

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

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Abstract

Aim: To compare the clinical performance and marginal bone levels of implants restored with platform-switching (PS) or platform-matching (PM) abutments.

Materials and Methods: Adult patients missing two or more adjacent teeth in the posterior mandible received 2–4 CAMLOG SCREW-LINE implants and were randomly allocated to the PM or PS group, receiving the corresponding prosthetic components from surgery onwards. Implants were conventionally loaded with single cemented crowns. Patients were followed annually for 5 years. Outcome measures were marginal bone level changes, implant survival, performance of the prosthetic components and clinical parameters plaque index, sulcus bleeding index and pocket probing depth.

Results: Thirty-three patients received 72 implants in the PM group, and thirty-five patients received 74 implants in the PS group. Sixty patients attended the final appointment, 31 had received PS components and 29 had received PM components with 65 and 63 implants, respectively. Global survival rate was 96.6% with no differences between groups ($p = 0.647$). After 5 years of functional loading, PS restored implants presented 0.23mm (95% CI: [0.03, 0.43], $p = 0.025$) lower marginal bone level changes. The two groups were declared non-equivalent.

Conclusion: Patients requiring implant supported restorations in healed bounded or free end edentulous gaps of the mandible benefit from the use of PS components in terms of peri-implant marginal bone level maintenance, though it may not be clinically noticeable.

KEYWORDS

bone level, crestal bone preservation, implant, implant success, platform match, platform switching, randomized clinical trial, standardized radiograph

This trial on commercially available medical devices was exempt from registration on the European Clinical Trials Registration Database, as stated in the Directive 2001/20/EC, which does not apply to medical devices, active implantable medical devices and in vitro diagnostic medical devices as defined in Community legislation.

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1 | INTRODUCTION

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. The process of bone remodelling around the implants has been considered a normal time-dependent phenomenon, particularly during the first year following the surgical implantation, to which contribute clinical, individual and device-related factors (Clementini et al., 2014; Hermann, Lerner, & Palti, 2007). Platform switching (PS), 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 (Canullo & Rasperini, 2007; Lazzara & Porter, 2006; Vigolo & Givani, 2009).

Some authors have advanced with a biological rationale supporting the platform-switching concept, related to the increase in the horizontal peri-implant biological width (Cochran et al., 2013; Farronato et al., 2012) and correspondent reduction in the inflammatory sulcus infiltrate that contributes to the process leading to bone resorption (Broggini et al., 2006). Other authors claim that the effect is due to a reduction in the stress transmitted to the peri-implant bone, which establishes a more favourable biomechanical situation (Maeda, Miura, Taki, & Sogo, 2007).

Nevertheless, the clinical results associated with the feature are contradictory. While some randomized clinical trials corroborate the theories showing approximately 0.3 mm lower bone loss at short term and medium term, others fail to detect such differences between switched and matched restorative components (Enkling et al., 2011; Pieri, Aldini, Marchetti, & Corinaldesi, 2011).

Systematic reviews on the concept of platform switching and the effect on peri-implant bone resorption stress the high heterogeneity of results arising from studies with unclear and high risk of bias and emphasize the urgency for prospective, randomized controlled clinical studies with limited confounders and long-term results (Annibaldi et al., 2012; Atieh, Ibrahim, & Atieh, 2010; Strietzel, Neumann, & Hertel, 2014).

Under this assumption, it has been strongly advised that clinical investigations on the effect of platform-switching should consider uniform design, preferably presenting comparable conditions regarding the implant and abutment diameter, the implant-abutment connection type, the implant surface at the neck portion and insertion depth as well as longer observation periods of at least 5 years, that is, excluding or exactly documenting possible confounding factors.

The present study aims at that literature gap and was designed to compare the clinical performance and radiographic marginal bone level changes in implants with similar outer geometry and internal connection restored with platform-switching or platform-matching prosthetic components after 5 years of function. Our hypothesis was that the true difference in marginal bone levels of implants restored with PS prosthetic components and those restored with PM components would lie outside of a clinically unimportant equivalence margin of 0.2 mm.

Clinical Relevance

Scientific rationale for the study: The use of mismatching components has been advocated to have a biological or biomechanical effect on the preservation of marginal bone levels but the literature is sparse on long-term unbiased clinical trials to corroborate the theories.

Principal findings: After 5 years, platform-switching restored implants have similar clinical performance but have lower bone loss than those restored with matching components.

Practical implications: Within the same implant system, the use of platform-switching components from surgery onwards is expected to preserve marginal bone more predictably and therefore improve the long-term result of the rehabilitation.

2 | MATERIALS AND METHODS

2.1 | Trial design

The study was designed as a multicentre randomized controlled trial of parallel group design, with 1/1 allocation ratio, to evaluate radiographic bone level changes associated with the use of platform-switching or platform-matching abutments on CAMLOG® SCREW-LINE implants after 5 years of clinical service.

2.2 | Participants

Adult patients (18 years or older) requiring an implant-supported prosthesis in the posterior mandible to replace two or more adjacent teeth and able to understand and sign a written informed consent form were eligible for this study. 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 procedures.

Patients with uncontrolled systemic diseases, bone-modifying medications, previous head or neck radiation therapy, inability to perform adequate oral health or smoking habits superior to 10 cigarettes/day were excluded. Local exclusion criteria included previous history of implant failure and untreated periodontitis, as well as thin soft tissue biotype in the prospective implant position with less than 4 mm of firmly attached keratinized mucosa in the buccal-lingual direction, as measured with a periodontal probe. Patients would not be randomized if the implant did not achieve primary stability or was inappropriately positioned to fulfil the prosthetic requirements.

The procedures 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). All interventions performed within the scope of the trial honoured the ethical principles stated in the Declaration of Helsinki.

