

Peri-implant marginal bone loss reduction with platform switching components: 5-year post-loading results of an equivalence randomized clinical trial

Salomão Rocha¹, Wilfried Wagner², Jörg Wiltfang³, Ana Messias¹, Maximilian Moergel², Eleonore Behrens³, Pedro Nicolau¹, Fernando Guerra¹



1- Faculty of Medicine, University of Coimbra, Portugal
2- Medical Center of the Johannes Gutenberg University, Mainz, Germany
3- Schleswig-Holstein University Hospital, University of Kiel, Germany



Introduction & Purpose

The maintenance or improvement of the surgically achieved peri-implant bone levels is crucial for the long-term success and good aesthetic results of implant therapy. Platform switching, defined as the act of changing an implant abutment to one with a smaller diameter in order to place the implant-abutment interface medial to the edge of the implant platform, is a prosthesis-modifiable factor that has been reported to have a positive effect in marginal bone levels associated with a biological or a biomechanical effect. However, the clinical results associated to the feature are contradictory, with studies reporting both positive or neutral results. The aim of the present study is to compare the clinical performance and radiographic marginal bone level changes of implants with similar outer geometry and internal connection restored with platform-switching (PS) or platform-matching (PM) prosthetic components after 5 years of function. Our hypothesis was that within an equivalence margin of 0.2mm, marginal bone level changes in the implants restored with PS prosthetic components would be equivalent to those of PM restored implants.

Methods

Study design & settings

Multicentre randomized controlled trial of parallel group design, with 1/1 allocation ratio, that took place in the university outpatient facilities of three centres located in Germany (Mainz and Kiel) and Portugal (Coimbra) after local approval of the competent Ethics Committees (FECI 09/1308 and CES/0156).

Participants

Adult patients (18 years or older) requiring an implant-supported prosthesis in the posterior mandible to replace two or more adjacent teeth. Inclusion criteria required healed edentulous sites bounded mesially by a natural tooth with adequate bone volume for the insertion of dental implants without bone regeneration.

Interventions

Patients underwent full thickness flap surgery to receive 2-3 CAMLOG® SCREW-LINE implants with Promote® plus surface according to the instructions of the manufacturer. If the implants achieved sufficient primary stability, the patients were allocated by opening of an opaque envelope containing the randomization information. The operator then fitted the corresponding PS or PM healing caps and sutured the flap promoting transgingival healing. Definite cemented crowns with PS or PM abutments were conventionally loaded. Procedures are represented in figure 1.

Exposure

Patients were randomized to receive either platform switching (PS) or platform matching (PM) prosthetic components from surgery onwards.

Outcomes

The primary outcome measure was the peri-implant marginal bone level change from loading to each of the following annual appointments up to 5 years, measured as the distance from the implant shoulder to the first visible bone contact (DIB) at the mesial and distal aspects of the implant. Secondary outcomes included implant survival and success, pocket probing depth (PD), plaque index (PI) and sulcus bleeding index (SBI).

Analytics

Sample size calculations assumed that the study was designed as a parallel group trial to test for equivalence, considering a nil effective difference between normally distributed groups with 0.3mm SD and an equivalence limit of 0.2mm. At 80% power, 64 implants were required per treatment arm, corresponding to 21 (16 to 32) patients per group. To evaluate the main effects of the randomization on the mean DIB over time, a repeated-measures mixed effects model with random intercepts and slopes was built using an auto-regressive heterogeneous covariance pattern, considering random effects produced by clustering of implants within patients and centres.

