



Article

Behavior of soft tissue around platform-switched implants and non-platform-switched implants: a comparative three-year clinical study.

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Abstract:

Background: To verify the influence of platform switching (PS) on soft tissue behavior by comparing the soft tissue stability around implants with and without PS during 3 years of follow-up.

Methods: The study included patients treated with fixed dentures supported by implants with an internal connection. The radiographic distance between the first bone to implant contact and implant shoulder (FBIC) was assessed. Plus, the presence of keratinized facial mucosa and the prosthetic crown height (TH) were monitored for 3 years from the delivery of the definitive crown. These parameters were measured for 2 different groups: platform-switched implants in the PS group and non-platform-switched (NPS) implants in the NPS group.

Results: 77 implants were considered in the statistical analysis. After three years, the overall FBIC mean value was $0,31 \pm 1,00$ mm. However, the mean FBIC was $0,66 \pm 0,97$ mm for the NPS group and $-0,05 \pm 0,91$ mm for the PS group. Moreover, a mean recession of $0,54 \pm 1,39$ mm was measured for the NPS group, whereas a mean coronal migration of $0,17 \pm 0,95$ mm was measured for the PS group. A significant correlation was also found between the presence of PS and Δ TH ($p \leq 0,01$) over the three years of follow-up.

Conclusions: The absence or presence of platform switching would appear to affect the tendency of the gingival buccal margin towards recession or creeping. Plus, implant-abutment platform switching seems to help prevent peri-implant soft tissue recession over time when compared to implants without PS.

Keywords: dental implants; tissue engineering; platform switching; implant connection; soft tissue maturation.

1. Introduction

Fulfilling the aesthetic expectations of patients is nowadays one of the most challenging tasks in implant dentistry [1]. In the last few years, attention has moved to the long-term aesthetic outcomes [2]. As a result, the success criteria in implantology have changed, according to the evolution of implant design and patient requests [3]. An

osseointegrated implant under functional load, yet which does not integrate perfectly in the patient's oral cavity from the aesthetic point of view, can no longer be considered acceptable, especially for single implant restorations in the anterior area, where aesthetic outcome plays a fundamental role and is a need for the patient [1]. Certainly, the position of the implant, as well as the quantity and quality of the hard and soft tissues, and their adaptation over time are all factors that condition the aesthetic result of an implant-supported rehabilitation [4]. Araujo and colleagues [5] reported that important changes can impact hard and soft tissue following dental extractions and continue until 2 years after implant insertion and prosthetic rehabilitation [4, 5]. These variations are related to vascular support reduction and loss of mechanical function [4, 6]. In particular, soft tissue needs to adapt to the condition of the local setting [4, 7]. The potential causes of esthetic implant failures have previously been analyzed by Buser, including anatomic factors, such as horizontal or vertical bone deficiencies, and iatrogenic factors, such as wrong implant selection or incorrect implant positioning, where all were noted as critical for an esthetic implant-supported restoration [8]. Meanwhile, Wang investigated the soft tissue thickness around implant-supported restorations and the impact of thin and thick soft tissue biotypes [9]. The findings confirmed the soft tissue biotype as an important parameter in aesthetic implant restoration, improving immediate implant success and preventing future mucosal recession [9]. Another factor influencing the soft tissue stability around dental implants over time is the prosthetic emergence profile [10]. In particular, the proper prosthetic contour and maintenance of the right amount of tissue were considered key factors [10]. Essentially, the aesthetic outcome of an implant-supported restoration seems to be strictly related to the buccal hard- and soft-tissue height [1]. The effect of platform switching (Fig. 1), highlighted by Lazzara [11], is currently well-established in literature. Dental implants incorporating platform switching (PS) preserve the crestal bone around the top of the implant and alter the starting point from which crestal bone remodeling occurs [11]. Following the crestal bone position overtime has also shown that the soft tissue stability is also affected by the presence of platform switching [12]. When analyzing the peri-implant soft tissue with PS implants, Tarnow found that PS seemed to help in preserving the ridge dimensions and enhancing the peri-implant soft tissue stability [12]. Accordingly, the present study attempted to verify the influence of PS on soft tissue, by comparing the soft tissue stability around implants with and without PS during 3 years follow-up after definitive crown placement.

