CLINICAL TRIALS

Influence of Platform Switching on Bone-level Alterations: A Three-year Randomized Clinical Trial

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Abstract: *The concept of platform switching has been introduced to implant dentistry based on clinical observations of reduced peri-implant crestal bone loss. However, published data are controversial, and most studies are limited to 12 months. The aim of the present randomized clinical trial was to test the hypothesis that platform switching has a positive impact on crestal bone-level changes after 3 years. Two implants with a diameter of 4 mm were inserted crestally in the posterior mandible of 25 patients. The intraindividual allocation of platform switching (3.3-mm platform) and the standard implant (4-mm platform) was randomized. After 3 months of submerged healing, single-tooth crowns were cemented. Patients were followed up at short intervals for monitoring of healing and oral hygiene. Statistical analysis for the influence of time and platform type on bone levels employed the Brunner-Langer model. At 3 years, the mean radiographic peri-implant bone loss was 0.69 ± 0.43 mm (platform switching) and 0.74 ± 0.57 mm (standard platform). The mean intraindividual difference was 0.05 ± 0.58 mm (95% confidence interval: $-0.19, 0.29$). Crestal bone-level alteration depended on time ($p < .001$) but*

not on platform type ($p = .363$). The present randomized clinical trial could not confirm the hypothesis of a reduced peri-implant crestal bone loss, when implants had been restored according to the concept of platform switching (ClinicalTrials.gov NCT01917305).

Key Words: dental implant-abutment connection, dental implant-abutment designs, dental implant-abutment interface, dental implant, single-tooth dental implant, alveolar bone loss.

Introduction

After implant surgery, peri-implant crestal bone-level alterations occur (Astrand *et al.*, 2004; Laurell and Lundgren, 2011). A possible cause of this phenomenon is the bacterial colonization of the microgap between implant and abutment if its location is close to the bone. Subsequently, the emerging abutment-associated inflammatory cell infiltrate can provoke bone resorption (Ericsson *et al.*, 1995).

Platform switching is a prosthetic concept to use an abutment with a smaller diameter than the diameter of the implant shoulder so that the micro-gap is located more distant to the first

bone-implant contact. This configuration results in a circular horizontal step, which may enable a horizontal extension of the biological width. Compared with the conventional restorative procedure using an identical-sized implant and suprastructure diameter (standard platform), platform switching is suggested to prevent or reduce crestal bone loss (Lazzara and Porter, 2006; Vela-Nebot *et al.*, 2006; Canullo and Rasperini, 2007; Cappiello *et al.*, 2008; Trammell *et al.*, 2009; Vigolo and Givani, 2009; Canullo *et al.*, 2010; Fickl *et al.*, 2010). Even though other clinical studies failed to demonstrate a significant difference (Crespi *et al.*, 2009; Kielbassa *et al.*, 2009; Enkling *et al.*, 2011), a systematic review and meta-analysis (Atieh *et al.*, 2010) concluded that platform switching may preserve interimplant bone height and that the degree of marginal bone resorption is inversely related to the extent of the implant-abutment mismatch. Further long-term, well-conducted randomized controlled studies would be needed to confirm the validity of this concept (Atieh *et al.*, 2010). Indeed, most published studies have only twelve-month follow-ups, and there is still a paucity of three-year data from randomized clinical trials (Lang and Jepsen, 2009). Therefore, it was the aim of this randomized clinical

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trial, with a three-year follow-up, to test the hypothesis of an influence of platform switching on marginal bone-level alterations.

Materials & Methods

A randomized within-subject control trial was designed (Appendix Figure 1). Following power calculations, 25 test persons (10 women, 15 men, 51 ± 10.5 years old) were enrolled. The patients were informed in detail about the possible risks and benefits, and all signed an informed consent. The study protocol was reviewed and approved by the Clinical Trials Committee of the University of Witten/Herdecke, Witten, Germany (32/2006, 22.05.06) and registered (ClinicalTrials.gov NCT01917305). Inclusion criteria for the study patients were good general health and absence of infectious disease, diabetes, osteopathy, and radiation therapy in the head and neck area. Other requirements included good oral hygiene, no active periodontitis, no drugs influencing bone metabolism, no lactating or pregnant women, an edentulous gap (≥ 16 mm) in the posterior mandible for placement of 2 implants, 4 mm of keratinized mucosa in the prospective implant position in the buccolingual direction, and a medium or thick soft tissue biotype. Sufficient bone height above the alveolar nerve (≥ 12 mm) and bony width at the alveolar crest (≥ 7 mm) were prerequisites so that no bone recontouring or augmentation procedures were necessary. The extraction of the missing teeth dated back at least 6 months.