2.3 | Interventions

Patients were given prophylactic antibiotic therapy at the discretion of the investigator and according to the standard procedures of the centre. All patients were treated under local anaesthesia. A full-thickness flap approach was used to grant visual access for placement of 2 or 3 commercially available CAMLOG® SCREW-LINE implants with Promote® plus surface (CAMLOG Biotechnologies AG) and a 0.4 mm long machined collar in the edentulous site, respecting a minimum distance of 3 mm between implants and 1.5–2 mm between the implant and the neighbouring tooth. Implant site was prepared according to the standard manufacturer instructions. The clinician was allowed to decide the optimal diameter (3.8, 4.3 or 5.0 mm) and length (9, 11, and 13 mm) of the implant based on the preoperative radiographic evaluation (using periapical radiographs, panoramic radiographs or both, according to the needs of each case) and clinical inspection of the bone volume available at the site.

Once the implant was inserted into the bone with sufficient primary stability (manual assessment), allocation of the patient was revealed by opening a sequentially numbered opaque sealed envelope corresponding to the patient recruitment number. The operator then fitted the corresponding PS or PM caps and sutured the flap promoting transgingival healing. Patients were instructed to use an extra-soft toothbrush in the site and to rinse three times per day with chlorhexidine (0.12%) until sutures were removed (7 days).

After a healing period of 8 to 12 weeks or 12 to 18 weeks in the case of type I-III or type IV bone, respectively, the definite abutments were fitted with 20 Ncm torque and the implants restored with single cement-retained crowns.

The mismatch of the PS group was 0.3 mm for the 3.8 and 4.3 implants and 0.35 mm for the 5.0 implants.

Follow-up visits were scheduled every 12 months after loading for the entire duration of the study.

2.4 | Outcomes

This study tested the null hypothesis that the clinical and radiographic performance of CAMLOG® SCREW-LINE implants restored with platform-switching prosthetic components is not equivalent to that of the same type of implants restored with platform-matching prosthetic components, against the alternative hypothesis of equivalence.

The primary outcome measure was the peri-implant marginal bone level change from loading to each of the following annual appointments. Bone level measurements were performed on standardized intra-oral digital radiographs taken immediately after surgery, at prosthesis delivery, and at 12, 24, 36, 48 and 60 months

post-loading. Consistent image projection geometry was obtained by the customization of a standard sensor holder (Dentsply rinn XCP-DS®) with acrylic to promote cross-arch stabilization and individualization of the extension cone paralleling system, as previously described by the authors (Guerra et al., 2014; Messias et al., 2013). In each radiograph, the distance from the implant shoulder to the first visible bone contact (DIB) at the mesial and distal aspects of the implant was measured to the nearest 0.1 mm using the software ImageJ 1.44 (<http://imagej.nih.gov/ij/>). Measurements were obtained by one investigator at each centre and validated by an independent external examiner. Intra-class correlation coefficient determined excellent agreement of the measurements obtained by the investigators and the independent examiner (ICC = 0.902 using a two-way mixed effects model where people effects are random and measures effects are fixed with absolute agreement definition). Notwithstanding that, compulsory agreement between measurements from the centre and the external evaluation had to be reached for all cases presenting differences superior to 0.2 mm. Mesial and distal measurements were subsequently averaged to determine mean implant bone level.

Secondary outcome measures were implant survival; implant success based on assessment of implant mobility, peri-implant radiolucency, peri-implant recurrent infection with suppuration and subjective complaints such as pain, foreign body sensation, and/or dysesthesia, as defined by Buser et al. (2002); and complications and adverse events, assessed at any time point post-surgery. Performance of the prosthetic components was also evaluated. Additionally, plaque index (PI) and sulcus bleeding index (SBI) at accessible buccal, lingual distal and mesial sites on each implant were measured according to the criteria described by Mombelli, Oosten, Schurch, and Land (1987) annually up to 5 years. In both indexes, the implant received the worst score measured at the four sites. Pocket probing depth (PPD) was measured at the same sites, and the four values were averaged into a single value per implant.

2.5 | Sample size determination

The sample size calculations were performed considering that the study was designed as a parallel group trial to test for equivalence of peri-implant marginal bone level changes in the groups receiving switching or matching prosthetic components, from loading to 60 months.

Calculations assumed a nil effective difference between normally distributed groups with 0.3 mm SD and an equivalence limit of 0.2 mm.

Since the analysis of marginal bone level changes was planned for all patients at each annual follow-up after loading until study completion (with a total of five analysis), the power analysis significance level was adjusted for 0.01 to correct for multiple analysis and to maintain the overall false positive error rate at 0.05. At 80% power, 64 implants were required per treatment arm, corresponding to 21 (16 to 32) patients per group for randomization according to protocol. This number was increased by a factor of approximately 20% to compensate for possible losses to follow-up.

2.6 | Randomization and blinding

For allocation of the participants, an investigator with no clinical involvement in the trial generated the randomization sequence with 1:1 allocation ratio using random block sizes of 4 and 6. The allocation sequence was concealed from the clinicians enrolling the participants and performing the surgical procedures by the use of sequentially numbered, opaque and sealed envelopes that had been prepared by the independent investigator. Eligible patients were submitted to the standard surgical procedures, and if all inclusion criteria were met after the insertion of the implants, the envelopes were opened rendering the treatment group. The patient then received the corresponding PS or PM components in all implants installed at the edentulous site. The envelope would not be opened if any of the implants did not meet the inclusion criteria.

Though the prosthetic procedures were identical in the two groups, the differences in the geometry of the components prevented blinding of clinicians and assessors. No effort was made to keep the assignment concealed from the participants since it was not deemed to cause differential attrition.

2.7 | Statistical methods

Statistical analysis was carried out with the software IBM® SPSS® Statistics version 23.

