Bone and Soft Tissue Response in Bone-Level Implants Restored with Platform Switching: A 5-Year Clinical Prospective Study

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Purpose: *The aim of this prospective study was to evaluate radiographic levels of peri-implant bone crest as well as soft tissue response, papilla height, and buccal mucosa recession, in bone-level implants restored with platform switching after 1-year and 5-year follow-ups.* ***Materials and Methods:*** *This prospective study called for the placement of 59 implants to obtain a target of 90% power. To compensate for possible dropouts, the sample size was adjusted to 67 implants. To assess marginal bone level changes, periapical radiographs were taken at baseline, 1 year, and 5 years after the definitive restorations. Peri-implant soft tissue modifications were evaluated by performing a photographic sequence at 15 days, 1 year, and 5 years after implant restoration. Parameters measured were: (1) distance from the tip of the papilla to the contact point and (2) apicocoronal crown length.* ***Results:*** *A one-way analysis of variance (ANOVA rank test) was used to compare quantitative data among the three time points studied. Mean marginal bone level changes were as follows: –0.06 ± 0.32 mm from baseline to 1 year, –0.23 ± 0.38 mm from 1 to 5 years, and –0.28 ± 0.45 mm from baseline to 5 years. In bone-level outcomes, no statistically significant differences were found between baseline and 1 year, while the mean differences between 1 and 5 years and baseline and 5 years showed statistically significant differences. In the soft tissue analysis, the distance from the tip of the papilla to the contact point showed the following values: baseline, 2.08 mm; 1 year, 1.54 mm; 5 years, 1.31 mm. No statistically significant differences were found between baseline and 1 year, whereas statistically significant differences between the 1 and 5 years and baseline and 5 years were found. Apicocoronal crown length measurements showed the following values: baseline, 9.44 mm; 1 year, 9.28 mm; 5 years, 9.81 mm. No significant differences were found between times studied.* ***Conclusion:*** *This prospective clinical study of 67 bone-level implants restored according to the platform-switching concept reported that radiographic levels of peri-implant bone crest were statistically significant between 1 and 5 years and baseline and 5 years. For the soft tissue response, the greatest reduction in the distance from the papilla to the contact point from 1 to 5 years and baseline to 5 years was observed. No significant differences were shown in the buccal margin.*
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Based on the success of implant therapy, current finishing criteria include both functional and esthetic aspects.[1–4] Preservation of interproximal bone and associated soft tissue is essential to achieve esthetic success with implant restoration. It should be borne in mind that any alteration in the bone level is accompanied by a subsequent soft tissue reaction.[5] Therefore, bone stability is a key factor in itself, and is also important for the associated preservation of soft tissues.[6] Implant therapy involves many variables that must be controlled carefully. Traditionally, bone loss of up to 1.5 mm during the first year and not more than 0.2 mm per year thereafter has been accepted as a criterion for successful treatment.[7] During the mid-1980s, the first wide-diameter implants, designed primarily for the

posterior region, were fitted. Due to a lack of suitable components, prosthetic implants were loaded with standard-diameter abutments, known as platform switching. Radiographically, it was observed that, after loading, initial remodeling had not occurred, giving rise to the platform-switching method.[5,8,9] Reducing the diameter of the abutment in relation to the diameter of the implant body results in less resorption of peri-implant crestal bone, which in theory can preserve soft tissues.[10] Several studies have found that soft tissues respond more favorably to platform switching of implants than to platform matching, in which the same diameter of implants and abutments is used.[11–14] Many hypotheses have been proposed in an attempt to explain the benefits of using abutments with platform switching, such as: positioning the implant-abutment connection away from the bone crest, thus allowing the biologic width to be determined horizontally; increasing the distance between the inflammatory cell infiltrate and the bone crest; and improving the distribution of the load level of the implant abutment.[9,15–19] However, controversy remains about the value of the platform-switching concept and its effect on bone and soft tissue preservation. Some authors have found no significant differences between platform matching versus platform switching.[20–28] It seems that the choice of using conventional matching or platform switching is often based on a manufacturer's recommendation rather than scientific evidence.

In this context, the aim of this study was to assess radiographic peri-implant bone changes and to evaluate soft tissue modifications at 1-year and 5-year follow-ups of bone-level implants restored according to the platform-switching protocol.

MATERIALS AND METHODS

This prospective study was conducted in the Prosthodontics Department, Faculty of Medicine and Dentistry, University of Santiago de Compostela, Spain, enlisting patients presenting to the service for implant rehabilitation from October 2009 to May 2010.

