Received: 21 May 2019 | Revised: 23 June 2019 | Accepted: 6 July 2019

DOI: 10.1111/jcpe.13169

IMPLANT DENTISTRY

Journal of Clinical Periodontology WILEY

# Adjunctive effect of modifying the implant-supported prosthesis in the treatment of peri-implant mucositis

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## Abstract

**Aim:** To evaluate the adjunctive effect of modifying the implant-supported prosthesis to facilitate access to oral hygiene when treating peri-implant mucositis.

**Material and methods:** A 6-month randomized clinical trial was designed. Patients with peri-implant mucositis were treated by implant surface debridement with plastic curettes and a plastic tipped ultrasonic device. Then, they were randomly assigned to either modifying their prosthesis to allow for better oral hygiene (test group) or not (control group). Subsequently in both groups, individualized oral hygiene instructions were provided. Clinical and radiographical outcomes were evaluated at baseline and 1, 3 and 6 months after treatment.

**Results:** 48 patients were included, and 45 completed the clinical trial (24 test and 21 control patients). After 6 months, changes in the modified bleeding index between the control and test groups were 0.50 (standard deviation –*SD* = 0.70) and 1.14 (*SD* = 0.96), respectively ($p = 0.01$). The changes in implant probing pocket depth at 6 months were −0.02 (*SD* = 0.61) and 0.31 (*SD* = 1.20) mm, respectively ($p = 0.04$).

**Conclusions:** Modifying the contour of the prostheses to improve access for oral hygiene significantly improved the clinical outcomes after standard mechanical treatment of peri-implant mucositis.

KEYWORDS

dental implant, dental prosthesis, implant-supported, non-surgical treatment, peri-implant mucositis

## 1 | INTRODUCTION

Peri-implant diseases are inflammatory conditions affecting peri-implant tissues, triggered by the presence of peri-implant biofilms in susceptible individuals (Merli et al., 2014). Peri-implant diseases were redefined at the 2017 World Workshop on the Classification of Periodontal and Peri-implant Diseases and Conditions and were classified in peri-implant mucositis (PM), characterized by the presence of reversible inflammatory changes, as bleeding on gentle probing, erythema, swelling and/or suppuration in the mucosa around an implant and peri-implantitis (PI), in which the inflammation of the mucosa is followed by progressive loss of the supporting bone (Berglundh et al., 2018).

The relative importance of these diseases has evolved due to the use of different case definitions resulting in very heterogeneous prevalence data. During the 8th European Workshop in Periodontology (2012), Sanz and Chapple (2012) suggested the use of international accepted case definitions for future epidemiological research. Using these recommendations, a population-based study assessing the prevalence of peri-implant diseases in the Swedish population

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reported that 42.2% of the patients suffered PM, while PI was present in 21.7% (Derks et al., 2016). A similar analysis, from a multicentre cross-sectional study in Spain, evaluating 474 implants in 275 patients, reported a prevalence of PM in 27% (95% CI 22–32) and PI in 24% (95% CI 19–29) of the patients, respectively (Rodrigo et al., 2018). These high figures clearly underscore the need to find effective preventive and therapeutic modalities to control peri-implant diseases.

Since PM precedes peri-implantitis, the primary prevention of PI involves the treatment of PM (Salvi & Zitzmann, 2014), and therefore, the aim of PM therapy should be the resolution of peri-implant mucosal inflammation as determined by the absence of bleeding on probing (BOP).

Many studies have shown that non-surgical mechanical treatment can successfully control PM, reducing plaque and bleeding scores (Renvert, Roos-Jansaker, & Claffey, 2008). However, in some of these clinical studies, several weeks after therapy, there was a recurrence of the disease in a significant percentage of patients (Blasi et al., 2016; Heitz-Mayfield et al., 2011). One of these studies is a randomized clinical trial (RCT), which reported a complete resolution of inflammation in 76% of the implants at one month after mechanical instrumentation, while only 38% of those treated implants remained healthy at 3 months post-therapy (Heitz-Mayfield et al., 2011).

Even though individual subject's characteristics, such as genetic factors, history of periodontitis, tobacco smoking, systemic conditions, may modulate the immune response and hence the degree of inflammation (Casado, Villas-Boas, de Mello, Duarte, & Granjeiro, 2013; Laine, Morre, Murillo, van Winkelhoff, & Pena, 2005; Pimentel et al., 2018), the occurrence of PM is mainly influenced by plaque accumulation and therefore effective oral hygiene is fundamental in their prevention and management. In fact, different clinical studies have reported a cause-and-effect relationship between experimental plaque accumulation and the development of PM (Pontoriero et al., 1994; Zitzmann, Berglundh, Marinello, & Lindhe, 2001). Similarly, the reversibility of experimental PM after the re-institution of plaque control has been confirmed by the decrease to baseline values of crevicular fluid levels of host-derived biomarkers (Salvi et al., 2012).

Apart from oral hygiene practices, other local factors may have an impact on how biofilm accumulates on implant and abutment surfaces, such as the micro-surface topography of implants and abutments (Nascimento et al., 2014), the absence of keratinized tissue (Boynuegri, Nemli, & Kasko, 2013) or an inappropriate prosthesis design with contours that prevent adequate oral hygiene practices (Serino & Strom, 2009). In these situations, standard mechanical therapies may not be sufficient for an adequate management of PM. It was, therefore, the aim of this randomized clinical trial to evaluate the adjunctive effect of modifying the contours of the prosthesis to facilitate plaque access to oral hygiene in patients suffering from PM.

