

# Implant Abutment Cleaning by Plasma of Argon: 5-Year Follow-Up of a Randomized Controlled Trial

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**Background:** Contamination of implant abutments could potentially influence the peri-implant tissue inflammatory response. The aim of the present study is to assess the radiographic bone changes around customized, platform-switched abutments placed according to the “one-abutment-one-time” protocol, with and without plasma of argon cleaning treatment.

**Methods:** Thirty healthy patients with thin gingival biotype (<1 mm) and history of periodontal disease received one maxillary implant each. Immediately before abutment connection, patients were randomly assigned to control group (cleaning protocol by steaming) or test group (plasma of argon treatment). Outcome measures were: 1) success rate of implants and prostheses; 2) biologic and prosthetic complications; 3) peri-implant marginal bone loss (MBL); 4) esthetic and periodontal parameters; and 5) patient satisfaction.

**Results:** Neither implants nor prostheses were lost in either group at the 5-year follow-up examination. Overall, both groups showed a slight amount of peri-implant bone loss from baseline to 5 years. A statistically higher mean MBL was found in the control group compared with the test group at 6, 24, and 60 months after crown connection. Nevertheless, during the entire follow-up period, intragroup comparison demonstrated statistically significant mean MBL in the control group, but not in the test group. The test group showed a higher mean gain at the soft tissue margin, but not for the papilla. All implants showed good periodontal parameters, with no significant differences between groups.

**Conclusion:** Plasma of argon could be used to disinfect implant abutments before insertion to minimize future peri-implant bone resorption. *J Periodontol* 2016;87:434-442.

## KEY WORDS

Argon; bone resorption; dental implant-abutment interface; dental implant platform switching; esthetics; titanium.

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A prerequisite for functionally and esthetically successful implant treatment is the achievement and maintenance of osseointegration, represented by peri-implant soft and hard tissue stability.<sup>1</sup> As described by Albrektsson et al.,<sup>2</sup> when a pure titanium external hex implant is used, a certain amount of physiologic marginal bone loss (MBL) can be observed around a dental implant in the first year after placement. This phenomenon can be verified both horizontally and vertically, regardless of the prosthetic interfaces and design, and could be attributed to the existence of a microgap or polished collar.<sup>3</sup> Switching the external hex to internal hex implant interface or narrowing the implant–abutment interface might minimize this effect, reducing the observed amount of bone loss.<sup>3-5</sup> From a biomechanical point of view, the presence of a non-matching, smaller-diameter abutment is thought to spread the biologic width on the horizontal plane.<sup>6</sup>

Presence of microbiologic contamination has been observed on prosthetic components after laboratory procedures and handling by office personnel.<sup>7</sup> Such debris could directly or indirectly trigger the inflammatory response of peri-implant tissues.<sup>8</sup> Different cleaning methods have been used to disinfect the abutments before insertion, including the use of autoclaves, ovens, chemical agents (e.g., ethylene oxide), and plasma treatment.<sup>7,9,10</sup>

Plasma of argon (PA) treatment has been used successfully for deactivation of bacteria,<sup>11,12</sup> even in biofilms.<sup>13</sup> Although conventional sterilization techniques could affect properties of the instrument surface,<sup>10</sup> plasma sterilization can preserve surface integrity.<sup>7,14</sup> From a physical-chemical point of view, low-temperature plasma is usually adopted to remove organic residues from surfaces. It works within vacuum chambers, where atmospheric gases have been evacuated to <13 Pascal (measure of atmospheric pressure). These low pressures allow for accelerated electrons, preserve the integrity of materials, remove chemical traces left from former treatments,<sup>15</sup> and effectively produce cleaner surfaces.<sup>16</sup>