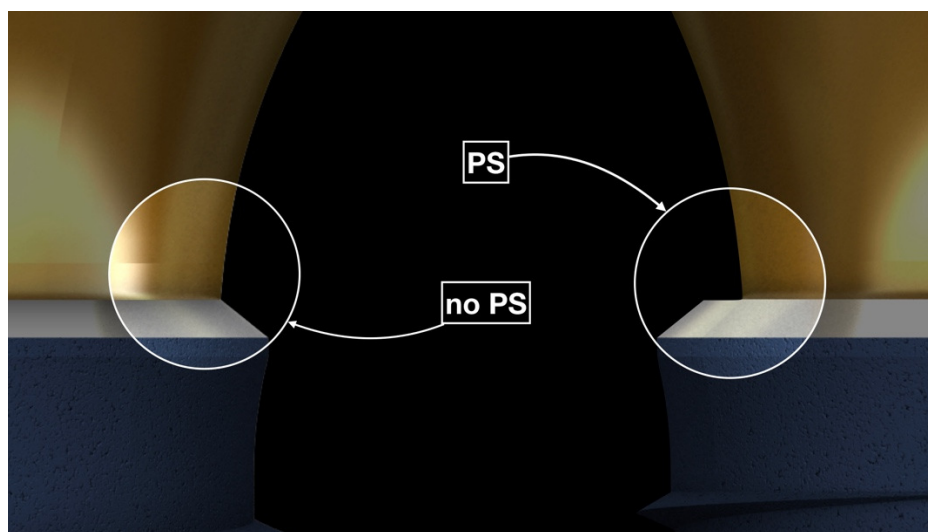


Figure 1. Two implant designs: with platform switching technology and without.

2. Materials and Methods

Patient selection

The present prospective study was conducted in accordance with the fundamental principles of the 1975 Helsinki Declaration on clinical research involving human subjects (revised in 2008), and was also approved by the ethics committee of Insubria University (#826-0034086) "Studies on the survival and the surgical-prosthetic success of dental implants: Influence of the implant-abutment connection". One hundred seventy-eight consecutive patients referred for implant rehabilitation of partially edentulous ridges from Oct 2011 to Mar 2014 were identified as candidates for dental implant treatment based on clinical and radiographic examination.

The inclusion criteria were: single or multiple mandibular and maxillary partial edentulism with the need for implant rehabilitation and age ≥ 18 at the time of surgery. The exclusion criteria were: poor oral hygiene (full-mouth plaque score FMPS $> 25\%$ and full-mouth bleeding score FMBS $> 25\%$), abuse of alcohol or drugs, presence of acute oral infections, remote or recent radiation therapy in the oro-maxillofacial area, recent chemotherapy, and pregnancy. Other exclusion criteria included a lack of facial keratinized mucosa, the need for soft tissue and bone augmentation at any stage of the treatment, and the need for post extractive implant placement. Moreover, any implant showing signs of mucositis or periimplantitis over time was also excluded.

Surgical protocol

The patients were clinically and radiographically evaluated to design the proper treatment plan. Panoramic and perio-apical imaging were used as the first-level exam to evaluate the bone quantity before implant placement. In the case of suspected bone deficiency, a cone-beam TC was performed as a second level exam to assess the alveolar ridge width. The oral hygiene, soft tissue health, amount of keratinized gingiva, stability of the remaining teeth, and other factors potentially influencing the treatment plan were all clinically evaluated. Patients presenting posterior maxillary edentulism with a bone ridge height < 8 mm were treated with a sinus lift and heterologous bone graft. Except for sinus augmentation procedures, all other cases requiring a GBR technique were eliminated from the study. An antibiotic prophylaxis of amoxicillin + clavulanic acid 2 g/day for 6 days, starting with 2 g 1 h before surgery or clindamycin 600 mg/day for 6 days in penicillin-allergic patients was prescribed to reduce the risk of infections. Anti-inflammatory therapy with NSAIDs was also recommended: ketoprofen lysine 80 mg/day for 3 days, starting with 80 mg 1 h before surgery. A local anesthesia of articaine + adrenalin 1:50.000 was administered at the site of intervention and articaine + adrenalin 1: 100.000 at other sites. A two-stage surgical technique was used for the implant placement. A full-thickness mucoperiosteal flap was elevated to expose the underlying alveolar bone and allow implant placement in the correct prosthetically driven position. The optimal implant site was prepared at 800 rpm according to the company indications (MegaGen Implants, Seoul, South Korea). The inter-implant distance was at least 3 mm, while an interproximal space of 1.5 to 3 mm was observed between an implant and an adjacent tooth [2]. The implants were positioned in the bleeding socket with hand pressure and driven to their final position using a dedicated mounter at 60 rpm. The implants were all placed 0,5 mm sub-crestally, referring to the buccal bone, as recommended by the manufacturer. A torque value between 30 and 60 Nm was accepted, depending on the bone density. The repositioned mucoperiosteal flap was then secured with a tension-free suture for primary healing and to avoid bacterial contamination. All