**Clinical Relevance**

*Scientific rationale for the study*: Peri-implant mucositis is a highly prevalent and recurrent disease. Non-surgical mechanical treatment has demonstrated to be efficacious in the treatment of peri-implant mucositis by reducing mucosal inflammation, although these results have not been predictably been maintained long term and there is a need to identify adjunctive approaches to improve this predictability.
*Principal findings*: By reducing the contours in the implant-supported prostheses, facilitating oral hygiene resulted in higher bleeding and probing depth reduction over time.
*Practical implications*: These results provide evidence that proper prosthesis design is an important factor in the maintenance of peri-implant health.

## 2 | MATERIALS AND METHODS

### 2.1 | Ethical issues

This study was performed according to the principles outlined in the Declaration of Helsinki and Ethical Conduct for Research with Human Beings and after the approval of the Ethics Committee of the Universitat Internacional de Catalunya (UIC) (Ref. PER-ECL-2017-01). Experimental procedures were performed between January 2017 and July 2018. Written informed consent was required from all participants after being informed of the study. The trial was registered at ClinicalTrials.gov (NCT03540290).

### 2.2 | Study design

The present study was a prospective randomized controlled intervention trial with a 6-month follow-up. Figure 1 describes the flow chart of the study. The reporting of this clinical trial has followed the Consolidated Standards of Reporting (CONSORT) guidelines.

Randomization of patients was performed using a computer-generated list with permuted blocks of four. Allocation concealment was assured by using sealed opaque envelopes that assigned patients to their respective treatment groups. These envelopes were labelled with the patient study number, and only open once mechanical debridement therapy was finished.

### 2.3 | Study population

Patients attending the Department of Periodontology at UIC and diagnosed with PM were recruited consecutively. One calibrated investigator (B.dT) evaluated patients for screening and was responsible for enrolling them in the study if they fulfilled the following inclusion and exclusion criteria.

Patients were required to have, at least, one titanium implant exhibiting PM (bleeding on gentle probing—i.e. 0.20 N—in at least one site) and a screw-retained single tooth and bridgework implant-supported restoration with an inappropriate prosthesis design or

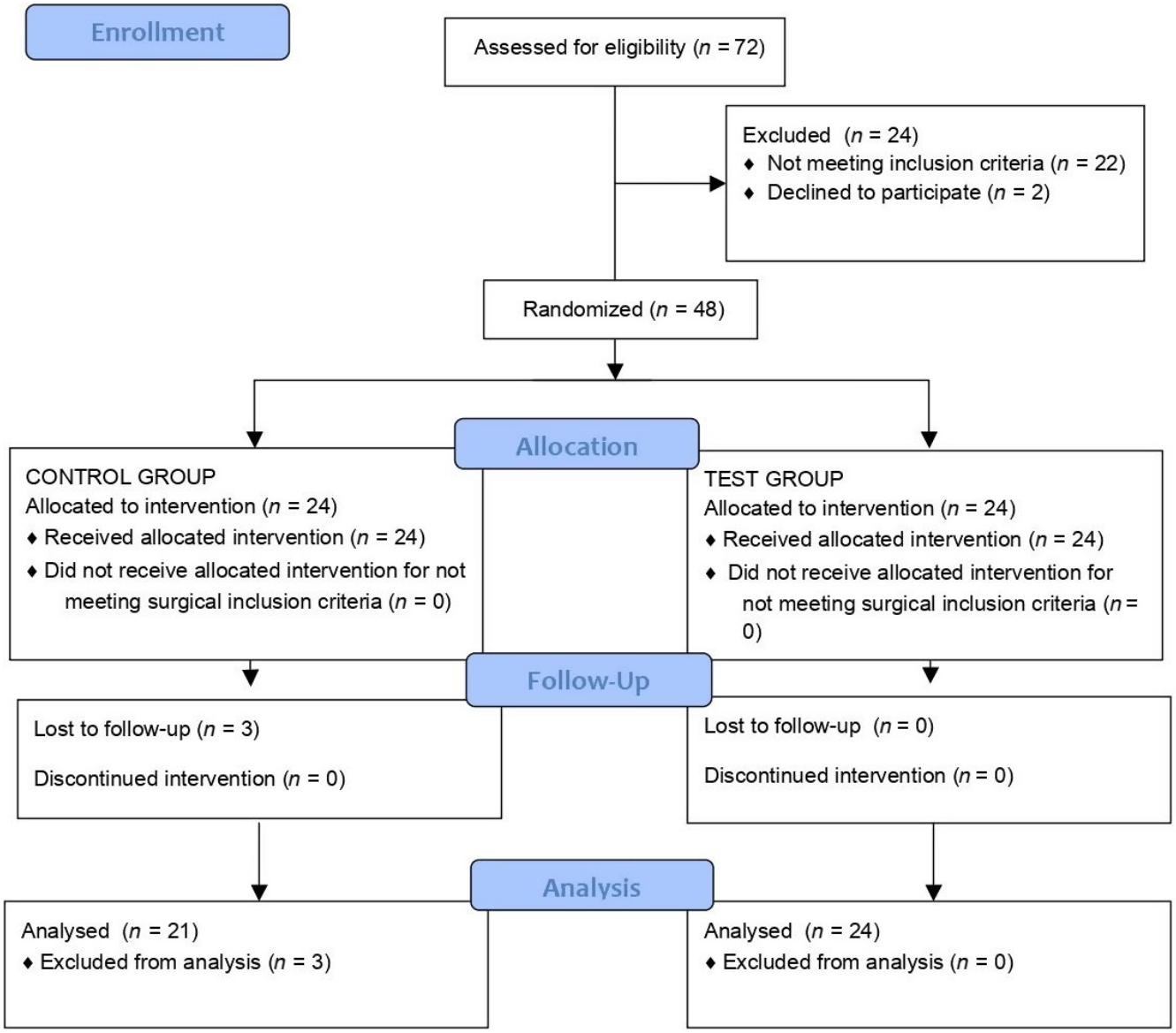


**FIGURE 1** CONSORT flow diagram of the study

contour (over-contoured prosthesis, prostheses presenting closed embrasures, a convex emergence profile or excessive buccal flanges) that made difficult oral hygiene access to the neck of the implant by an interproximal brush of 0.4 mm in diameter (Interprox®, Dentaid) (Figures 2a, b and 3a).

