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Platform switching vs regular platform implants: Nine-month post-loading results from a randomised controlled trial

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Key words *abutment connection, dental implants, platform switching*

Purpose: To compare the clinical outcome of platform switching (PS) and regular platform (RP) implants in bilateral single molar replacements.

Material and methods: This study was designed as a randomised, controlled, split-mouth trial. Eighteen patients, with bilaterally missing single molars had one site randomly assigned to a PS implant or a RP implant. A total of 36 implants were bilaterally installed. Both implants were loaded with screw retained temporary crowns 3 months after implant insertion and with screw retained definitive crowns 3 months later. Outcome measures were implant/crown failure, complications, radiographic marginal bone-level changes, pocket probing depth (PPD) and bleeding on probing (BOP). Clinical data were collected at baseline 6 and 12 months after implant placement.

Results: No patients dropped out and no implant failed. No prosthetic or major biological complications were observed. One year after implant placement, mean marginal bone level was 0.93 ± 0.26 mm (95% CI 0.81 to 1.05) in RP group and 0.84 ± 0.23 mm (95% CI 0.73 to 0.95) in the PS group and no statistically significant differences between the two groups were observed ($P = 0.18$). Mean PPD and BOP values were, 6 and 12 months after implant placement, 2.74 ± 0.49 mm (95% CI 2.51 to 2.97) and 1.28 ± 0.75 (95% CI 0.93 to 1.63) in the RP group, and 2.70 ± 0.38 mm (95% CI 2.53 to 2.88) and 1.39 ± 0.78 (95% CI 1.03 to 1.75) in the PS group respectively, with no statistical differences between groups ($P = 0.81$ and $P = 0.16$, respectively).

Conclusions: No statistically significant difference was observed between platform switched and non-platform switched implants.

Conflict of interest statement: *This study was not supported by any company and there is no conflict of interest.*

Introduction

Maintenance of marginal bone levels around dental implants have been a major topic of research[1]. When an implant is installed, normally, bone loss occurs around its neck. The literature contains numerous studies describing peri-implant marginal bone levels. These studies typically report that crestal bone levels are -1.5 to -2.0 mm below the implant-abutment junction (IAJ) at 1 year following implant restorations, which may also be dependent on the location of the IAJ relative to the bone[2,3].

Marginal crestal bone loss at implants is often attributed to a microbial effect[4]. The bacterial presence at the interface of implant-abutment junction seems to contaminate the micro-gap coronally, api-

cally, and laterally for 0.5 to 0.6 mm[5]. Marginal bone loss around implants is also related to other parameters, such as periodontal biotypes[6,7], biological width formation[3], and distance between implants[8].

The concept of platform switching, introduced by Lazzara and Potter[9] and Gardner[10], suggested the use of an abutment or a supra-structure with a diameter at the implant-platform smaller than the implant diameter. This configuration results in a circular horizontal step, which enables a horizontal extension of the biological width. The rationale for such platform switching is to locate the micro-gap of the implant abutment connection away from the vertical bone-to-implant contact area. Compared with a conventional restorative procedure using an identical size implant and supra-structure diameter, platform switching has been suggested to prevent or reduce crestal bone loss[9-11].

To date, the results of platform switching have been controversial, but most clinical studies have reported a positive impact of platform switching on crestal bone stability. The reduction in bone loss does appear to correlate with the size of the circular step.

In the present study, we tested the hypothesis that platform switching (PS) and regular platform (RP) implants would have different outcomes in bilateral single molar replacements versus the alternative hypothesis of there being no difference. This trial is reported according to the CONSORT statement (http://www.consort-statement.org) for improving the quality of reporting of parallel-group randomised trials.

Materials and methods

Study design and patient selection

This study was designed as a randomised, controlled, split-mouth trial. The study was approved by the local Ethics Board (2028) and registered on ClinicalTrials.gov (NCT02123420) and was conducted in accordance with Helsinki Declaration guidelines between November 2011 and February 2013. Data were analysed at the Dentistry Unit of the University Hospital of Sassari, Italy. Patients were selected according to the following main inclusion and exclusion criteria.

