 ± 0.99	1.13 ± 1.25	1.0 ± 1.2	1.19 ± 0.91	1.0 ± 0.97	1.57 ± 0.76	1.57 ± 0.76
BOP (%)	4.8	8.1	0	5.9	13.3	13.3	0	6.3	7.1	7.1

mv = mean value; sd = standard deviation.

Table 4. Comparison of the changes (Δ) over the study period between Groups A-D.

Parameters	Group A	Group B	Group C	Group D	P value	P value comparison					
						A vs B	A vs C	A vs D	B vs C	B vs D	C vs D
Implant based (n= 101)											
PPD (Δ in mm)	-0.46 ± 1.10	-0.54 ± 1.14	0.43 ± 2.03	-0.05 ± 1.63	0.04 ^a	1.00	0.13	0.84	0.11	0.81	1.00
MR (Δ in mm)	0.00 ± 0.59	0.12 ± 1.11	0.23 ± 0.82	0.10 ± 0.77	0.74 ^b	-	-	-	-	-	-
BOP (Δ in %)	-0.04 ± 0.20	0.00 ± 0.28	-0.10 ± 0.31	0.00 ± 0.00	0.37 ^b	-	-	-	-	-	-
Patient based (n= 62)											
PPD (Δ in mm)	-0.59 ± 1.28	-0.53 ± 0.99	0.19 ± 2.10	-0.43 ± 1.74	0.35 ^a	-	-	-	-	-	-
MR (Δ in mm)	0.00 ± 0.71	0.13 ± 0.99	0.19 ± 0.91	0.00 ± 0.78	0.85 ^b	-	-	-	-	-	-
BOP (Δ in %)	-0.06 ± 0.24	0.00 ± 0.38	-0.06 ± 0.25	0.00 ± 0.00	0.83 ^b	-	-	-	-	-	-

For the changes between t0 and t1, mean value and standard deviation is presented. Significant results are highlighted in bold (significance level $P < 0.05$).

* A post-hoc testing, comparing the singular groups was only executed if an overall significant P-value could be found.

^a Kruskal-Wallis test.

^b Chi-squared test.

differences between t0 and t1 were found ($P > 0.05$; Table 3). Comparing the change over time between groups, only PPD showed a significant result in the implant-based analysis ($P = 0.04$). However, in the following post-hoc analysis, no significant findings were detected (Table 4).

Regardless of group, considering all of the determined values for PPD, MR, and BOP, the location of the implants (upper vs. lower jaw; $P = 0.02$), the type of implant ($P = 0.01$), and the age of the subjects ($P = 0.04$) had a significant influence on BOP at follow-up. The subject's gender, API, and periodontal situation had no significant influence ($P > 0.05$) on PPD, MR, and BOP at follow-up.

Discussion

The prevalence of peri-implant mucositis and peri-implantitis was reported at 43% and 22%,¹⁵ thus highlighting frequent biological complications in implant dentistry. However, it is possible to avoid mucositis and peri-implantitis with sufficient maintenance.^{17,22} Thus, prevention strategies concerning peri-implant mucositis and peri-implantitis are of high importance.

The present multicenter study evaluated the efficacy of four different professional approaches during SIT based on the following parameters: PPD, MR, and BOP. The preventive approaches of Groups A, C, and D resulted in no significant change ($P > 0.05$) in PPD, MR, or BOP between baseline and follow-up, thus demonstrating that these approaches are efficient options in removing bacterial plaque from implant restoration surfaces and implant pockets to maintain peri-implant health in the short term. This finding is in line with a recent meta-analysis.¹⁷

Implants of participants allocated to Group B (mechanical debridement using manual curettes, air polishing with glycine

powder, and prophylaxis brush) showed no significant change ($P > 0.05$) between baseline and follow-up in MR and BOP; however, a significant difference ($P = 0.022$) between baseline and follow-up was observed in PPD. This was a significant increase but lies within a non-pathological range. In this regard, it must be emphasized that BOP is the key parameter in evaluating mucosal health and diagnosing peri-implant mucositis (peri-implant inflammation).¹¹ Despite the significant increase of PPD, there was no concurrent increase in BOP, so peri-implant tissues could be considered healthy.

The supplemental application of CHX varnish in the peri-implant tissues used in groups C and D showed no significant benefit ($P > 0.05$) in reducing PPD, MR, and BOP in the short term compared to Groups A and B (comparison groups). Similarly, in a meta-analysis,²⁷ there was no significant decrease in BOP, gingival index or probing depth scores at mucositis sites in the short term after using adjuvant CHX. This is in line with the literature, which shows no evidence for the adjuvant use of CHX.¹⁶ Further research is needed to evaluate a possible long-term impact of adjunctive measures on peri-implant health.

Furthermore, the additional use of glycine powder air polishing in Groups B and D did not reveal any major improvements in the short term compared to mechanical therapy in Groups A and C. There was no significant decrease in PPD, MR, and BOP ($P > 0.05$) in the short term. However, air polishing with glycine powder was not associated with any side effects (e.g., emphysema formation) and is a safe device for supra- and submucosal plaque removal at implant sites.²⁸

Therefore, there is no proof of superiority of any of the investigated approaches in short-term peri-implant maintenance. These data are in accordance with the recent literature^{15,29} showing that mechanical debridement (with or without the use

of polishing devices, together with individual oral hygiene instructions) as the current standard of care to prevent peri-implant inflammation and manage peri-implant mucositis for the primary prevention of peri-implantitis.