Inclusion Criteria

Inclusion requirements were as follows: patients with good oral hygiene and absence of periodontitis who required dental rehabilitation with a fixed implant-supported prosthesis; tooth loss for at least 6 months; edentulous areas in the premolar area with a natural tooth mesial and distal to the implant site; sufficient width and height of bone for placement of one implant without regeneration procedures; bone types II and III according to the classification of Lekholm and Zarb[29]; soft tissues free of clinical signs of inflammation; sufficient keratinized gingiva (≥ 4 mm); full-mouth plaque score and full-mouth bleeding score < 25%; and in the opposite arch, natural dentition or teeth or implant-supported restorations.

Exclusion Criteria

Exclusion requirements were as follows: bone types I and IV according to the classification of Lekholm and Zarb[29]; signs or symptoms of temporomandibular disorders or parafunctional activities; patients who had undergone previous implant surgery at the intervention site; heavy smokers (> 10 cigarettes/day); alcoholics or drug abusers; lactating or pregnant patients; and patients undergoing pharmacotherapy bearing upon osseointegration or with systemic diseases.

Study Design and Sample Size Calculation

Sample size calculation was conducted using a two-sided α of .05 to detect a mean difference of 0.30 ± 0.50 mm. A target of 90% power requires a sample size of n = 59 implants. To compensate for possible dropouts, the sample size was adjusted to 67 implants.

All participants who met the inclusion criteria had been previously informed about the purpose of the study and the need for follow-up over several years, for which they signed an informed consent. At the start of the study, 67 bone-level implants (Institut Straumann) that were 3.3 (8 implants), 4.1 (48 implants), and 4.8 mm (11 implants) in diameter with an implant-abutment mismatch of 0.25, 0.4, and 0.75 mm, respectively, and lengths between 8 and 12 mm, were placed.

First, marginal bone level (MBL) changes were analyzed at the stage of prosthesis delivery (baseline), and at the 1-year and 5-year follow-up assessments. Secondly, papilla height and buccal mucosa recession were measured at three checkpoints: 15 days, 1 year, and 5 years after implant loading. Both parameters were chosen because they are reported in the literature to be the most important.[30–32]

Clinical Procedures

Surgical and prosthetic procedures were performed according to the manufacturer's instructions and established protocols.[33] All patients received a single 2 g dose of amoxicillin or, if allergic to penicillin, clyndamicin tablets 1 hour before surgery.[34] Local anesthesia was induced using articaine with epinephrine (1:200,000; Artinibsa). All implants were placed using a conventional approach. A supracrestal incision was made, and the small flap was elevated to avoid any damage to the periosteum and to provide the blood supply during the healing time. All implants were placed at bone level and, due to good primary stability, healing abutments were left uncovered. The flaps were sutured with sterile surgical silk 3.0 sutures (LorcaMarín). Radiographs were taken

for a clinical intraoperative control. Patients were provided with guidance regarding oral hygiene, and were instructed to use chlorhexidine mouthwash 0.12% for 1 minute, three times per day for 1 week. At 2 weeks after surgery, sutures were removed. No provisional restoration was performed during the healing time; therefore, after a period of osseointegration at least 2 months after surgery, implant loading was begun by fitting single, cemented metal-ceramic crown restorations with an adhesive bonding agent (Panavia F Kuraray Medical). Every 6 months, all patients involved in the study underwent clinical assessment of soft tissue. Plaque Index[35] and Bleeding Index[35,36] were evaluated, and probing pocket depth[37] was measured at the mesial and distal levels of the teeth adjacent to the implant with a periodontal probe (Periodontal probe SM-12 Bontempi).

Radiographic Assessment

Radiographic examination was performed using periapical radiographs (Kodak Ultraspeed Dental Film; Eastman Kodak), with the dental radiology system Siemens Heliodent model X1744 MD set at 70 kV and 7 mA (Sirona Dental System). Radiographs were taken according to the long-cone paralleling technique, using a positioner (X-ray Holders KerrHawe) parallel to the implant axis and perpendicular to the cone of rays, and a bite registration with silicone putty consistency (Aquasil Soft Putty/Regular Set, Dentsply DeTrey) in which the patient leaves the imprint of the occlusal surfaces. This technique allows the repositioning of the image plate in future radiographic examinations. The accuracy of this technique has been previously demonstrated, showing a precision value of 0.44 mm.[38]