Bone level changes from surgery or loading to 60 months were compared using a univariate approach. To evaluate the main effect of the randomization on DIB over time, a multilevel mixed effects model with random intercepts and slopes was built accounting for implant clustering within patients and centres, assigning a scaled identity structure for the covariance of random effects and a heterogeneous first-order auto-regressive covariance pattern for the repeated measures.

The two one-sided tests (TOST) approach was applied on the estimated effect of randomization in order to assist decision-making regarding the null hypothesis of non-equivalence and considering the pre-specified equivalence margin of ± 0.2 mm (Mascha & Sessler, 2011).

Implant survival was analysed with Kaplan–Meier curve and the log-rank test. Clinical outcomes PI and SBI were evaluated with the chi-square test and PPD with the *t* test. Significance level was set at 0.05.

3 | RESULTS

Preliminary results of the present work, which is now presented in the final version after 5 years of clinical service of the implants, have been reported by Guerra et al. (2014) and Rocha et al. (2016).

Recruitment took place between May 2009 and November 2011 and 70 patients underwent surgery. After implant insertion, two patients did not meet the inclusion criteria and were excluded whereas the remaining 68 had their sites treated according to the allocated interventions. Ten of these patients were eligible to receive implants in both quadrants and underwent a second surgical protocol. This intervention was considered a protocol violation, and the implants were excluded

from the analysis. During the follow-up period, a total of 6 patients dropped out: 4 patients (3 PS and 1 PM) could no longer be contacted after various attempts, one patient withdrew consent (PM), and one patient died of causes non-related to the device (PM). After 5 years, 60 patients attended the final appointment of the study, 31 had received PS components and 29 had received PM components with 65 and 63 implants, respectively. The study flow chart is represented in Figure 1.

3.1 | Subjects and implants

Baseline demographic characteristics of the study population, as well as clinical parameters and implant distribution, are summarized in Table 1. No major deviations generated from patient attrition during the 5 years. Patient compliance was reflected on the improvement of oral hygiene from the initial assessment to the end of the study ($p < 0.01$).

3.2 | Bone level changes

Marginal bone levels were measured for all patients that attended the final appointment, representing 128 implants. However, it was not possible to extract data from the radiographs of the loading day in three patients, all with PM abutment (seven implants). Consequently, bone level changes from loading to 60 months were only available for 121 implants (65 PS and 56 PM). Data from the remaining appointments were available for those implants and considered for the mixed effects model on DIB analysis over time. A representative case of each group is presented in Figure 2.

From loading to 60 months, 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, corresponding to a significant mean difference of 0.23 mm (95% CI: [0.03, 0.43], $p = 0.025$). From the moment of surgery to 60 months, the mean difference between groups increased to 0.34 mm (95% CI: [0.14, 0.54], $p = 0.001$).

Mean DIB over time is represented in Figure 3. After surgery, both groups presented bone loss until the loading moment. From that point onwards, the PM matching group stabilized DIB whereas a recuperation trend was observed for the PS group until the 24-month follow-up. DIB stabilized for the PS group from that moment onwards. The mean estimated difference in the marginal bone levels of PS and PM restored implants after 60 months was 0.29 mm (95% CI: [0.07, 0.50], $p = 0.08$), as detailed in Table 2.

Using $\alpha = 0.05$ and equivalence bounds from -0.2 to 0.2 mm, the equivalence test was non-significant ($p = 0.21$). Based on the interpretation of the TOST *p*-value and graphic representation of the confidence interval (Figure 4), the null hypothesis of non-equivalence of platform switching could not be rejected.

3.3 | Implant survival and success

One patient of the PS group lost two implants during the healing period. In the PM group, one patient (two implants) was declared a failure at the 24-month follow-up due to excessive bone loss but