PA treatment has been proven effective for surface modifications, making surfaces hydrophilic and increasing the surface energy of the external oxide layer that interacts with proteins and cells of surrounding tissue, improving adhesion.<sup>17</sup> Additionally, treatment with plasma has been demonstrated to increase the surface energy at the atomic and molecular level, enhancing wettability and cell spreading on dental implant metals, resulting in favorable cell responses.<sup>18-20</sup> Accordingly, it was confirmed that plasma treatment of titanium surfaces can improve cell adhesion.<sup>20,21</sup> A 2-year interim study suggested that removal of contaminants from titanium abutments using PA cleaning treatment allowed for better peri-implant maintenance of marginal bone levels, including in critical conditions such as in patients with a history of periodontal disease or with thin gingival biotype, compared with 30-second steam-cleaning of titanium abutments.<sup>22</sup> Therefore, the aim of this 5-year postloading randomized controlled clinical study is to assess the clinical parameters and radiographic bone changes around customized, platform-switched abutments with and without PA cleaning.

The present report was written in accordance with the Consolidated Standards of Reporting Trials (CONSORT) statement<sup>23</sup> for the reporting of randomized controlled trials.

## MATERIALS AND METHODS

In January 2010, at the Department of Oral Surgery, University of Valencia, Spain, a randomized, matched, triple-masked, controlled clinical trial was designed to test the cleaning effect of PA versus steam-cleaning on non-sterile implant customized abutments. Patients aged  $\geq 18$  years, previously treated for periodontal disease according to a comprehensive treatment strategy<sup>24</sup> and requiring a single implant in the esthetic area (maxillary premolar to premolar), were selected for this study. Each patient had a bone crest allowing the insertion of a 4-mm platform implant without further bone augmentation procedures and had thin ( $\leq 1$  mm) gingival biotype,<sup>25</sup> measured by a previously reported protocol.<sup>22</sup> Exclusion criteria were: 1) relevant medical conditions (American Society of An-

esthesiologists III and IV); 2) smoking >10 cigarettes/day or pipe or cigar smoking; 3) plaque index (PI) and bleeding on probing (BOP) >25%; 4) referral only for implant placement or unable to attend the 5-year follow-up after prosthetic loading; 5) pregnancy or lactation; 6) history of bisphosphonate therapy; and 7) presence of sites with acute infection.

Thirty patients (12 males and 18 females, aged 31 to 79 years; mean age: 58.2 years) who met the inclusion criteria were asked to participate and were enrolled in consecutive order from January to September 2010. Every patient was required to sign written informed consent after detailed explanation of the study protocol. The investigation was conducted according to the principles embodied in the Helsinki Declaration. All procedures and materials in the present prospective study were approved by the local Ethical Committee of the University of Valencia. All patients were followed for a period of 5 years after prosthetic rehabilitation. This study was registered at Clinicaltrials.gov (NCT02552810).

### *Surgical and Prosthetic Protocols*

Before treatment, a full-mouth professional hygiene appointment was scheduled. Patients received 1 g amoxicillin/clavulanic acid 1 hour before surgery and continued with 2 g per day for 6 days. One experienced surgeon (LC) performed all the treatments. After local anesthesia with articaine,<sup>§</sup> a small flap was reflected. Using an individualized surgical stent, after previous cone-beam computed tomography, the implants were inserted 0.5 mm below the crestal bone level using as reference the buccal bone wall, maintaining  $\geq 1$  mm of buccal bone wall. All implants were 3.8 mm in diameter, 10 to 13 mm long.<sup>||</sup> Intrasurgical impressions were taken. Finally, sutures were performed, and implants were left to heal submerged for the whole osseointegration period. A Maryland bridge was adapted for esthetic purposes. Patients were asked to follow classic postoperative prescriptions.<sup>21</sup> Sutures were removed after 10 to 14 days.

Six to 8 weeks later, a second surgery was performed. Immediately after cover screw removal, in both groups, a titanium grade 5 abutment with 0.3 mm of implant/abutment mismatching was used. Milled abutments of the control group were cleaned by steam for 30 seconds.<sup>¶</sup> Test group abutments underwent PA treatment (75 W power and  $-10$  MPa pressure for 12 minutes at room temperature) in a plasma reactor.<sup>#</sup> Both treatments were performed in the same clinic but in a different room. All the abutments were handed to the clinician in a sterile envelope, without the possibility to evaluate the treatment undergone, during second surgery. The abutments were screwed at 32 N/cm

§ Ubistesin, 3M ESPE, St Paul, MN.

|| Premium SP Implants, Sweden & Martina, Padua, Italy.

