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Effect of platform switching on peri-implant bone levels: a randomized clinical trial

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Abstract

Objective: The concept of platform switching has been introduced to implant dentistry based on observations of reduced peri-implant bone loss. However, randomized clinical trials are still lacking. This study aimed to test the hypothesis that platform switching has a positive impact on crestal bone-level changes.

Material and methods: Two implants with diameters of 4 mm were inserted epicrestally into one side of the posterior mandibles of 25 subjects. After 3 months of submerged healing, the reentry surgery was performed. On the randomly placed test implant, an abutment 3.3 mm in diameter was mounted, resulting in a horizontal circular step of 0.35 mm (platform switching). The control implant was straight, with an abutment 4 mm in diameter. Single-tooth crowns were cemented provisionally. All patients were monitored at short intervals over the course of 1 year. Standardized radiographs and microbiological samples from the implants' inner spaces were obtained at baseline (implant surgery), and after 3, 4, and 12 months.

Results: After 1 year, the mean radiographic vertical bone loss at the test implants was 0.53 ± 0.35 mm and at the control implants, it was 0.58 ± 0.55 mm. The mean intraindividual difference was 0.05 ± 0.56 mm, which is significantly <0.35 mm ($P=0.0093$, *post hoc* power 79.9%). The crestal bone-level changes depended on time ($P<0.001$), but not on platform switching ($P=0.4$). The implants' internal spaces were contaminated by bacteria, with no significant differences in the total counts between the test and the control at any time point ($P=0.98$).

Conclusions: The present randomized clinical trial could not confirm the hypothesis of a reduced peri-implant bone loss at implants restored according to the concept of platform switching.

Marginal crestal bone loss at implants is often attributed to a microbial impact (Lindhe & Meyle 2008). It appears that with two-piece implants, an abutment-associated inflammatory cell infiltrate (ICT) forms around the bacterially contaminated micro-gap between the implant and the abutment and extends from the micro-gap coronally, apically, and laterally for 0.5–0.6 mm (Ericsson et al. 1995, 1996). In animal studies, it was shown that by positioning the micro-gap more apically, i.e., below the crestal bone, the abutment ICT is established subcrestally following bone resorption (Hermann et al. 2000).

The concept of platform switching suggests an abutment or a suprastructure with a diameter at the implant-platform level that is 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 platform switching is to locate the micro-gap of the implant–abutment connec-

tion away from the vertical bone-to-implant contact area. Compared with the conventional restorative procedure using an identical size implant and suprastructure diameter, platform switching is suggested to prevent or reduce crestal bone loss (Gardner 2005; Brogini et al. 2006; Lazzara & Porter 2006; Prosper et al. 2009).

So far, the results on platform switching are controversial, but most clinical studies have reported a positive impact of platform switching on crestal bone stability. The reduction in bone loss appears to be correlated with the size of the circular step. In a prospective clinical study involving 69 implants in 31 patients, Canullo and colleagues found a bone loss of 1.49 mm at implants with matching abutments, 0.99 mm at implants with a 0.2 mm circular step, 0.82 mm with a 0.5 mm step, and 0.56 mm with a 0.85 mm step. Thus, the mean positive impact on bone resorption 33 months after implant operation was larger in size than the circular

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step of platform switching (Canullo et al. 2010). This is in agreement with the results of Hürzeler et al. (2007) and Vela-Nebot et al. (2006), who reported that by circular steps of 0.45 and 0.5 mm, respectively, the implants with platform switching exhibited 1.8 mm less bone loss than the implants without platform switching within 12 and 6 months, respectively, after implant operation. Also, Capiello et al. (2008) studied 131 implants in 45 patients and found a bone-protective effect of 0.72 mm that was larger in size than the circular step of 0.4 mm. In contrast to these results, Vigolo et al. (2009) found a significantly different bone resorption pattern in a clinical study with 182 implants in 144 patients with a 60-month follow-up after crown mounting, with platform-switching implants showing 0.3 mm less crestal bone loss than implants with matching abutments; however, the circular step was 0.45 mm and, therefore, larger than the difference in bone remodeling. Also, Trammel et al. (2009) reported a statistically significant bone-protective effect of platform switching of 0.2 mm, which was smaller than the circular step, for 25 implants in 10 patients after a 24-month follow-up. Crespi and colleagues, however, did not find any differences in crestal bone loss when comparing platform switching and nonplatform switching. They used different implant systems and performed immediate implant placement and immediate loading (Crespi et al. 2009). This was in agreement with two animal studies that did not show significantly different bone resorption patterns at implants with platform switching compared with implants and matching abutments (Weng et al. 2008; Becker et al. 2009). To date, data from RCTs comparing marginal bone-level alterations on two adjacent implants restored with and without platform switching, exhibiting an identical diameter (4 mm) and the same design characteristics, have been missing.