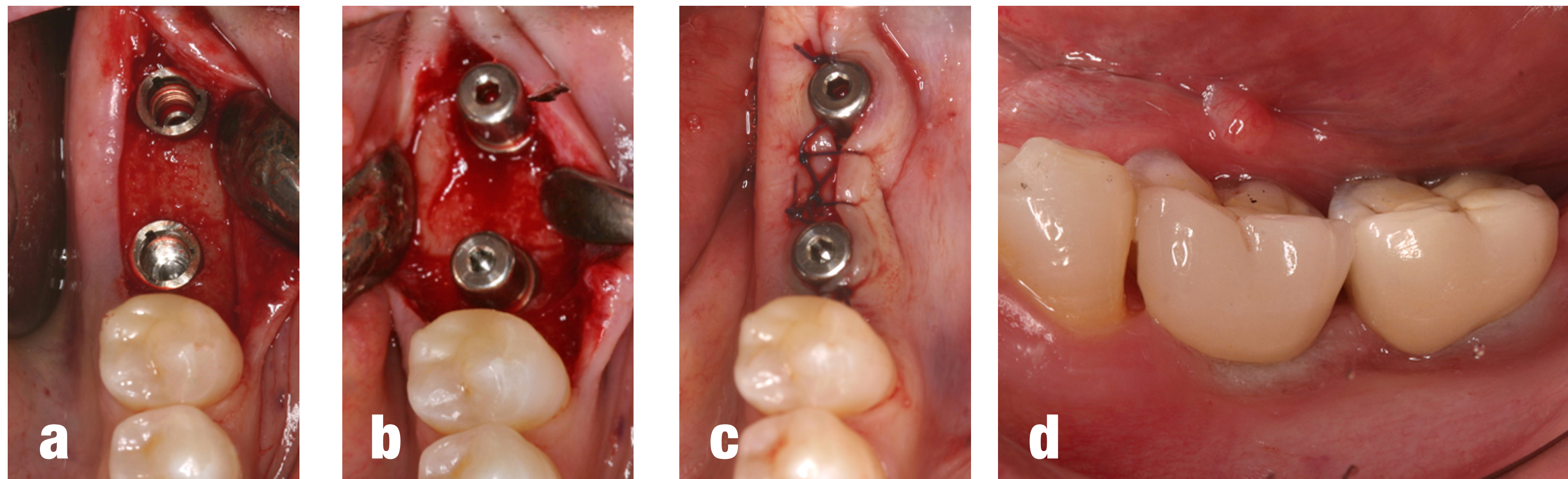


Figure 1- Sequence of procedures: **a)** Surgical installation of the implants; **b)** Insertion of the randomized prosthetic component; **c)** Transgingival healing; **d)** Conventional loading with cemented crowns

Results

Patient recruitment took place between May 2009 and November 2011 and 70 patients underwent surgery. After 5 years, 60 patients attended the final appointment, 31 had received PS components and 29 had received PM components (figure 2). Baseline demographics of the study population, clinical parameters and implant distribution were similar between groups and no major deviations generated from patient attrition.