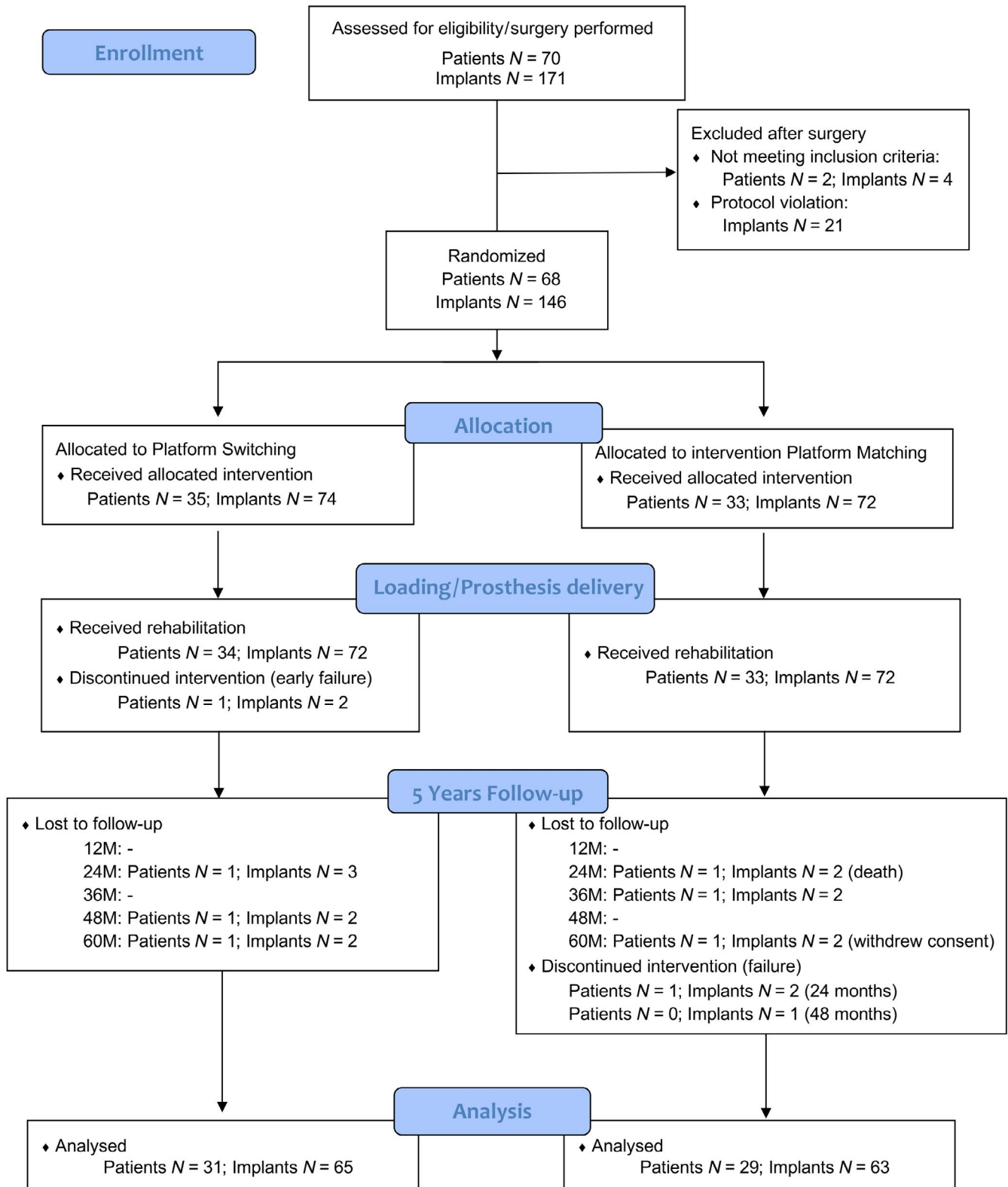


FIGURE 1 CONSORT flow chart of the study

explantation was only performed at the 60-month visit. Also in the same group, one implant was removed at the 48-month visit due to infection and mobility. The global survival rate was 96.6% with no differences between groups ($p = 0.647$).

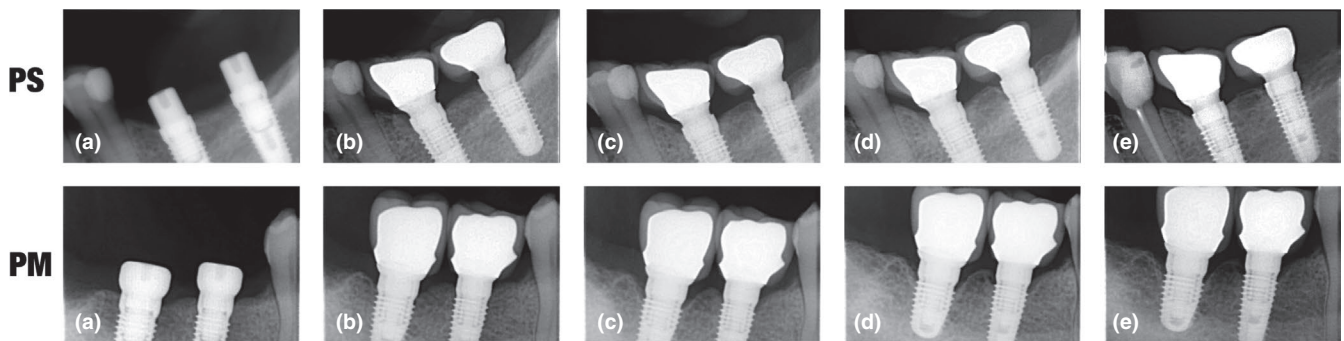
One PS implant with fracture of the restoration showed signs of radiolucency at the 60-month visit. At the same visit, a PM implant presented with a saucer-like bone defect compatible with peri-implantitis.

TABLE 1 Demographic and clinical parameters of the study population and implanted sites at baseline and 60-month follow-up

	PS		PM	
	Surgery	60 months	Surgery	60 months
Characteristics (N)	35	31	33	29
Mean age (SD) (years)	52.84 (10.38)	52.52 (10.11)	49.97 (14.77)	49.76 (15.52)
Gender				
Male/Female	18/17	16/15	19/14	17/12
Quadrants randomized				
2 adjacent implants	31	28	27	23
3 adjacent implants	4	3	6	6
Implants (n)				
Total	74	65	72	63
Centre 1	12	12	12	12
Centre 2	25	18	22	16
Centre 3	37	35	38	35
Diameter, n implants (%)				
∅ 3.8 mm	30 (40.5)	26 (40.0)	31 (43.1)	23 (37.7)
∅ 4.30 mm	30 (40.5)	25 (38.5)	32 (44.4)	29 (42.9)
∅ 5.0 mm	14 (18.9)	14 (21.5)	9 (12.5)	9 (14.8)
Bone quality, n implants (%)				
Type I	4 (5.4)	4 (6.2)	4 (5.6)	3 (4.9)
Type II	40 (54.1)	34 (52.3)	45 (62.5)	46 (59.0)
Type III	26 (35.1)	23 (35.4)	22 (30.6)	21 (34.4)
Type IV	4 (5.4)	4 (6.2)	1 (1.4)	1 (1.6)
Oral hygiene, n patients (%)				
Excellent	1 (2.9)	5 (16.1)	0 (0.0)	6 (20.7)
Good	25 (71.4)	24 (77.4)	29 (87.9)	21 (72.4)
Fair	8 (22.9)	2 (6.5)	4 (12.1)	2 (6.9)
Poor	1 (2.9)	0 (0.0)	0 (0.0)	0 (0.0)

Note: % within randomization.

Abbreviations: PM, platform-matching; PS, platform-switching.