Therefore, it was the aim of this randomized trial to test the hypothesis that platform switching would significantly reduce peri-implant bone loss during the first year after implant placement.

Material and methods

Experimental design

A prospective, single-blind, controlled clinical trial was designed. Twenty-five patients randomly received two implants in the posterior mandible, which were restored with (test) or without (control) platform switching after a submerged healing phase of 3 months. Patients were examined and data were collected at five time points, with the time of surgery as the baseline. Standardized radiographs and microbiological

samples of the implants' internal spaces were obtained at each time point, except month 8.

Subjects

Twenty-five patients (10 females, 15 males, age 51 ± 10.5 years) were recruited at the Dental Clinic Bochum/University of Witten-Herdecke, Germany, for the study. Prerequisites for inclusion in the study were good general health and absence of infectious disease, diabetes, and osteopathy. Other requirements included no active periodontitis, no drugs influencing bone metabolism, no lactating or pregnant women, an edentulous gap in the posterior mandible for the placement of two implants, sufficient bone height above the alveolar nerve, bone width for the placement of implants 9.5 mm in length and 4 mm in diameter, 4 mm of keratinized mucosa in the prospective implant position in the buccolingual direction, and a medium or a thick soft-tissue biotype.

The patients were informed in detail about the possible risks and benefits, and all signed an informed consent. The study was performed in compliance with Good Clinical Practice and the Declaration of Helsinki last revised Edinburgh 2000; the study protocol was reviewed and approved by the Clinical Trials Committee of the University of Witten/Herdecke, Witten, Germany.

Implants

The implant system used in the present study was the SIC Ace[®] implant (SIC-Invent, Basel, Switzerland). It has an internal hex connection with an interlocking clearance fit (Zipprich et al. 2007) and a medium-rough sand-blasted, acid-etched surface. All implants used in the study had a length of 9.5 mm and a diameter of 4 mm. The standard SIC Ace[®] implants are designed for platform switching, with a 45° beveled platform switching shoulder, resulting in a circular step of 0.35 mm (Fig. 1a). The corresponding abutment has a diameter of 3.3 mm. The control implant was manufactured without the bevel, but with an identical internal configuration for abutment connection. The abutment with a 4 mm diameter could be used (Fig. 1b).

Radiographic examination and evaluation

The radiographic assessments were based on four standardized panoramic images taken immediately after implant surgery (baseline), immediately before reentry (3 months post-op), immediately after crown insertion (4 months post-op), and at the second recall (12 months post-op). For standardization, the patients' mandibles were fixated by a customized bite splint, and the panorex unit was readjusted individually to the respective patient position. The digital orthopantomographs were obtained with the

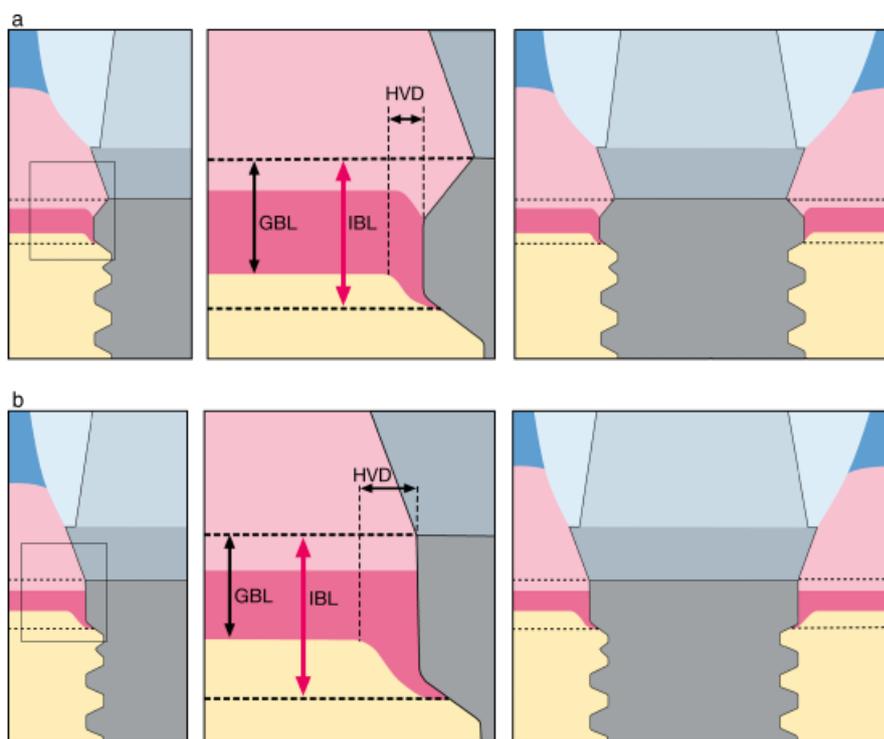


Fig. 1. (a) Study results after 1 year: bone-level alterations at the implant with platform switching (Test). (b) Study results after 1 year: bone-level alterations at the implant without platform switching (Control). The red area demonstrates the bone-level alteration since baseline (implant insertion operation); measured distances from reference points: IBL, vertical bone level at the implant; reference point: micro-gap HVD, horizontal aspect of the vertical bony defect at the implant; reference point: implant surface GBL, general horizontal bone level; reference point: micro-gap.

