Iorio-Siciliano Vincenzo (Orcid ID: 0000-0002-1968-0021)
Salvi Giovanni E (Orcid ID: 0000-0001-5523-3192)

Resolution of peri-implant mucositis at tissue-and bone-level implants: A 6-month prospective controlled clinical trial.

Running title: Treatment of peri-implant mucositis at dental implants.

Iorio-Siciliano Vincenzo[1], Blasi Andrea[1], Isola Gaetano[2], Sculean Anton[3], Salvi Giovanni E.[3], Ramaglia Luca[1]

[1] Department of Periodontology, University of Naples Federico II, Via S. Pansini 5,80131-Naples (Italy)

[2] Department of General Surgery and Medical-Surgical Specialties, Unit of Periodontology, University of Catania, Via S. Sofia 78,98125, Catania, Italy.

[3] Department of Periodontology, School of Dental Medicine, University of Bern, Freiburgstrasse 7CH-3010 Bern, Switzerland.

Correspondence

Iorio-Siciliano Vincenzo

Department of Periodontology, University of Naples Federico II

Via S. Pansini 5,80131-Naples (Italy)

e-mail: enzois@libero.it

Author contributions:

I.S.V conceived the idea and treated the patients, B.A. performed the statistical analysis, I.G. collected the data, S.A., G.G.E. and R.L. led the writing.

ABSTRACT

Objective: To compare resolution of inflammation of naturally-occurring peri-implant mucositis (PM) at tissue-level (TL) and bone-level (BL) implants after non-surgical mechanical debridement.

Material and methods: Fifty-four patients with 74 Implants with PM were allocated in two groups (39 TL and 35 BL implants) and treated by means of subgingival debridement using a sonic scaler with a plastic tip without adjunctive measures. At baseline and at 1,3,6 months the full-mouth plaque score (FMPS), full-mouth bleeding score (FMBS), probing depth (PD), bleeding on probing (BOP) and modified plaque index (mPlI) were recorded. The primary outcome was BOP change.

Results: After 6 months, the FMPS, FMBS, PD and number of implants with plaque decreased statistically significantly in each group ($p<0.05$), however no statistically significant differences were found between TL and BL implants ($p>0.05$).

After 6 months, 17 (43.6%) TL and 14 (40%) BL implants showed a BOP-change of (17.9%) and (11.4%) respectively. No statistical difference was recorded between groups.

Conclusions: Within the limitations of present study, the findings showed no statistically significant differences in terms of changes in clinical parameters following non-surgical mechanical treatment of PM at TL and BL implants. A complete resolution of PM (i.e no BOP at all implant sites) was not achieved in both groups.

Word count: 5895

INTRODUCTION

Implant-supported dental prostheses are considered an effective and predictable therapy for the rehabilitation of partially and fully edentulous patients (Bornstein, Halbritter, Harnisch, Weber, Buser, 2009). Many studies reported a high survival and success rates greater than 95% in medium and long terms (Iorio-Siciliano, et al., 2015, Iorio-Siciliano, Blasi, Iorio-Siciliano, Isola, Ramaglia, 2021), however, titanium implants are not free of complications such as peri-implant mucositis (PM) and peri-implantitis (Daubert, Weinstein, Bordin, Leroux, Flemmig, 2015, Papathanasiou, Finkelman, Hanley, O Parashis, 2016). PM is an inflammatory lesion in the soft tissues around dental implants without peri-implant bone loss caused by biofilm accumulation in peri-implant sulcus (Pontoriero, et al.,1994, Salvi, Aglietta, Eick, 2012, Heitz-Mayfield & Salvi 2018). Clinically, this inflammation is characterized by bleeding on probing, erythema, swelling and suppuration without PD increase (Renvert, Persson, Pirih, Camargo, 2018). Although the inflammation affects the peri-implant soft tissues, an untreated PM may determine an irreversible marginal bone loss (Schwarz, Derks, Monje, Wang,2018, Costa, et al., 2012) and for this reason it is considered the precursor of peri-implantitis (Salvi, Cosgarea, Sculean, 2019). For these reasons, the treatment of PM should be considered the prerequisite for the prevention of peri-implantitis (Jepsen, et al., 2015). Several studies demonstrated the efficacy of professional biofilm removal (Meyer, et al.,2017) in combination to patient-administered mechanical and chemical plaque control protocols in the management of PM (Salvi, Zitzmann, 2014). In majority of those studies an improvement of the clinical parameters (e.g., BOP reduction) and the reversibility of PM was recorded, but the resolution of peri-implant soft tissues inflammation (all sites around implants with BOP-negative) was not always achieved (Schwarz, Becker, Renvert, 2015). Non-surgical debridement alone is effective in reducing

peri-implant mucositis; however, a complete healing was recorded in 43.7% of the treated implants (Maximo, de Mendonca, Renata Santos, 2009). For these reasons, many authors proposed to treat the PM by means of different anti-infective protocols based on professional biofilm removal with adjunctive measures (Schwarz, Becker, Sager,2015). In general, the application of adjunctive devices determines a reduction of the percentage of sites with BOP-positive, but they fail to obtain a complete healing in the most part of the cases. Resolution of PM was recorded in 38% and 29% of the cases when non-surgical debridement was performed in combination to chlorhexidine gel application (Heitz-Mayfield, Salvi, Botticelli, 2011) or to glycine powder air-polishing (Ji, Tan, Wang, Cao, Jin, 2014), respectively. Recently, Iorio-Siciliano and co-workers evaluated the effects of adjunctive delivery of a sodium hypochlorite gel in the treatment of PM, but only the 45% of the implants showed a resolution of peri-implant inflammation (Iorio-Siciliano, Blasi, Stratul, 2020). Probably, the lack of complete healing depends not only on the anti-infective protocol applied, but also on other factors related to implants (e.g., inadequate prosthesis design or deep mucosal tunnel) that do not allow an accurate biofilm removal from the peri-implant sulcus, and lead to its early accumulation after non-surgical instrumentation (Renvert, Polyzois, 2015). The presence of an inadequate prosthesis rehabilitation may contribute to biofilm accumulation and to consequent recurrence peri-implant inflammation. An over-contoured restoration (e.g., emergence angle > 30 degrees), determines more pronounced plaque retention and more inflammation compared to well-designed prostheses (Katafuchi, Weinstein, Leroux, Chen, Daubert,2018). Likewise, the interproximal open contacts between implant prostheses and natural teeth (Latimer, Gharpure, Kahng, Aljofi, Daubert, 2021) or an inadequate access to interproximal hygiene (Takamoli, Pascual, Martinez-Amargant, 2021) are considered risk indicators for peri-implant diseases. de Tapia and co-workers obtained a complete healing of peri-implant mucositis in 66.6% of the patients, when the inappropriate prostheses were modified to facilitate oral hygiene access after non-

surgical debridement (de Tapia, et al., 2019). Another factor influencing the complete resolution of PM after non-surgical debridement is the deep mucosal tunnel around dental implants. A deeper mucosal tunnel (i.e., ≥3 mm) appears to have an impact not upon the development, but upon the resolution of experimentally induced peri-implant mucositis (Chan, Pelekos, Ho, Cortellini, Tonetti,2019).