The presence of >1 mm of keratinized peri-implant mucosa and a good level of oral hygiene (plaque index < 25%) (O'Leary, Drake, & Naylor, 1972) were required. Furthermore subjects had to be free of relevant systemic diseases that might influence outcomes of the therapy and only non-smokers or light smokers (<10 cigarettes/day) were included.

Patients with untreated periodontal conditions, pregnant or lactating women, and those patients who had received systemic antibiotics or mucositis treatment in the previous three months were excluded from the study, as well as those receiving corticoids or medication known to have an effect on gingival growth (i.e. calcium channel antagonists, immunosuppressants or antiepileptic drugs).

## 2.4 | Treatment

### 2.4.1 | Debridement

All subjects received a session of full-mouth professional prophylaxis, including scaling and tooth polishing. On the affected implants, the crowns or the bridgeworks were removed and supra- and sub-gingival debridement of the implant surface, the implant neck and the abutment was carried out by means of a combination of ultrasonics (DTE-D5, Woodpecker®) with a plastic tip (Hu-Friedy®) and plastic curettes (Hu-Friedy®). Finally, the prostheses were repositioned and the prosthetic components were polished with a rubber cup.

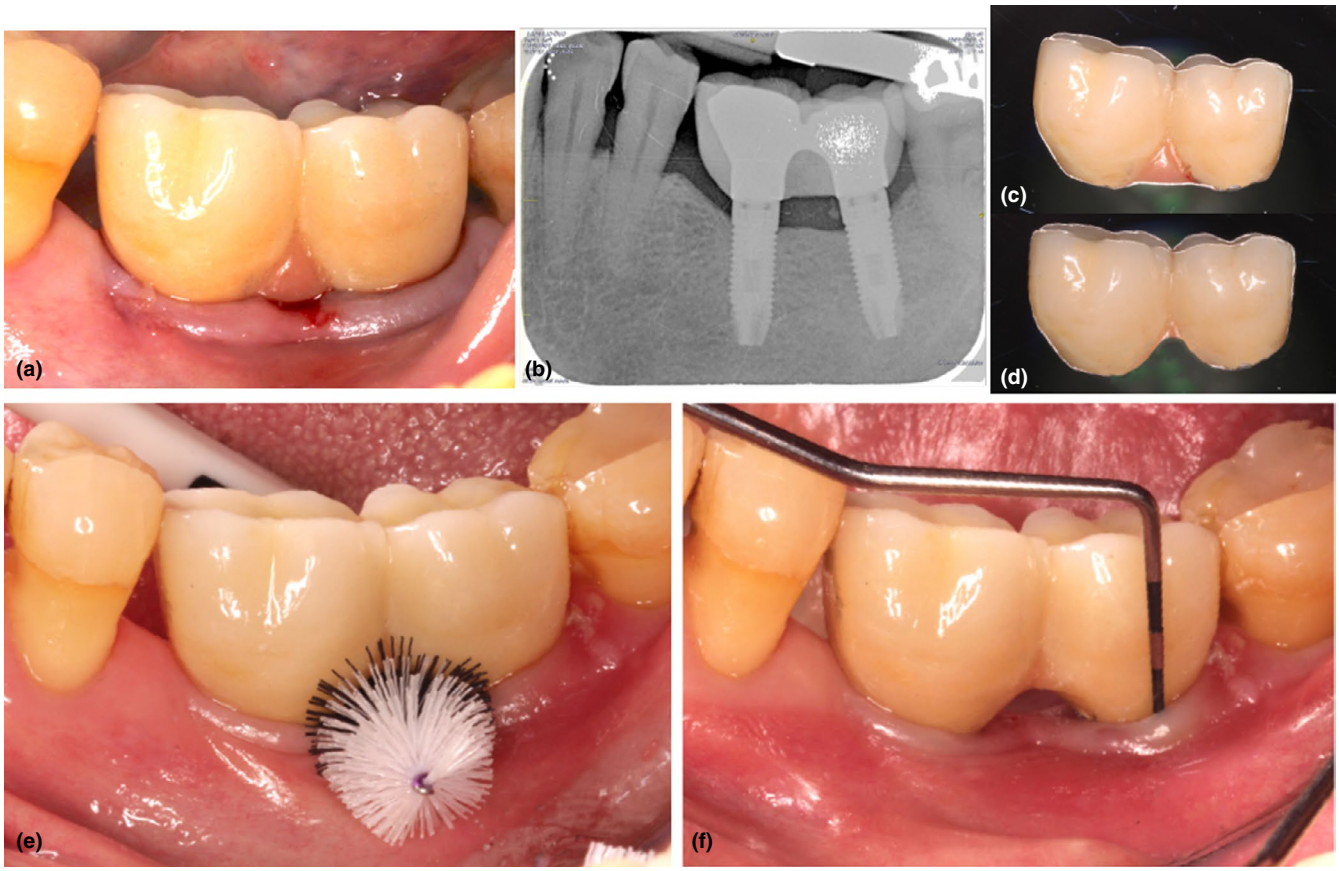


**FIGURE 2** (a) Clinical situation at baseline; (b) Radiographic situation at baseline; (c) Initial prosthesis over-contoured design; (d) Prosthesis after modification in order to allow better hygiene access; (e) Individualized oral hygiene instructions after prosthesis modification and mechanical debridement. (f) Clinical situation 6 months after treatment

Once debridement was completed, patients were randomly assigned to the test or control groups:

1. Control group: Individualized oral hygiene instructions were provided after the mechanical debridement session.
2. Test group: The affected implant prosthesis was modified to facilitate oral hygiene access, using the following protocol (Figures 2c, d and 3b):
   a Thick grit diamond bur (Komet Dental®, Iberica Tools SL)
   b Fine grit diamond bur (Komet Dental®)
   c Ceramic polishing kit (Komet Dental®)
   (i) Blue disc: for rough surfaces.
   (ii) Pink disc: for regular surfaces.
   (iii) Grey disc: for fine surfaces.