Inclusion criteria:

- the need for a single bilateral fixed implant-supported crown in the molar area
- stable interocclusal contacts
- age ≥ 18 years
- provided written informed consent
- residual bone height ≥ 10 mm
- residual bone thickness ≥ 6 mm with at least 5 mm of keratinised gingiva crestally.

Exclusion criteria:

- general contraindications for implant surgery
- lack of occluding dentition in the area intended for implant placement
- periodontitis
- bruxism
- immunosuppression
- previous history of irradiation of the head and neck area
- uncontrolled diabetes
- heavy smoker (>10 cigarettes/day)
- poor oral hygiene
- current or past treatment with bisphosphonates
- substance abuse
- psychiatric disorder
- inability to complete follow-up ≥ 1 year
- lactation
- implant insertion torque less than 35 Ncm.

Patients were recruited in three different centres (Surgical Microsurgical Medicine Department, University of Sassari, and two private offices in Sardinia). The study was explained thoroughly and all participants provided written informed consent prior to enrolment. Patients were treated by the same oral surgeon (SM) following the same surgical and prosthetic protocol.

Clinical procedures

All patients were evaluated clinically and their medical histories were recorded. Preliminary screening, including the acquisition of intraoral and panoramic radiographs (Fig 1), was performed to evaluate potential patients' eligibility. Patients who met the selection criteria received oral hygiene instructions and debridement, if required, after which bone volumes were analysed using cone beam computed tomography (CBCT; Imaging Sciences International, Hatfield, PA, USA).

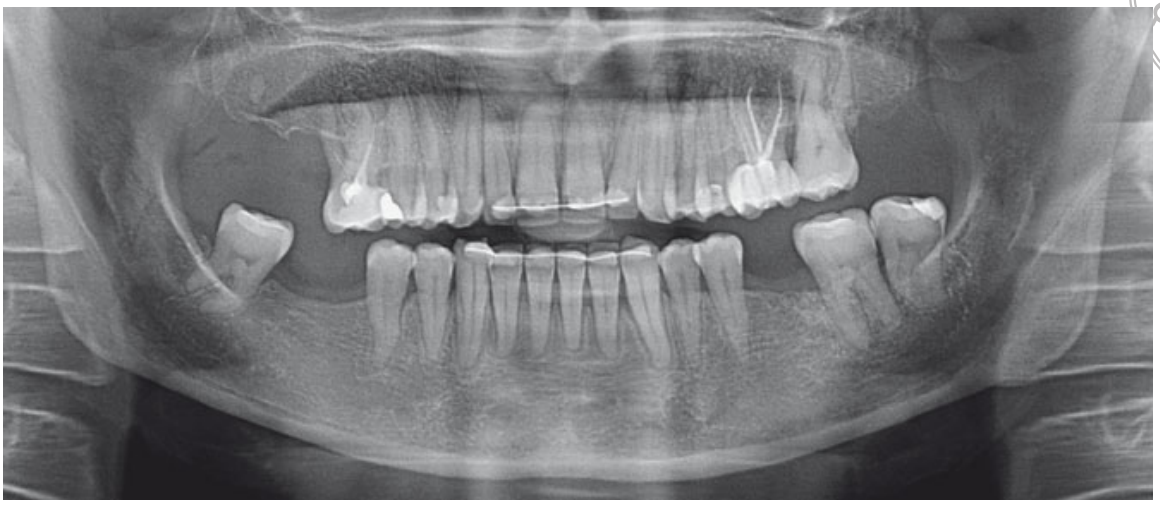

Fig 1 Preoperative panoramic radiograph.

Fig 2 Regular platform (RP) and platform switching (PS) implants.