In other words, sometime the interface between the abutment and the implant shoulder is located deeply in subgingival position creating an area with a difficult access for the professional biofilm removal. In these and other situations, the presence of tissue-level implants with a smooth collar (e.g., implant neck ≥ 1.8 mm) could have a more cleanable surface respect to implant with bone level design. Scientific evidence demonstrated that tissue-level implants (TL) and bone-level implants (BL) show no differences in terms of osseointegration (Jung, et al., 2008, Cochran, et al., 2009) and soft tissue integration (Abrahamsson, Berglundh, Lindhe,1996). Both procedures (i.e., submerged or transmucosal) result in similar outcomes in regard to crestal bone level changes and to stability of clinical parameters (i.e., PD, REC and BOP) (Hämmerle, et al., 2012, Sanz, et al., 2015, Flores-Guillen, Alvarez-Novoa, Barbieri,2018), and there are not differences in the prevalence of PM (Rokn, et al., 2017, Monje, et al., 2018, French, Grandin, Ofec, 2019).

In our knowledge, there is limited evidence on the clinical resolution of PM at implants with different neck design. Hence, the aim of present study was to evaluate the effects of non-surgical mechanical instrumentation in the management of naturally-occurring PM at implants with different neck configurations.

MATERIAL AND METHODS

Study design

A prospective controlled clinical trial with a 6-month follow-up was designed. Implants diagnosed with PM and subjected to non-surgical mechanical treatment were allocated to test (i.e., tissue-level implants, TL) or control group (i.e., bone-level implants, BL) respectively. Blinding was not performed for clinical operators.

The null hypothesis of no statistical differences in terms of changes in bleeding on probing (BOP) between test and control groups was tested. The present trial was performed between February 2021 and December 2021. The study was registered on ClinicalTrial.gov registry (ID:NCT04751565) and it was conducted in observance to the Principles of the Declaration of Helsinki on experimentation involving human subjects. The research protocol was reviewed and approved by the Institutional Review Board of the University of Catania (approval number: 125/2020/PO). In addition, written consent was obtained from all patients before the study. The study was reported according to STROBE Statement.

Sample size calculation

Since no previous studies compared the soft tissue healing of naturally-occurring peri-implant mucositis (PM) at tissue-level (TL) and bone-level (BL) implants following non-surgical mechanical debridement, the sample size was set a priori at 60 patients with 80 implants.

Participants

All subjects were recruited from the Unit of Periodontology, University of Catania (Italy). Data were collected in the same center, while the statistical analysis was performed at the Department of Periodontology, University of Naples Federico II (Italy).

The following eligibility criteria were followed:

<u>Inclusion criteria</u>

- Male and female aged $\geq$ 18 years;

- TL and BL titanium implants with smooth necks supporting cemented or screw-retained single-unit crowns diagnosed with PM. On the basis of the Consensus Report of the 2017 World Workshop (Berglundh et al 2018), implants showing at least one ~~with~~ BOP-positive site were considered affected by mucositis;

- Implants placed in both arches;

- Patients with gingivitis or treated periodontitis (i.e., absence of residual PD $\geq$ 5 mm);

- Presence at least of 2 mm of keratinized mucosa at implant sites.

<u>Exclusion criteria</u>

- Presence of systemic diseases;

- Pregnant and lactating females;

- Smokers $\geq$ 10 cigarettes/day;

- Use of inflammatory drugs or antibiotics within 3 months prior to study recruitment;

- Implants with modified (i.e., micro-rough) necks;

- Interproximal open contacts between implant restoration and adjacent teeth;

- Peri-implantitis (Berglundh, et al.,2018).

Outcome measures

The primary outcome variable was change in BOP (Renvert, et al.,2018).

For each patient the following secondary outcomes were also assessed:

- Full mouth plaque score (FMPS) (O'Leary, Drake, Naylor,1972) and full mouth bleeding score (FMBS) (Claffey, Nylund, Kiger, Garrett, Egelberg,1990) representing the percentage of sites covered with plaque and with bleeding on probing in the entire dentition;

- Presence of plaque at implant sites according to plaque index (PlI)(Silness, Loe,1964) and modified plaque index (mPlI) (Mombelli, van Oosten, Schürch, Lang, 1987);

- Pocket probing depth (PD) measured from the peri-implant mucosal margin to the bottom of the sulcus.

All peri-implant parameters were assessed at six sites (i.e., mesio-buccal, buccal, disto-buccal, disto-oral, oral and mesio-oral) using a manual periodontal probe (PerioWise color coded probe, Premier, Plymouth Meeting, PA, USA) with a probing force of approximately 0.2 N (Figure 1-2). The clinical parameters were recorded at baseline and after 1-, 3- and 6-months follow-up by one experienced examiner (I.G.) while treatment was provided by one experienced periodontist (I.S.V.).

In addition, the following outcomes were evaluated:
- Disease resolution, considered as no BOP at all implants proceeding from the same patient.
- Treatment success, considered as implants without BOP.
- Number Needed to Treat (NNT), considered as the number of implants needed to be treated to prevent PM.

Clinical procedures

Prior to the baseline examination all subjects were instructed to achieve an adequate self-performed oral hygiene practice. To exclude implants with peri-implantitis a radiograph was taken for all implants prior to start of therapy. After full mouth supragingival scaling performed by means of ultrasonic device with metal tips, in the same session, the implants diagnosed with PM were treated by means of subgingival debridement using a sonic scaler with a plastic tip at maximum power (Kavo SONICflex, Biberach, Germany) (Figure 3). A polishing using rotating instrument and a rubber cup with low abrasive polishing paste was performed at the end of the non-surgical mechanical debridement. After completion of the therapy no chlorhexidine mouthwash, systemic antibiotics or inflammatory drugs were prescribed.

All patients were indicated to brush the interproximal area between implant and teeth by means of cylindrical or conical brushes or in case of difficult access a floss threader or specialized floss with a built-in threader was recommended. All patients were recalled at 1-, 3-, and 6-months following treatment (Figure 4). During the follow-up visits the clinical parameters were recorded and oral hygiene instructions were reinforced.

Statistical analysis

The statistical analysis was made by means of a statistical software package (IBM-SPSS, IBM inc. Armonk, NY). Age, FMPS, FMBS and PD were expressed as means and standard deviations (SD), while implants with positive mPlI and BOP were reported as frequencies and percentages. Patient was considered as statistical unit. In order to avoid bias, when multiple implants were present in the same patient, an average value of PD, and of percentages of implants with positive mPli and BOP was considered for statistical analysis. A generalized linear model for repeated measures was designed to evaluate variations in BOP, mPlI, PD, FMBS and FMPS among groups during observation time. The effects of gender, smoking habits and history of periodontitis were considered in the statistical analysis.

In addition, an implant-based analysis was also performed. Student's t-test was used to calculate the differences between TL and BL groups in mean age, while differences in gender, smoking habit, and number of patients with a history of periodontitis were calculated using Fisher's exact test. The differences in implant location were verified by means of chi-square test.