By raising a full-thickness flap, 2 neighboring implants with a diameter of 4 mm and a length of 9.5 mm were placed with the implant platform at bone level (*i.e.*, crestally). The minimum interimplant distance was defined as 4 mm and the minimum distance between implant and neighboring tooth, as 2 mm. The implants (SICace, SIC-Invent AG, Basel, Switzerland) had a medium rough surface including the implant collar and an internal hexagonal implant-abutment connection. The allocation of the platform-switching and standard-platform implants was randomized by means of a computer-generated list

Figure 1.

The measured distances at the radiographs: (a) platform switching and (b) standard platform. The red area demonstrates the bone-level alteration since baseline (implant insertion operation).

Measured distances from reference points: IBL, vertical bone level at the implant (reference point, microgap); HVD, horizontal aspect of the vertical bony defect at the implant (reference point, implant surface); GBL, general horizontal bone level (reference point, microgap).

before surgery. Allocation was implemented by an independent examiner not involved in the surgery or the examinations. The size of platform switching (*i.e.*, the circular step) was 0.35 mm: implant shoulder diameter = 4.0 mm *vs.* abutment diameter at platform = 3.3 mm. After 3 months of submerged healing, the implants were reopened, and after 4 months, crowns were cemented on the implants, one with standard platform and one with platform switching. A strict dental hygiene protocol was carried out, and oral hygiene, as well as peri-implant health, was monitored by full-mouth sulcular bleeding index, full-mouth plaque index, and peri-implant probing depth:

baseline (T0), reopening (3 months = T1), crown mounting (4 months = T2), and at check-ups of 8 (T3), 12 (T4), 25 (T5), and 38 (T6) months.

Standardized digital orthopantomographs (Promax RPX 232574, Planmeca, Helsinki, Finland) were taken at every time point beside T3 (8-month follow-up). The regions of interest on the radiographic images were magnified with software tools (Dimaxis Software 4.3.1, Planmeca, Helsinki, Finland) to the highest possible level (20 $\times$), and the bone height measurements (precision of 0.01 mm) were always calibrated at the respective implant length of 9.5 mm. Three calibrated dentists experienced

in oral radiology performed the radiographic evaluation independently. The following measurements were obtained from the radiographs. The marginal bone levels at the mesial and distal implant surfaces were assessed by measuring the distance between a reference point at the implant and the bone level: the reference point for the vertical implant bone level (IBL) and the general horizontal bone level (GBL) was the microgap between implant body and abutment; for the horizontal extent of the vertical defect (HVD), it was the implant surface adjacent to the crestal edge of the vertical bony defect. At each implant, 6 measurements were performed (Figure 1): vertical bone loss (ΔIBL = difference to T0), mesial and distal; horizontal extent of the vertical bony defect (ΔHVD = difference to T0), mesial and distal; general horizontal bone loss (ΔGBL = difference to T0), mesial and distal. More detailed information regarding the study protocol was already published with the presentation of the 1-year data (Enkling *et al.*, 2011).

Statistical Methods

Differences between ΔIBL at platform-switching and standard-platform implants were chosen as the primary outcome parameter. Sample-size calculations were done using G*Power 3 for matched pairs (Faul *et al.*, 2009). Based on data from previous studies on implants in the lower jaw (Astrand *et al.*, 1999), it was considered possible to detect a true difference of at least 0.35 mm with a standard deviation of 0.65 between the platform-switching and standard-platform implants in this randomized within-subject-control design with 80% power and 23 patients. This estimate was based on a 1-tailed test of matched pairs conducted at the 5% level of significance. To compensate for possible dropouts, the sample size was adjusted to 25 patients.

The following hypothesis was tested: Alteration of the vertical IBL (ΔIBL) after 3 years is dependent on platform type (platform switching *vs.* standard platform) and time after surgery, as tested with the nonparametric model of Brunner and Langer (Brunner *et al.*, 2002) using SAS

Figure 2.