Risk factors for developing peri-implant inflammation have been considered by only a few studies, indicating that a history of periodontal disease, smoking, systemic diseases, radiation therapy, abutment surface characteristics, the size of keratinized tissue, genetics, gender, and function time of implants may cause peri-implant inflammation.^{30,31} Based on individual risk and lifestyle factors and clinical findings, there is a need to individualize professional preventive measures. Recommendations have been made^{15,29} regarding risk factor control, behavioral interventions, and psychological approaches to behavioral change (i.e., smoking) to achieve self-administered health of peri-implant tissues.

The current study revealed that the location of implants had a significant influence ($P=0.02$) on BOP. It was established that the cortical and alveolar bones in the maxilla have a lower density compared with the mandible,³² which leads to a higher susceptibility to inflammation. This could explain the findings in the current study. However, further research is needed to evaluate the relationship between the location of implants and susceptibility to inflammation. Furthermore, it was shown that the age of the subjects had a significant influence ($P=0.04$) on BOP. In the present study, no subjects under 48 years of age showed positive BOP scores in follow-up, but 3.0-20.8% of the subjects aged 49 years and above exhibited positive BOP scores. Similar results were observed in another study.³³ BOP positive scores for teeth were constantly increasing with increasing patient age. Elderly subjects are frequently affected by increased levels of chronic inflammation; an impaired immune function is associated with aging, which leads to increased inflammatory reactions.³⁴ Likewise, it should be underscored that the demographic of older adults is growing, resulting in an increased number of subjects with physical or cognitive limitations. Increasing the frequency of SIT and examinations can help promote the optimal maintenance of oral hygiene.¹⁷ To date, however, age has not been described as a risk factor for the development of peri-implant inflammation.^{30,31} In addition, it was found that the type of implant had a significant influence ($P=0.01$) on BOP. Although the evidence is weak, different abutment surface characteristics and the implant neck design may play a role in the quality and quantity of plaque accumulation.³⁰ Smoking and periodontal history are the most important risk factors for peri-implant diseases.^{8,16} In the short-term maintenance of the current study, no influence of periodontal history on peri-implant inflammation could be shown ($P>0.05$), and smokers were excluded.

Although the research has been completed successfully, there were some limitations to this study. The design of the study fulfills the qualifications for a prospective, randomized controlled trial. Because of the different locations, more than one hygienist collected data. The complete blinding of participants and hygienists was thus not possible due to the applied approaches. Furthermore, one of the inclusion criteria, requiring at least eight subjects (two per group) from each practice, led to a high loss of participants during follow-up for

analysis. Although it was ensured that motivated and prevention-oriented individuals were included in this study to minimize the influence of individual skills and compliance, the loss of subjects to follow-up was high, and the relatively small number of treated subjects and implants resulted in data limitations. Accordingly, the power of the current study may be too low to draw strong conclusions. A specific power calculation was not performed beforehand but would have been helpful to ensure powerful results. Furthermore, these are only short-term results for an examination period of 1 year. Based on the results of the current study, it is impossible to estimate any long-term results for mucositis and peri-implantitis.

One further limitation is the age difference between the groups in the final analysis. The subjects were matched on age and gender during follow-up; however, the age distribution for final analysis was influenced by the loss of participants during follow-up. Furthermore, bacterial load and inflammatory markers [e.g., interleukin, matrix-metalloproteinase (MMP)] may be of interest. Nevertheless, recent studies from this working group showed that potentially periodontal pathogenic bacteria and the aMMP-8 concentration do not provide sufficient information in this context, particularly in subjects undergoing peri-implant maintenance.^{35,36} Nonetheless, there is no clear evidence for the appropriate prevention approach for peri-implant diseases. The current study serves as a basis for further research, which is needed to confirm the results.

Within the limitations, the current study showed that mechanical debridement is able to prevent peri-implant inflammation in the first year after implant restoration. The supplemental application of CHX varnish had no significant additional benefit. The results indicated that the location of implants, the type of implant, and the age of subjects had significant influences on mucosal inflammation.

- a. American Eagle Instruments, Inc, Missoula, MT, USA.
- b. KaVo Dental, Biberach, Germany.
- c. Ivoclar Vivadent AG, Schaan, Liechtenstein.
- d. Piezon, EMS, Munich, Germany.
- e. EMS, Munich, Germany.
- f. Hu-Friedy, Chicago, IL, USA.
- g. Procter & Gamble GmbH, Schwalbach am Taunus, Germany.
- h. Philips GmbH, Hamburg, Germany.
- i. Sunstar, Schönau, Germany.
- j. CP GABA, Hamburg, Germany.
- k. GlaxoSmithKline, Munich, Germany.
- l. ParoStatus.de GmbH, Berlin, Germany.
- m. SPSS, IBM Germany GmbH, Ehningen, Germany.

Disclosure statement: The authors declared no financial or other relationships that might lead to a conflict of interest. Dr. Ziebolz and Dr. Klipp contributed equally in this work.

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