Once the prosthesis was modified, individualized oral hygiene instructions were provided (Figures 2e and 3c).

### 2.4.2 | Oral hygiene instructions

Patients were instructed to brush the implants twice daily to remove supragingival biofilms with a low-abrasive dentifrice and to use specific cylindrical or conical brushes (Interprox®, Dentaid) in the interproximal area. Patients were indicated to brush under, around and in the peri-implant crevice circumferentially. In cases where access with an inter-dental brush was not possible, patients were instructed to use a floss threader or specialized floss with a built-in threader (Super Floss®, OralB®, Procter & Gamble) and to wrap in a circle and move it towards the peri-implant crevice. Patients were reinstructed at each clinical evaluation. All treatments were performed by the same operator (C.M).

## 2.5 | Clinical and radiographic examination

At baseline and 1 (1 m), 3 (3 m) and 6 months (6 m) after treatment (Figures 2f and 3d), one calibrated examiner (B.dT) recorded the following clinical variables using an electronic, pressure-calibrated probe (PA_ON Probe, Orange Dental®, Aspachstr), with a standardized probing force of 0.20 N. Although attempts to blind the examiner were made, it was not feasible due to the easy identification of the patients belonging to the test group.

At the full-mouth level, the following parameters were evaluated:

1. Full-mouth plaque Index (FMPI), assessed dichotomously at four sites per tooth (mesial, buccal, distal and lingual).
2. Full-mouth bleeding index (FMBI), assessed dichotomously as the presence or absence of bleeding after 30 s of gently probing (Ainamo & Bay, 1975).

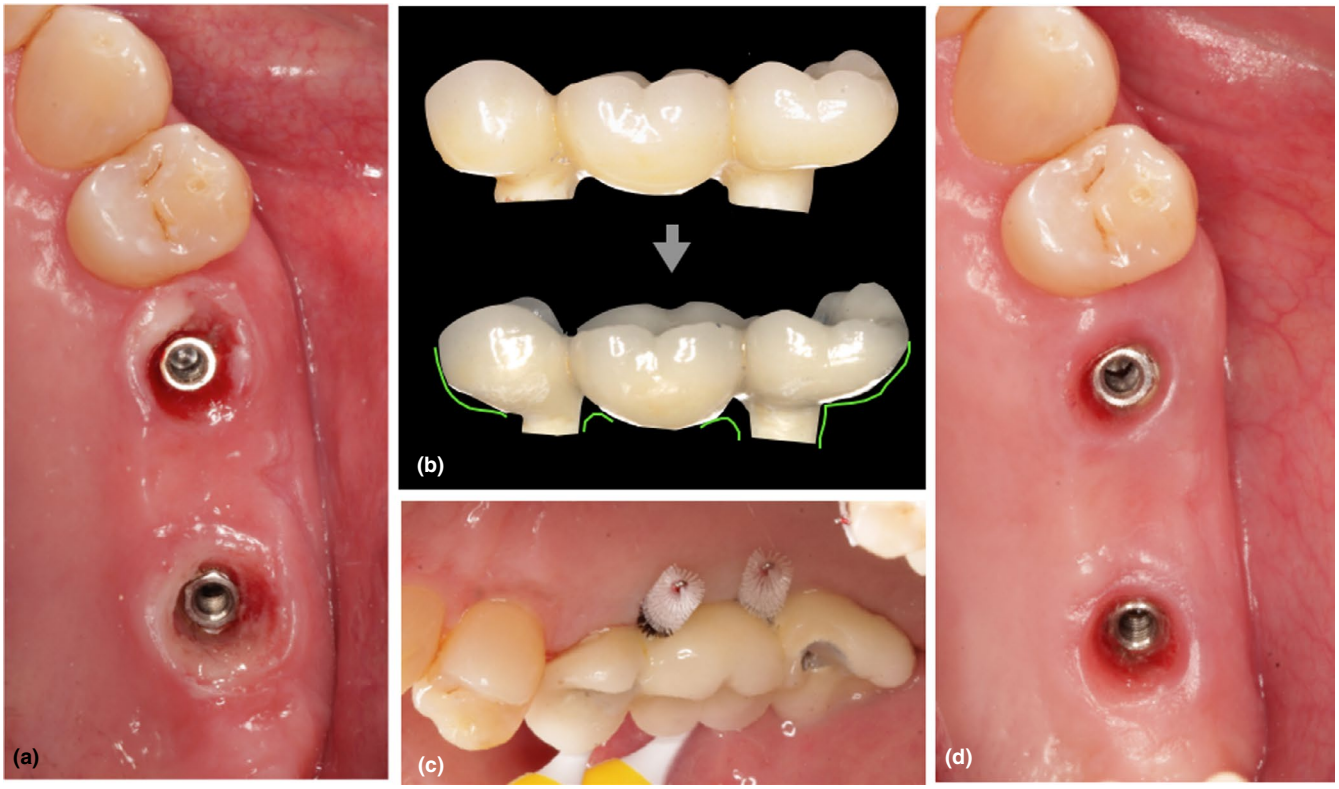


**FIGURE 3** (a) Baseline clinical situation after prosthesis removal; (b) Over-contoured prosthesis design and modification in order to allow proper biofilm control; (c) Individualized oral hygiene instructions after prosthesis modification and mechanical debridement; (d) Clinical situation 6 months after treatment

3. Full-mouth probing pocket depth (FMPPD), measured at six sites around each tooth, except third molars.

At a local level, in six sites around each implant, the following clinical variables were recorded:

1. Modified plaque index (mPI) (Mombelli, Oosten, Schurch, & Land, 1987)
2. Modified bleeding index (mBI) (Mombelli et al., 1987), dichotomized in the presence/absence of bleeding and selected as the primary outcome (BOP).
3. Suppuration on probing (SOP), assessed dichotomously as the presence or absence of suppuration within 30 s after probing.
4. Implant probing pocket depth (PPDi), measured from the mucosal margin to the bottom of the probable pocket.
5. Implant mucosal recession (MRi), measured from the implant neck to the mucosal margin.