the implants were placed in native crestal bone. No implant was placed in a post-extractive or regenerated site. All patients observed a 10-day liquid diet, plus 15 days of soft foods following implant placement. Oral hygiene included the modified Bass brushing technique and 30-second 0.2% chlorhexidine rinses three times a day for one week after surgery. The patients were recommended not to use removable partial dentures with mucosal support over the surgery site. In some cases, an adhesive provisional Maryland bridge was applied, taking care not to touch the tissue over the implant.

Prosthetic protocol

The osteointegration time was set at 3 months for the mandibular implants and 6 months for the maxillary implants. During the second-stage surgery, a mid-crestal mesiodistal flap was cut for minimal displacement of the keratinized tissue. The cover screw was manually removed using a dedicated screwdriver and replaced with a healing abutment. An initial impression was taken using alginate to create an individualized impression tray. A second impression using polyether (3M™ Impregum™) was then taken using the individualized open tray for a pick-up technique. Using a randomization table, the implants were assigned to either the PS group or the NPS group and the appropriate type of prosthodontics then requested from the technician.

A resin screw-retained provisional prosthesis was delivered 2 weeks after the second-stage surgery. The provisional prosthesis was removed after 3 months and another impression taken to manufacture the definitive metal-ceramic prosthesis according to the group assignment. All the rehabilitations were cemented on milled standard abutments providing for a juxta-gingival emergence profile. The implants belonging to the PS group were rehabilitated with an internal conical 5° per side abutment, creating PS. Meanwhile, the rehabilitation for the NPS group used an internal flat-to-flat abutment connection with a matching platform (no PS) abutment.

The occlusion was checked to remove pre-contacts and all interferences in centric, lateral, and protrusive movements. The definitive rehabilitations included both single crowns and partial fixed prostheses, to a maximum of 4 elements.

Data collection

A database was created to collect and process all the implant and patient information. Patient anamnestic data were collected from the clinical exam and anamnesis. The analyzed variables were: sex, age, smoking status and number of cigarettes/day (smoker: ≥10 cigarettes/day), systemic diseases, chronic or aggressive periodontitis, parafunction (bruxism, clenching), level of oral hygiene (0 to 4 score), and number of professional oral hygiene procedures in the last 3 years.

The implant parameters analyzed at the time of the first surgery were: length, diameter, jaw position (maxilla/mandible/anterior/posterior), insertion torque, implant connection, and residual buccal bone width. Intraoral radiographs were used to evaluate the implants at the time of implant placement, when delivering the provisional and final crowns, and at yearly follow-up appointments after the final rehabilitation. The implant depth (Fig. 2) was determined based on a periapical radiograph at the time of implant placement and recorded as the average distance from the implant shoulder to the first radiographic bone to implant contact (FBIC).

After delivering the definitive crown, the presence of keratinized facial mucosa was checked and the prosthetic crown height (TH) quantified (Fig. 3). The TH was measured as the distance between the buccal gingival zenith and the crown incisal edge according

to the main axis of the crown itself (Fig. 3). This measurement was performed using a periodontal probe (UNC 15, University of North Carolina, USA). The baseline value was set at the time of the definitive prosthesis delivery, and the measurement was then repeated at 1, 2, and 3 years of follow-up from the final crown delivery.



Figure 2. FBIC measure.