¶ VAP 1, Zhermack, Marl, Germany.

# Diener Electronic, Jettingen, Germany.

according to manufacturer specifications, and the provisional restoration was placed. Finally, 2 to 3 weeks later, a definitive implant-supported single crown was cemented. After the delivery of definitive restorations, patients were offered supportive periodontal therapy, which was provided at intervals of 3 to 6 months. Each recall visit during the 5-year follow-up period comprised an oral hygiene control with motivation and instructions when necessary. Subgingival scaling and root planing was performed at tooth surfaces with probing depth (PD) >4 mm and/or positive BOP.\*\*

### Outcomes

Primary outcomes were the success and survival rates of the implants and prostheses.<sup>26,27</sup> Secondary outcome measure was marginal bone level changes. At the time of crown connection (T0), periapical standardized digital radiographs with an individual customized digital film holder were taken and used as baseline. The same analysis was performed at 6 (T1), 24 (T2), 48 (T4), and 60 (T5) months after final restoration delivery to assess MBL changes longitudinally. Measurement of MBL around implants was performed using image analysis software<sup>††</sup> able to compensate for radiographic distortion.<sup>22</sup> The software was calibrated using the known distance between two adjacent threads (0.60 mm).

Mesial and distal bone level changes were calculated. To better define peri-implant bone loss, minimizing the effect of interproximal bone peaks, MBL changes were measured according to the previous interim study. Esthetic and periodontal parameters, as well as patient satisfaction, were considered the third outcome measure.

Mesial and distal papilla height and buccal peri-implant mucosa changes at the zenith (REC) were measured using a customized prefabricated stent at definitive crown delivery and then at the 5-year examination.<sup>28</sup> At each follow-up, modified PI<sup>24</sup> and BOP<sup>24</sup> were measured. Patient satisfaction was assessed at the 5-year follow-up examination. Patients provided personal overall satisfaction scores regarding masticatory function and the esthetics of their restorations on a visual analog scale (VAS). A blinded assessor asked participants to give their degree of satisfaction with the function and esthetics of their prosthesis on a 100-mm scale between 0 (maximal dissatisfaction) and 100 (maximal satisfaction).

All radiographic measurements, soft tissue assessments, and periodontal examinations were carried out by masked calibrated examiners (MT and DP-O).

Before the start of the study, the examiner was trained to adequate levels of accuracy and reproducibility in recording the clinical and radiographic parameters and indices. Calibration of the three masked examiners was

performed by triplicate measurements before the beginning of the study. To assess the interobserver agreement of radiographic evaluation, linear weighted  $\kappa$  values were calculated.

### Sample Size Calculation and Randomization

Sample size calculation and randomization process was described in the interim study.<sup>22</sup>

### Statistical Analyses

A biostatistician analyzed the data using statistical software.<sup>‡‡</sup> A descriptive analysis was performed using mean, SD, median, and 95% confidence interval (CI). The data distribution of average MBL changes was plotted in a box-plot, and mean values with SDs were calculated. Comparisons among time points were made for each group by paired *t* test to detect any changes in MBL during follow-up. Non-parametric Mann-Whitney *U* test was conducted to highlight differences in mean MBL changes between test and control groups. *R*<sup>2</sup> values for regression models during time points were also calculated (Fig. 1). All statistical comparisons were conducted as two-tailed analysis, and *P* < 0.05 was set as the level of significance.