Individual acrylic resin occlusal stents, exhibiting six vertical grooves per implant (mesiobuccal, midbuccal, distobuccal, mesiolingual, midlingual and distolingual), were built in order to allow a reproducible direction and angulation during probing.

In addition, a periapical radiograph of all implants involved in the study was taken at 3 and 6 months after treatment, in order to detect any loss of supporting bone.

## 2.6 | Data and statistical analysis

Sample-size calculation was based on the assumption of 85% resolution of bleeding on probing in PM sites at one month compared with the 72% resolution reported (Heitz-Mayfield et al., 2011) without modifying the prosthesis contours. To detect these differences, each study group was estimated to require 24 patients. This calculation assumed an alpha error of 0.05, a beta error of 0.2 and a statistical power of 80%, also accounting for a likely 20% loss of subjects during the follow-up.

The examiner (B.dT) followed a calibration exercise by evaluating peri-implant soft tissue parameters (PPDi and mBI) in five patients with PM, in two subsequent visits, 48 hr apart. The intra-examiner reproducibility resulted in intra-class correlation coefficients of 0.90 [95% confidence interval (CI) 0.45 to 0.98, standard error (SE) 0.15] and 0.85 [95% CI 0.28–0.98, (SE) 0.19] for PPDi and mBI, respectively.

The primary outcome variable, mBI, was dichotomized according to the presence/absence of bleeding (BOP). The remaining secondary outcomes (FMPI, FMBI, FMPPD, mBI, mPI, SOP, PPDi and MRi) were expressed either in continuous values or in percentages. Since the unit of analysis was the patient, the outcome variables registered for each selected implant (mPI, mBI, SOP, PPDi and MRi) were averaged by patient. Other variables of interest, such as sociodemographic and clinical characteristics of the patients were also evaluated and reported.

**TABLE 1** Sociodemographic data at baseline (T0). Data are presented as mean [standard deviation (*SD*)] or number (percentage)

| | Total | Control group | Test group | *P value* |
|---|---|---|---|---|
| *n* patients included | 48 | 24 | 24 | |
| *n* patients analysed | 45 | 21 | 24 | |
| *n* implants[c] | 145 | 73 | 72 | 1 |
| Years of implant in function[c] | 9.7 (5.1) | 9.1 (4.83) | 10.2 (5.38) | 0.5 |
| Age: mean (*SD*)[b] | 61 (11.2) | 61.2 (12.9) | 60.9 (9.9) | 0.94 |
| Gender[a] | | | | |
| Male: *n* (%) | 23 (51.1) | 8 (38) | 15 (62.5) | 0.2 |
| Female: *n* (%) | 22 (48.9) | 13 (62) | 9 (37.5) | |
| Tobacco[b] | | | | |
| Light smokers: *n* (%) | 1 (4.4) | 1 (4.8) | 1 (4.2) | 1 |
| Never smokers: *n* (%) | 43 (95.6) | 20 (95.2) | 23 (95.8) | |
| Type of restoration[a] | | | | |
| Single crown: *n* (%) | 13 (28.9) | 6 (28.6) | 7 (29.2) | 0.36 |
| Fixed partial denture: *n* (%) | 29 (64.4) | 13 (61.9) | 16 (66.7) | |
| Hybrid prosthesis: *n* (%) | 2 (4.4) | 2 (9.5) | 0 (0) | |
| Full fixed ceramic denture: *n* (%) | 1 (2.2) | 0 (0) | 1 (4.1) | |

[a]Chi-square or Fisher's test.
[b]Mann–Whitney *U* test.
[c]Independent *t* test.

The normality of the data was calculated using the Shapiro–Wilk test and presented as mean and standard deviations (*SD*). When normality could not be assumed, the data were presented as medians and interquartile ranges. Categorical data were shown as percentage of positive patients. The relationship between two qualitative variables was verified using chi-squared test or Fisher's exact test (if the frequency was lower than five cases). Quantitative variables were compared using Student's *t* test or Mann–Whitney *U* test. Changes compared with baseline were analysed by Student´s *t* test for paired data, Wilcoxon non-parametric test or McNemar's test.

A Per Protocol analysis was performed due to the limited data collected from patients lost during follow-up, and a generalized estimating equation (GEE), using the Poisson family, was performed to determine and analyse the association between baseline PPDi and age with the proportion of BOP, in order to adjust for potential confounders. Furthermore, with the aim to identify the BOP prevalence ratio (PR) in the test group at every time point, a first-order interaction between time and group allocation was performed. Level of significance was set at 0.05. The version 3.5.2 of software R (SPSS Inc., Chicago, IL, USA) was used for all analyses.

## 3 | RESULTS

Sociodemographic and baseline characteristics of the patients are detailed in Table 1. The sample was initially composed of 48 patients (twenty-four males and twenty-four females). Three patients on the control group were lost during follow-up, before the first post-treatment visit, one of them refused to continue the treatment and the other due to employment-related reasons. The remaining subjects (45) completed all the evaluations, and their data were available for analysis. The mean age was 60.9 years (*SD* = 9.9) in the test group and 61.2 years (*SD* = 12.9) in the control group. Only two patients (4.5%) were light smokers (<10 cig/day). One of them belonged to the test group and the other one to the control group.