Mean $\pm$ standard deviation of the vertical implant bone-level alteration (ΔIBL) at platform-switching and at standard-platform implants (data presentation adapted from Astrand *et al.*, 2004).

0 months, implant insertion; 4 months, implant loading.

9.2 software (SAS Institute, Heidelberg, Germany). Bone loss was expected to be less at platform-switching implants than at standard-platform implants. An additional hypothesis was tested in an explorative manner—namely, that bone-level alterations at standard-platform and platform-switching implants are equal at every follow-up appointment. The equivalence interval was defined as ± 0.4 mm—that is, the clinically relevant difference in bone-level alteration (Astrand *et al.*, 1999). To test for equivalence, Wilcoxon signed-rank tests were applied for each time point with the software R (R Foundation for Statistical Computing, Vienna, Austria): hypothesis A, true location > -0.4 mm; hypothesis B, true location < 0.4 mm.

Results

All patients were available for all follow-up examinations. After 3 years, the implant survival rate was 100%. Patients presented with good oral hygiene and healthy peri-implant conditions (Appendix Tables 1 and 2). The progression of bone loss over time was similar for platform-switching and standard-platform implants (Figure 2), with mean intraindividual differences between the 2 treatment modalities always less than 0.1 mm. The bone-level alteration depended on time ($p < .001$) but not platform type ($p = .363$) and not the interaction of time and type ($p =$

.953). At T6, the intraindividual difference between both platform types was 0.05 ± 0.58 mm (95% confidence interval, $-0.19, 0.29$) (Figure 3, Appendix Figure 2). Regarding the defined equivalence range of ± 0.4 mm, the intraindividual bone-level alteration was statistically equivalent for both platform types at every time point after implant insertion (all $p \leq .007$). The mean vertical change of the first bone-implant contact (IBL T0 *vs.* T6) was at platform switching 0.69 ± 0.43 mm and at standard platform 0.74 ± 0.57 mm. Based on implant loading as baseline, after 3 years (T2 *vs.* T6), the mean bone-level alteration at platform switching was -0.31 ± 0.56 mm (median, -0.25 mm) and at standard platform -0.27 ± 0.47 mm (median, -0.33 mm). At T6, triangular bony defects were found in 13 platform-switching and 10 standard-platform implants: the vertical defects measured from the new general bone level (GBL) had about the same depth (difference between IBL and GBL) and width (HVD). The mean of the mesial and distal measurements of the alteration of IBL, HVD, and GBL compared with baseline (*i.e.*, ΔIBL , ΔHVD , ΔGBL) are presented in the Table.

Discussion

Based on the results of the three-year follow-up, the hypothesis of an impact of platform switching on peri-implant bone-level alterations had to be rejected.

Figure 3.

Examples of radiographs at implant placement (baseline) and 12, 25, and 38 months postoperatively. (a–d) Platform switching (left) experienced more peri-implant crestal bone loss than did standard platform (right): standard platform better (ST). (e–h) Platform switching (left) experienced less peri-implant crestal bone loss than did standard platform (right): platform switching better (PS).

There was only a limited but statistically significant mean bone-level alteration over time in both platform types, which reached the set definition of equivalence at every follow-up appointment. Peri-implant bone-level alteration took mainly place during the first 4 months, when the peri-implant mucosa was frequently manipulated (Becker *et al.*, 2012). This time-related crestal bone-level change is typical at implants and has been reported for other implant systems (Astrand *et al.*, 2004). Three years after implant surgery and loading, both platform types fulfilled

the accepted implant success criteria (Albrektsson and Isidor, 1994; Misch *et al.*, 2008): Based on implant surgery as baseline, the median bone-level alteration at platform switching was -0.68 mm and at standard platform -0.70 mm. Thus, all studied implants fulfilled the criteria of success, as no implant showed bone loss of more than 2 mm (Misch *et al.*, 2008). If the set baseline was implant loading, only a minimal change occurred, with a median of -0.25 mm in platform switching and -0.33 mm in standard-platform implants. Thus, all implants of

both types were successful, since the definition for success allows up to 1.7 mm of vertical bone loss after 3 years of implant loading (Albrektsson and Isidor, 1994).