**FIGURE 2** Representative radiographic images of PS and PM restored implants at (a) surgery; (b) loading; (c) 1 year; (d) 3 years; and (e) 5 years. Platform switching in the top row, platform matching in the bottom row. Notice the bone remodelling around the implant neck in the bottom row, not evident in the upper case

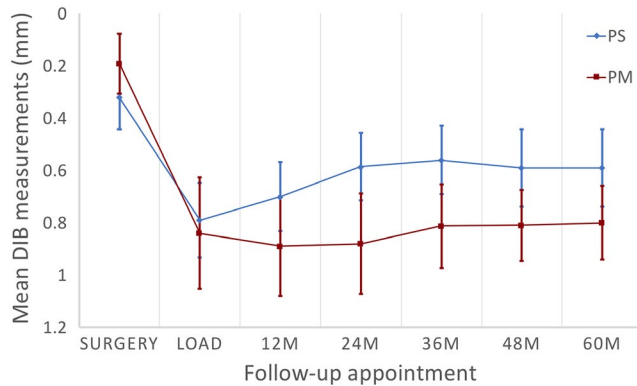


FIGURE 3 Mean distance from the implant shoulder to the first visible bone contact (DIB) in each period of evaluation, for PS and PM restored implants. Error bars represent 95% CI for the mean. Values in millimetres

3.4 | Prosthetic performance

Through the 5 years of the study, only two restorations required replacement, one due to lack of retention (PS) and one due to fracture (PM). Additionally, in the PS group there was decementation of one restoration and fracture of another.

3.5 | Plaque index, sulcus bleeding index and probing depth

Detailed results of the clinical outcomes are available in Table 3. The number of implants with no plaque slightly decreased over time but no differences were observed between groups. At 60 months, all implants were either scored 0 or 1. No major changes were observed for SBI in the follow-up appointments. The PM group presented higher frequencies of implants with no bleeding but with no differences for the PS group. The mean pocket probing depth was within the clinically acceptable values throughout the study. No differences were observed between PS and PM ($p = 0.746$).

4 | DISCUSSION

This multicentre randomized trial evaluated the clinical performance and the marginal bone level changes in implants placed in the posterior mandible restored with single-unit platform switched or matched restorations. Based on the clinical performance and differences in marginal bone levels that are outside of the equivalence margin interval of -0.2 to 0.2 mm (0.29 mm (95% CI: [0.07, 0.50])), it was not possible to reject the null hypothesis of non-equivalence of the platform-switching and platform-matching groups. Additionally, the results indicate that platform switching apparently promotes better preservation of marginal bone levels.

It is now clear that the differences promoted by the use of PS abutments ensue loading and are stabilized after 24 months of

TABLE 2 Multilevel mixed effects analysis of DIB over time

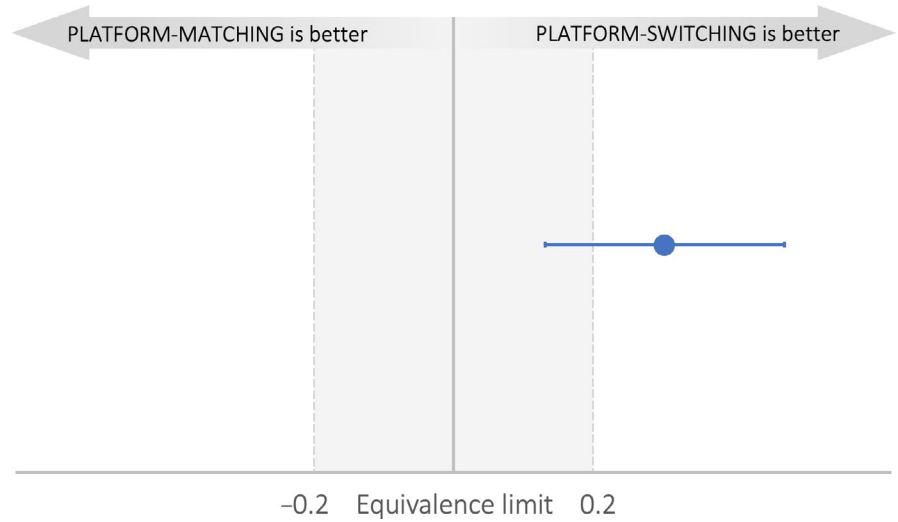
Fixed effects	Estimate	<i>p</i>	95% CI
Intercept	0.87	<0.01	[0.72, 1.03]
Randomization			
PS	-0.29	0.008	[-0.50, -0.08]
PM	Reference category		
Time			
Surgery	-0.68	<0.01	[-0.82, -0.54]
Loading	-0.00	0.998	[-0.14, 0.13]
12 M	0.02	0.674	[-0.07, 0.11]
24 M	0.01	0.693	[-0.05, 0.08]
36 M	0.04	0.137	[-0.01, 0.10]
48 M	0.01	0.804	[-0.04, 0.04]
60 M	Reference category		
Interaction			
PS*Surgery	0.41	<0.01	[0.22, 0.61]
PS*Loading	0.22	0.023	[0.03, 0.41]
PS*12M	0.11	0.096	[-0.02, 0.23]
PS*24M	0.00	0.945	[-0.09, 0.09]
PS*36M	-0.02	0.656	[-0.10, 0.06]
PS*48M	-0.02	0.474	[-0.08, 0.04]
PS*60M	Reference category		

Note: PM and 60 M set as reference categories. The estimate for randomization reflects the difference in DIB measurements between PM and PS implants at the end of the study (60 M). At any period, the mean DIB of a PM implant is given by the corresponding coefficients of Intercept + Time. Mean DIB measurements of PS implants are given by Intercept + Randomization + Time + Interaction of the intended period. 95% confidence interval. Estimates in millimetres. Abbreviations: PM, platform-matching; PS, platform-switching.

function, as observed by the DIB progression over time (Figure 3). This observation reinforces from a clinical point of view, the results of finite element analysis supporting the biomechanical theory (Canullo, Pace, Coelho, Sciubba, & Voza, 2011; Maeda et al., 2007; Pessoa et al., 2014). However, it is important to notice that the difference between groups increases when the whole period is considered, that is, from surgery to 60 months. This suggests that the use of PS healing abutments during the osseointegration stage also contributes to the better preservation of marginal bone and could be associated with the establishment of a more favourable peri-implant biological width, similar to the results described by Hermann, Buser, Schenk, Schoolfield, and Cochran (2001). In this case, the wider soft tissue acts as seal (Sculean, Gruber, & Bosshardt, 2014) and further shifts the inflammatory content of the connective tissue inwards in the implant-abutment junction, reducing the effect of the surgical trauma-induced inflammation on the alveolar bone (Canullo, Pellegrini, et al., 2011; Luongo et al., 2008).