A total of 152 implants affected with PM and overhanging prostheses were treated and analysed, representing a mean of three implants per patient in each group (range 1–10). The mean function time of the selected implants was 9.1 years (*SD* = 4.83) in the control group and 10.2 (*SD* = 5.38) years in the test group. All patients were compliant with the study and did not present relevant complications. Only four patients referred slight tenderness during the first days after instrumentation.

### 3.1 | Clinical outcomes

Mean clinical parameters at baseline and after 1, 3 and 6 months are summarized in Table 2 [median and interquartilic range (IQR) are depicted in Table 1 in supplementary material]. At baseline, statistical analysis failed to demonstrate significant differences between groups for any clinical parameter ($p > 0.05$), except for PPDi [control group, 2.86 (*SD* = 0.69); test group, 3.27 (*SD* = 1.02); $p < 0.01$]. Changes in clinical variables, at the implant level, between baseline-1 m, baseline-3 m, baseline-6 m and 3–6 m, are represented in Table 3 (median and IQR are depicted in Table 2 in supplementary material).

Full-mouth clinical outcome variables (FMPI, FMBI, FMPPD) remained stable during the whole study time, without revealing any statistically significant differences between test and control groups ($p > 0.05$).

After 1 month of healing, an overall improvement in clinical implant parameters (mBI, mPI and PPDi) was found in both control

**TABLE 2** Mean clinical parameters measured at baseline, 1 month (1 m), 3 months (3 m) and 6 months (6 m). Data are presented as mean (standard deviation, *SD*) and percentage

| | Baseline | | | 1 m | | | 3 m | | | 6 m | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Control group | Test group | *p* value | Control group | Test group | *p* value | Control group | Test group | *p* value | Control group | Test group | *p* value |
| FMPI (%) | 0.23 (0.04) | 0.25 (0.17) | 0.84[a] | 0.18 (0.05) | 0.18 (0.04) | 0.9[a] | 0.21 (0.04) | 0.22 (0.17) | 0.12[a] | 0.21 (0.03) | 0.21 (0.04) | 0.73[a] |
| FMBI (%) | 0.21 (0.09) | 0.20 (0.08) | 0.94[a] | 0.19 (0.10) | 0.16 (0.09) | 0.43[a] | 0.20 (0.09) | 0.19 (0.05) | 0.89[a] | 0.21 (0.08) | 0.18 (0.05) | 0.32[a] |
| FMPPD (mm) | 2.52 (0.40) | 2.63 (0.42) | 0.44[a] | 2.49 (0.33) | 2.57 (0.30) | 0.54[a] | 2.52 (0.40) | 2.63 (0.42) | 0.45[a] | 2.49 (0.28) | 2.55 (0.28) | 0.37[a] |
| mPI | 1.47 (0.70) | 1.17 (0.99) | 0.06[a] | 0.72 (0.55) | 0.56 (0.69) | 0.06[a] | 0.49 (0.42) | 0.25 (0.33) | **0.01**[a] | 0.49 (0.19) | 0.44 (0.33) | **<0.01**[a] |
| mBI | 1.13 (0.57) | 1.33 (0.78) | 0.49[a] | 0.65 (0.58) | 0.55 (0.61) | 0.41[a] | 0.53 (0.48) | 0.26 (0.29) | 0.05[a] | 0.62 (0.39) | 0.19 (0.32) | **<0.01**[a] |
| BOP (%) | 21 (100%) | 24 (100%) | 1[b] | 15 (71.4%) | 16 (66.6%) | 0.98[a] | 15 (71.4%) | 13 (54.16%) | 0.37[a] | 19 (90.4%) | 8 (33.3%) | **<0.001**[a] |
| SOP (%) | 2 (9.5%) | 5 (20.8%) | 0.52[b] | 2 (9.5%) | 4 (16.6%) | 0.79[a] | 2 (9.5%) | 1 (4.1%) | 0.90[a] | 4 (19%) | 1 (4.1%) | 0.26[a] |
| PPDi (mm) | 2.86 (0.69) | 3.27 (1.02) | **0.01**[a] | 2.74 (0.50) | 3.05 (0.59) | 0.07[a] | 2.77 (0.51) | 2.86 (0.74) | 1[a] | 2.88 (0.64) | 2.96 (0.80) | 0.9[a] |
| MRi (mm) | 0.30 (0.50) | 0.25 (0.47) | 0.33[a] | 0.51 (0.73) | 0.31 (0.54) | 0.18[a] | 0.52 (0.73) | 0.31 (0.55) | 0.13[a] | 0.52 (0.73) | 0.32 (0.54) | 0.16[a] |

*Note:* In bold, statistically significant differences between groups (test and control) ($p < 0.05$).

Abbreviations: FMPI, full-mouth plaque index (O'Leary et al., 1972); FMBI, full-mouth bleeding index (Ainamo & Bay, 1975); FMPPD, full-mouth probing pocket depth; mPI, modified plaque index (Mombelli et al., 1987); mBI, modified bleeding index (Mombelli et al., 1987); SOP, suppuration on probing; BOP, bleeding on probing, yes or no; PPDi, implant probing pocket depth; MRi, Marginal recession of the implant.

[a]Comparison between groups (Mann–Whitney *U* test).

[b]Chi-squared test.

and test groups without any significant differences between them ($p > 0.05$). Fifteen patients (28.6%) in the control group and 16 subjects (33.3%) in the test group exhibited a complete resolution of inflammation, without depicting any BOP or SOP. Likewise, changes over time did not reveal statistically significant differences between the groups.