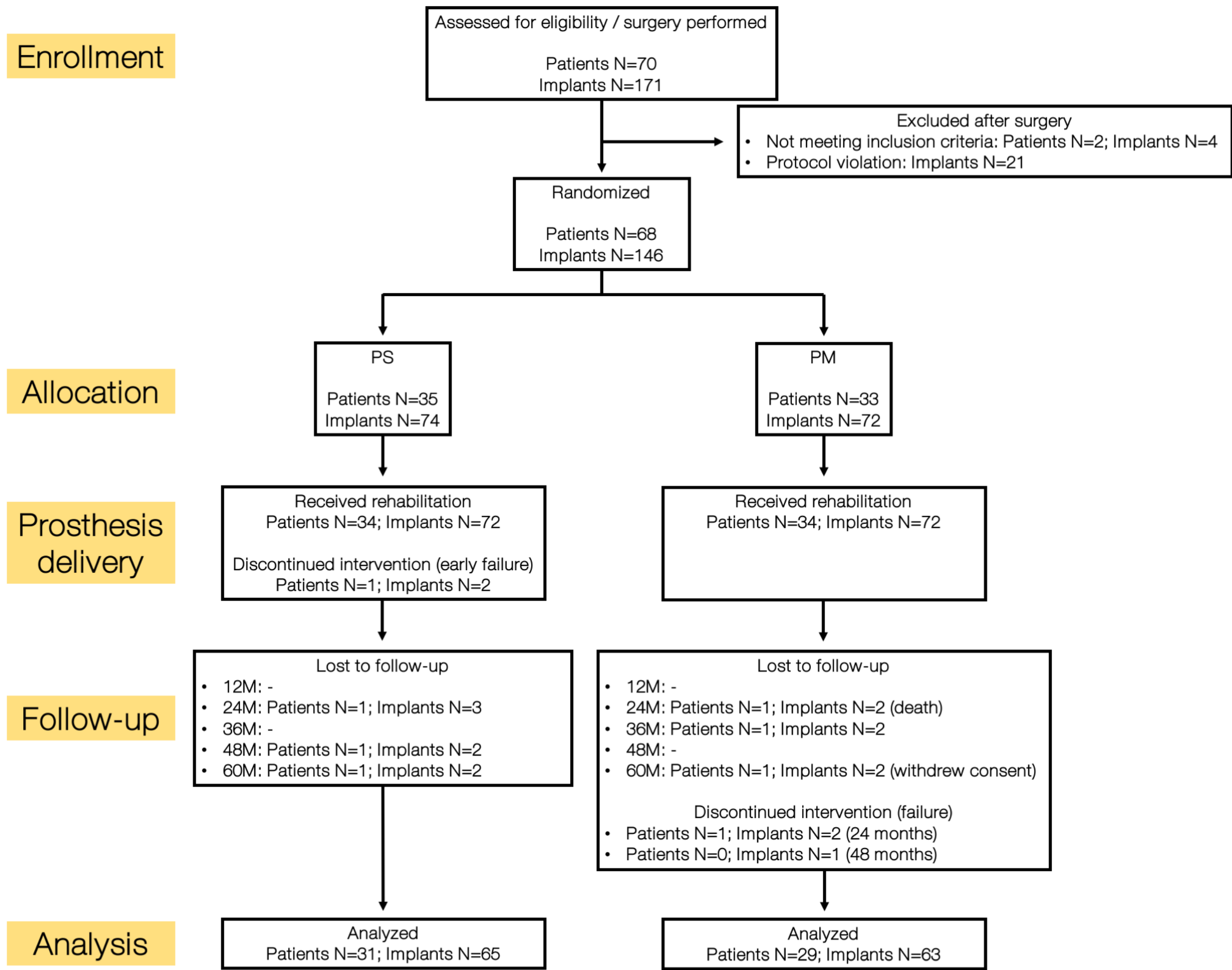


Figure 2- CONSORT flow-chart

From loading to the 5th year follow-up, the PS group had 0.19 ± 0.53 mm bone gain, whereas the PM group had a residual bone loss of -0.04 ± 0.58 mm. Figure 3 presents a representative case of each group. The estimate for the effect of PS on marginal bone levels obtained from the mixed effects model accounting for the variability of individual responses (random effects) was 0.28mm (95% CI: [0.06, 0.49], $p=0.011$) reduction in marginal bone resorption after 5 years of service. Figure 4 presents the mean bone levels (DIB) at each annual appointment. The global survival rate was 96.6% with no differences between groups ($p=0.647$). The clinical parameters were within acceptable ranges throughout the study and no differences were detected between groups.