Each radiograph was captured by a Nikon D1 Digital Reflex camera (Nikon Medical Objective, Nikon) and was then processed by a Hewlett Packard processor (Intel Core Duo, Hewlett Packard). For the digital processing, an image measuring program, NIH ImageJ (Wayne Rasband, National Institutes of Health) was used. On each image, measurements were taken of the distance between the first point of bone-to-implant contact (BIC) and the implant shoulder and mesial and distal sites. Each radiograph was calibrated with reference to the implant diameter (Fig 1). Three observers (L.L., B.R., L.S.) defined landmarks in the bone and the implant for measurement and consensus between two or more of the observers. If all three opinions differed, the landmarks were considered too difficult to measure and so were discarded from the study. The level of peri-implant bone measurement was evaluated at the stage of prosthesis delivery (baseline), and at 1-year and 5-year follow-up assessments.

Soft Tissue Assessment

To assess the peri-implant soft tissue, a photographic sequence at 15 days, 1 year, and 5 years after implant loading was performed, with the camera placed in a tripod in a perpendicular position to the buccal surface of the restoration and at a distance of 50 cm. Photographs of implants and surrounding soft tissues were taken by the same operator (B.R.) using the same camera (D1, Nikon Medical Objective).

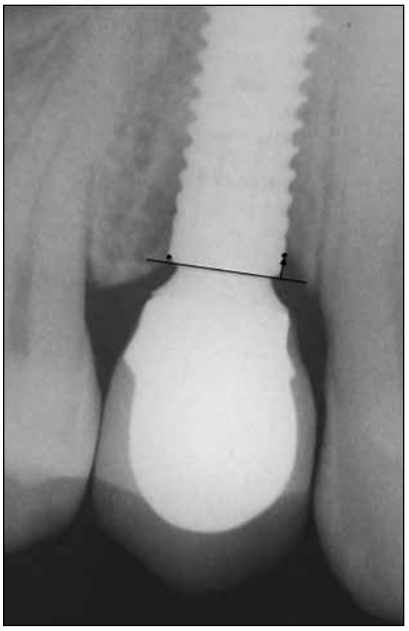

Fig 1 Reference points for measuring the distance between the bone-to-implant contact and the implant shoulder.

Parameters measured for the soft tissue assessment were as follows: distance from the tip of the papilla to the contact point; to standardize the points to be measured, a superfloss thread (Procter & Gamble UK) was placed in the interproximal space of the implant-supported crown to determine the precise location of the contact point. The measurements were made between the top of the papilla and the contact point defined with the thread (Fig 2) and apicocoronal crown length; to assess sulcular recession, one vertical measurement was made from the most apical extent of the facial sulcus to the cusp tip (Fig 2).

The measurements were performed using ImageJ software (NIH). To calibrate the measures, a periodontal probe (Periodontal probe SM-12, Bontempi) was used to assess each image. Two independent investigators (L.S., L.L.) established the measuring points; in case of a discrepancy, a third researcher established consensus. The same examiner measured the distances.

Statistical Analysis

Initially, a variable was created to measure the difference between the variables measured at baseline, 1 year, and 5 years. A descriptive data set rated the differences between the three time points. A one-way

Fig 2 Photographic sequence for the assessment of soft tissues: *(a)* baseline, *(b)* 1 year, and *(c)* 5 years. *(a)* Red lines represent the distance from the tip of the papilla to the contact point, mesial and distal points, respectively, and the apicocoronal crown length.