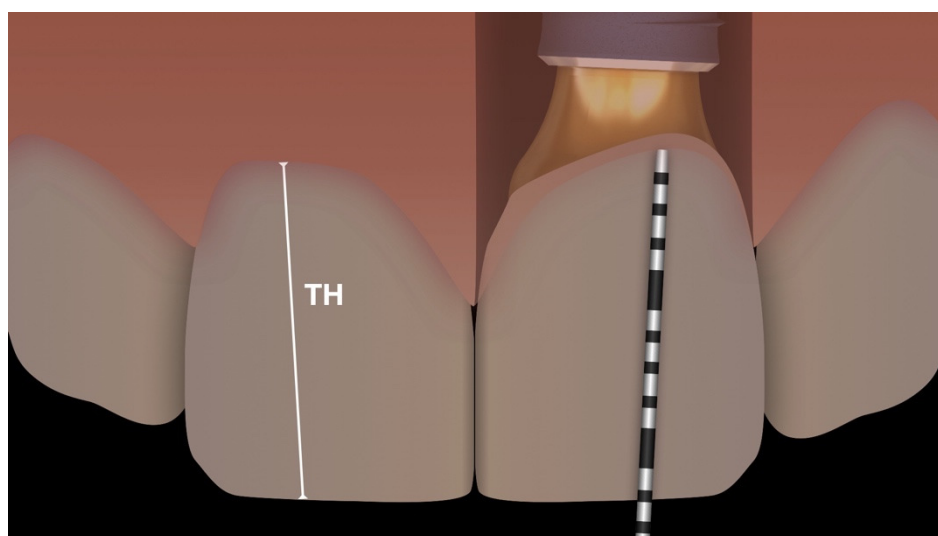


Figure 3. TH measurement through the probe. tooth height (TH) measured as the distance between the buccal gingival zenith and the crown incisal edge, according to the main axis of the crown.

Statistical analysis:

A descriptive analysis was produced for the consecutively enrolled implants. The total follow-up time was 3 years from the time of the definitive prosthesis delivery, which occurred 3 to 6 months from the provisional prosthetic positioning. The TH baseline was determined at the time of definitive crown delivery and the follow-up values were measured at 1, 2, and 3 years after. All data were then inserted into statistical software and processed (SPSS 20, IBM). The implants were divided into two groups according to the presence of platform switching (PS group) or no platform switching (NPS group). The

TH was measured using deltas (Δ TH). The delta was measured by subtracting the follow-up TH value from the baseline TH. Consequently, positive values were associated with soft tissue recession, while negative values were related to coronal gingiva repositioning, referred to as definitive prosthodontic rehabilitation. Hence, recession was identified when the free buccal gingival margin measured at the zenith shifted apically. Meanwhile, gingival growth was associated with a coronal soft tissue migration of the gum. The means and statistical correlation refer to Δ TH depending on the PS grouping.

Sample Size calculations and Correlation Analysis:

The sample size was calculated (G*Power 3.1) before the patient enrollment, based on two independent groups with a continuous distribution. As the distribution was supposed to be normal, a two sample two-tail t-test was applied. A sample size of 39 subjects per group was used in order to detect a 0,1 mm difference in the gingival height and 0,15 mm standard deviation, with a required significance level of 0.05 and 80% power. At the end of the data gathering period, a Shapiro-Wilk test for normality was used to assess the sample distribution. Where the null-hypotheses were rejected, the samples were evaluated as non-normally distributed and a Mann-Whitney test applied to the independent samples.

3. Results

A total of 90 implants were placed according to the standardized surgical and prosthetic protocols established at the beginning of the prospective study.

Among the 90 implants enrolled in the study, 77 implants were finally considered in the statistical analysis. The drop-out implants were: 2 due to missing radiographs during the treatment, 9 belonging to patients who were unable to attend the follow-up, were no longer contactable, or moved to a different city, and 2 that presented signs of mucositis during the observation period. All the implants (AnyRidge, MegaGen, Seoul, South Korea) provided a flat-to-flat connection with the same-brand abutment and were placed in both the anterior and posterior region, and upper and lower jaw. The implant distribution is reported in Table 1.

Table 1. Implant distribution considering implant site and features.