Promax RPX 232574 (Planmeca, Helsinki, Finland) and evaluated and measured using the Dimaxis Software 4.3.1 (Planmeca) with a measuring precision of 0.01 mm. The regions of interest on the radiographic images were magnified using the software tools to the highest possible level ($\times 20$), and the bone height measurements were always calibrated at the respective implant length of 9.5 mm.

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 for the general horizontal bone level (GBL) was the micro-gap between implant body and abutment, and for the horizontal extent of the vertical defect (HVD), the implant shoulder adjacent to the crestal edge of the vertical bony defect. At each implant, six measurements were performed (Fig. 1a and b): IBL: A, mesial, B, distal; HVD: C, mesial, D, distal; GBL: E, mesial, F, distal. HVD and VVD are horizontal and vertical measuring units to describe angular bony defects, whereby GBL is the horizontal level at which the angular defect begins. Three calibrated dentists experienced in oral radiology performed the radiographic evaluation independently, resulting in a total of 3600 measurements. If the differences in measurements among the three examiners were 0.1 mm or less, the mean of the three measurements was used. If the differences were >0.1 mm, the three examiners re-analyzed the specific implant together, and consensus was sought.

Clinical procedure, randomization, and allocation concealment

In January 2007, after a promotion of the study in the local press, more than 200 persons were screened as potential study subjects (Fig. 2). Twenty-five patients were selected according to the inclusion and exclusion criteria; the subjects gave their informed consent and were enrolled in the study. In April 2007, all implant surgeries were performed within 1 week at the Dental Clinic Bochum/University of Witten-Herdecke, Germany. After a terminal injection with local anesthetics (Ultracain UDS Forte, epinephrine 1:100,000, Sanofi-Aventis, Paris, France), a crestal incision was made, a full-thickness flap was raised, the surgical site was exposed, and the implants were inserted at the bone level. The minimal distance between the two implants was 3 mm and between the tooth and the implant, it

was 2 mm. Surgical bone recontouring of the alveolar bone was not allowed. For each patient, the locations of the test and control implants were randomized according to a computer-generated list. The implants healed in a submerged position. In July 2007, 3 months after the implant operation, the implants were exposed after elevating a mini full-thickness flap. After implant insertion and after second-stage surgery, the test persons rinsed with a 0.2% chlorhexidine gluconate mouthwash (Meridol Perio, GABA, Therwil, Switzerland) twice daily for 1 min for 1 week until removal of the sutures. After 2 weeks, impressions were taken; after another week, a try-in of the casted crown frameworks was performed. After 7 days (4 months after the implant operation), fully ceramic-veneered casted single crowns were produced, SIC Ace[®] standard titanium abutments (SIC No. 936163) were tightened with 25 Ncm on the implants, and the crowns were mounted on the abutments with provisional cement. Follow-up appointments were scheduled at 8 and 12 months post-implant insertion for the assessment of oral and implant health and hygiene based on the full-mouth sulcular bleeding index (Muhlemann & Son 1971), full-mouth plaque index (Silness & Loe 1964), peri-implant probing depth, and sulcular flow rate. Moreover, at the 15 appointments of the study, the oral hygiene of the test subjects was reinforced by hygiene reinstruction or, if necessary, by professional plaque control.

Microbiological analysis

Microbiological samples were harvested from the implant internal cavity at surgery (baseline), at second-stage surgery (3 months), at placement of the suprastructure (4 months), and at the second recall (12 months). At the second recall, the crowns and abutments had to be removed. After harvesting the microbiological samples from the implants' inner cavities, the abutments were tightened, and the crowns were again mounted with provisional cement. All microbiological samples were collected in a standardized way by the same investigator. Samples were taken using three consecutively inserted sterile paper points (ISO #90, Roeko, Langenau, Germany), which were inserted into the internal cavity of the implant for 20 s and then immediately transferred into a sterile transport tube for evaluation by real-time PCR (Carpegen[®] Perio Diagnostics, Carpegen GmbH, Münster, Germany) for determination of the total bacterial counts (TBC) (Jervoe-Storm et al. 2005). Before sampling,

selected implants and their adjacent regions were isolated with cotton rolls; great care was taken to avoid any kind of contamination of the implants during removal of the internal screw.