Friedman's test for repeated measures was used to assess the intra-group comparisons for mPlI, BOP and PD at baseline, 1-, 3-, and 6-months. Inter-group comparisons at baseline, 1-, 3-, and 6-months were analyzed by means of Mann-Withney's test. Differences in number of implants with BOP-negative were tested using chi-square test and NNT was calculated. Treatment success was defined as an implant with all sites BOP-negative.

Patients who declined participation to the study were excluded from the final analysis.

A p-value <0.05 was set to accept a statistically significant difference.

RESULTS

Subject accountability

A total of 60 patients with 80 implants (30 patients with 41 TL implants and 30 patients with 39 BL implants) were enrolled in the present study. After 6 months of observation, 54 patients with 74 implants (28 patients with 39 TL implants, and 26 with 35 BL implants) were available for the statistical analysis. In the test group, 36 Tissue Level Implants, (Straumann® Dental Implants System, Switzerland) with a sandblasted and acid-etched surface (SLA) and 3 Single-Stage implants, (BioHorizons System®, USA) with a tricalcium phosphate resorbable blasted textured (RBT) surface were enrolled. In the control group, 18 JD Evolution® implants, (JDental Care Implant System, Italy) with bioactive endosseous surface, 7 Internal implants, (BioHorizons System®, USA) with a tricalcium phosphate resorbable blasted textured (RBT) endosseous surface, 6 Premium® Implants, (Sweden&Martina, Italy) with zirconium sand-blasted acid-etched titanium surface (ZirTi) and 4 Xive-S® (Dentsply Sirona Implants, USA) with nano-structured Ca-incorporated oxide surface were selected. Six patients with 6 implants (2 patients with 2 TL implants and 4 patients with 4 BL implants) declined participation to the study for health problems. During the follow-up no implants were lost, and no complications were recorded.

Study participants characteristics

The demographic data of study population are summarized in Table 1. No statistical differences were noted between groups ($p>0.05$) (Tab.1). Nineteen TL implants were placed in the maxilla and 20 in the mandible, meanwhile 15 BL implants were installed in the maxilla and 20 in the mandible, respectively. No statistically significant difference was recorded with respect to implant locations between groups ($p>0.05$) (Tab.2).

Clinical outcomes

After 6 months, FMPS and FMBS decreased significantly in both groups ($p < 0.05$). At baseline, FMPS was 42.6±9.3% and 43.9±7.4% for patients with TL and BL implants, while a FMPS of 23.5±5.5% and 21.3±3.7% was recorded after 6-months observation times. After 6-months follow-up the FMBS changed from 32.5±6.5% to 21.7±2.5% in patients treated by means of TL implants and from 34.2±5.1% to 19.8±3.8% in patients with BL implants. No statistically significant differences were recorded between groups at baseline, 1,3, and 6-months follow-up ($p > 0.05$) (Tab.3).

Table 4 shows the results of patient-based analysis. The levels of BOP, mPlI, PD, FMBS and FMPS changed significantly during observation time ($p < 0.001$). This aspect is reflected in the graphs with values at all evaluation time points constantly lower than values at baseline. When considering the effect of potential confounding factors between subjects (test/control group, gender, smoking habits, and history of periodontitis) group significantly affected PD ($p < 0.05$) and gender significantly affected FMPS ($p < 0.05$). No other significant effect was recorded for any of the other included factors. Figure 5 shows the variations of BOP levels in TL and BL groups. In both groups, a steady decrease was recorded at 1-month follow-up, then the values increase to reach a plateau at 3- and 6-months follow-up (Figure 5). The levels of mPlI are reported in figure 6. Likewise, a steady decrease at 1-month was recorded for both groups. However, the levels of mPlI increase at 3- and 6-months in TL group, while they remain stable in BL group (Figure 6).

At baseline, PD values were statistically significant different ($p < 0.001$) between TL and BL groups, but no statistically significant differences were recorded at follow-up (Figure 7).

A higher variability of FMPS in females than in males was noted, nevertheless no significantly statistical differences were recorded at any time point. At 3-months, an increase of FMPS in female subjects was reported. Although no statistically significant difference (p=0.14) was found, this variation was a reflection of the different distribution of genders between TL and BL groups. Hence, FMPS was higher in TL group with respect to BL group (Figure 8).

The levels of FMBS are illustrated in figure 9. In both groups, FMBS decreases steadily at 1-month, but the parameter remains stable at 3- and 6-months follow-up.

Table 5 and table 6 report the findings of implant-based analysis. In table 5 the number of implants with plaque, number of implants with BOP-positive and PD changes at baseline and after 1,3, and 6-months were reported.

After 6-months following therapy, the number of implants with plaque reduced statistically significantly (p<0.05) from 32 to 22 in patients with TL implants and from 34 to 22 in patients treated using BL implants. No statistically significant differences were recorded with respect to the number of implants with plaque between groups at baseline,1,3, and 6-months follow-up (p>0.05).

Before the treatment of PM, 39 (100%) and 35 (100%) of the implants in TL and BL groups, respectively, were BOP-positive. After a 6-months follow-up, 22 (56%; CI 41-71%) TL implants showed a BOP-positive sites, while 21 (60%; CI 44-74%) implants with BOP-positive sites were observed in patients treated by means of BL implants. Statistically significant differences between baseline and 1-, 3-, and 6-months follow-up were recorded (p<0.05). On the contrary, inter-group comparisons did not show statistically significant differences (p>0.05).

The PD decreased significantly from 3.50±0.99 mm to 2.94±0.64 mm for the TL implants and from 4.17±0.99 mm to 2.94±0.53 mm for BL implants, after 6-months follow-up time

(*p*<0.05), while no statistically significant differences between groups at baseline and after 1,3 and 6-months were noted (*p*>0.05) (Tab.5).

Treatment success

Table 6 summarizes the number and percentages of implants without BOP.

One month following therapy, 61.5% of TL implants and 51.4% of BL implants resulted in disease resolution. At 6 months, the percentage of implants without BOP was 43.6% for TL and 40% for BL implants, respectively. No statistically significant difference (*p*>0.05) between groups was observed. A statistically significant reduction (*p*<0.05) was observed for TL implants between the 1- and 6-month follow-ups. At 1-month the NTT was 9.9, while after 3 and 6 months a NTT of 30.3 and 27.8 were recorded. (Tab. 6).

DISCUSSION

The present study aimed at comparing the resolution of naturally-occurring PM around TL and BL implants following non-surgical mechanical debridement. After 6 months of observation, all clinical parameters improved significantly in both groups. However, the inter-group comparison showed no statistically significant differences. Hence, the null hypothesis of non-statistically significant difference between groups was confirmed.

For many years the scientific community has debated whether tissue-level or bone-level implants yielded clinical advantages. Nowadays, the two implant types proved successful regarding the clinical and radiographic parameters (Vianna, et al., 2018). However, the peri-implant soft-tissue response at TL and BL implants had not been investigated.