Position	Abutment	Upper Jaw	Lower Jaw
Anterior	PS	4	-
	No PS	5	3
Posterior	PS	14	20
	No PS	9	22

The FBIC mean for the evaluated implants at the time of placement was $-0,28 \pm 0,67$ mm. However, at the 3-year follow-up, the FBIC mean was $0,66 \pm 0,97$ mm for the NPS group and $-0,05 \pm 0,91$ mm for the PS group (Table 2). The group distribution was: 39 implants (50,6%) in the NPS group and 38 implants (50,4%) in the PS group. After 3 years, a mean recession (Δ TH) of $0,54 \pm 1,93$ mm was recorded for the NPS group, whereas a mean coronal migration of $0,17 \pm 0,91$ was recorded for the PS group (Table 3). In more detail, no correlation was found at the 1-year follow-up $p = 0.090$. However, the 2-year ($p = 0.015$, mean = -0.11 mm, S.D. = 0.84 mm, $d = -0.62$, d C.I = $-1.08 -0.16$) and 3-year ($p = 0.031$, mean = -0.17 mm, S.D = 0.95 mm, $d = -0.59$, C.I. $-1.05 -0.13$) follow-up data indicated significantly lower gingival recession in the PS group compared to the NPS group.

FBIC values and correlations for PS and NPS implants

	Platform Switching (PS)			No Platform Switching (NPS)			Student T significance	Cohen's <i>d</i> effect size	95% Confidence Intervals for Cohen's <i>d</i>
	n	Mean	S.D.	n	Mean	S.D.			
ΔFBIC 1Y	38	-0,179	0,633	39	0,577	0,836	p ≤ 0,001	1.018	0.544 - 1.493
ΔFBIC 2Y	38	0,229	0,932	39	0,777	1,068	p = 0,019	0.546	0.091 - 1.001
ΔFBIC 3Y	38	0,368	0,901	39	0,800	1,129	p = 0,068	0.422	-0.03 - 0.874

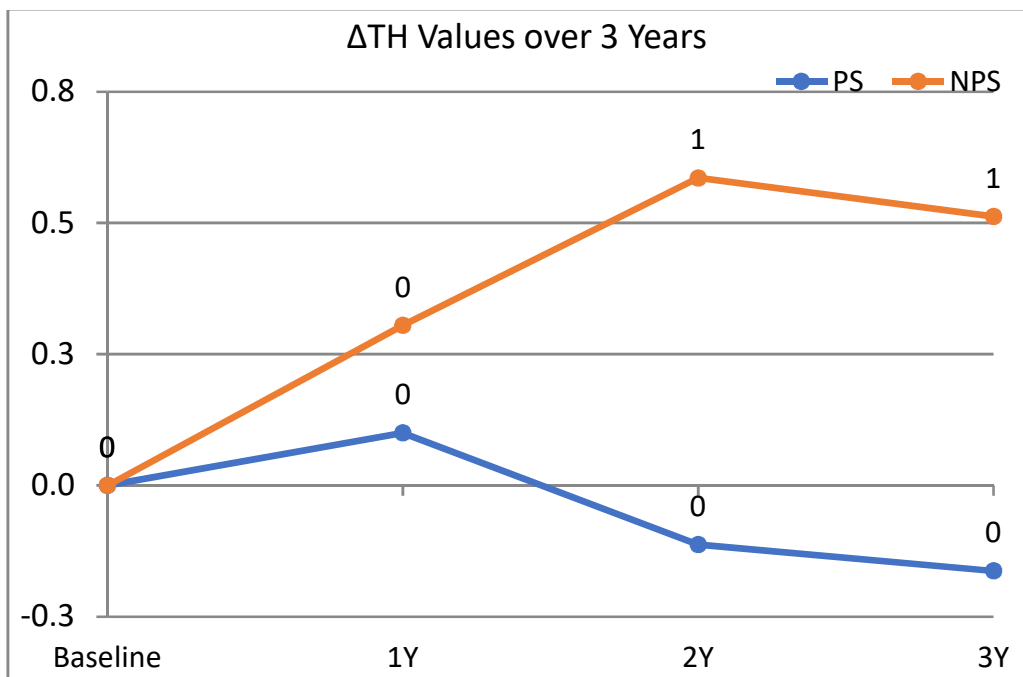
FBIC values and correlations for PS and NPS implants

	Switching (PS)			Non Switching (NPS)			Mann Whitney significance	Cohen's <i>d</i> effect size	95% Confidence Intervals for Cohen's <i>d</i>
	n	Mean	S.D.	n	Mean	S.D.			
FBIC 2Y	38	-0,187	0,879	39	0,633	0,924	p ≤ 0,001	0.909	0.44 - 1.378
FBIC 3Y	38	0,407	0,914	39	0,656	0,970	p = 0,003	0.747	0.285 - 1.209
FBIC 1Y	38	0,237	0,804	39	0,721	1,050	p = 0,016	0.517	0.063 - 0.971

Table 1. FBIC and ΔFBIC values during follow-up period. Amount of bone loss (mm) was higher for NPS implants compared to PS implants during observation period.