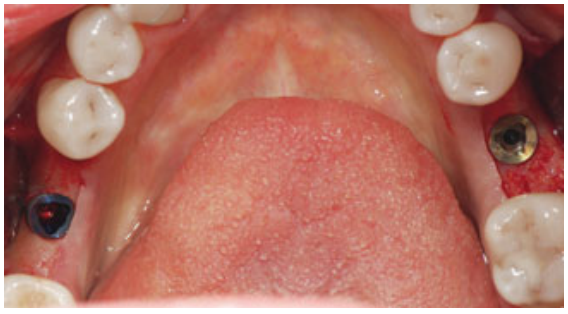

Fig 3 Clinical view: platform switched (right) and regular platform implants (left) after installation.

All patients received amoxicillin and clavulanic acid (Augmentin, GlaxoSmithKline, Verona, Italy) 1 g twice daily from 1 h before implant placement to 6 days post-surgery. Prior to implant placement, patients rinsed for 1 min with 0.2% chlorhexidine (Curasept, Curaden Healthcare, Saronno, VA, Italy) mouthwash and local anaesthesia was induced using articaine with adrenaline (1:100,000; Pierrel, Milan, Italy). Implants (Nobel Replace Tapered Groovy, Nobel Biocare, Goteborg, Sweden) were placed using a conventional approach: an intrasulcular and crestal incision was performed and a mucoperiosteal flap was elevated. Drills were used to prepare the recipient bed and all implants were installed with an insertion torque >35 and <45 Ncm, as measured with a manual torque wrench by the surgical operator. Once the implant site was prepared to receive a 4.3 or 5.0 mm-diameter implant, the envelope containing a randomisation code to assign the PS and the RP implant site was opened by a blinded independent physician (RP), (i.e. the surgical site was prepared by the surgeon without prior knowledge of the implant to be placed). Both sites received tapered implants with an anodised surface. One site received a Nobel Replace Tapered Groovy PS implant (Nobel Biocare, Goteborg, Sweden), with diameters of 4.3 or 5.0 mm and lengths of 10 or 8 mm (PS group). The platform connection of implants with a diameter of 4.3 mm was 3.5 mm, while the platform connection of implants with diameter of 5.0 mm was 4.3 mm. The contralateral site received identical implants with a Replace Select connection (RP group), platform connection diameter was the same diameter of the implant platform (Figs 2 and 3). Healing abutments were connected to implants at the time of surgery. The flaps were then sutured with Vicryl 4.0 sutures (Vicryl, Ethicon J&J International, Sint-Stevens-Woluwe, Belgium).

Baseline intraoral radiographs were taken of both sides with a parallel technique at the time of surgery. When the bone levels around the study implants were inconclusive, a second radiograph was taken. A total of 80 mg of ketoprofen (Oki; Dompe, Milan, Italy) two or three times daily were prescribed for as

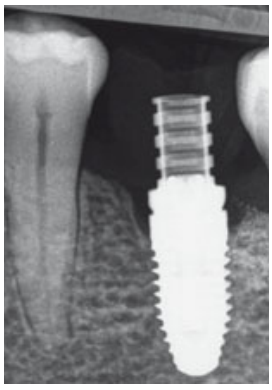

Fig 4 Intraoral radiograph 6 months after implant placement: PS implant.

Fig 5 Intraoral radiograph 6 months after implant placement: RP implant.

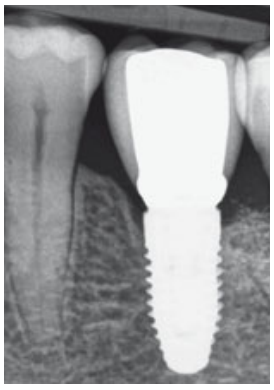

Fig 6 Intraoral radiograph 12 months after implant placement: PS implant.