The results of the present study are in agreement with Renvert and co-workers (Renvert, Roos-Jansaker, Claffey, 2008) on the effectiveness of nonsurgical mechanical debridement in the reduction of sites with plaque and with BOP-positive. Likewise, Maximo and co-workers reported a plaque and BOP reduction of 56.2% and 64.5% associated to a

significant changes in levels of *Porphyromons gingivalis*, *Treponema socranskii* and proportions of red complex after treatment of PM by means of non-surgical mechanical debridement alone (Maximo, et al., 2009). Despite an improvement of clinical parameters at implant sites was recorded, the present study indicates that the resolution of inflammation in peri-implant soft tissues (i.e., no BOP) was not achieved in all patients.

After a 6-months follow-up, disease resolution occurred was observed at 43.6% of TL and 40% of BL implants.

One of the potential explanations for the incomplete resolution of peri-implant soft tissue inflammation may be due to the depth of the mucosal tunnel around implants (Chan, et al.,2019). The depth of the mucosal tunnel depends on factors such as thickness of soft tissues and insertion depth of implant, evaluable when the screw-retained restorations are removed. Unfortunately, these parameters could not be assessed in the present study because the majority of the single-unit crowns were cemented, thus representing a limitation.

These findings are in agreement with the results of a previous systematic review indicating that non-surgical mechanical debridement failed to lead to complete healing of PM (Schwarz, et al., 2015).

In the present study, 43 implants (22 TL and 21 BL implants, respectively) with BOP-positive (58.1%) were recorded after 6-months. Similar results (51.1% of implants with BOP-positive) were reported by Hallström and co-workers (Hallström, Persson, Lindgren, Olofsson, Renvert, 2012), however the authors did not perform a separate statistical analysis for TL and BL implants.

In the majority of trials on the treatment of PM the primary outcome was based on PD reduction (Derks, et al., 2022), while in the present study the BOP was set as primary outcome. In agreement to a previous report by Renvert and co-workers 2018 (Renvert, et

al.,2018), the PD changes cannot be considered as primary diagnostic parameter for PM, because the probing depth at implant sites depends on the height of the soft tissues at implant location (i.e., mucosal tunnel). Although the use of a dichotomous primary outcome (i.e., presence or absence of BOP) requires a large sample of patients to obtain a statistically significant difference between groups, the present study should not be interpreted as an underpowered trial, because it was designed as a comparative study where randomization was not feasible. In addition, a sample size calculation was not performed, due to the fact that no previous studies compared soft tissue healing of naturally-occurring peri-implant mucositis (PM) at tissue-level (TL) and bone-level (BL) implants after non-surgical mechanical debridement. The sample size was set a priori because the present investigation reports a proof of principle demonstrating lack of statistically significant differences in terms of changes in clinical parameters following non-surgical mechanical treatment of PM at TL and BL implants. All patients enrolled in the present trial were rehabilitated by means of TL and BL implants with a non-modified neck due to enhanced possibility for decontamination of the neck area (Teughels, Van Assche, Sliepen, Quirynen, 2006) and reduced biofilm accumulation (Hermann, et al., 2020) compared with implants with a modified neck surface. Findings of previous studies reported no impact of PM therapy on changes in BOP scores (Bollen, et al.,1996) and changes in crevicular fluid biomarkers (Wennerberg, Sennerby, Kultje, Lekholm, 2003) when implants with modified surfaces were compared with those with non-modified surfaces (Schwarz et al.,2014). Both treatment groups of the present trial included only implants supporting single-unit crowns in order to facilitate biofilm removal. In fact, the accessibility to biofilm removal is a crucial point in the management of PM and the single-unit crown offers a better access for biofilm control with respect to implant-supported fixed dental prostheses (FDPs) (Romandini, et al., 2020).

Likewise, the association between biofilm accumulation and restoration type (i.e., single-unit crowns vs. FDPs) was also reported in another study (Rodrigo, et al., 2018) and may be explained by the more difficult access to oral hygiene procedures. The lack of accessibility for self-performed interproximal oral hygiene, using at least a 0.5 mm interproximal brush is associated to peri-implant disease and in particular to PM (Pons, Nart, Valles, Salvi, Monje, 2021). For these reasons, FDPs and full-arch fixed restorations were excluded from the present study.

The implants of both groups were treated using the same clinical procedure. Although different devices were proposed to decontaminate the implant necks without modification of the titanium surface (Cafiero, et al., 2017), in this study a sonic scaler with plastic tip was used. The choice of this device was based on a previous study comparing four clinical procedures (i.e., sonic scaler with plastic tip, glycine powder, titanium curettes and rubber cup) to remove the biofilm from the implant surface (Blasi, et al., 2016). This study reported a statistically significant reduction in the number of implants with plaque and BOP-positive sites when the sonic scaler with plastic tip was used to remove the biofilm compared with others instruments.

Patients were instructed not to use chlorhexidine mouthwash after treatment of PM, although it is a standard of care to prescribe mouthwashes in combination of non-surgical mechanical debridement. Several study outcomes indicated that mouthwashes do not influence the outcome of PM healing. Thöne-Mühling (Thöne-Mühling, et al., 2010) reported no statistically significant differences in terms of BOP reduction when PM was treated by means of non-surgical debridement with or without chlorhexidine mouthwash (i.e., 0.17% vs. 0.16%). Menezes and co-workers (Menezes, Fernandes-Costa, Silva-Neto, Calderon, Gurgel,2016) evaluated the efficacy of 0.12% chlorhexidine mouthwash in the treatment of PM and no statistically significant differences were found with respect to the placebo. These results are corroborated by a recent study conducted by Philip and co-workers (Philip, Laine,

Wismeijer,2020) who did not observe significant effects in BOP reduction when chlorhexidine mouthwash was prescribed, confirming that mechanical debridement alone is effective in treatment of PM. Therefore, the adjunctive delivery of antiseptics in combination with mechanical instrumentation of PM seems not to offer clinical benefits (Ramanauskaite,Fretwurst,Schwarz,2021).

In conclusion, within the limitations of the present study, the results indicated an improvement in clinical parameters of implants diagnosed with naturally-occurring PM following non-surgical mechanical instrumentation irrespective of the implant neck configuration. In both groups resolution of soft tissue inflammation was not achieved following a 6-month healing period.

Conflict of interest

Vincenzo Iorio-Siciliano declares that he has no conflict of interest related to this study.
Blasi Andrea declares that he has no conflict of interest related to this study.
Isola Gaetano declares that he has no conflict of interest related to this study.
Sculean Anton declares that he has no conflict of interest related to this study.
Salvi Giovanni E declares that he has no conflict of interest related to this study.
Ramaglia Luca declares that he has not conflict of interest related to this study.

REFERENCES

1. Abrahamsson,I.,Berglundh,T.,Lindhe,J.(1996). The peri-implant hard and soft tissue at different implant systems. A comparative study in the dog. Clinical Oral Implants Research, 7,212-219. doi: 10.1034/j.1600-0501.1996.070303.x.