## RESULTS

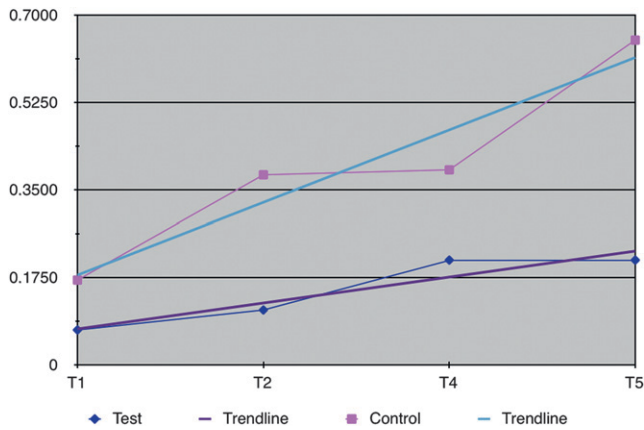
A flowchart of trial phases is shown in Figure 2. Overall, 35 patients were screened for eligibility in the trial, but five were not included for the following reasons: two were in need of bone augmentation at the implant sites; two were unable to commit to a 5-year recall plan; and one refused to sign the informed consent. Thirty patients (12 males and 18 females) were considered eligible and were consecutively enrolled in the study from January to September 2010. The last follow-up was done August 2015. Patient and implant characteristics are reported in Table 1.

No dropouts occurred during the entire follow-up. All the data collected were included in the statistical analysis. No deviation from the original protocol occurred, and all patients were treated according to the allocated interventions. Neither implants nor prostheses were lost in either group at the 5-year follow-up examination. All surgical interventions and postoperative healing periods were without any major complication. In the first postoperative day, minimal postoperative swelling was noticed in two patients in each group. After 1 week, as well as at the second-stage surgery, no discomfort was noticed. During the healing period, no exposure of the cover screw was experienced in either group. No prosthetic or biologic complications occurred during the period of the study in either group.

\*\* PCP (INC-15, Hu-Friedy, Chicago, IL).

†† Autocad 2006, v.254.10, Autodesk, San Rafael, CA.

‡‡ SPSS for Mac OS X, v.22.0, IBM, Chicago, IL.



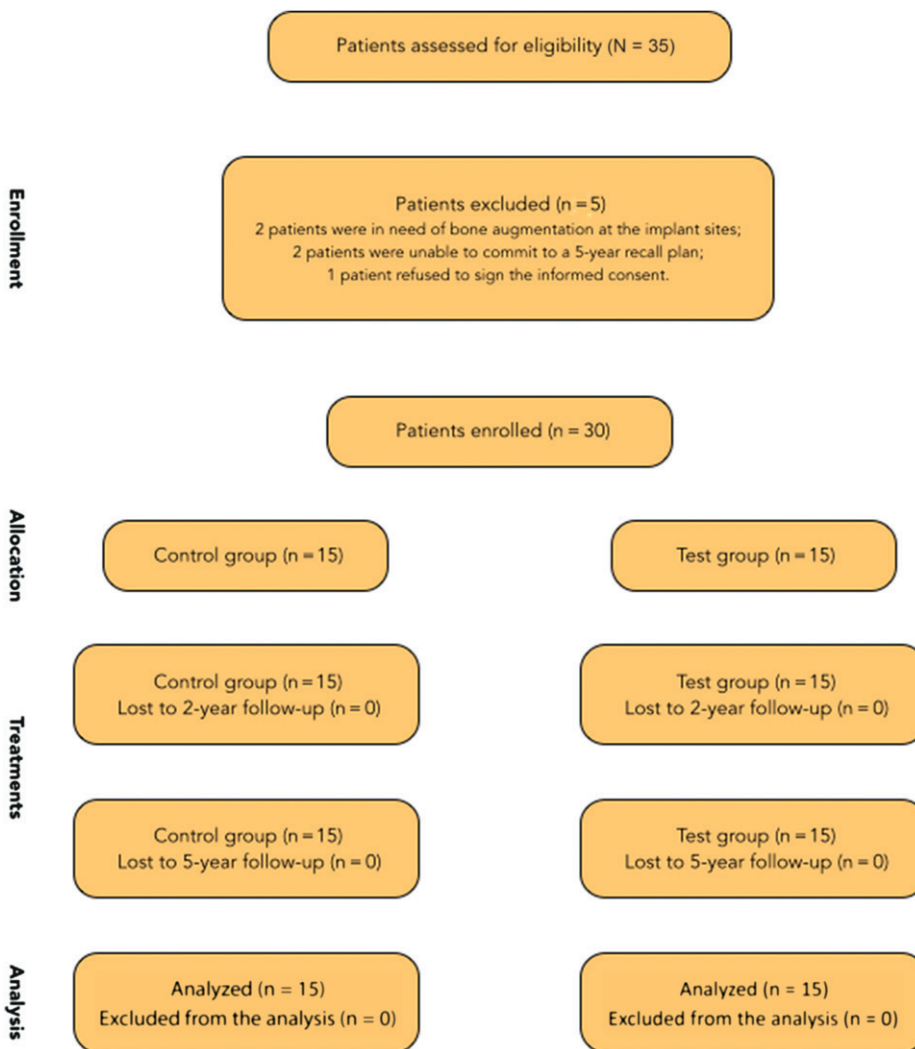
**Figure 1.**  $R^2$  values for regression models: test group  $R^2 = 0.9072$ , control group  $R^2 = 0.8895$ .