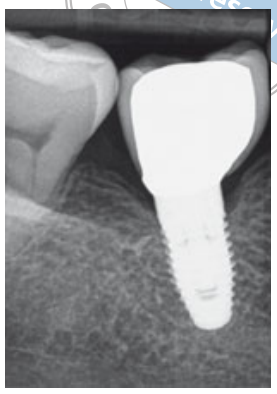

Fig 7 Intraoral radiograph 12 months after implant placement: RP implant.

long as required. Patients were instructed to rinse with 0.2% chlorhexidine (Curasept) for 2 weeks and to stay on a soft diet regimen for 10 days. Sutures were removed after 2 weeks. After 3 months, implants were checked, radiographically and manually, for stability and silicone impressions were taken bilaterally. Customised cast models were then produced. After 1 week, screw-retained temporary resin crowns were delivered on temporary titanium abutments. At 6 months after surgery, definitive metal or zirconia ceramic screw-retained crowns were delivered. Intraoral radiographs of the study implants were taken at implant placement (baseline) and after 3 months post-loading (Figs 4 and 5) and 9 months post-loading (Figs 6 and 7).

Patients were then enrolled in an oral hygiene program with monitoring every 3 months for 1 year following surgery.

Outcome measures

The following outcome measures were used:

Implant/crown failure

Removal of implants was dictated by instability, progressive marginal bone loss, infection, or implant fracture. The replacement for any reason of the definitive crown was considered a prosthetic failure. The stability of individual implants was measured by the prosthodontist (PM) at the time of definitive crown delivery (6 months after implant placement) by applying 35 Ncm of removal torque. After 1 year (9 months after loading), implant stability was tested manually by the same prosthodontist (PM), with two dental mirror handles.

Complications

Prosthetic complications, such as fractures or provisional and definitive ceramic crown chipping, abutment mobility and biological complications, such as wound or implant infection, mucositis, abscesses, or peri-implantitis, were recorded.

Marginal bone levels

Peri-implant marginal bone levels were evaluated on intraoral digital radiographs taken with the parallel technique at the time of implant placement, and at 6 and 12 months, (3 and 9 months after loading). If radiographs were inconclusive, they were repeated. A radiologist (FG), unaffiliated with the study centre, interpreted all radiographs. The distances from the mesial and distal interproximal bone to the reference point (the horizontal interface between the implant and abutment) were measured with a software measurement tool (NIH Scion Image, ver. 4.0.2, Frederick, MD, USA), calibrated against the space between two threads to the nearest 0.1 mm, and the mean of these two measurements was calculated for each implant. The measurements were recorded with reference to the implant axis.

Peri-implant mucosal response

Probing pocket depth (PPD) and bleeding-on-probing (BOP) were measured by a blinded operator

(AD) with a periodontal probe (PCP-UNC 15, Hu-Friedy Manufacturing, Chicago, IL, USA) at 6 and 12 months, (3 and 9 months after loading). Three vestibular and three lingual values were collected for each implant.

Sample size and randomisation

Since this study is intended to be preliminary to a larger clinical trial, an *a priori* sample size calculation was not performed.

With each included patient, the right or left molar was randomly allocated to receive either platform switching (PS) or regular platform (RP) implants, (same implants with same diameter with same type of connection differing only in abutment diameter). The randomisation code was created by computer software (Excel, Microsoft, Redmond, WA, USA) by combining a sequence of randomised non-consecutive numbers matching the two different procedures (PS versus RP implants) with the right or left tooth, and was assigned by an independent operator (RP) not involved in the trial, and numbers were placed in envelopes. Data were collected in spreadsheets (Excel) by an independent physician (FS) at the Dentistry Unit, University of Sassari, Italy.

Statistical analysis

Statistical analyses were conducted using QI Macros SPC software (ver. 2010, KnowWare International, Denver, CO, USA) for Microsoft Office Excel. Differences between platform switched and regular platform implants were analysed using a matched paired *t* tests conducted at the 5% level of significance. Values considered included peri-implant bone level, and PPD and BOP at the insertion and 6 and 12 months after implant placement. All values were presented as mean, mean difference, standard deviation and 95% confidence intervals.