The results of the current study oppose the absence of differences between matching and switching abutments reported in the single 5-year pragmatic randomized clinical trial available in the

FIGURE 4 Non-equivalence of PS when compared to PM restored implants determined from the estimated mean difference in marginal bone after 60M and corresponding 95% CI. Values in millimetres



literature (Esposito et al., 2016), but point in the same direction than those of the systematic reviews on the effect of the use of PS prosthetic components. The systematic reviews of Annibali et al. (2012) and Chrcanovic, Albrektsson, and Wennerberg (2015)

reported average mean differences of 0.44 mm (95% CI: [0.20, 0.69]) and 0.29 mm (95% CI: [0.19, 0.38]), respectively, increasing with larger mismatch between implant and abutment and with increasing follow-up time. However, those results were derived from

TABLE 3 Summary of the measurement of the clinical parameters

	PS		PM		
	N	0/1/2/3 (%)	N	0/1/2/3 (%)	
Plaque index (Score 0-3)					
Loading	68	66.2/23.5/10.3/-	69	87.0/11.6/1.4/-	
12 months	72	76.4/23.6/-/-	70	75.7/24.3/-/-	
24 months	69	65.2/33.3/1.4/-	68	52.9/42.6/4.4/-	
36 months	67	55.2/44.8/-/-	60	51.7/48.3/-/-	
48 months	62	46.8/48.4/4.8/-	65	53.8/44.6/1.5/-	
60 months	65	56.9/43.1/-/-	63	52.4/47.6/-/-	
Sulcus bleeding index (Score 0-3)					
Loading	68	85.3/14.7/-/-	69	94.2/5.8/-/-	
12 months	72	56.9/36.1/6.9/-	70	60.0/32.9/7.1/-	
24 months	69	47.8/36.2/14.5/1.4	68	51.5/42.6/5.9/-	
36 months	67	44.8/47.8/7.5/-	60	51.7/41.7/6.7/-	
48 months	62	45.2/53.2/1.6/-	65	61.5/38.5/-/-	
60 months	65	44.6/55.4/-/-	63	60.3/39.7/-/-	
		PS		PM	
		N	Mean ± SD	N	Mean ± SD
Pocket probing depth					
Loading	64	1.78 ± 0.79	61	1.69 ± 0.51	
12 months	72	2.21 ± 0.47	67	2.46 ± 0.51	
24 months	69	2.35 ± 0.71	68	2.42 ± 0.57	
36 months	67	2.08 ± 0.60	60	2.22 ± 0.66	
48 months	62	2.19 ± 0.54	65	2.38 ± 0.84	
60 months	65	2.13 ± 0.62	63	2.14 ± 0.71	

Note: Relative frequencies of the scores attributed to the implants (PI, SBI). Mean (±SD) pocket probing depth, in millimetres.

Abbreviations: PM, platform-matching; PS, platform-switching.

a limited number of studies with high risk of bias in one or more domains or low reliability due to the limited sample size. Such limitations are not identifiable in the present study, but the results also indicate that the two groups are not equivalent in terms of marginal bone levels (Figure 4), even though the mismatch is lower than the generality reported in the literature. After 5 years, peri-implant bone is set 0.29 mm (95% CI: [0.07, 0.50]) more coronal in the PS group. This is an important conclusion to be taken from the present study that was designed with particular attention to potential sources of bias to produce solid results on whether the PS components are equivalent to PM components on the preservation of marginal bone. Firstly, the difference between the two groups was located exclusively at the prosthetic components, not at the implant nor at the surgical technique. The use of a single family of implants for both groups, with equal outer geometry, surface treatment and type of connection prevents possible modifications of the tested effect since those features have also been implicated in peri-implant marginal bone resorption (Abrahamsson & Berglundh, 2009; Arnhart et al., 2012; Schwarz, Hegewald, & Becker, 2014).

Main limitation of the present study is related to the exclusion of the implants that were inserted in the contra-lateral edentulous areas of patients that had already received implants. This second surgical procedure was considered a protocol violation because the parallel assignment was disregarded. The exclusion of those implants contributed for a considerable reduction in the initial implant sample size detailed in the study flow chart (Figure 1), which was not compensated because of the risk of overextension of the enrolment period that could compromise the feasibility of the study. This loss, however, did not compromise the minimal sample size determined a priori in the power analysis.

It is also important to notice that, as consequence of the radiographic evaluation method, peri-implant marginal bone levels were only assessed on a bi-dimensional scale, at the mesial and distal aspects of the implants. However, bone remodelling around dental implants is a tri-dimensional process that occurs as result of surgical trauma or saucerization. Measurement of buccal bone resorption, which is important in the support of the buccal soft tissues (Merheb, Quiryren, & Teughels, 2014), would only have been possible if patients were submitted to computed tomography (CT) or cone beam computed tomography (CBCT) in every appointment, which was not standard of care at the time the study was implemented and is probably an excessive radiation exposure for a regular follow-up. Periapical radiographs remain an adequate method to evaluate bone levels (Meijndert, Meijer, Raghoobar, & Vissink, 2004), and the use of individualized sensor holders standardizes image acquisition throughout the follow-up periods, prevents image distortion and guarantees precision of the linear measurements.