At the time of definitive prosthesis delivery (T0), periapical radiographs revealed no bone defect around implants in either group. Overall, both groups showed a slight amount of peri-implant bone with function over the implant–abutment junction. At the last follow-up examination (5 years in function), MBL was  $0.21 \pm 0.21$  mm in the test group versus  $0.65 \pm 0.36$  mm in the control group. The comparison between test and control group was statistically significant at T1 ( $P = 0.006$ ), T2 ( $P = 0.03$ ), and T5 ( $P = 0.04$ ). The results of mean MBL among groups and time points are summarized in Table 2. Intragroup comparison revealed no statistically significant differences between 6 and 24 months of follow-up ( $P$  values 0.57 and 0.44 in the control and test groups, respectively). In contrast, between 6 and 60 months of follow-up, a statistically significant difference appeared in the control group ( $P = 0.001$ ), but not in the test group ( $P = 0.15$ ) (Table 2). Implant MBL between the two treatment groups at different time points is illustrated in Figures 3 and 4. A weighted  $\kappa$  value of 0.81 was calculated for all the radiographic measurements.

At 5 years after loading, patients in the test group showed a statistically significant ( $P < 0.05$ ) mean REC of  $0.58$  mm ( $\pm 0.66$  mm), compared with  $0.22$  mm ( $\pm 0.35$  mm) in the control group. Mesial and distal soft tissue dimensions (papilla height) were similar in the two groups (test group =  $0.48 \pm 0.40$  mm; control group =  $0.39 \pm 0.31$  mm), with no statistically significant difference between them (Table 2).

At the 5-year follow-up examination, BOP was reported in one patient (6.6%) of the test group; in the control group, BOP was detected in three patients (20%). No significant difference was found between groups ( $P = 0.60$ ). PI  $> 25\%$  was reported in two patients (13.3%) of each group. No significant difference was found between groups ( $P > 0.99$ ).

The results of the VAS revealed that all the participants after 5 years of follow-up were functionally and esthetically satisfied with their restorations. The average VAS score was  $95.1$  (SD = 2.8; range, 80 to 100) and  $96.0$  (SD = 4.1; range, 80 to 100) for esthetics and  $97.1$  (SD = 2.3;



**Figure 2.** CONSORT flow diagram.

**Table 1.**  
**Patient and Implant Characteristics**

Parameters	Test Group	Control Group
Females (n)	5	7
Mean (range) age at insertion (years)	56.3 (31 to 77)	60.1 (37 to 79)
PD (% of patients with PD >4; mean $\pm$ SD)	15 $\pm$ 2	16 $\pm$ 3
BOP (%; mean $\pm$ SD)	13 $\pm$ 1	14 $\pm$ 1
Light smokers (<10 cigarettes/day) (n)	2	2
Placed implants (n)	15	15
Incisor	6	4
Canine	1	3
Premolar	8	8

range, 90 to 100) and 96.8 (SD = 1.9; range, 90 to 100) for function in the control and test groups, respectively. All periodontal and esthetic data are summarized in Table 2.