Approximately 50% of the vertical bone loss (Δ IBL) was part of the GBL alteration (Δ GBL). Δ GBL might have occurred regardless of implant placement, since raising a flap at implant placement and at second-stage surgery could have influenced the bone resorption (Enkling *et al.*, 2011). In the present study, the bone-level alterations at implants with

Table.

Peri-implant Bone-level Alterations at Platform-switching and Standard-platform Implants

Time: Alterations	Standard Platform		Platform Switching		Difference (Switching – Standard)	
	Mean ± SD	Median (95% CI)	Mean ± SD	Median (95% CI)	Mean ± SD	Median (95% CI)
T1: 3 mo						
Δ IBL	−0.38 ± 0.43	−0.30 (−0.45, −0.10)	−0.33 ± 0.52	−0.05 (−0.41, 0.00)	0.05 ± 0.51	0.04 (−0.02, 0.25)
Δ HVD	−0.2 ± 0.41	0 (0.00, 0.00)	−0.15 ± 0.33	0 (0.00, 0.00)	0.05 ± 0.47	0 (0.00, 0.00)
Δ GBL	−0.26 ± 0.33	−0.17 (−0.38, 0.00)	−0.1 ± 0.21	0 (−0.05, 0.00)	0.16 ± 0.36	0.04 (0.00, 0.23)
T2: 4 mo						
Δ IBL	−0.46 ± 0.55	−0.55 (−0.70, −0.20)	−0.44 ± 0.42	−0.39 (−0.61, −0.21)	0.01 ± 0.57	0.14 (−0.34, 0.28)
Δ HVD	−0.25 ± 0.39	0 (−0.37, 0.00)	−0.22 ± 0.36	0 (−0.29, 0.00)	0.03 ± 0.47	0 (0.00, 0.13)
Δ GBL	−0.20 ± 0.46	−0.11 (−0.27, 0.00)	−0.22 ± 0.25	−0.21 (−0.29, 0.00)	−0.02 ± 0.42	0 (−0.28, 0.27)
T4: 12 mo						
Δ IBL	−0.58 ± 0.55	−0.63 (−0.92, −0.43)	−0.53 ± 0.35	−0.61 (−0.70, −0.28)	0.05 ± 0.56	0.05 (−0.18, 0.32)
Δ HVD	−0.35 ± 0.44	−0.32 (−0.57, 0.00)	−0.21 ± 0.38	0 (0.00, 0.00)	0.14 ± 0.61	0 (0.00, 0.40)
Δ GBL	−0.19 ± 0.47	−0.18 (−0.37, 0.00)	−0.34 ± 0.35	−0.30 (−0.50, 0.00)	−0.15 ± 0.46	−0.04 (−0.30, 0.00)
T5: 25 mo						
Δ IBL	−0.63 ± 0.57	−0.64 (−1.00, −0.44)	−0.56 ± 0.35	−0.61 (−0.74, −0.45)	0.07 ± 0.60	0.05 (−0.18, 0.30)
Δ HVD	−0.32 ± 0.45	−0.30 (−0.57, 0.00)	−0.31 ± 0.38	−0.20 (−0.40, 0.00)	0.13 ± 0.55	0 (−0.20, 0.35)
Δ GBL	−0.30 ± 0.47	−0.28 (−0.47, 0.00)	−0.34 ± 0.45	−0.35 (−0.50, 0.00)	−0.04 ± 0.46	−0.03 (−0.25, 0.20)
T6: 38 mo						
Δ IBL	−0.74 ± 0.57	−0.70 (−1.02, −0.50)	−0.69 ± 0.43	−0.68 (−0.87, −0.40)	0.05 ± 0.58	0.07 (−0.19, 0.29)
Δ HVD	−0.30 ± 0.47	−0.28 (−0.49, 0.00)	−0.35 ± 0.48	−0.20 (−0.45, 0.00)	−0.05 ± 0.56	0 (−0.33, 0.25)
Δ GBL	−0.46 ± 0.37	−0.40 (−0.61, −0.30)	−0.35 ± 0.50	−0.35 (−0.55, 0.06)	0.10 ± 0.59	0.05 (−0.35, 0.40)

Mean of the mesial and distal measurements (mm) on the radiographs compared with baseline (0 months) are displayed: ΔIBL, vertical bone-level alteration; ΔHVD, horizontal component of the vertical bony defect; ΔGBL, general horizontal bone-level alteration. CI, confidence interval.