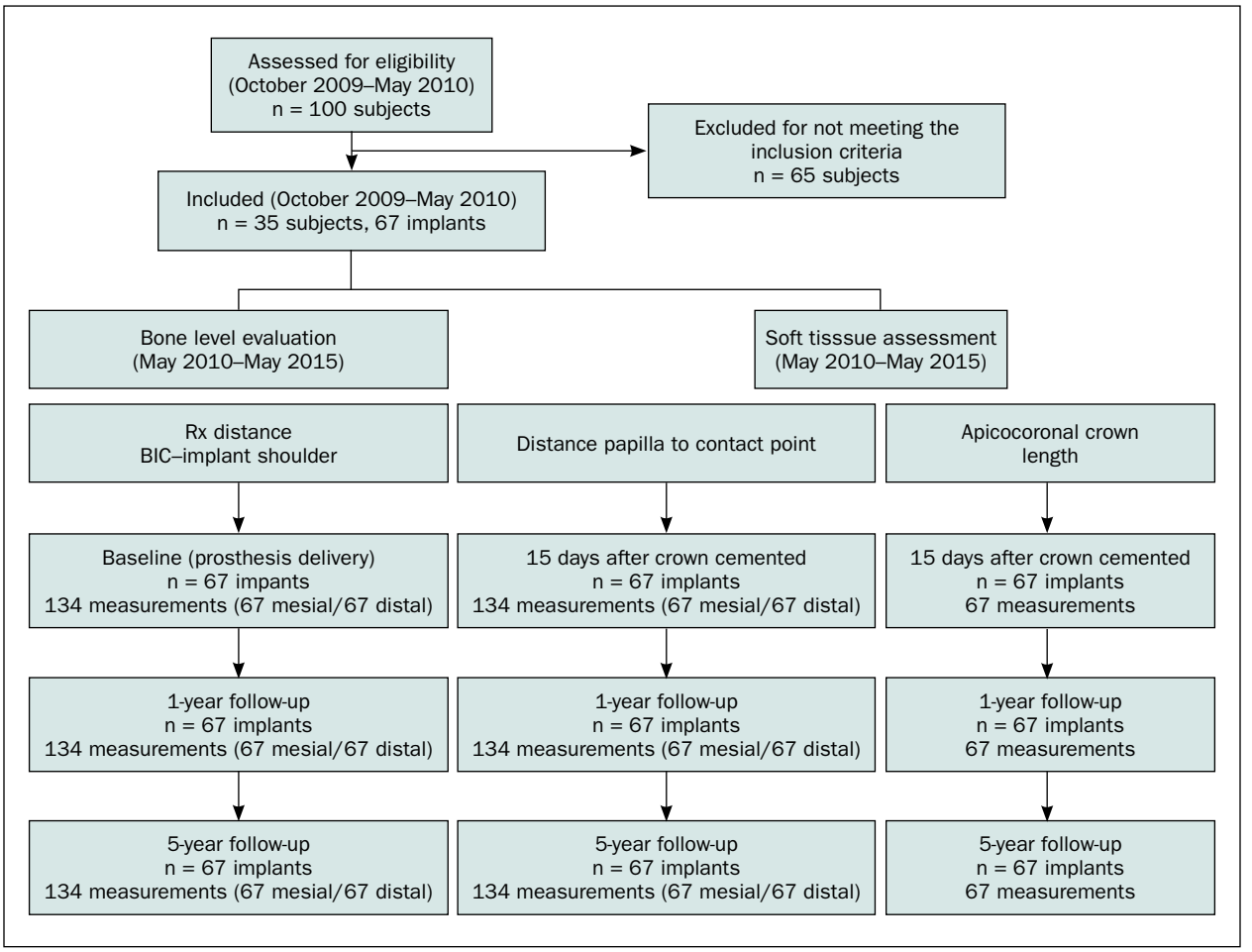

Fig 3 Study sample flow chart.

analysis of variance (ANOVA) was used to compare quantitative data among the three time points studied if a normal distribution was found; a Kruskal-Wallis ANOVA ranks test was used if distributions were not normal. Post hoc analyses were performed when appropriate. For contrasts of normality, the Shapiro-Wilks test was selected, and Levene's test was used to check whether the samples exhibited this homogeneity of variances (homoscedasticity). Differences were considered significant if $P < .05$. Statistical treatment of the data was performed using R software (R Core Team [2014]; R is a language and environment for statistical computing [R Foundation for Statistical Computing, http://www.R-project.org/]).

Table 1 Outcome Measures of BIC and MBL Changes at the Three Time Points Analyzed

Time point	Baseline	1 y	5 y	Baseline–1 y	1 y–5 y	Baseline–5 y
BIC ± SD (mm)	0.64 ± 0.55	0.59 ± 0.54	0.35 ± 0.36			
MBL ± SD (mm)				–0.06 ± 0.32	–0.23 ± 0.38	–0.28 ± 0.45
P				.3493	.0062	.0014

Table 2 Distance from Tip of Papilla to Contact Point and Apicocoronal Crown Length

	Time points	Mean ± SD (mm)	Range	*P* value (time intervals)
Distance papilla-contact point	Baseline	2.08 ± 1.70	0.00–4.89	> .05[a]
	1 y	1.54 ± 1.74	0.00–4.28	< .05[b]
	5 y	1.31 ± 0.78	0.00–4.55	< .05[c]
Apicocoronal crown length	Baseline	9.44 ± 1.70	5.81–12.50	> .05[a]
	1 y	9.28 ± 1.74	5.39–11.52	> .05[b]
	5 y	9.81 ± 2.71	5.15–15.40	> .05[c]

[a]Baseline–1 y.
[b]1y – 5y.
[c]Baseline–5 y.