## DISCUSSION

The present 5-year study confirms the outcomes of the already published interim study with 2-year follow-up.<sup>22</sup> That interim study supported PA as an effective treatment for removal of contaminants from titanium abutments, which in turn results in better peri-implant marginal bone compared with steam disinfection.<sup>22</sup> The 100% implant and prosthesis survival rate after 5 years of prosthetic loading suggests the stability of implant therapy regardless of disinfection method. However, the PA treatment group had a significantly lower amount of MBL compared with the steam disinfection group. In fact, it was demonstrated that abutment customization produces micropollutants (residual of lubricant mixed with traces of titanium and other metals),<sup>7</sup> which could directly and indirectly activate an inflammatory response.<sup>8</sup> At the same time, abutment cleaning by steam leaves a number of microparticles, which cannot be detected if the abutment is cleaned by ultrasound or PA.<sup>7</sup>

Patients with thin soft tissues or with a history of periodontal disease have been specifically selected because they present major risk factors for MBL.<sup>29-31</sup> Additionally, only bone loss was used for the analysis, ignoring bone gain where present. Considering also bone gain (only present in the test group) differences could have been even more significant. These considerations should help to understand the quality of the surgical (guided surgery with minimal flap, submerged healing) and prosthetic (platform switching and one-abutment/one-time prosthetic protocol) procedure in the present study. In fact, despite the host challenge clinical conditions, the control group results were in line

with previously published trials reporting MBL longitudinal values.<sup>32,33</sup> Significantly better results in the test group might be exclusively correlated to the “ultra-cleaning” of the abutment.

Going into detail to better understand the pathologic pathway, intragroup analysis revealed no statistically significant differences in the test group; however, significance was reached in the control group. This demonstrated that, after 5 years of loading, although abutment of plasma cleaning allows stabilizing marginal bone levels, the presence of contaminated and polluted abutments could jeopardize the effect of ultraconservative surgical/prosthetic protocols. At the 6-month follow-up, no MBL changes were found in nine test patients (60%) and two control patients (13%). At 24 months, no MBL changes were highlighted in eight test patients (53%) and one control patient (6%). All the patients in the control group showed a slight amount of peri-implant bone loss at the 48- and 60-month time points, whereas seven (47%) and six (40%) patients of the test group, respectively, showed no bone loss (Fig. 3). Moreover, in four test patients, bone level was described to grow coronally to the implant-abutment junction at the first two follow-ups. However, although no changes in periodontal parameters were described, a breakdown of tissue-implant complex homeostasis was highlighted. This might represent a drawback in the longitudinal behavior of the implant, because the rough surface at the implant collar was exposed to a microbiologically contaminated environment. It could be speculated that this significant bone loss peak was detected at two different time points (T1 and T5) with an intermediate steady state.

Two different etiologic pathways could have determined the increase of bone loss in the control group: presence of metallic and carbonic contaminants on the implant abutment surface (possibly related to the early bone loss peak) and microbiologic contamination at