Generalization of the present results must take into account the eligibility criteria to participate in the trial, namely the inclusion only of systemically healthy patients with healed edentulous sites and adequate bone volume to receive dental implants covered by at least

4 mm of keratinized soft tissue. The last, as reported by Hsu, Lin, and Wang (2017), seems to be a crucial factor for the preservation of marginal bone levels, contributing for the success of the rehabilitations. Notwithstanding that and taking into consideration the validity of these results, we believe that any patient receiving implants in any healed bounded or free end edentulous gaps would benefit from the use of PS prosthetic components from the early stages of the rehabilitation (i.e. from surgery onwards), as long as strict hygiene and motivation follow-up programme is established to ensure patient compliance.

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CONFLICT OF INTEREST

The authors declare that they have no additional conflict of interests related to this study.

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REFERENCES

- Abrahamsson, I., & Berglundh, T. (2009). Effects of different implant surfaces and designs on marginal bone-level alterations: A review. *Clinical Oral Implants Research*, 20(Suppl. 4), 207-215. <https://doi.org/10.1111/j.1600-0501.2009.01783.x>
- Annibali, S., Bignozzi, I., Cristalli, M. P., Graziani, F., La Monaca, G., & Polimeni, A. (2012). Peri-implant marginal bone level: A systematic review and meta-analysis of studies comparing platform switching versus conventionally restored implants. *Journal of Clinical Periodontology*, 39, 1097-1113. <https://doi.org/10.1111/j.1600-051X.2012.01930.x>
- Arnhart, C., Kielbassa, A. M., Martinez-de Fuentes, R., Goldstein, M., Jackowski, J., Lorenzoni, M., ... Strub, J. R. (2012). Comparison of variable-thread tapered implant designs to a standard tapered implant design after immediate loading. A 3-year multicentre randomised controlled trial. *European Journal of Oral Implantology*, 5, 123-136.
- Atieh, M. A., Ibrahim, H. M., & Atieh, A. H. (2010). Platform switching for marginal bone preservation around dental implants: A systematic review and meta-analysis. *Journal of Periodontology*, 81, 1350-1366. <https://doi.org/10.1902/jop.2010.100232>
- Broggini, N., McManus, L. M., Hermann, J. S., Medina, R., Schenk, R. K., Buser, D., & Cochran, D. L. (2006). Peri-implant inflammation defined by the implant-abutment interface. *Journal of Dental Research*, 85, 473-478. <https://doi.org/10.1177/154405910608500515>
- Buser, D., Ingimarsson, S., Dula, K., Lussi, A., Hirt, H. P., & Belser, U. C. (2002). Long-term stability of osseointegrated implants in augmented bone: A 5-year prospective study in partially edentulous patients. *International Journal of Periodontics and Restorative Dentistry*, 22, 109-117.
- Canullo, L., Pace, F., Coelho, P., Sciubba, E., & Voza, I. (2011). The influence of platform switching on the biomechanical aspects of the