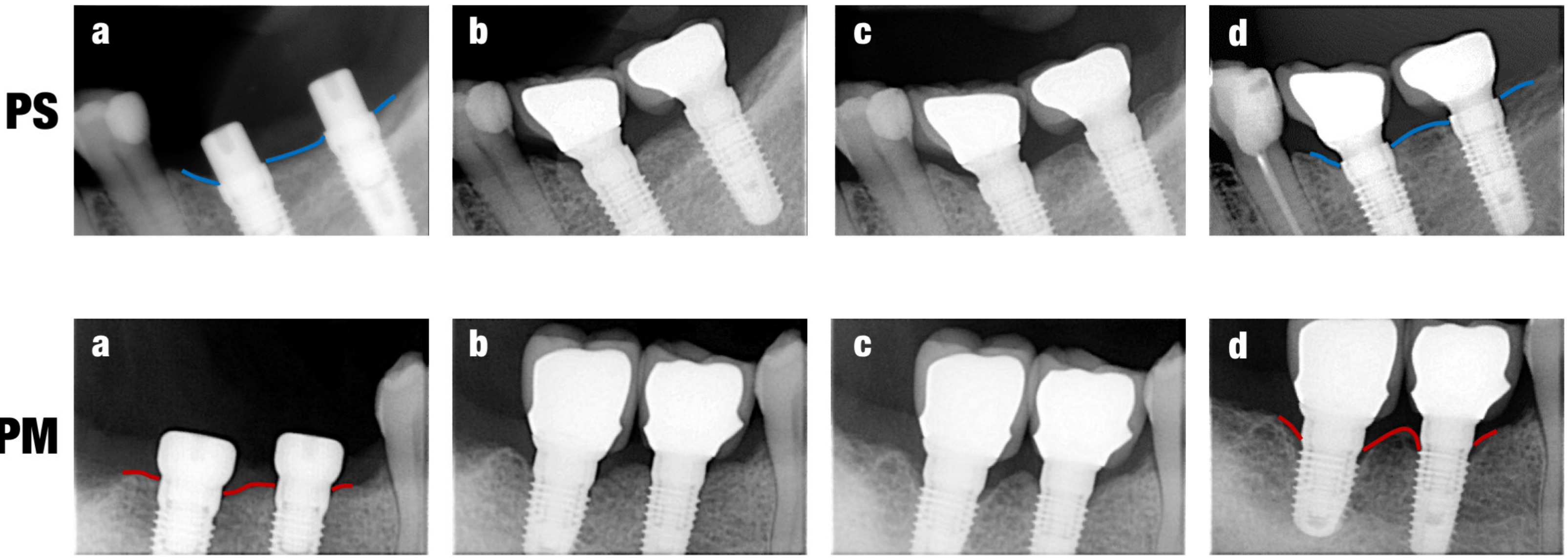


Figure 3- Sequence of radiographs for each group, PS in the upper line, PM in the bottom: **a)** Surgical installation of the implants; **b)** Prosthesis delivery; **c)** 1 year follow-up; **d)** 5-years follow-up