At the 3-m evaluation, statistically significant differences in mPI were observed ($p = 0.01$), with lower values for the test group [0.25 (*SD* = 0.3), vs. 0.49 (*SD* = 0.42) in the control group], due to a larger decrease in mPI in the test group. Similarly, a further improvement in mBI was found in both groups, but a trend towards a higher reduction in the test, when compared with the control group, could be observed [0.53 (*SD* 0.48) and 0.26 (*SD* 0.29), respectively; $p = 0.05$].

Finally, at 6m, mBI suffered a rebound to 0.62 (*SD* = 0.39) in the control group, while in the test group an additional reduction was observed, to 0.19 (*SD* = 0.32). Differences between groups were statistically significant ($p < 0.01$). Even though there was a slight rebound in mean plaque levels in the test group, statistically significant differences between test and control groups remained at this final visit evaluation [0.44 (*SD* = 0.33) and 0.49 (*SD* = 0.19), respectively; $p < 0.01$]. The trends in the outcome variables mBi and mPi are shown in Figure 4.

At 6 months, complete resolution of inflammation (i.e. no BOP and no SOP) was achieved in 66.6% (16) of the patients in the test group, versus only in 9.6% (2) of the patients in the control group, being these differences statistically significant ($p < 0.01$).

Differences between the test and control groups for PPDi and MRi were not significantly different at the 1, 3 or 6-month evaluations. However, when changes in PPDi were compared, the test group showed a significantly higher reduction 3 months after treatment [0.4 (*SD* = 1.13) vs. 0.08 (*SD* = 0.53); $p = 0.03$] and at 6-month visit [0.31 (*SD* = 1.2) vs. −0.02 (*SD* = 0.61); $p = 0.04$].

### 3.2 | GEE regression analysis

The GEE model is detailed in Table 3. It showed that neither age ($p = 0.11$) nor baseline PPDi ($p = 0.06$) had a significant impact on mBI at any time point during the study.

When studying the interaction between group allocation and time of evaluation, belonging to the test group reduced the PR of BOP to 0.90 (95% CI 0.64–1.27, $p = 0.56$) at 1 m and to 0.85 (95% CI 0.65–1.12, $p = 0.25$) at 3 m. These results, however, did not reach statistical significance. At the 6-m evaluation, belonging to the test group decreased significantly the PR to 0.42 (95% CI 0.26–0.69, $p < 0.001$).

## 4 | DISCUSSION

This clinical trial was designed to test the hypothesis whether modifying the prosthesis contours for allowing a better access for plaque control had a significant impact on the outcome variables relevant in the treatment of PM.

**TABLE 3** Comparison of mean clinical changes in implant variables between baseline to 1-month evaluation (1 m), baseline to 3-month evaluation (3 m), baseline to 6-month evaluation (6 m) and from 3 to 6 m. Data are presented as mean (standard deviation, *SD*)

| | Changes baseline-1 m | | | Changes baseline-3 m | | | Changes baseline-6 m | | | Changes 3–6 m | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Control group | Test group | *p* value | Control group | Test group | *p* value | Control group | Test group | *p* value | Control group | Test group | *p* value |
| mPI | 0.75 (0.69) | 0.61 (0.98) | 0.29[b] | 0.98 (0.87) | 0.92 (0.96) | 0.62[b] | 0.98 (0.81) | 0.98 (1.08) | 0.73[b] | 0.01 (0.29) | 0.05 (0.37) | 0.27[b] |
| mBI | 0.47 (0.51) | 0.79 (0.71) | 0.10[a] | 0.59 (0.80) | 1.07 (0.77) | **0.04**[a] | 0.50 (0.70) | 1.14 (0.96) | **0.01**[a] | −0.09 (0.42) | 0.07 (0.41) | 0.21[a] |
| PPDi (mm) | 0.12 (0.33) | 0.22 (0.92) | 0.16[b] | 0.08 (0.53) | 0.40 (1.13) | **0.03**[b] | −0.02 (0.61) | 0.31 (1.20) | **0.04**[b] | −0.11 (0.33) | −0.09 (0.42) | 0.88[b] |
| MRi (mm) | −0.21 (0.59) | −0.06 (0.16) | 0.47[b] | −0.22 (0.59) | 0.06 (0.16) | 0.19[b] | 0.22 (0.59) | 0.07 (0.16) | 0.41[b] | 0.00 (0.03) | −0.01 (0.04) | 0.69[b] |

*Note:* In bold, statistically significant differences between groups (test and control) ($p < 0.05$).
Abbreviations: mPI, modified plaque index (Mombelli et al., 1987); mBI, modified bleeding index (Mombelli et al., 1987); PPDi, implant probing pocket depth; MRi, marginal recession of the implant.
[a]*p* values were derived from independent *t* test.
[b]*p* values were derived from Mann–Whitney *U* test.







**FIGURE 4** Changes in mBI, modified bleeding index (Mombelli et al., 1987) and mPI, modified plaque index (Mombelli et al., 1987) during the course of the study

Since both groups underwent standard mechanical therapy for the treatment of peri-implant mucositis, all the outcome variables were significantly reduced in both groups at 1 month (mBI, BOP, mPI and PPDi). The fact that the prostheses were removed prior the instrumentation allowed a proper access for the debridement. However, at subsequent visits the trend of these clinical variables was different between groups, having the test group a consistent improvement in the measured clinical parameters throughout the experimental period, while in the control group there was a clear rebound. These results, therefore, clearly indicate that the adjunctive modification of the prosthesis contours resulted in a significant reduction in the peri-implant mucosa inflammation and in the percentage of sites with a complete resolution of the inflammation

when compared to the standard treatment alone for a postoperative period of 6 months.