2. Berglundh ,T., Armitage,G., Araujo,MG.,Avila-Ortiz,G., Blanco,J.,Camargo,PM.,Chen, S.,Cochran,D., Derks,J.,Figuero,E.,Heitz-Mayfield,LJA.,Huynh-Ba,G.,Iacono,V.,Koo,K.,Lambert,F.,McCauley,L.,Quyrinen,M.,Renvert,S.,Salvi,GE., Schwarz,F.,Tarnow,D.,Tomasi,C.,Wang,HL.,Zitzmann,N.(2018). Peri-implant diseases and condition: Consensus report of workgroup 4 of the 2017 world workshop on the classification of periodontal and peri-implant diseases and conditions. Journal of Clinical Periodontology,45(suppl 20),S286-S291. doi: 10111/jcpe.12957

3. Blasi, A.,Iorio-Siciliano,V.,Pacenza,C.,Pomigi,F.,Matarasso,S,.Rasperini,G.(2016). Biofilm removal from implants supported restoration using different instruments: a 6-month comparative multicenter clinical study. Clinical Oral Implants Research, 27,e68-e73.doi:10.1111/clr.12530

4. Bollen,C.M.,Papaioanno,W.,Van Eldere,J.,Schepers,E.,Quirynen,M., van Steenberghe,D.(1996). The influence of abutment surface roughness on plaque accumulation and peri-implant mucositis. Clinical Oral Implants Research,7,201-211. doi:10.1034/j.1600-0501.1996.070302.x.

5. Bornstein, M.M.,Halbritter, S. Harnisch, H., Weber, H.P., Buser, D. (2009). A retrospective analysis of patients reffered for implants placement to a speciality clinic regarding indication, surgical procedures and early failures. International Journal of Oral & Maxillofacial Implants, 23,1109-1116. doi:10.7892/BORIS.27149

6. Cafiero, C., Aglietta, M., Iorio-Siciliano, V., Salvi, G.E., Blasi, A., Matarasso, S.(2017). Implant surface roughness alterations induced by different prophylactic procedures: an in vitro study. Clinical Oral Implants Research, 28,e16-e20. doi: 10.1111/clr.12849

7. Chan,D.,Pelekos,G.,Ho,D.,Cortellini,P.,Tonetti,M.S. (2019). The depth of implant mucosal tunnel modifies the development and resolution of experimental mucositis: a case-control study. Journal of Clinical Periodontology, 46,248-255. doi:10.1111/jcpe.13066

8. Claffey,N.,Nylund,K.,Kiger,R.,Garrett,S.,Egelberg,J. (1990). Diagnostic predictability of scores of plaque,bleeding, suppuration and probing depth for probing attachment loss.3 ½ years of observation following initial periodontal therapy. Journal of Clinical Periodontology,17,108-114. doi:10.1111/j.1600-051x.1990.tb01071.x.

9. Cochran,D.L.,Bosshardt, D.D.,Grize,L., Higginbottom,F.L.,Jones,A.A:,Jung,R.E., Wieland,M., Dard,M. (2009). Bone response to loaded implants with non-matching implant-abutment diameters in the canine mandible. Journal of Periodontology, 80, 609-617. doi: 10.1902/jop.2009.080323

10. Costa,F.O.,Takenaka-Martinez,S.,Cota,L.O.,Ferreira,S.D.,Silva,G.L.,Costa,J.E. (2012). Peri-implant disease in subjects with and without preventive maintenance: a 5-year follow-up. Journal of Clinical Periodontology, 39,173-181. doi: 10.1111/j.1600-051x.2011.01819.x

11. Daubert,D.M.,Weinstein,B.F.,Bordin,S.,Leroux,B.G.,Flemmig,T.F.(2015).Prevalence and predictive factors for peri-implant disease and implant failure: a cross-sectional analysis. Journal of Periodontology, 86,337-347. doi:10.1902/jop.2014.140438

12. Derks, J., Ichioka,Y.,Dionigi,C.,Eriksson,A.T.,Berglundh,J.,Tomasi,C.,Graziani,F. (2022). Prevention and management of peri-implant mucositis and peri-implantitis: A systematic review of outcome measures used in clinical studies in the last 10 years. Clinical Oral Implants Research , accepted for publication.doi:10.1111/clr.13925

13. de Tapia,B.,Mozas,C.,Valles,C.,Nart,J.,Sanz,M.,Herrera,D.(2019). Adjunctive effect of modifying the implant-supported prosthesis in treatment of peri-implant mucositis.

Journal of Clinical Periodontology, 46, 1050-1060. doi: 10.1111/jcpe.13169

14. Flores-Guillen,J.,Alvarez-Novoa,C.,Barbieri,G.,Martin,C.,Sanz,M.(2018).
Five-years outcomes of a randomized clinical trial comparing bone-level implants
with either submerged or transmucosal healing.
Journal of Clinical Periodontology, 45,125-135. doi: 10.1111/jcpe.12832

15. French,D.,Grandin,H.M.,Ofec,R.(2019). Retrospective cohort study of 4,591 dental
implants : Analysis of risk indicators for bone loss and prevalence of peri-implant
mucositis and peri-implantitis. Journal of Periodontology, 90,691-700.
doi: 10.1002/JPER.18-0236

16. Hallstrom,H.,Persson,G.R.,Lindgren,S.,Olofsson,M.,Renvert,S.   (2012) Systemic
antibiotics
and debridement of peri-implant mucositis. A randomized clinical trial.
Journal of Clinical Periodontology,39,574-581.doi:10.1111/j.1600-051x.2012.01884.x.

17. Hammerle, C.H.F.,Jung,R.E.,Sanz,M.,Chen,S.,Martin,W.C.,Jackowski,J., on behalf
of this multicenter study group: Ivanoff,C-J.,Cordaro,L.,Ganeles,J.,Weingart,D.,
Wiltfang,J.,Gahlert,M.(2012). Submerged and transmucosal healing yield the same
clinical outcomes with two-piece implants in the anterior maxilla and mandible:
interim 1-year results of a randomized, controlled clinical trial. Clinical Oral Implants
Research 23,211-219. doi: 10.1111/j.1600-0501.2011.02210.x

18. Heitz-Mayfield,L.J.,Salvi ,G.E.,Botticelli,D.,Mombelli,A.,Faddy,M.,Lang,N.P. (2011).
Anti-infective treatment of peri-implant mucositis: a randomized controlled clinical
trial. Clinical Oral Implants Research, 22,237-241. doi:10.1111/j.1600-
0501.2010.02078.x

19. Heitz-Mayfield,L.J.,Salvi ,G.E.(2018).Peri-implant mucositis. Journal of Clinical
Periodontology,45,(Suppl 20),S237-S245. doi: 10.1111/jcpe.12953.