Statistical methods

According to the sample size calculation, 25 subjects were included in the study. The primary end-point of the study was the change in the "IBL."

The primary hypothesis to be tested was as follows:

- (i) 1 year after implant insertion, the test implant shows at least 0.35 mm less bone loss than the control implant.

The secondary hypotheses to be tested were as follows:

- (i) The IBL values change within the study period.
- (ii) This change depends on the implant type.
- (iii) There is a difference between the TBC of the test and the control implants over the study period.

Differences between IBL at the test and the control implants were chosen as the primary outcome parameter. Sample-size calculations were performed using G*Power 3 for matched pairs (Faul et al. 2009). Based on data from previous studies on implants in the lower jaw and in accordance with power calculations of other studies (Hildebolt et al. 1998; Astrand et al. 1999), it was considered possible to detect a true difference of at least 0.35 mm with an SD of 0.65 between the test and the control implants in this randomized split-mouth study design with 80% power and 23 patients. This estimate was based on a one-tailed test of matched pairs conducted at the 5% level of significance. To compensate for possible dropouts in this prospective 5-year clinical trial, the sample size was adjusted to 25 patients.

The primary hypothesis (i) was that 1 year after implant placement, the control implant would lose at least 0.35 mm more bone than the test implant, meaning that the intraindividual difference of the IBL values between test and control would be 0.35 mm or more. The primary hypothesis was tested using the Wilcoxon test. The global test of the dependence of the IBL value on implant type (hypothesis iii) and time (hypothesis ii) was tested using the nonparametric model of Brunner et al. (2002). The intraindividual difference between the TBC of the test and control implants over the study period (hypothesis iv) was also tested globally using the nonparametric model of Brunner and Langer. The software SAS 9.2 (SAS Institute, Heidelberg,

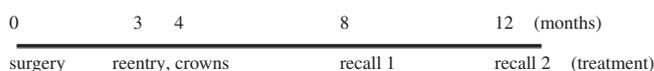


Fig. 2. Time schedule of the study.

Germany) was used for the Brunner–Langer model. The Wilcoxon tests were performed using the software R (R Foundation for Statistical Computing, Vienna, Austria), and for the *post hoc* power analysis, the software PASS (NCSS, Kaysville, UT, USA) was used. The graphs were designed using the software Prism4 (GraphPad SoftwareFirma, La Jolla, CA, USA).

Results

All patients were available for all follow-up examinations. After 1 year, the implant survival rate was 100%. Patients presented with good oral hygiene (Table 1) and healthy peri-implant conditions: the maximum probing depth around the implants was 3 mm, and no bleeding was observed on probing.

On the radiographs, two types of bone-level changes were found: (1) a general horizontal bone loss (GBL) and (2) a defect with a vertical (VVD) and a horizontal (HVD) component. The vertical IBL was the sum of GBL and VVD. At the 1-year follow-up, compared with the baseline, the bone-level changes (Δ) were as follows: Δ IBL (mean of the distances A, B) was -0.53 ± 0.35 mm for the test implants and -0.58 ± 0.55 mm for the control implants; Δ GBL (mean of the distances E, F) was -0.34 ± 0.35 mm for the

test implants and -0.19 ± 0.47 mm for the control implants; and HVD (mean of the distances C, D) was -0.21 ± 0.38 mm for the test implants and -0.35 ± 0.44 mm for the control implants (Table 2). In general, VVD and HVD were similar; the vertical defect measured from the new general bone level had about the same depth and width (Fig. 1a and b).

After 1 year, the intraindividual difference was small: 0.05 ± 0.56 mm for IBL and 0.14 ± 0.61 mm for HVD. The box plot for the intraindividual differences of IBL between test and control shows that the values vary around zero (Fig. 3); in some patients, bone levels were better maintained at implants with platform switching, whereas in other patients, bone levels were better maintained at implants without platform switching (Fig. 4a and b). The nonparametric 95% lower confidence bound for the median of the intraindividual difference of IBL between control and test was -0.18 mm and hence smaller than 0.35 mm. Therefore, hypothesis (i) had to be rejected ($P=0.9907$). Because the P -value was close to 1 and the nonparametric 95% upper confidence bound was 0.32 mm and therefore smaller than 0.35 mm, the opposite hypothesis was tested exploratively. The difference in IBL between test and control was significantly smaller than 0.35 mm ($P=0.0093$, *post hoc* power 79.9%).