This tendency of improvement in clinical parameters over time has been previously reported in other RCTs studying the efficacy of interventions to treat PM (Riben-Grundstrom, Norderyd, Andre, & Renvert, 2015). However, in this investigation this continuous improvement was only observed in the test group, with reductions in mBI between baseline-1 m, baseline-3 m, and baseline-6 m accounting for 0.79 (*SD* = 0.71), 1.07 (*SD* = 0.77) and 1.14 (*SD* = 0.96), respectively. Conversely, in the control group, there was a worsening in mBI between 3 and 6 months [−0.09 (*SD* = 0.42)].

One month following treatment, 33.3% of patients in the test and 28.6% in the control groups demonstrated a complete resolution of BOP. These percentages, however, decreased to 9.6% at 6 months in the control group. These results with the conventional treatment to manage PM were markedly inferior to those reported previously in the literature ranging between 38% and 83.3% (Hallstrom, Persson, Lindgren, Olofsson, & Renvert, 2012; Heitz-Mayfield et al., 2011; Menezes, Fernandes-Costa, Silva-Neto, Calderon, & Gurgel, 2016; Pulcini et al., 2019; Riben-Grundstrom et al., 2015). In contrast, in the test group, this percentage increased to 66.6%. When comparing with other studies, it should be noted that only patients with a prosthesis being considered as inappropriate were selected, what may explain clearly the poor results in the resolution of the inflammation. Conversely, the continuous increase in disease resolution shown in the test group underlies the importance of modifying the prosthesis contours in these patients.

These clear differences in the changes in the outcome variables assessing inflammation of the peri-implant tissues did not match, however, with the results regarding plaque accumulation. Although statistically significant differences were observed between groups for mPi at 3 ($p = 0.01$) and 6 months ($p < 0.01$), when assessing the changes in plaque overtime, there were no statistically significant differences between the groups. An explanation for this fact might be that mPi was registered with the prostheses in place. More revealing results could have been obtained if plaque accumulation had been recorded directly from the neck of the implant, removing the prostheses, where a direct impact in tissue health is found.

At baseline, differences in probing pocket depth (PPDi) were significantly higher in the test group compared with the control group [3.27 (*SD* = 1.02) mm vs. 2.86 (*SD* = 0.69) mm, respectively]. However, there are other factors that influence the position of the peri-implant mucosal margin and probing depth other than the inflammatory changes, such as the implant depth; implant angulation or the thickness of the peri-implant mucosa (Renvert, Persson, Pirih, & Camargo, 2018). In fact, the GEE analysis has shown that after adjusting for baseline PPDi, differences between groups in mBI at 6-month evaluation were still statistically significant, and baseline PPDi had no impact in the results at any time point ($p = 0.06$).

The general patient variables, such as FMPI, FMBI and FMPPD, remained stable during the study, without any statistical differences between the groups, since these affect the patient as a whole, including his/her cognitive level and patient skills in performing oral hygiene practices, as well as their compliance and behaviour.

The possible influence of the prosthesis design on the peri-implant tissue health has been studied by other researchers; Serino and Strom (2009) stressed the importance of the implant-supported prosthesis design in order to promote accessibility to oral hygiene around implants. In this study, clinical variables of those subjects referring PI were analysed in order to elucidate its relationship with the development of the disease. The site-level analysis showed that a high proportion of implants with the diagnosis of PI (48%) were associated with no access for appropriate oral hygiene measures (65% positive predictive value). Those implants reporting a proper ability to perform hygiene measures had only 4% of PI (82% negative predictive value). Results derived from this study emphasize the importance of local factors such as accessibility for oral hygiene at the implant sites. Furthermore, in a cross-sectional study (Katafuchi, Weinstein, Leroux, Chen, & Daubert, 2018), the emergence angle and emergence profiles of the restoration (convex, straight, concave) were evaluated to determine their association with PI. An angle of the restoration higher than 30 was associated with a significantly higher prevalence of PI (28.8% vs. 16.3%, respectively). These results clearly suggest that over-contoured restorations around dental implants (wide emergence angle and convex profile) have a negative impact on the peri-implant health and could increase the risk of developing PI.

It is not only important to achieve an excellent adaptation between the prosthetic abutment and the implant, but also an adequate design and contour of the prosthesis particularly at the connection of the implant shoulder to the secondary components (Chaves, Stephen Lovell, & Tahmasebi, 2013).

The impact of these factors on the development of PM has the same or even a greater importance, since PM precedes PI in the same way than gingivitis precedes periodontitis. Although the conversion of PM to PI is difficult to evaluate in longitudinal studies, it has been shown that those patients with PM in the absence of supportive therapy have a higher incidence of PI after 5 years (Costa et al., 2012). Thus, the endpoint of the prevention of PI shall aim at the prevention of PM.

In spite of the results shown in this clinical trial, they should be interpreted with caution, blinding of the examiner could not be performed due to the easy identification of the patients belonging to the test group. Furthermore, a longer follow-up may be needed to assess the persistence of these results over time.

## 5 | CONCLUSIONS

Despite the limitations of this clinical trial, it has demonstrated that the modification of the prosthesis contours, when this restoration has been considered inappropriately designed, rendered significant benefits in reducing peri-implant mucosal inflammation and in achieving a higher resolution of the inflammation. In these patients, these results consistently improved during the 6-month

duration of this study, in contrast with the results from the control group where mucosal inflammation clearly rebounded after 3 months.

## ACKNOWLEDGEMENTS

The authors express their gratitude to Queralt Miró, Universitat Internacional de Catalunya, for her help in the statistical analysis.

## CONFLICT OF INTEREST

The authors declare no conflict of interests related to the content of this manuscript.

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## SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

**How to cite this article:** de Tapia B, Mozas C, Valles C, Nart J, Sanz M, Herrera D. Adjunctive effect of modifying the implant-supported prosthesis in the treatment of peri-implant mucositis. *J Clin Periodontol*. 2019;46:1050–1060. https://doi.org/10.1111/jcpe.13169