20. Hermann, H.,Kern,J-S.,Kern,T.,Lautensack,J.,Conrads,G.,Wolfart,S.(2020).
Early and mature biofilm on four different dental implant materials:an in vivo human

study. Clinical Oral Implants Research, 31,1094-1104. doi:10.11117clr.13656

21. Iorio-Siciliano,V.,Matarasso,R.,Guarnieri,R.,Nicolò,M.,Farronato,D.,Matarasso,S. (2015). Soft tissue conditions and marginal bone levels of implants with laser-microtextured collar:a 5-year, retrospective,controlled study. Clinical Oral Implants Research, 26,257-262. doi: 10.1111/clr.12518

22. Iorio-Siciliano,V.,Blasi,A.,Stratul,S.I.,Ramaglia,L.,Sculean,A.,Salvi,G.E.,Rusu,D. (2020). Anti-infective therapy of peri-implant mucositis with adjunctive delivery of a sodium hypochlorite gel: a 6-month randomized triple-blind controlled clinical trial. Clinical Oral Investigations, 24,1971-1979. doi: 10.1007/s00784-019-03060-2

23. Iorio-Siciliano,V., Blasi,A.,Iorio-Siciliano,A.,Isola,G.,Ramaglia,L.(2021).Clinical and radiographic outcomes of implants with two different collar surfaces in treated periodontitis patients: a 10-year retrospective study. International Journal of Periodontics and Restorative Dentistry, 41,e-233-e-242. doi:10.11607/prd.4819

24. Jepsen,S.,Berglundh,T.,Genco,R.,Aass,A.,Demirel,K.,Derks,K.,Zitzmann,N.U. (2015). Primary prevention of peri-implantitis: managing peri-implant mucositis. Journal of Clinical Periodontology, 42(suppl 16),S152-S157.doi: 10.1111/jcpe.12369

25. Ji,Y.J.,Tan,Z.H.,Wang,R.,Cao,J.,Jin,L.J. (2014). Effect of glycine powder air-polishing as an adjunct in the treatment of peri-implant mucositis:a pilot clinical trial. Clinical Oral Implants Research, 25, 683-689. doi: 10.1111/clr.12123

26. Jung,R.E.,Jones,A.A.,Higginbottom,F.L.,Wilson,T.G.,Schoolfield,J.,Buser,D. Hammerle,C.H.F.,Cochran, D.L. (2008). The influence of non-matching implant and abutment diameters on radiographic crestal bone levels in dogs. Journal of Periodontology, 79,260-270. doi:10.1902/jop.2008.070132

27. Katafuchi,M.,Weinstein,B.F.,Leroux, B.G., Chen,Y.W., Daubert, D.M.(2018). Restoration contour is a risk indicator for peri-implantitis: a cross-sectional radiographic analysis. Journal of Clinical Periodontology, 45,225-232.

doi: 10.1111/jcpe.12829

28. Latimer,J.M.,Gharpure,A.S.,Kahng,H.J.,Aljofi,F.E.,Daubert,D.M.(2021). Interproximal open contacts between implant restorations and adjacent natural teeth as a risk-indicator for peri-implant disease-a cross-sectional study. Clinical Oral Implants Research, 32, 598-607. doi: 10.1111/clr.13730

29. Maximo,M.B.,de Mendonca,A.C.,Renata-Santos,V.,Figuereido,L.C., Feres,M.,Duarte, P.M.(2009). Short-term clinical and microbiological evaluations of peri-implant diseases before and after mechanical anti-infective therapies. Clinical Oral Implants Research, 20,99-108. doi:10.1111/j.1600-0501.2008.01618.x

30. Menezes,K.M.,Fernandes-Costa,A.N.,Silva-Neto,R.,Calderon,P.S.,Gurgel,B.C.V. (2016). Efficacy of 0.12%Chlorhexidine gluconate for non-surgical treatment of peri-implant mucositis. Journal of Periodontology, 87,1305-1313. doi:10.1902/jop.2016.160144

31. Meyer,S.,Giannopoulou,C.,Courvoisier,D.,Schimmel,M.,Muller,F.,Mombelli,A.(2017) .Experimental mucositis and experimental gingivitis in person aged 70 or over.Clinical and biological responses. Clinical Oral Implants Research, 28,1005-1012. doi:10.1111/clr.12912

32. Mombelli,A.,van Oosten,M.A.C.,Schurch,E.,Lang,N.P.(1987). The microbiota associated with successful or failing osseointegrated titanium implants. Oral Microbiology Immunology, 2, 145-151. doi: 10.1111/j1399-302x.1987.tb00298.x.

33. Monje,A.,Caballe-Serrano,J.,Nart,J.,Penarrocha,D.,Wang,H.L.,Rakic,M.(2018). Diagnostic accuracy of clinical parameters to monitor peri-implant conditions: a matched case-control study. Journal of Periodontology, 89,407-417. doi: 10.1002/JPER.17.0454

34. O'Leary,T.J.,Drake,R.B.,Naylor,J.E.(1972). The plaque control record. Journal of Periodontology, 43,38. doi: 10.1902/1972.43.1.38

35. Papathanasiou,E.,Finkelman,M.,Hanley,M.,Parashis,A.O.(2016).Prevalence, etiology and treatment of peri-implant mucositis and peri-implantitis: a survey of periodontists in United States. Journal of Periodontology, 87,493-501. doi:10.1902/jop.2015.150476

36. Philip,J.,Laine,M.L.,Wismeijer,D.(2020).Adjunctive effect of mouthrinse on treatment of peri-implant mucositis using mechanical debridement: a randomized clinical trial. Journal of Clinical Periodontology, 47,883,891. doi:10.1111/jcpe.13295.

37. Pons,R.,Nart,J.,Valles,C.,Salvi,G.E.,Monje,A.(2021). Self-administrated proximal Implant-supported hygiene measures and the association to peri-implant conditions. Journal of Periodontology, 92,389-399. doi:10.1002/JPER.20-0193

38. Pontoriero,R.,Tonelli,M.P.,Carnevale,G.,Mombelli,A.,Nyman,S.R.,Lang,N.P.(1994). Experimentally induced peri-implant mucositis. A clinical study in humans. Clinical Oral Implants Research, 5,254-259. doi:10.1034/j.1600-0501.1994.050409.x

39. Ramanauskaite,A., Fretwurst,T.,Schwarz,F.(2021). 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. International journal of implant dentistry, 7,112. doi: 10.1186/s40729-021-00388-x

40. Renvert,S.,Roos-Jansaker,A-M.,Claffey,N.(2008). Non-surgical treatment of peri-implant mucositis and peri-implantitis: a literature review. Journal of Clinical Periodontology, 35 (suppl.8), 305-3015. doi: 10.1111/j.1600-051X.2008.01276.x

41. Renvert,S.,Polyzois,I. (2015). Risk indicators for peri-implant mucositis: a systematic literature review. Journal of Clinical Periodontology, 42(suppl 16),S172-S186. doi: 10.1111/jcpe.12346.

42. Renvert,S.,Persson,G.R.,Pirih,F.Q.,Camargo,P.M.(2018).Peri-implant health, peri-implant mucositis, and peri-implantitis: case definitions and diagnostic

considerations. Journal of Clinical Periodontology, 45(suppl 20),S278-S285. doi:10.1111/jcpe.12956

43. Rodrigo,D.,Sanz-Sanchez,I.,Figuero,E.,Llodrà,J.C.,Bravo,M., Caffesse,R.G.,Vallcorba, Vallcorba,N.,Guerrero,A.,Herrera,D.(2018).Prevalence and risk indicators of peri-implant diseases in Spain. Journal of Clinical Periodontology, 45,1510-1520. doi:10.1111/jcpe.13017

44. Rokn,A.,Aslroosta,H.,Akbari,S.,Najafi,H.,Zaveri,F.,Hashemi,K.(2017). Prevalence of peri-implantitis in patients not participating in well-designed supportive periodontal treatments:a cross-sectional study. Clinical Oral Implants Research, 28,314-319. doi:10.1111/clr.12800

45. Romandini,M.,Lima,C.,Pedrinaci,I.,Araoz,A.,Soldini,M.C.,Sanz,M.(2020). Clinical signs,symptoms,perceptions, and impact on quality of life in patients suffering from peri-implant diseases: a university-representative cross-sectional study. Clinical Oral Implants Research, 32,100-111. doi: 10.1111/clr.13683.