The Brunner–Langer model was able to demonstrate that the changes in IBL were significantly dependent on time ($P<0.001$), but not on the implant type ($P=0.4$) or an interaction of time and implant type ($P=0.571$). The main bone remodeling occurred for all implants within the first 4 months after implant insertion, with approximately 0.15 mm vertical bone loss per month. Between the crown placement and the second recall, only a minimal additional vertical bone loss of approximately -0.1 ± 0.35 mm was observed. The progression of bone loss over time was similar for the test and the control

implants (Fig. 5a and b), with the mean intraindividual differences between the two treatment modalities always <0.1 mm.

The Brunner–Langer model showed that the TBC was significantly dependent on time ($P<0.001$), but not on implant type ($P=0.982$) or an interaction of time and implant type ($P=0.453$). TBC were high in both implant types at baseline, and slightly higher counts were found in the test group (difference control minus test: -3.7×10^6 , 95% CI [-10.5×10^6 ; 1.2×10^6]). TBC decreased from baseline to the 12-month evaluation in both implant types to almost the same level (Table 3).

Discussion

The results of the present study indicate that the primary hypothesis (i) must be rejected. The mean intraindividual difference in the Δ IBL values after 1 year was 0.05 ± 0.56 mm and, therefore, statistically significant smaller than the expected 0.35 mm, the extent of the platform shifting ($P=0.0093$, *post hoc* power 79.9%). In some patients, the implants with platform switching lost more bone, whereas in other patients, the implants without platform switching lost more bone (Fig. 4a and b). A significant peri-implant bone-level alteration was observed

Table 1. Full-mouth plaque index (PI, Silness & Loe 1964) and sulcular bleeding index (SBI, Muhlemann & Son 1971), categorized in time (n = 25)

Index	Time	Mean	SD	Minimum	Maximum
PI	Before	0.55	0.32	0.18	1.38
	3 months	0.52	0.33	0.14	1.38
	4 months	0.45	0.29	0.07	0.97
	8 months	0.28	0.21	0	0.73
	12 months	0.36	0.23	0	0.86
SBI	Before	0.34	0.27	0	0.9
	3 months	0.52	0.4	0	1
	4 months	0.32	0.24	0	0.9
	8 months	0.21	0.19	0	0.8
	12 months	0.25	0.24	0	0.83

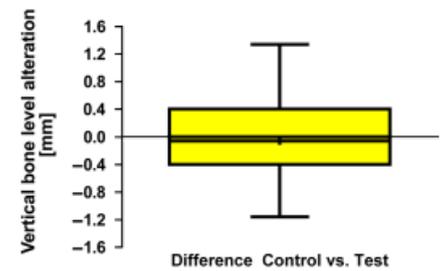


Fig. 3. Box plot showing the intraindividual difference in the vertical bone-level alterations of implants with (Test) and without (Control) platform switching after 12 months.

Table 2. Peri-implant bone-level alterations compared with the baseline (0 months) for time and implants with (Test) and without (Control) platform switching: mean of the mesial and distal measurements on the radiographs (mm) (Fig. 1a and b)

Time	Measured distance	Control				Test				Difference (Test – Control)			
		Mean	SD	Median	95% CI for the median	Mean	SD	Median	95% CI for the median	Mean	SD	Median	95% CI for the median
3 months	Δ IBL	-0.38	0.43	-0.3	-0.45; -0.1	-0.33	0.52	-0.05	-0.41; 0	0.05	0.51	0.04	-0.02; 0.25
	Δ HVD	-0.2	0.41	0	0; 0	-0.15	0.33	0	0; 0	0.05	0.47	0	0; 0
	Δ GBL	-0.26	0.33	-0.17	-0.38; 0	-0.1	0.21	0	-0.05; 0	0.16	0.36	0.04	0; 0.23
4 months	Δ IBL	-0.46	0.55	-0.55	-0.7; -0.2	-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	-0.22	0.36	0	-0.29; 0	0.03	0.47	0	0; 0.13
	Δ GBL	-0.2	0.46	-0.11	-0.27; 0	-0.22	0.25	-0.21	-0.29; 0	-0.02	0.42	0	-0.28; 0.27
12 months	Δ IBL	-0.58	0.55	-0.63	-0.92; -0.43	-0.53	0.35	-0.61	-0.7; -0.28	0.05	0.56	0.05	-0.18; 0.32
	Δ HVD	-0.35	0.44	-0.32	-0.57; 0	-0.21	0.38	0	0; 0	0.14	0.61	0	0; 0.4
	Δ GBL	-0.19	0.47	-0.18	-0.37; 0	-0.34	0.35	-0.3	-0.5; 0	-0.15	0.46	-0.04	-0.3; 0

Δ IBL, vertical bone-level alteration at the implant compared with the baseline (0 months); Δ HVD, horizontal component of the vertical bony defect at the implant, alteration compared with the baseline (0 months); Δ GBL, general horizontal bone-level alteration compared with the baseline (0 months).