RESULTS

Among 100 patients who were referred to the Prosthodontics Department for implant therapy in the posterior region, 35 subjects who met the inclusion and exclusion criteria were included and received 67 bone-level implants. The sample group consisted of 20 men and 15 women aged between 25 and 67 years (mean age: 47.1 years). No dropouts occurred during the entire 5-year follow-up period (Fig 3). Patients were enrolled from October 2009 to May 2010. Patient evaluation ended in May 2015.

Radiographic Changes in Bone Level

Results obtained from 134 measurements of bone loss after definitive restoration in bone-level implants restored with platform switching showed the following measurements for BIC: at baseline, 0.64 ± 0.55 mm; at 1 year, 0.59 ± 0.54 mm; at 5 years, 0.35 ± 0.36 mm. Mean MBL changes were: –0.06 ± 0.32 mm from baseline to 1 year, with a significance level of $P = .3493$; –0.23 ± 0.38 mm from 1 year to 5 years ($P = .0062$); and –0.28 ± 0.45 mm between baseline and 5 years ($P = .0014$). Thus, no significant differences were found between baseline and 1 year, while the other periods showed statistically significant differences between the means. The results for BIC and MBL changes are shown in Table 1.

Soft Tissue Changes

The distance from the tip of the papilla to the contact point is shown in Table 2 and Fig 2. At baseline, the mean distance was 2.08 ± 1.70 mm (range: 0.00 to 4.89 mm). After 1 year, the distance was 1.54 ± 1.74 mm (range: 0.00 to 4.28 mm), and at 5 years, it was 1.31 ± 0.78 mm (range: 0.00 to 4.55 mm). The mean difference between baseline and 1 year was not statistically significant ($P > .05$). However, the mean differences for the other two time periods studied (1 to 5 years and baseline to 5 years) exhibited statistically significant differences ($P < .05$). Apicocoronal crown length is shown in Table 2 and Fig 2. At baseline, a mean length of 9.44 ± 1.70 mm was obtained (range: 5.81 to 12.50 mm). After 1 year, the mean length was 9.28 ± 1.74 mm (range: 5.39 to 11.52 mm), while at the 5-year follow-up, the mean length was 9.81 ± 2.71 mm (range: 5.15 to 15.40 mm). No statistically significant differences were found between baseline and 1 year, 1 to 5 years, and baseline to 5 years ($P = .295$).

DISCUSSION

This prospective clinical study was carried out with the aim of assessing the behavior of bone and soft tissue associated with bone-level implants restored according to the platform-switching system. To the authors' knowledge, the platform-switching concept has been widely reviewed in the literature. The most recent systematic reviews reported generally good results for peri-implant bone and soft tissue preservation.[39–45] Atieh et al[39] analyzed a total of 10 randomized controlled trials (RCT), and reported significantly lower bone loss in implants restored with platform switching vs platform matching (mean difference: –0.37 mm). Serrano-Sánchez et al[40] reported a bone loss of 0.05 to 1.4 mm for those implants restored according to the platform-switching concept in a follow-up period after definitive restoration of 4 to 169