46. Salvi,G.E,Aglietta,M.,Eick,S.,Sculean,A.,Lang,N.P.,Ramseier,C.A.(2012). Reversibility of experimental peri-implant mucositis compared with experimental gingivitis in human. Clinical Oral Implants Research, 23,182-190. doi: 10.1111/j.1600-0501.2011.02220.x

47. Salvi ,G.E., Zitzmann,N.U. (2014). The effects of anti-infective preventive measures on the occurrence of biologic implant complications and implant loss:asystematic review. International Journal of Oral and Maxillofacial Implants, 29(suppl),292-307. doi:10.11607/jomi.2014suppl.g5.1

48. Salvi,G.E.,Cosgarea,R.,Sculean,A.(2019). Prevalence of periimplant diseases. Implant Dentistry, 28,100-102. doi: 10.1097/ID.0000000000000872

49. Sanz,M.,Ivanoff,C-J.,Weingart,D.,Wiltfang,J.,Gahlert,M.,Cordaro,L.,Ganeles,J., Bragger,U.,Jackowski,J.,Martin,W.C.,Jung,R.E.,Chen,S.,Hammerle,C.H.F.(2015). clinical and radiologic outcomes after submerged and transmucosal implant

placement with two-piece implants in the anterior maxilla and mandible: 3-year results of a randomized controlled clinical trial. Clinical Implant Dentistry and Related Research, 17,234-246.doi:10.1111/cld.12107

50. Silness,J.,Loe,H.(1964). Periodontal disease in pregnancy.II.Correlation between hygiene and periodontal condition. Acta Odontologica Scandinavica, 22,121-135. doi:10.3109/00016356408993968

51. Schwarz,F.,Mihatovic,I.,Golubovic,V.,Eick,S.,Iglhaut,T.,Becker,J (2014). Experimental peri-implant mucositis at different implant surfaces. Journal of Clinical Periodontology,41,513-520. doi: 10.1111/jcpe.12240.

52. Schwarz, F.,Becker,K.,Renvert,S.(2015).Efficacy of air polishing for the non-surgical treatment of peri-implant diseases. A systematic review. Journal of Clinical Periodontology, 42,951-959. doi: 10.1111/jcpe.12454

53. Schwarz,F.,Becker,K.,Sager,M.(2015). Efficacy of professionally administrated plaque removal with or without adjunctive measures for the treatment of peri-implant mucositis.A systematic review and meta-analysis. Journal of Clinical Periodontology, 42 (Suppl 16), S202-S213. doi: 10.1111/jcpe.12349

54. Schwarz,F.,Derks,J.,Monje,A.,Wang,H.L.(2018). Peri-implantitis. Journal of Clinical Periodontology, 45, S246-S266. doi: 10.1111/jcpe.12954

55. Takamoli,J.,Pascual,A.,Martinez-Amargant,J., Garcia-Mur,B., Nart,J.,Valles,C. (2021). Implant failure and associated risk indicators : a retrospective study. Clinical Oral Implants Research, 32,619-628. doi: 10.1111/clr.1372

56. Teughels,W.,Van Assche,N.,Sliepen,I.,Quirynen,M.(2006).Effect of material characteristics and/or abutment topography on biofilm development. Clinical Oral Implants Research, 17(suppl 2), 68-81. doi:10.1111/j.1600-0501-2006.01353.x.

57. Thone-Muhling,M.,Swierkot,K.,Nonnenmacher,C.,Mutters,R.,Flores-de-Jacoby,L., Mengel,R.(2010).Comparison of two full-mouth approaches in the treatment of

peri-implant mucositis: a pilot study. Clinical Oral Implants Research, 21,504-512.
doi: 10.1111/j.1600-0501.2009.011861.x

58. Vianna,T.T.,Taiete,T.,Casarin,R.C.V.,Giorgi,M.C.C. Aguiar,F.H.B.,Silverio,K.G., Nociti,F.H.J.,Sallum,E.A.,Casati,M.Z.(2018). Evaluation of peri-implant marginal tissues around tissue-level and bone-level implants in patients with a history of chronic periodontitis. Journal of Clinical Periodontology, 45,1255-1265.
doi: 10.1111/jcpe.12999

59. Wennerberg,A.,Sennerby,L.,Kultje,C.,Lekholm,U.(2003). Some soft tissue characteristics at implant abutment with different surface topography. A study in humans. Journal of Clinical Periodontology, 30,88-94.
doi:10.1034/J.1600-051x.2003.10026.x.

TABLES

TAB.1 Patient's characteristics available for the analysis

	Gender (M/F)	Mean Age (years)	Age Range (years)	N° of smokers	N° of patients with past history of periodontitis
Patients with Tissue-level Implants (N=28)	8/20	49.5±12.4	29-68	4	8
Patients with Bone-Level Implants (N=26)	13/13	47.0±11.5	25-70	4	6
Significance	0.09*	0.40*	■	0.99*	0.79*

*No statistically significant difference
N= number of patients
M=male
F=female

TAB.2 Implant location available for the analysis.

	Anterior Maxilla	Posterior Maxilla	Anterior Mandible	Posterior Mandible

Tissue-level Implants (N=39)	4	15	0	20
Bone-Level Implants (N=35)	2	13	1	19
Significance	0.31*			

*No statistically significant difference
N= number of patients

TAB.3 FMPS and FMBS at baseline and after 1-, 3- and 6-months follow-up.

	Baseline	1 months	3 months	6 months	Significance
FMPS (%)					
Tissue-level Implants (N=39)	42.6±9.3	23.0±4.5	24.7±4.9	23.5±5.5	0.0001 **
Bone-Level Implants (N=35)	43.9±7.4	21.9±2.9	22.5±3.9	21.3±3.7	0.0001 **
Significance	0.21 *	0.21 *	0.56 *	0.35 *	
FMBS (%)					
Tissue-level Implants (N=39)	32.5±6.5	20.1±5.0	21.7±2.5	21.7±2.5	0.0001 **
Bone-Level Implants (N=35)	34.2±5.1	18.2±5.0	19.9±4.2	19.8±3.8	0.0001 **
Significance	0.02 **	0.96 *	0.33 *	0.52 *	