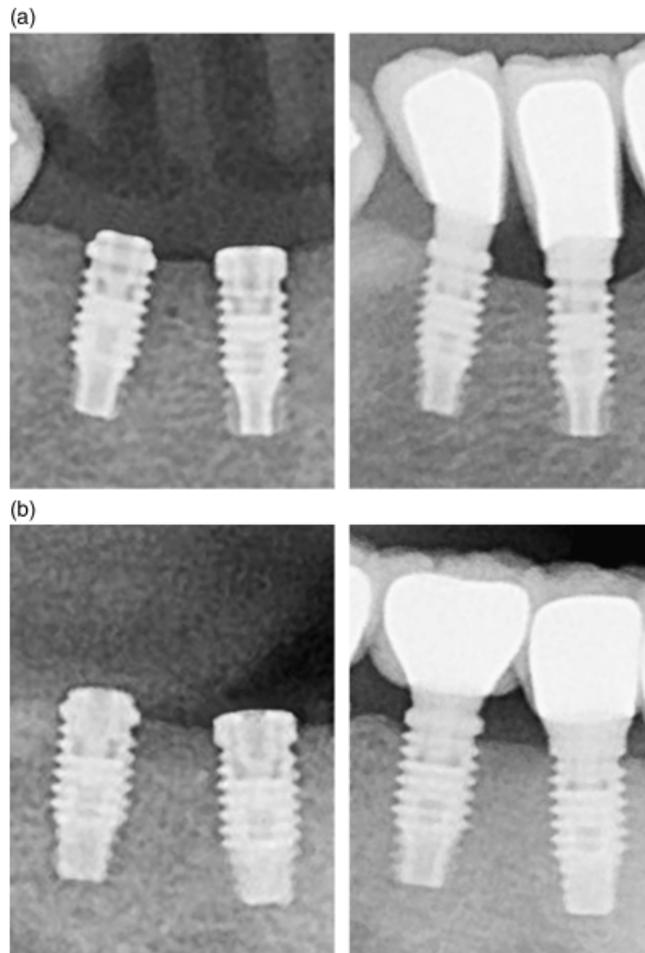


Fig. 4. Radiographs at implant placement and at 12 months post-op. (a) The test implant (left) underwent less peri-implant crestal bone loss than the control implant (right). (b) The test implant (left) underwent more peri-implant crestal bone loss than the control implant (right).

over time ($P < 0.001$), and this mainly took place during the first 4 months; i.e., between implant operation, reopening, impression, framework try-in, and crown mounting (the period when the peri-implant mucosa was frequently manipulated) (Abrahamsson et al. 1997). Between both treatment modalities, no difference in the peri-implant bone resorption pattern could be measured at any time ($P = 0.4$): the bone loss developed with a similar magnitude and velocity. From the 4- to the 12-month follow-ups, i.e., during the loaded period, only a minimal change of 0.1 ± 0.35 mm occurred. This time-related crestal bone-level change is typical at implants, and has also been reported for other implant systems (Brägger et al. 1998; Astrand et al. 2004; Brogгинi et al. 2006).

Compared with the baseline, a Δ GBL of -0.19 ± 0.47 mm at control and -0.34 ± 0.35 mm at test was measured 1 year after implant placement. Raising a flap at implant placement and at second-stage surgery could influence and accelerate bone resorption. Thus, Δ GBL might occur regardless of implant placement. In addition to

GBL, vertical defects were detected. The mean horizontal extent of this HVD was 0.14 mm larger for the control than for the test implants after 12 months. Nevertheless, the vertical defects were throughout similar in width and depth, which is in accordance with the results of Rodriguez-Ciurana et al. (2009). The intraindividual difference of the HVD values between the test and the control implants was related to the fact that the Δ GBL was generally more pronounced at the region of the test than of the control implants; therefore, the vertical defects around the test implants had, on average, merged more into the general horizontal bone loss than was the case around the control implants. The fine vertical defects around the implants may have been induced by surgical trauma during implant site preparation and implant insertion. Stresses build up in the cortical bone during surgery, which can lead to local necrosis permanently manifested by the formation of small vertical defects (Eriksson et al. 1984).

In the present study, measurements of the crestal bone level were performed with standar-

dized panoramic images. Radiographs are reliable and serve as an alternative to the histological evaluation (Albandar 1989; Schulze et al. 2000; Hermann et al. 2001a; Deppe et al. 2004). 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 (Benn 1990). 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; Rockenbach et al. 2003; Deserno et al. 2009). Peri-implant bony defects measured with panoramic radiographs may be overestimated by 52% compared with the histological measurements (De Smet et al. 2002), but because both implants were immediately adjacent to each other on the same radiograph, this was similar for both test and control.