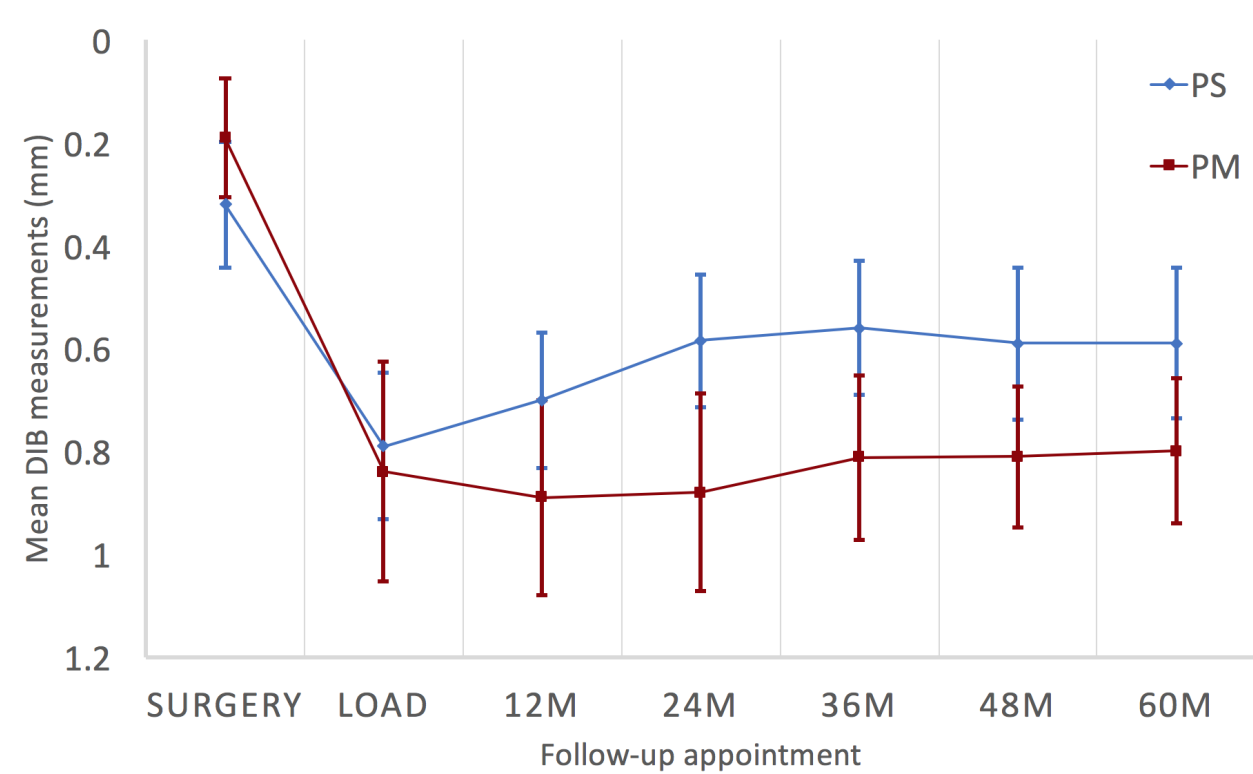


Figure 4- Mean DIB at each appointment (95% CI)

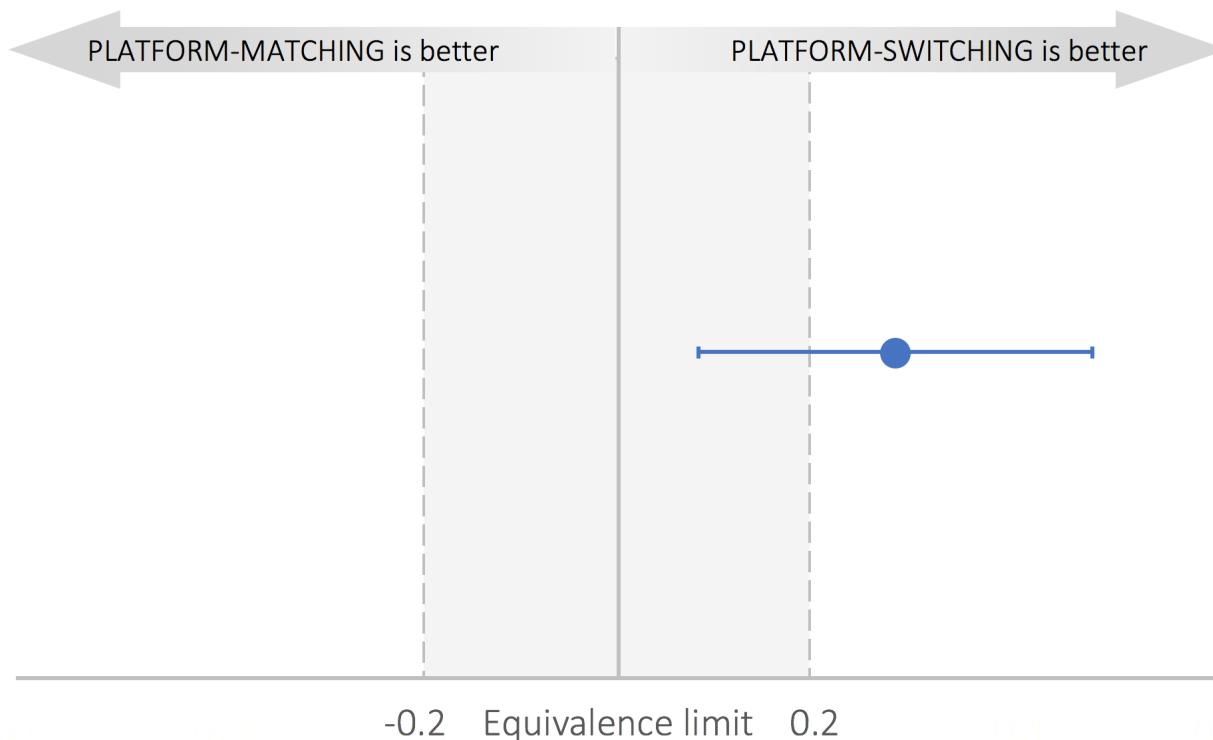


Figure 5- Equivalence graphic. Mean difference (95% CI)

Conclusions

Platform switching components are superior to platform matching components in the prevention of peri-implant marginal bone resorption of adjacent implants placed in the posterior mandible over a 5-year period.

Disclosure

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