**Table 2.****MBL and Periodontal and Esthetic Parameters During Follow-Ups Between Groups**

Parameter	Test Group	Control Group	P
MBL, mm			
6 months (T1)			0.006*
Mean ± SD	-0.07 ± 0.34	-0.17 ± 0.17	
95% CI	-0.19 to 0.19	-0.26 to -0.04	
24 months (T2)			0.03*
Mean ± SD	-0.11 ± 0.14	-0.38 ± 0.43	
95% CI	-0.07 to 0.07	-0.48 to 0.06	
48 months (T4)			0.40
Mean ± SD	-0.21 ± 0.36	-0.39 ± 0.39	
95% CI	0.2 to -0.36	-0.05 to -0.71	
60 months (T5)			0.04*
Mean ± SD	-0.21 ± 0.21	-0.65 ± 0.36	
95% CI	0.08 to -0.44	-0.29 to -0.91	
P	0.15	0.001*	
REC (mean ± SD)	0.58 ± 0.66	0.22 ± 0.35	<0.001*
BOP, %	6.6	20.0	0.60
PI, %	13.3	13.3	<0.99
VAS (esthetic)			—
Mean ± SD	96.0 ± 4.1	95.1 ± 2.8	
Range	80 to 100	80 to 100	
VAS (function)			—
Mean ± SD	96.8 ± 1.9	97.1 ± 2.3	
Range	80 to 100	90 to 100	

\* Statistically significant difference.

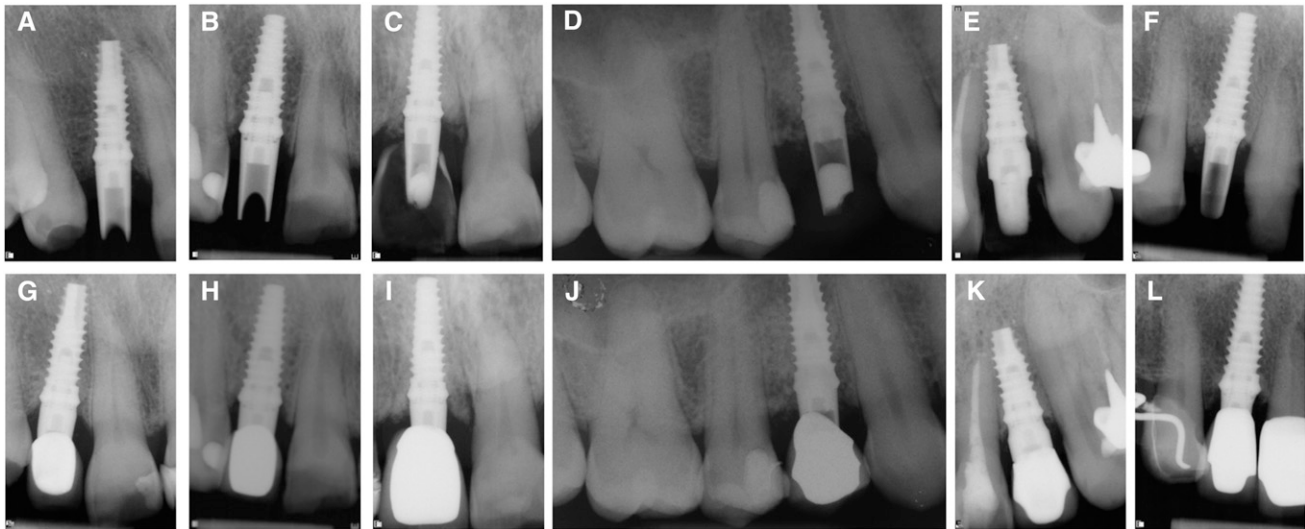
the implant–abutment connection (possibly related to the longitudinal bone resorption phase).<sup>34</sup> In fact, metallic microwears have been postulated to activate osteoclastogenesis.<sup>8</sup> At the same time, carbon remnants could represent an obstacle for bone and soft tissue cell precursors during the first healing phase after abutment connection, therefore jeopardizing the connective tissue seal around the crestal module.<sup>35</sup> The presence of remnants on the screw and the abutment might also negatively affect the biomechanical behavior of the implant–abutment complex.<sup>36</sup> This microscopic instability might increase the bacterial contamination at the implant–abutment junction and therefore trigger the late bone loss. These speculations could be confirmed through the presence of a larger sample of implants with no MBL and even bone regeneration over the implant collar in the test group and the absence of this phenomenon in the control group.