The calculated effect sizes (Cohen’s d) also confirmed the clinical relevance of these findings. Due to the drop-out rate, the power achieved for the present sample study was 76% for the 2-year follow-up and 70% for the 3-year follow-up

Consequently, these outcomes confirm that the absence or presence of platform switching would appear to affect the tendency of the gingival buccal margin towards recession or creeping over time (Table 3) (Graphic 1). Creeping has been defined as coronal growth of the gum margin in the absence of any inflammatory sign [13].



Graphic 1 ΔTH during follow-up period: NPS implants exhibited greater recession when compared to PS implants. Negative values (mm) mean creeping or coronal migration of gingival margin, positive values mean recession.

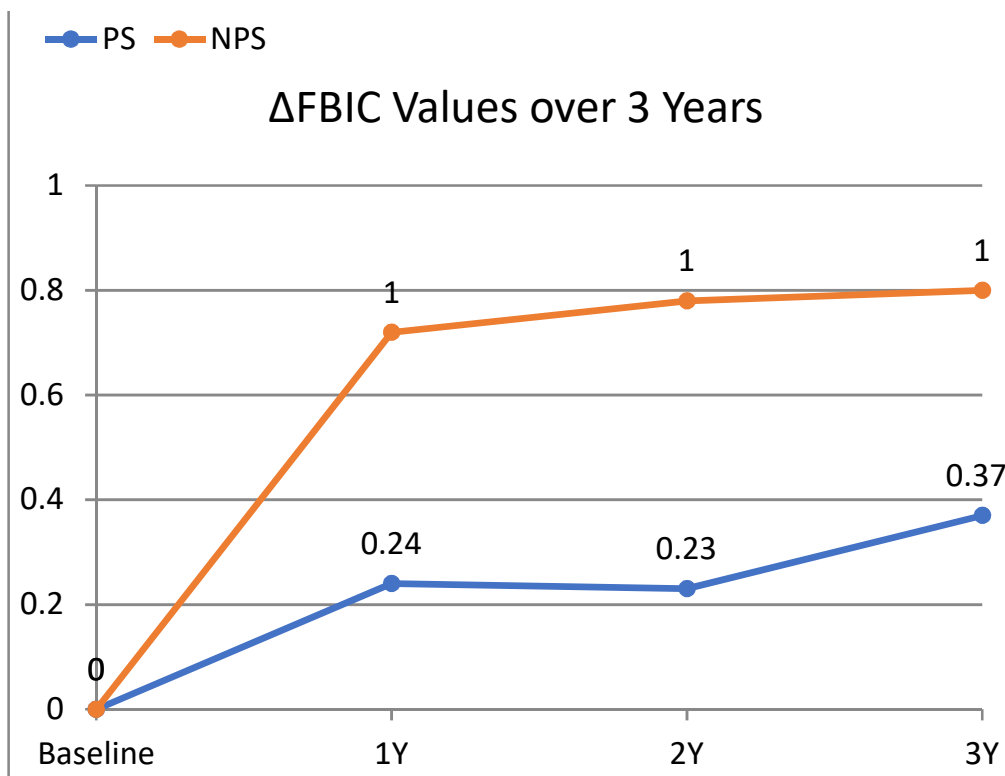
ΔTH values and correlations for PS and NPS implants

	Platform Switching (PS)			No Platform Switching (NPS)			Mann-Whitney significance	Cohen’s d effect size	95% Confidence Intervals for Cohen’s d
	n	Mean	S.D.	n	Mean	S.D.			
ΔTH 1Y	38	0,105	0,495	39	0,320	0,612	p = 0,09	d = -0,764	- 1.226 0.30
ΔTH 2Y	38	-0,118	0,842	39	0,615	1,421	p = 0,015	d = -0,626	- 1.084 0.169

ΔTH 3Y	38	-0,171	0,953	39	0,538	1,388	$p = 0,031$	$d = -0,594$	-
									1.051
									-
									0.138

Table 2. Correlation between prosthetic crown height variation (ΔTH) and presence or absence of platform switching at 1, 2, and 3 years. Difference becomes significant (Mann-Whitney, 95% conf.) at 2 and 3 years from delivery of final crown.