Results

Twenty-five patients were screened between May and October 2011, but 7 patients did not meet the selection criteria for the following reasons: 3 refused to adhere to a strict clinical and radiological follow-up, 3 had insufficient bone height, and 1 had insufficient bone width. Eighteen patients (8 males, 10 females), with a mean age of 48 (range, 28 to 70 years) were considered eligible and treated. No patient dropped out of the study within 1 year after implant insertion, (9 months after loading). No deviation from the protocol occurred. Data were collected at baseline, 6 and 12 months after implant insertion, (3 and 9 months after loading). In total, 36 implants were placed in sites healed for at least 2 months with an insertion torque between 35 and 45 Ncm.

Implant survival

No implant mobility, infection, or implant fracture occurred. All implants were stable at the end of the study.

Prosthetic and biological complications

No prosthetic complication was observed. No major biological complications were recorded in either treatment group. One patient had bilateral peri-implant mucosal inflammation with BOP after 6 months. Improved oral hygiene reduced the peri-implant inflammation. One patient experienced mucosal inflammation with BOP (RP group) after 3 months. After oral hygiene instruction, the inflammation resolved.

Peri-implant marginal bone levels (Tables 1a and 1b)

The average change in interproximal marginal bone level was analysed for each implant. Mean marginal bone levels after 6 months, (3 months after loading) were 0.63 ± 0.17 (95% CI = 0.55 0.71) for regular platform (RP) implants and 0.58 ± 0.17 (95% CI = 0.50 0.64) for platform switching (PS) implants. No statistically significant difference was observed between the groups ($P = 0.14$).

After 12 months, (9 months after loading) the mean marginal bone levels were 0.93 ± 0.26 (95% CI = 0.81 1.05) for RP implants and 0.84 ± 0.23 (95% CI = 0.73 0.95) for PS implants. No statistically significant difference was observed between the groups ($P = 0.18$) (Table 1a). After 6 months (3 months after loading), the difference of marginal

Table 1a Mean marginal bone levels in mm. Statistical analysis between groups.

	Regular (RP)		Switch (PS)		*P* α = 0.05	Mean difference	
	Mean ± SD	95% CI	Mean ± SD	95% CI		Mean ± SD	95% CI
Insertion	0.37 ± 0.18	0.29 to 0.45	0.35 ± 0.18	0.27 to 0.43	0.55	0.02 ± 0.16	-0.10 to 0.05
6 months	0.63 ± 0.17	0.55 to 0.71	0.58 ± 0.17	0.50 to 0.64	0.14	0.05 ± 0.14	-0.12 to 0.01
12 months	0.93 ± 0.26	0.81 to 1.05	0.84 ± 0.23	0.73 to 0.95	0.18	0.09 ± 0.27	-0.22 to 0.04

*Values represent mean ± SD (patients n = 18)
No significant differences among groups (*P* >0.05)

Table 1b Difference of marginal bone level changes between the two groups. Statistical analysis between groups.

	Regular (RP)		Switch (PS)		*P* α = 0.05	Mean difference	
	Mean ± SD	95% CI	Mean ± SD	95% CI		Mean ± SD	95% CI
6 months	0.26 ± 0.15	0.19 to 0.33	0.23 ± 0.13	0.17 - 0.30	0.57	-0.03 ± 0.22	-0.13 to 0.07
12 months	0.56 ± 0.22	0.46 - 0.66	0.50 ± 0.27	0.37 - 0.62	0.38	-0.07 ± 0.31	-0.21 to 0.08

*Values represent mean ± SD (patients n = 18)
No significant differences among groups (*P* >0.05)

bone level changes between the two groups was 0.26 ± 0.15 (95% CI = 0.19 to 0.33) for RP implants and 0.23 ± 0.13 (95% CI = 0.17 - 0.30) for PS implants. No statistically significant difference was observed between the groups (*P* = 0.57) (Table 1b).

After 12 months, the difference of marginal bone level changes between the two groups was 0.56 ± 0.22 (95% CI = 0.46 - 0.66) for RP implants and 0.50 ± 0.27 (95% CI = 0.37 - 0.62) for PS implants. No statistically significant difference was observed between the groups (*P* = 0.38).