In the present study, the bone-level alterations at implants with platform switching and at implants with matching abutments were similar to the data from the literature for implants with platform switching (Vela-Nebot et al. 2006). Therefore, the results for the control group were better than the data from implants with matching abutments in comparative studies (Vela-Nebot et al. 2006) or the reference criterion for implant success with 1.5 mm bone resorption after 1 year (Albrektsson et al. 1986; Albrektsson & Isidor 1994), which has also been used for comparing the data of implants with platform switching (Cochran et al. 2009). Our data, which showed no relevant bone-protective effect of platform switching, are in agreement with results from animal studies, in which no differences in vertical bone-level alterations between platform switching and nonplatform switching implants could be demonstrated (Weng et al. 2008; Becker et al. 2009). The reason for the differences between the findings of the present study and clinical data in the literature with regard to platform switching 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 (Hürzeler et al. 2007; Cappiello et al. 2008; Crespi et al. 2009; Prosper et al. 2009; Trammell et al. 2009; Canullo et al. 2010). Therefore, implant diameter may be biased with respect to bone-level alteration. In the present study, to the best of our knowledge, identical implants, different only at the implant shoulder, inserted into similar sites were intraindividually compared for the first time. Platform switching was first defined as "altering the horizontal position of the micro-gap" by Gardner (2005). Before the concept of platform switching was adopted from implant companies, this technique

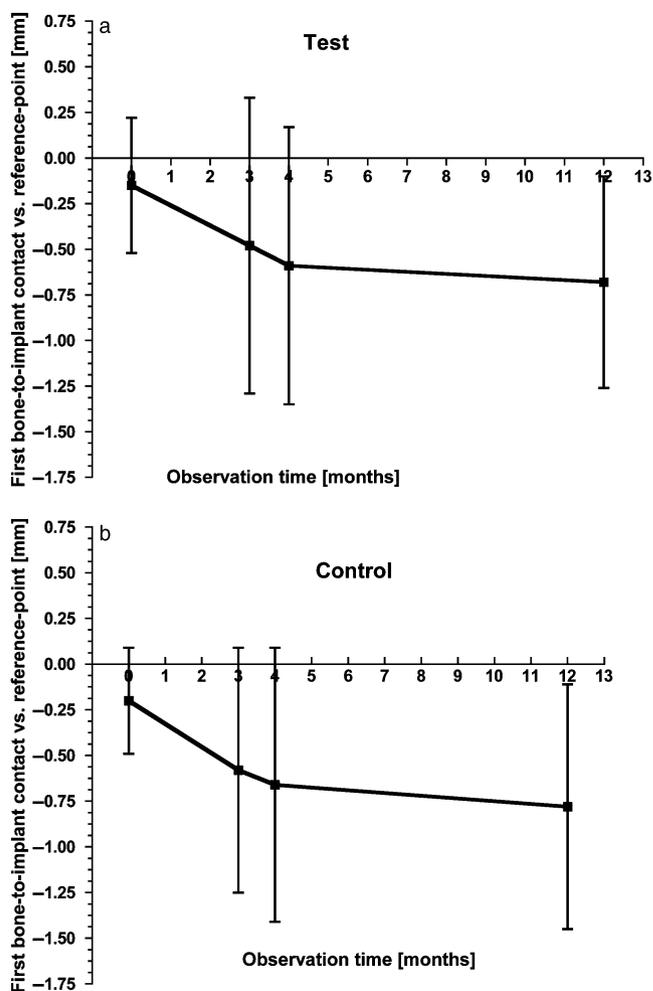


Fig. 5. (a and b): Means ± SD of the vertical implant bone level, i.e., first marginal bone-to-implant contact in relation to the reference point (implant–abutment micro-gap) at the test and control implants (data presentation adapted from Astrand et al. 2004). The bone level was measured immediately after implant surgery (baseline = 0 months), immediately before reentry (3 months post-op), immediately after crown insertion (4 months post-op), and at the second recall (12 months post-op). A negative value at the Y-axis indicates that the most coronal bone-to-implant contact was more apical than the reference point, and vice versa.

Table 3. Total bacterial counts (TBC) in samples from the internal cavities of test and control implants analyzed with real-time PCR

Time	TBC control		TBC test		TBC difference	
	Mean	95% CI	Mean	95% CI	Mean	95% CI
0 months	18.8	10.7; 24.7	22.5	16.8; 28.5	- 3.7	- 10.5; 1.2
3 months	7.4	4.0; 7.6	6.7	4; 6.5	0.7	- 1.1; 2.8
4 months	3	1.9; 3.9	3	1.8; 4.1	0.03	- 0.9; 1
12 months	3.6	2.1; 4.3	3.6	1.7; 3.8	0.01	- 0.1; 1.4

The Brunner–Langer model showed that the TBC was significantly dependent on time ($P < 0.001$), but not on implant type ($P = 0.982$) or an interaction of time and implant type ($P = 0.453$).