The effect of the abutment platform switching seemed to reach a plateau around the second year after prosthesis positioning, as shown in Table 3. Moreover, a greater marginal bone loss was observed in the NPS group over the follow-up period (Table 2) (Graphic 2).



Graphic 2 $\Delta FBIC$ values during follow-up period. Amount of bone loss (mm) was higher for NPS implants compared to PS implants during observation period.

4. Discussion

Many clinical studies and systematic reviews have already shown that platform switching at the implant-abutment interface significantly reduces crestal bone loss in comparison with a regular flat-to-flat connection [14], which has led to the increased use of platform switching in regular clinical implantology. Several studies have also reported reduced bone resorption with platform-switched implants when compared with platform-matched implants [15]. From a technical point of view, the switching platform preserves the crestal bone by providing a horizontal biological width formation over the implant neck [16] and shifting the implant-abutment microgap away from the bone crest [17]. The microgap is one of the major factors related to apical bone remodeling [18]. Yet, despite extensive data on soft tissue stability around platform-switched implants [19, 20, 21, 22, 23], there is still limited comparative information of implants with and without PS. In the present study, that followed 77 dental implants for 3 years from prosthetic

delivery, apical repositioning of the soft tissue was observed in both the PS and NPS groups during the first year. However, the second year showed divergent behavior between the two groups, where the PS group showed a reduced vertical crown dimension due to soft tissue creeping, while the NPS group exhibited soft tissue apical recession. Moreover, after 3 years, the PS group showed increased soft tissue creeping values.

Another important factor influencing bone remodeling around PS implants is the soft tissue thickness at the time of implant placement [17]. The behavior of PS implants with thin (<2mm) and thick (>2mm) soft tissue was previously analyzed by Linkevicius, where thin peri-implant soft tissue at the time of implant placement did not prevent bone loss, while thick tissue maintained the crestal bone level with minimal remodeling [17]. Therefore, with a thin biotype, platform switching may be insufficient to prevent soft tissue recession over time around a dental implant. In this case, soft tissue augmentation is needed at the time of implant placement [17].

An experimental study on humans showed that at 8 weeks, the soft tissue consists of a barrier epithelium of 1.9 mm and connective tissue portion of 1.7 mm [24, 25]. This suggests that the bone undergoes remodeling to create sufficient space for a peri-implant seal to be formed [24].

One of the functions of the connective tissue zone is to support the epithelial tissue and limit its apical migration [19]. PS implants facilitate the formation of a connective tissue ring over the implant shoulder [20], creating thicker connective tissue that can provide better protection of the surrounding bone and reduce bone remodeling in the apical direction [16].

Therefore, the present study can provide a biological explanation for the absence of recession with PS implants. The formation of a connective ring facilitated by a PS implant may result in thicker connective tissue [25], which in turn may prevent bone remodeling [16]. This bone stability may then result in better tissue stability, and a thicker connective tissue has the potential to creep [26].

Notwithstanding, the present study has several limitations, as the results may have been influenced by the position of the implant in the mouth (maxilla, mandible, anterior, posterior) and the soft tissue thickness at the time of implant placement.

5. Conclusions

The absence or presence of platform switching would appear to affect the tendency of the gingival buccal margin towards recession or creeping. Implant-abutment platform switching also seems to prevent peri-implant soft tissue recession over time when compared to implants with no dimension switching of the abutment.

Furthermore, the platform switching effect seemed to reach a plateau around the second year after prosthesis positioning.

Author Contributions: DF conceived the ideas and performed the surgeries; AP, PP, and MM collected the data; DL analyzed the data; and MM, DL, and DF led the writing. All authors gave final approval of the manuscript and agree to be accountable for all aspects of the work.

Funding: "This research received no external funding".

Institutional Review Board Statement: "The study was conducted according to the guidelines of the Declaration of Helsinki, and approved by the Institutional Review Board (or Ethics Committee) of University of Insubria (protocol code #826-0034086)".

Informed Consent Statement: "Informed consent was obtained from all subjects involved in the study." OR "Patient consent was waived due to REASON (please provide a detailed justification)."

Conflicts of Interest: "The authors declare no conflict of interest."

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