Peri-implant mucosal response (Tables 2a, 2b and 3a, 3b)

The mean PPD values were 2.74 ± 0.49 mm (95% CI = 2.51 2.97) for RP implants and 2.70 ± 0.38 mm (95% CI = 2.53 2.88) for PS implants (Table 2a). No statistically significant difference was found between the groups after 12 months, (9 months after loading; *P* = 0.81). Changes in PPD values after 6 months were 0.06 ± 0.40 mm (95% CI = -0.12 to 0.24) for RP implants and -0.04 ± 0.37 mm (95% CI =-0.21 to 0.13) for PS implants. No statistically significant difference was found between the groups (*P* = 0.51; Table 2b).

The mean BOP values were 1.28 ± 0.75 (95% CI = 0.93 1.63) for RP implants and 1.39 ± 0.78 (95% CI = 1.03 1.75) for PS implants (Table 3a). No statistically significant difference was found between the groups after 12 months, (9 months after loading; *P* = 0.16). Changes in BOP values after 6 months were -0.06 ± 0.94 (95% CI = -0.49 to 0.38) for RP implants and -0.11 ± 0.90 (95% CI = -0.53 to 0.30) for PS implants (Table 3b). No statistically significant difference was found between the groups (*P* = 0.77).

Discussion

The results of the present study indicate that the primary hypothesis that platform switching (PS) and regular platform (RP) implants would have different outcomes in bilateral single tooth replacements must be rejected. In fact, over a period of 1 year after implant placement, the results seem to demonstrate that implants restored according to the PS showed similar marginal bone loss as implants with matching implant-abutment diameters. This study was a randomised controlled trial and performed with the same implants with same diameters and the same connection, differing only for platform type (PS or RP) when compared with a split-mouth design.

A limitation of this study was the lack of allocation concealment due to the envelope opening before implant installation while it should be opened at healing

Table 2a Mean PPD values. Statistical analysis between groups.

	Regular (RP)		Switch (PS)		*P* α = 0.05	Mean difference	
	Mean ± SD	95% CI	Mean ± SD	95% CI		Mean ± SD	95% CI
6 months	2.67 ± 0.62	2.38 to 2.95	2.76 ± 0.55	2.51 to 3.01	0.66	0.10 ± 0.90	-0.32 to 0.51
12 months	2.74 ± 0.49	2.51 to 2.97	2.70 ± 0.38	2.53 to 2.88	0.81	0.00 ± 0.66	-0.30 to 0.30

*Values represent mean ± SD (patients n = 18)
No significant differences among groups (*P* >0.05)

Table 2b Changes in PPD values. Statistical analysis between groups.

	Regular (RP)		Switch (PS)		*P* α = 0.05	Mean difference	
	Mean ± SD	95% CI	Mean ± SD	95% CI		Mean ± SD	95% CI
t12-t6	0.06 ± 0.40	-0.12 to 0.24	-0.04 ± 0.37	-0.21 to 0.13	0.51	-0.10 ± 0.60	-0.37 ± 0.18

*Values represent mean ± SD (patients n = 18)
No significant differences among groups (*P* >0.05)

Table 3a Mean BOP values. Statistical analysis between groups.

	Regular (RP)		Switch (PS)		*P* α = 0.05	Mean difference	
	Mean ± SD	95% CI	Mean ± SD	95% CI		Mean ± SD	95% CI
6 months	1.33 ± 1.14	0.81 to 1.86	1.50 ± 0.92	1.07 to 1.93	0.45	0.17 ± 0.92	-0.26 ± 0.59
12 months	1.28 ± 0.75	0.93 ± 1.63	1.39 ± 0.78	1.03 to 1.75	0.16	0.11 ± 0.32	-0.04 ± 0.26

*Values represent mean ± SD (patients n = 18)
No significant differences among groups (*P* >0.05)

Table 3b Changes in BOP values. Statistical analysis between groups.