months. Annibali et al[41] carried out a systematic review and found no differences in survival rates between platform matching and platform switching after 36 months of follow-up. Implants restored by platform switching showed a lower degree of marginal bone loss over time (0 to 0.99 mm). Strietzel et al[42] reported a favorable trend toward platform switching, while Herekar et al[43] analyzed 10 randomized clinical trials and five controlled clinical trials and found a lower marginal bone loss around implants restored by platform switching. Chrcanovic et al[44] observed that implants restored with platform switching showed significantly lower marginal bone loss than implants restored with platform matching. The most recent systematic review[45] revealed a significant reduction in marginal bone loss for implants restored with platform switching compared with those restored with platform matching. Although most of the aforementioned studies are favorable to the concept of platform switching, other studies produced unfavorable results for platform switching.[20–28] Another previous review[46] provided a summary of current studies on the advantages and potential applications of this technique. The authors concluded that platform switching might preserve the crestal bone level and maintain the soft tissue level in the esthetic zone. Nevertheless, it is worth noting that the radiographic crestal bone level is only an indirect measure of the esthetic outcome. Therefore, the upgraded preservation of peri-implant bone around a platform-switched implant does not necessarily improve esthetics. Several researchers have studied soft tissue modification after abutment placement. Choquet et al[47] established that the papilla level around single-tooth implant restorations is mostly related to the bone level adjacent to the teeth, and more specifically, to the bone crest. Regenerating the papilla after single-implant treatment is considered successful if there is a distance of 5 mm between the contact point and the bony crest.[48] Another author established papilla regeneration as a regular finding that occurred in 83.9% of cases. Sulcular recession was less predictable and was observed in 59.6% of implants.[49] Cardaropoli et al[50] reported that the thickness of the labial mucosa was increased at crown placement followed by a slight remission at 1 year. Henriksson and Jemt[51] found that the buccal tissue increased significantly after abutment and implant crown placement. This increased buccal margin was reduced after 1 year. All these authors carried out their studies on conventional implants, and most of them referred only to the anterior sector. With the new design of implants, the platform-switching method, modification of the horizontal microgap position and marginal bone resorption could be reduced and, consequently, soft tissue support could be improved. One of the latest studies describes the preservation of peri-implant soft and hard tissues using platform switching of implants placed in immediate extraction sockets.[52] The authors concluded that the interproximal papilla showed no apical migration and, in some cases, a slightly increased papillary level was noticed. The mean papillary height gain was 0.25 mm, and the buccal margin did not show any perceptible change; in fact, when recession was assessed, a mean gain of 0.2 mm was observed. In another study,[14] a mean papillary height gain of 0.045 mm was reported, compared with a change of –0.88 mm in the control group. In a recent review and meta-analysis,[39] the authors concluded that platform switching may preserve the interimplant bone height and soft tissue levels.

In the present study, an implant system was used in conjunction with platform switching to improve and maintain hard and soft tissue levels. After 5 years of follow-up, the mean MBL was –0.28 ± 0.45 mm, similar to those outcomes reported by Hürzeler et al[12] (–0.22 ± 0.53 mm) and Herekar et al[43] (–0.34 mm). Mean differences between the three intervals studied increased with time, which means that bone-level implants restored with platform switching seem to offer good stability over time. There have already been many studies of the platform-switching concept compared with the platform-matched system. Nevertheless, a detailed analysis showed that the follow-up period did not exceed 36 months in most of them.[19,20,53,54] Only a few studies continued to 60 months of follow-up.[14,55–57]

With regard to the soft tissue analysis, it should be noted that all implants were placed in the posterior area, unlike in most studies where the implants were located anteriorly for esthetic purposes. After a year, there was a reduction in the distance from the papilla to the contact point of 0.54 mm, resulting in an increase of papillary height. After 5 years of follow-up, a reduction of 0.77 mm from the initial measurement was observed. The greatest reduction in that distance was observed when the periods measured were long, such as from the beginning to 5 years and from the first year to 5 years. In fact, in more than 50% of cases, there was complete filling of the interproximal space. It has not been previously described in the literature, which has generally reflected major changes during the first year, particularly between the first and sixth week after abutment placement.[58] In this study, no significant changes in the cervical-incisal crown length after 1 year or 5 years of follow-up were observed. The initial mean was 9.28 mm in the first year and 9.81 mm in the fifth year. There were no significant differences between the periods studied; therefore, the oral margin remained clinically unchanged. Thus, from a prosthetic point of view, a bone-level implant restored with platform switching offers a better emergence profile and esthetic advantages.

This prospective clinical study has no control group because the study is not intended to compare the results with other implant systems. In any case, there are few data on the bone-level implant system restored

with platform switching at 5 years in the literature. Another shortcoming of this study was measurement repeatability, especially for the soft tissue assessment. The method of measuring soft tissue using photographs has methodologic limitations, which the present study tried to avoid by working with a correct definition of landmarks and standardizing the distance and position of the photographs. Moreover, bone stability over time promotes soft tissue preservation. However, the outcomes found cannot be attributed only to the platform-switching concept. Taking into account possible error in the measurement method[38] (accuracy of 0.44 mm), as well as large standard deviation, the outcomes may be limited by these values. Therefore, the results should be interpreted with caution. Other factors such as the mucosal thickness, microbiologic status, insertion level, implant geometry, or type of connection could be responsible for such results.

CONCLUSIONS

In this prospective clinical study of 67 bone-level implants restored according to the platform-switching concept, the following observations were made. On one hand, radiographic levels of peri-implant bone crest were statistically significant between 1 year and 5 years and baseline and 5 years. On the other hand, in the soft tissue response, the greatest reduction in the distance from the papilla to the contact point was observed when the periods measured were long, from 1 year to 5 years, and baseline to 5 years. Meanwhile, no significant differences were shown in the buccal margin.

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