*No statistically significant difference
**Statistically significant difference

TAB.4 Univariate test within-subject effects

Source	Variable	Sum of squares (type III)	Degrees of freedom	Mean square	F	Significance
Time	BOP	59930.467	3	19976.822	18.308	0.0001**
	mPll	38729.408	3	12909.803	13.504	0.0001**
	PD	29.557	1.926	15.346	26.117	0.0001**
	FMBS	2840.198	2.065	1375.629	71.983	0.0001**
	FMPS	6892.846	1.723	4000.825	96.137	0.0001**
Time x group	BOP	1070.230	3	356.743	.327	0.806*
	mPll	7075.547	3	2358.516	2.467	0.065*
	PD	3.607	1.926	1.873	3.187	0.048**
	FMBS	57.665	2.065	27.930	1.461	0.237*
	FMPS	87.404	1.723	50.732	1.219	0.297*
Time x gender	BOP	2780.443	3	926.814	0.849	0.469*
	mPll	3367.612	3	1123.204	1.175	0.322*
	PD	0.746	1.928	0.388	0.660	0.514*
	FMBS	23.270	2.065	11.271	0.590	0.562*
	FMPS	301.960	1.723	175.267	4.212	0.024**
Time x smoke	BOP	1760.973	3	586.991	0.538	0.657*
	mPll	2250.534	3	750.178	0.785	0.505*
	PD	1.853	1.926	0.962	1.637	0.202*
	FMBS	18.219	2.065	8.824	0.462	0.501*

	FMPS	151.042	1.723	87.670	2.107	0.136*
Time x perio	BOP	2099.085	3	699.69.5	0.641	0.590*
	mPlI	4638.676	3	1546.225	1.617	0.189*
	PD	1.095	1.926	0.569	0.968	0.410*
	FMBS	38.664	2.065	18.727	0.980	0.405*
	FMPS	84.250	1.723	48.901	1.175	0.309*

*No statistically significant difference
**Statistically significant difference

TAB.5 Change in number of implants with plaque, number of implants with BOP-positive and probing depths (mean±SD), at baseline,1-,3-, and 6 months follow-up.

Number of implants with plaque (mPlI)					
	Baseline	1-month	3-months	6-months	Significance
Tissue-level Implants (N=39)	32	15	22	22	0.001 **
Bone-Level Implants (N=35)	34	19	19	22	0.0001 **
Significance	0.06 *	0.243 *	0.99 *	0.639 *	
Number of implants with BOP-positive					
	Baseline	1-month	3-months	6-months	Significance
Tissue-level Implants (N=39)	39	15	21	22	0.0001 **
Bone-Level Implants (N=35)	35	17	20	21	0.0001 **
Significance	0.99 *	0.482 *	0.818 *	0.816 *	
PD (mm)					
	Baseline	1-month	3-months	6-months	Significance
Tissue-level Implants (N=39)	3.50±0,99	2.83±0,79	2.78±0,73	2.94±0,64	0.005 **
Bone-Level Implants (N=35)	4.17±0,99	2.72±0,75	2.61±0,50	2.94±0,53	0.0001 **
Effect size	0,68	0,14	0,27	0	
Significance	0.05 *	0.67 *	0.43 *	0.99 *	

*No statistically significant difference
**Statistically significant difference
Implants with BOP are implants showing at least one site with BOP-positive
PD= Probing Depth

TAB.6 Number and percentage of BOP negative implants (treatment success) at 1-,3-, and 6 months follow-up.

BOP negative implants (N/%)				
	Tissue-level Implants (N=39)	Bone-level implants (N=35)	Significance	Number Needed to Treat (NNT)
1 month	24 (61.5%)	18 (51.4%)	0.482 *	9.9
3 months	18 (46.2%)	15 (42.9%)	0.818 *	30.3
6 months	17 (43.6%)	14 (40%)	0.816 *	27.8
Significance	0.005 **	0.197 *		

*No statistically significant difference
**Statistically significant difference
Treatment success defined as implants without BOP.

Figure 1 : Clinical parameters assessed at baseline.

Figure 2 : X-ray exam at baseline.

Figure 3 : Submucosal debridement using sonic scaler with plastic tip.

Figure 4 : Clinical parameters recorded at 6-months follow-up.

Figure 5 : Spaghetti Plot reports the BOP estimated marginal means.

Figure 6 : Spaghetti Plot shows the plaque estimated marginal means.

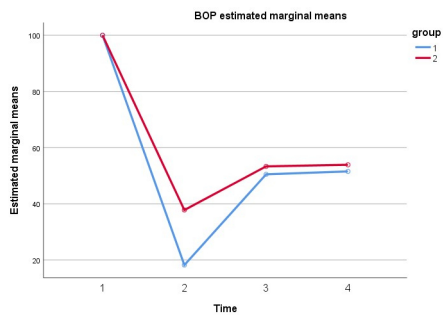Figure 7 : Spaghetti Plot illustrated the PD estimated marginal means.

Figure 8 : Spaghetti Plot reports the FMPS estimated marginal means.

Figure 9 : Spaghetti Plot shows the FMBS estimated marginal means.

CLR_14051_Figure1.JPG
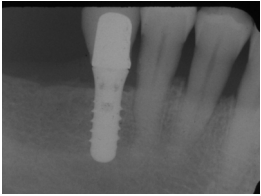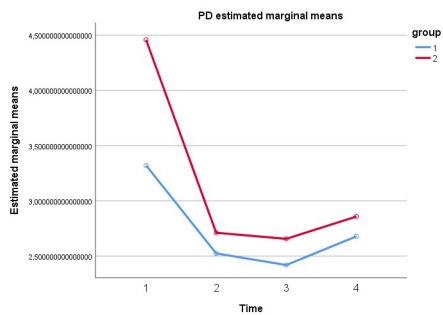
CLR_14051_Figure2.jpg

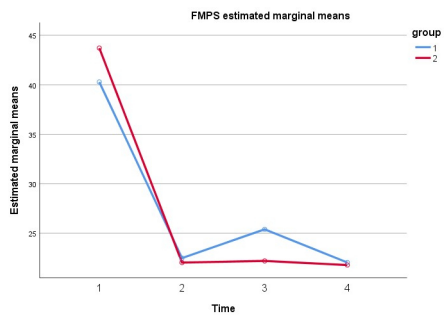CLR_14051_Figure3.JPG

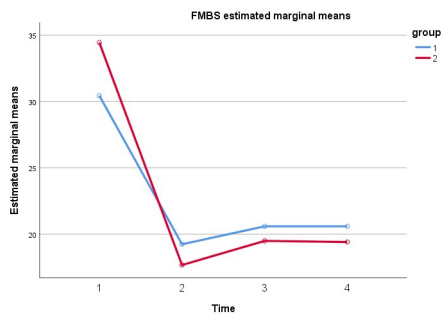CLR_14051_Figure4.JPG

CLR_14051_Figure5.jpg
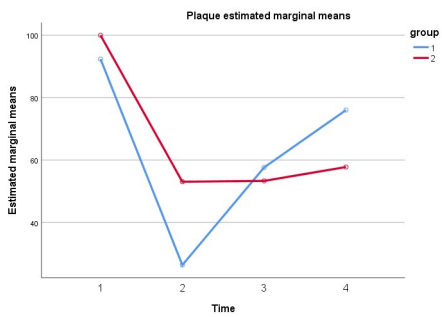
CLR_14051_Figure6.jpg

CLR_14051_Figure7.jpg

CLR_14051_Figure8.jpg

CLR_14051_Figure9.jpg