Data presented in 10^6 units.

could only be realized by using an abutment with a diameter smaller than that of the implant shoulder. However, this horizontal offset is associated with a sharp edge at the implant shoulder. As the platform switching concept was integrated into implant designs, most implant companies tried to avoid this sharp edge. Therefore, the

implant shoulders were slightly rounded or beveled like the implant used in the present study (SIC Ace[®], SIC-Invent). Because of the difference in the outer shape of the implant shoulder between the test and the control implant, the reference point was the micro-gap between the implant and the abutment. Hence, the micro-gap

was positioned epicrestally (Fig. 1a and b). All 50 implants studied had the same length (9.5 mm) and diameter (4 mm). Both implant groups had an identically sized internal space, and the configuration of the implant–abutment connection had identical internal connections with clearance fits that allowed a certain pumping effect between the implant inner cavity and the peri-implant environment close to the micro-gap (Zipprich et al. 2007). If a bone-protective effect of platform switching is to be proven, an internal connection with a clearance fit is ideal so that the effect of platform switching is assumed to be correlated with the micro-gap and its abutment ICT, whereas for the negative impact of the micro-gap on the bone, a certain mobility at the implant–abutment connection must be present (Hermann et al. 2001b). Capiello and colleagues compared an implant with an internal conical connection and a diameter of 4.8 mm with an implant of 4.1 mm diameter and a clearance fit connection. The advantage of the platform switching implants of 0.72 mm is that less bone resorption might be attributed to the different configurations of the internal connections and additionally to the difference in implant diameter (Cappiello et al. 2008). In the study of Vigolo and Givani with a 5-year follow-up, only implants with a 5 mm diameter were investigated to ensure no possible bias of implants' diameters; however, that study's definition of baseline was denture mounting. Therefore, bone-level alterations from implant operation to baseline were not monitored. The advantage of 0.3 mm less bone resorption at implants with platform switching might be attributed to the remodeling of the nonmeasured bone between the implant operation and the baseline (Vigolo & Givani 2009). If data from different studies are to be compared, the time point designated for baseline measurements is crucial. Some investigators used the surgical operation as the baseline (Vela-Nebot et al. 2006; Hürzeler et al. 2007; Crespi et al. 2009; Prosper et al. 2009; Canullo et al. 2010; Cocchetto et al. 2010), whereas others started their measurements when the prostheses were delivered (Hürzeler et al. 2007; Cappiello et al. 2008; Vigolo & Givani 2009). In the present study, as in other prospective implant studies, the main bone-level alteration occurred between implant operation and denture mounting (Astrand et al. 2004; Hürzeler et al. 2007). Therefore, the baseline definition of the present study was “implant operation,” the entire bone-level alteration after implant insertion was analyzed, and additionally, the date of “crown mounting” was documented radiographically.

Bacteria are considered to play an important role (Lindhe & Meyle 2008) in crestal bone loss at implants. The bacterial colonization can occur

as a consequence of leakage at the implant–abutment interface or as a result of contamination during implant placement (van Winkelhoff et al. 2000). In the present study, the TBC harvested from the inner cavities of both implant types were similar. The high counts of bacteria at baseline were possibly caused by unintentional contamination during surgery. Nevertheless, TBC decreased to almost the same level within the 12-month study time, with no significant differences between both implant types after 3, 4, and 12 months ($P=0.982$). Thus, a possible influence of differences in the bacterial colonization between test and control implants on the bone resorption, which could be a possible confounder, does not appear to have been present. With the standardized operation procedure at comparable surgical sites in the lower posterior arch and with constant oral hygiene control, other possible confounding factors should have been minimized.

In summary, the measured mean Δ IBL of <0.6 mm after 1 year is small and is comparable to the results of implants with platform switch-

ing and a tight inner cone connection (Astrand et al. 2004; Norton 2006). These results were achieved with and without platform switching using an interlocking clearance fit implant–abutment connection, i.e., no inner-cone connection. Therefore, the prosthetic restoration of the implant used in the present trial, i.e., treatment with or without platform switching, can be chosen according to the personal preferences of the clinician. At the annual examinations of this prospective 5-year clinical study, it has to be determined whether the bone level will stabilize at the 1-year level, as suggested by other prospective implant studies (Astrand et al. 2004), or whether, in the long term, an advantage of the platform-switching concept concerning the peri-implant bone-level alteration will be seen (Vigolo & Givani 2009).

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Supporting Information

Additional supporting information may be found in the online version of this article:

Table S1. Supporting information in accordance with the CONSORT Statement 2001 checklist used in reporting randomized trials.

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