	Regular (RP)		Switch (PS)		*P* α = 0.05	Mean difference	
	Mean ± SD	95% CI	Mean ± SD	95% CI		Mean ± SD	95% CI
t12-t6	-0.06 ± 0.94	-0.49 to 0.38	-0.11 ± 0.90	-0.53 to 0.30	0.77	-0.06 ± 0.80	-0.43 ± 0.32

*Values represent mean ± SD (patients n = 18)

No significant differences among groups (*P* >0.05)

abutment connection. Other limitations were that an *a priori* sample size calculation was not performed and that the follow-up period may be short.

The peri-implant crestal bone level was a criterion for implant success. Traditionally, radiographic marginal bone loss of -1.5 mm occurred during the first year after abutment connection at the second-stage surgery[1]. Less marginal remodelling might be beneficial for better implant-tissue stability, possibly with better aesthetic results.

It has been demonstrated that bone resorption around implants is the result of biomechanical and biological factors. In fact, several studies have shown the impact of biological width re-establishment[3-12] and implant diameter[13-15]. The same factors are considered to be involved in bone level changes around platform-switched implants. Broggini et al and Enkling et al[11,16] suggested that the microbiota at the implant-abutment junction might be a cause of early bone loss.

According to some reports, this problem can be avoided by moving the implant-abutment junction away from the bone crest. Lazzara and Porter[9] reviewed the concept of platform switching and stated that there was less bone loss around matching diameter implants when smaller diameter abutments were connected. Subsequently, several studies on PS proposed a positive effect of this concept compared with traditional restorations[16-18].

As a result, implant manufacturers have incorporated platform switching into their designs to reduce initial bone loss and enhance gingival contours and aesthetics. Cocchetto et al[17] in a non-randomised controlled study evaluated the biological effects of using a wide platform-switching restorative protocol in humans. The results of this study indicated that, when properly selected, patients receiving wide platform-switched implants experienced less crestal bone loss than with non-platform-switching implants. Bilhan et al[18] in a retrospective study compared bone around platform-switched and regular platform implants that supported removable prostheses and reported that the marginal bone loss was statistically significantly lower in platform-switching situations, with a follow-up of 36 months. Canullo et al[19], in a randomised controlled study, reported that implants restored according to the platform-switching concept experienced significantly less marginal bone loss than implants with matching implant-abutment diameters. Additionally, it was observed that marginal bone levels were better maintained with increasing implant-abutment mismatching. Trammell et al[20], in a non-randomised controlled study, measured the biological width with reduced and conventional platform abutments. Although the biological width was similar in both groups (1.57 ± 0.72 mm with the reduced platform and 1.53 ± 0.78 mm with conventional abutments), bone loss was significantly smaller with the reduced platform. Prosper et al[21], in a randomised controlled trial, found that the use of the platform-switching concept of implants with similar abutment diameter and larger implant platform significantly reduced post-restorative crestal bone loss when placed in both two-stage and one-stage techniques.

Atieh et al[22] observed that the degree of marginal bone resorption was inversely related to the extent of the implant-abutment mismatch. Vandeweghe and De Bruyn[23] suggested that that platform switching decreased bone loss by 30%. Although the sample size was limited, it seems that the creation of biological width affected peri-implant bone loss to a significant extent and that platform switching was effective only when the mucosal thickness allowed the establishment of biological width.

The results from our study differ from many previous reports. However most of comparative studies, compared, very often, wide-diameter versus regular-diameter implants, both restored with the same abutment[9-24] and mismatching was obtained by increasing the platform of the implant, and maintaining the same dimension of the abutment. Contrarily, in our study, we used implants of identical diameter in a split-mouth design. It is possible to speculate about the similar outcomes of same implants inserted in the same patients and about the Replace Select connection of implants with a groovy neck, but no major evidence can be obtained due to some limitations of the study: relatively short follow-up and the small sample size. It is probable that PS implants do not always show less implant bone loss than standard platform implants, although the results of our study should be confirmed in further clinical trials with larger samples and longer follow-up.

■ Conclusions

Platform switching and regular platform implants seem to have similar clinical outcomes in the bilateral single tooth replacements.

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