Inter- and intragroup comparison of esthetic parameters did not reach any statistical significance in interproximal papilla height, despite the thin biotype (<1 mm) used as inclusion criteria. This could be due to the minimally invasive surgical procedure and, overall, the presence of neighboring teeth, which

stabilized the mesial/distal bone peaks and therefore preserved the interproximal papilla height. In addition, it must be taken into consideration that implant esthetic outcomes are mostly influenced by the biotype and the shape of the abutment/restoration complex.<sup>37,38</sup> On the other hand, comparison of the buccal vertical gingival height demonstrated differences. The negative soft tissue behavior highlighted in the control group was described to be determined by an improper (too buccal) implant positioning. However, in the present study, all implants were inserted using a standardized surgical guide with cone-beam computed tomography control. An additional possible explanation for the test group improvement might be soft tissue adhesion to the cleaned abutment.

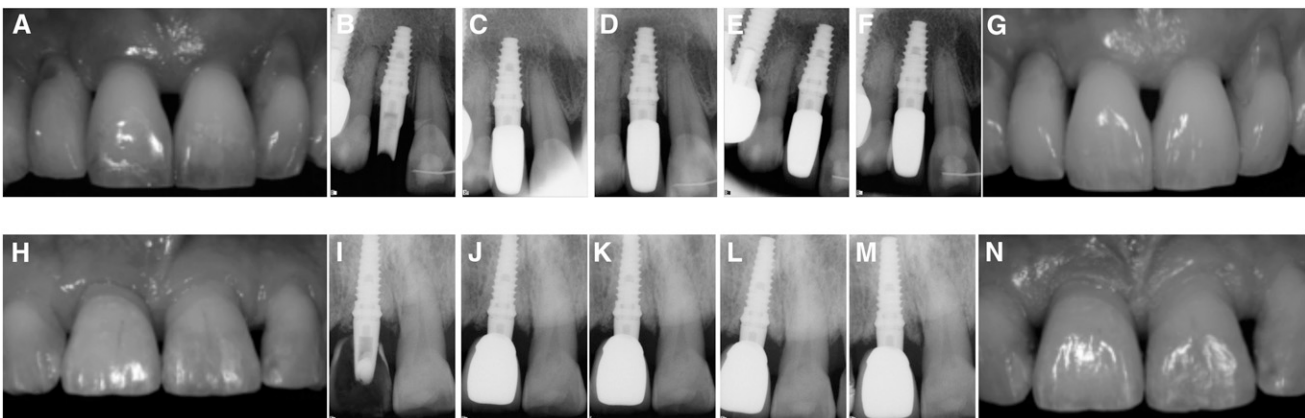
Thus the null hypothesis that marginal bone remodeling around PA-cleaned customized abutments would not differ from that of those undergoing steam-cleaning was rejected in favor of the alternative hypothesis.

Even though a power calculation was performed, the small sample size could represent one of the limitations of the present study. Nonetheless, this sample size can



**Figure 3.**

Test group patients showing no bone loss. **A through F)** Radiographs at T0. **G through L)** Radiographs at T5.



**Figure 4.**

Clinical and radiologic outcomes of control (**A through G**) and test groups (**H through N**) from T0 (left) to T5 (right).

be considered to be sufficient to detect the effect of PA cleaning treatment on implant abutments in patients with a history of periodontal disease and thin biotype. It is interesting to note that all patients included in this study, although controlled in a university department, were continuously monitored and treated for periodontal and implant maintenance over the study period, with no patient dropping out.

To better exploit ultracleaning advantages, implant abutments were connected at the second surgery, and this could represent another limitation. Hence the outcomes of the present study can be applied only to similar conditions.

### CONCLUSIONS

Within the limitations of the present study, the following conclusions can be drawn: in case of imme-

diately abutment connection, cleaning of the prosthetic components could benefit peri-implant crestal bone and soft tissue maintenance. In addition, PA could be used as a good method to disinfect implant abutments before insertion to minimize future peri-implant bone resorption. Further randomized controlled trials with larger sample sizes and longer follow-ups should be held to confirm the present data.

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