- implant-abutment system. A three dimensional finite element study. *Medicina Oral Patologia Oral y Cirugia Bucal*, 16, e852–856. <https://doi.org/10.4317/medoral.17243>
- Canullo, L., Pellegrini, G., Allievi, C., Trombelli, L., Annibaldi, S., & Dellavia, C. (2011). Soft tissues around long-term platform switching implant restorations: A histological human evaluation. Preliminary results. *Journal of Clinical Periodontology*, 38, 86–94. <https://doi.org/10.1111/j.1600-051X.2010.01641.x>
- Canullo, L., & Rasperini, G. (2007). Preservation of peri-implant soft and hard tissues using platform switching of implants placed in immediate extraction sockets: A proof-of-concept study with 12- to 36-month follow-up. *International Journal of Oral & Maxillofacial Implants*, 22, 995–1000.
- Chrcanovic, B. R., Albrektsson, T., & Wennerberg, A. (2015). Platform switch and dental implants: A meta-analysis. *Journal of Dentistry*, 43, 629–646. <https://doi.org/10.1016/j.jdent.2014.12.013>
- Clementini, M., Rossetti, P. H. O., Penarrocha, D., Micarelli, C., Bonachela, W. C., & Canullo, L. (2014). Systemic risk factors for peri-implant bone loss: A systematic review and meta-analysis. *International Journal of Oral and Maxillofacial Surgery*, 43, 323–334. <https://doi.org/10.1016/j.ijom.2013.11.012>
- Cochran, D. L., Mau, L. P., Higginbottom, F. L., Wilson, T. G., Bosshardt, D. D., Schoolfield, J., & Jones, A. A. (2013). Soft and hard tissue histologic dimensions around dental implants in the canine restored with smaller-diameter abutments: A paradigm shift in peri-implant biology. *International Journal of Oral & Maxillofacial Implants*, 28, 494–502. <https://doi.org/10.11607/jomi.3081>
- Enkling, N., Jöhren, P., Klimberg, V., Bayer, S., Mericske-Stern, R., & Jepsen, S. (2011). Effect of platform switching on peri-implant bone levels: A randomized clinical trial. *Clinical Oral Implants Research*, 22, 1185–1192. <https://doi.org/10.1111/j.1600-0501.2010.02090.x>
- Esposito, M., Maghaireh, H., Pistilli, R., Grusovin, M. G., Lee, S. T., Trullenque-Eriksson, A., & Gualini, F. (2016). Dental implants with internal versus external connections: 5-year post-loading results from a pragmatic multicenter randomised controlled trial. *European Journal of Oral Implantology*, 9(Suppl. 1), 129–141.
- Farronato, D., Santoro, G., Canullo, L., Botticelli, D., Maiorana, C., & Lang, N. P. (2012). Establishment of the epithelial attachment and connective tissue adaptation to implants installed under the concept of “platform switching”: A histologic study in minipigs. *Clinical Oral Implants Research*, 23, 90–94. <https://doi.org/10.1111/j.1600-0501.2011.02196.x>
- Guerra, F., Wagner, W., Wiltfang, J., Rocha, S., Moergel, M., Behrens, E., & Nicolau, P. (2014). Platform switch versus platform match in the posterior mandible: 1-year results of a multicentre randomized clinical trial. *Journal of Clinical Periodontology*, 41, 521–529. <https://doi.org/10.1111/jcpe.12244>
- Hermann, F., Lerner, H., & Palti, A. (2007). Factors influencing the preservation of the periimplant marginal bone. *Implant Dentistry*, 16, 165–175. <https://doi.org/10.1097/ID.0b013e318065aa81>
- Hermann, J. S., Buser, D., Schenk, R. K., Schoolfield, J. D., & Cochran, D. L. (2001). Biologic Width around one- and two-piece titanium implants. *Clinical Oral Implants Research*, 12, 559–571.
- Hsu, Y. T., Lin, G. H., & Wang, H. L. (2017). Effects of platform-switching on peri-implant soft and hard tissue outcomes: A systematic review and meta-analysis. *International Journal of Oral & Maxillofacial Implants*, 32, e9–e24. <https://doi.org/10.11607/jomi.5140>
- Lazzara, R. J., & Porter, S. S. (2006). Platform switching: A new concept in implant dentistry for controlling postrestorative crestal bone levels. *International Journal of Periodontics and Restorative Dentistry*, 26, 9–17.
- Luongo, R., Traini, T., Guidone, P. C., Bianco, G., Cocchetto, R., & Celletti, R. (2008). Hard and soft tissue responses to the platform-switching technique. *International Journal of Periodontics and Restorative Dentistry*, 28, 551–557.
- Maeda, Y., Miura, J., Taki, I., & Sogo, M. (2007). Biomechanical analysis on platform switching: Is there any biomechanical rationale? *Clinical Oral Implants Research*, 18, 581–584. <https://doi.org/10.1111/j.1600-0501.2007.01398.x>
- Mascha, E. J., & Sessler, D. I. (2011). Equivalence and noninferiority testing in regression models and repeated-measures designs. *Anesthesia and Analgesia*, 112, 678–687. <https://doi.org/10.1213/ANE.0b013e318206f872>
- Meijndert, L., Meijer, H. J., Raghoobar, G. M., & Vissink, A. (2004). A technique for standardized evaluation of soft and hard peri-implant tissues in partially edentulous patients. *Journal of Periodontology*, 75, 646–651. <https://doi.org/10.1902/jop.2004.75.5.646>
- Merheb, J., Quirynen, M., & Teughels, W. (2014). Critical buccal bone dimensions along implants. *Periodontology 2000*, 66, 97–105. <https://doi.org/10.1111/prd.12042>
- Messias, A., Tondela, J. P., Rocha, S., Reis, R., Nicolau, P., & Guerra, F. (2013). Acrylic customized x-ray positioning stent for prospective bone level analysis in long-term clinical implant studies. *Open Journal of Radiology*, 3, 136–142. <https://doi.org/10.4236/ojrad.2013.33023>
- Mombelli, A., van Oosten, M. A., Schurch, E. Jr, & Land, N. P. (1987). The microbiota associated with successful or failing osseointegrated titanium implants. *Oral Microbiology and Immunology*, 2, 145–151. <https://doi.org/10.1111/j.1399-302X.1987.tb00298.x>
- Pessoa, R. S., Bezerra, F. J., Sousa, R. M., Vander Sloten, J., Casati, M. Z., & Jaecques, S. V. (2014). Biomechanical evaluation of platform switching: Different mismatch sizes, connection types, and implant protocols. *Journal of Periodontology*, 85, 1161–1171. <https://doi.org/10.1902/jop.2014.130633>
- Pieri, F., Aldini, N. N., Marchetti, C., & Corinaldesi, G. (2011). Influence of implant-abutment interface design on bone and soft tissue levels around immediately placed and restored single-tooth implants: A randomized controlled clinical trial. *International Journal of Oral & Maxillofacial Implants*, 26, 169–178.
- Rocha, S., Wagner, W., Wiltfang, J., Nicolau, P., Moergel, M., Messias, A., ... Guerra, F. (2016). Effect of platform switching on crestal bone levels around implants in the posterior mandible: 3 years results from a multicentre randomized clinical trial. *Journal of Clinical Periodontology*, 43, 374–382. <https://doi.org/10.1111/jcpe.12522>
- Schwarz, F., Hegewald, A., & Becker, J. (2014). Impact of implant-abutment connection and positioning of the machined collar/microgap on crestal bone level changes: A systematic review. *Clinical Oral Implants Research*, 25, 417–425. <https://doi.org/10.1111/clr.12215>
- Sculean, A., Gruber, R., & Bosshardt, D. D. (2014). Soft tissue wound healing around teeth and dental implants. *Journal of Clinical Periodontology*, 41(Suppl. 15), S6–S22. <https://doi.org/10.1111/jcpe.12206>
- Strietzel, F. P., Neumann, K., & Hertel, M. (2014). Impact of platform switching on marginal peri-implant bone-level changes. A systematic review and meta-analysis. *Clinical Oral Implants Research*, 26, 342–358. <https://doi.org/10.1111/clr.12339>
- Vigolo, P., & Givani, A. (2009). Platform-switched restorations on wide-diameter implants: A 5-year clinical prospective study. *International Journal of Oral & Maxillofacial Implants*, 24, 103–109.

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