platform switching and at implants with standard platform were similar to the data from the literature for implants with platform switching (Vela-Nebot *et al.*, 2006). Therefore, the results for the standard-platform group were better than the data in comparative studies. The reason for the differences between the findings of the present study and published clinical data in the literature may be that, in comparative studies, mostly implants with a smaller diameter with matching abutments were compared with implants of a wider diameter and platform switching (Cappiello *et al.*, 2008; Crespi *et al.*, 2009; Prosper *et al.*, 2009; Canullo *et al.*, 2010; Fickl *et al.*, 2010) and different implant-abutment connections were used (Cappiello *et al.*, 2008). Thus, the

macroscopic design of the implant body, the implant geometry, and the implant-abutment connection but also the surface structure at the implant collar could have introduced bias with respect to bone-level alterations (Al-Nsour *et al.*, 2012; Annibali *et al.*, 2012). A recent meta-analysis reported mean marginal bone-level changes of 0.24 mm (Astra Tech Dental Implant System), 0.75 mm (Branemark System), and 0.48 mm (Straumann Dental Implant System) after 5 years of implant loading (Laurell and Lundgren, 2011). A possible reason for these differences in bone loss between implant systems is the design of the implant shoulder. Bone retention elements (*e.g.*, microthreads or a rougher surface at the implant neck compared

with a machined neck) are proposed to stabilize marginal bone levels (Hansson, 1999; Shin *et al.*, 2006). The neck of the studied implants (0.5 mm) was straight and showed a medium rough surface: The measured bone loss was mainly limited to this area. Beside the implant neck, the stress level in the cortical bone area around the implants is also affected by the design of the implant-abutment connection. A more rigid connection leads to a transfer of the forces from the cortical to the spongy bone area and minimizes peri-implant bone changes (Duyck *et al.*, 2001). The studied implants had a precise, internal hexagonal connection. Thus, the combination of the microstructured implant neck and the long internal connection (length, 2.3 mm) being

present in both implant platform types could have contributed to the limited bone-level alterations found.

Peri-implant bone loss is a phenomenon being anatomically site specific: In the mandible, less bone loss occurs than in the maxilla (Astrand *et al.*, 2004). Yet, bone loss is also dependent on individual patient factors. Thus, the study design, with 2 neighboring implants in the posterior mandible and the applicable statistical evaluation method, should have reduced possible bias and variance of the data.

Measurements of crestal bone levels were performed with standardized panoramic images. Panoramic images have been used in numerous clinical implant studies, although some authors rate the quality of the panoramic images inferior to that of the intraoral images. Nevertheless, *in vitro* studies could show that the panoramic image of the posterior mandibular region offers a quality that is comparable to intraoral films (De Smet *et al.*, 2002; Deserno *et al.*, 2009).

A shortcoming of the present study, which is based on radiographic bone-level assessments around 2 implants with a different shape of platforms, is the fact that examiner blinding is not possible. However, this is an inherent problem that also applies to all previous studies, and we tried to compensate for this by employing 3 independent examiners who had to reach consensus.

Recent systematic reviews (Al-Nsour *et al.*, 2012; Annibali *et al.*, 2012) that were based on the same studies came to the conclusion that platform switching exerted beneficial effects on peri-implant marginal bone and appeared to be useful in limiting bone resorption. However, only 2 studies have investigated marginal bone levels at implants with platform shifting over a period of 3 years or longer (Vigolo and Givani, 2009; Canullo *et al.*, 2011): Vigolo and Givani presented 5-year follow-up data of 182 implants in 142 patients with a statistically significant difference between bone loss at platform switching (0.9 ± 0.3 mm) and standard-platform implants (0.6 ± 0.2 mm) related to implant loading as baseline. Canullo and coworkers described in a three-year

preliminary report of 9 patients with 22 implants showing less bone loss with platform switching (mean values from 0.832 to 0.375 mm) than with standard-platform implants (mean, 1.358 mm).

Conclusion

Under the present study conditions—namely, using identical implants with different platforms over a three-year period—limited vertical bone loss was observed regardless if a platform-switching or a standard-platform concept was applied. Thus, the hypothesis of a bone resorption-preventing effect of platform switching could not be confirmed, and treatment can be chosen according to the preferences of the clinician.

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