J Clin Periodontol 2011 doi: 10.1111/j.1600-051X.2010.01683.x

Journal of Clinical Periodontology

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Open or submerged healing of implants with platform switching: a randomized, controlled clinical trial

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Enkling N, Jöhren P, Klimberg T, Mericske-Stern R, Jervøe-Storm P-M, Bayer S, Gülden N, Jepsen S. Open or submerged healing of implants with platform switching: a randomized, controlled clinical trial. J Clin Periodontol 2011; doi: 10.1111/j.1600-051X.2010.01683.x

Abstract

Aim: The temporal pattern of bone-level alterations in conventionally restored implants is dependent upon healing mode (open or submerged). This study examined the influence of healing on marginal bone levels at implants with a medium–rough surface including the implant collar and a clearance-fit implant–abutment connection restored according to a platform-switching concept.

Material and Methods: Two implants were placed in the posterior mandible of 21 test subjects, randomly assigned to open (OH) or submerged (SH) healing. Standardized radiographs were obtained after implant surgery, before re-entry, after crown mounting, 1 and 2 years after implant surgery, and evaluated for implant–bone-level alterations (ΔIBL). Bacterial samples of the implants' inner cavities were analysed by cultivation. Statistics: Brunner–Langer Model, equivalence testings by Wilcoxon's (equivalence range ± 0.4 mm).

Results: After 2 years, ΔIBL were -0.47 ± 0.46 mm (OH) and -0.54 ± 0.38 mm (SH). At the 1-year follow-up, all implants were contaminated with bacteria. ΔIBL ($p < 0.001$) and the amount of bacterial contamination ($p < 0.001$) significantly depended on time, but not on healing mode. ΔIBL of OH and SH were equivalent at all time points (all $p \leqslant 0.044$).

Conclusions: Platform-switched implants showed very limited peri-implant bone-level alterations. The healing-mode neither affected the total amount nor the temporal patterns of ΔIBL. Thus, the results for the tested implants with a non-rigid implant–abutment connection were similar to results reported previously for implants with a rigid implant–abutment connection.

Key words: bacterial contamination; bone-level alteration; bone loss; cultivation; healing mode; implant's inner cavity; non-rigid connection; open healing; platform switching; submerged healing

Accepted for publication 23 November 2010

In the first year after implant insertion, a physiological peri-implant bone-level alteration of 0.5–2 mm is expected. In the subsequent years, the rate of bone loss slows to about 0–0.2 mm per year (Albrektsson et al. 1986, Roos et al. 1997, Manz 2000, Cardaropoli et al. 2006). After 1 year, the same extent of marginal bone-level alteration at two-piece implants has been demonstrated regardless of healing mode (open or submerged). However, the temporal pattern of bone resorption differed; the open-healing procedure provoked immediate bone resorption, whereas under submerged healing conditions, bone resorption was limited before the re-opening operation and accelerated afterwards (Hermann et al. 1997, Fiorellini et al. 1999, Broggini et al. 2003). One possible reason for this crestal bone loss with two-piece implant systems is bacterial colonization of the micro-gap between the implant and abutment (Van Winkelhoff et al. 2000), which is related to the abutment-associated

Conflict of interest and source of funding statement:

The authors declare that they have no conflict of interest. The study was supported by the Schilli Implantology Circle and SICinvent AG, Basel, CH.

inflammatory cell infiltration (abutment ICT) close to the crestal bone (Ericsson et al. 1995, 1996, Todescan et al. 2002, Broggini et al. 2003, 2006, Piattelli et al. 2003).

These data about the differences in the temporal patterns of bone-level alterations between open and submerged healing conditions were obtained in studies using conventionally restored implants with clearance-fit implant–abutment connections. Platform switching refers to a prosthetic concept using an abutment with a smaller diameter than the diameter of the implant shoulder to locate the micro-gap further away from the most coronal bone-to-implant contact, thus minimizing bone resorption (Broggini et al. 2003, 2006, Gardner 2005, Prosper et al. 2009, Canullo et al. 2010). One clinical study suggested that there is minimal vertical bone loss and almost no difference regarding bone-level alterations at implants restored with non-matching abutments when comparing open and submerged healing conditions (Cecchinato et al. 2004). However, this study used implants with a tight inner cone implant–abutment connection. Implants with a tight inner cone connection are, from a mechanical point of view, comparable to one-piece implants (Zipprich et al. 2007), which generally show less bone loss than two-piece implants (Hermann et al. 1997, 2000, 2001, Buser et al. 1999, Manz 2000). Thus, the observed favorable results could be due to either the shape of the abutment, the tight inner cone connection, or a combination of both features. Implants with a rigid conical implant–abutment connection and platform switching demonstrate less crestal bone-level alterations than implants with a non-rigid clearance-fit connection and a matching outline (Astrand et al. 2004). But from a prosthodontic point of view, inner cone connections may also have disadvantages: (1) The vertical position of the abutment changes when the abutment screw is tightened with increased forces. This mean vertical difference of 89 μm at implants and 122 μm at laboratory implant replicas can inhibit passive fit of screwed multi-implant supra-structures (Dailey et al. 2009). (2) towing to the inner cone design, the implant crown's emergence profile can only start at a certain distance to the implant shoulder. This can impair the aesthetical results when implants are not inserted apically enough. Hence, it is advantageous if a clearance-fit implant–abutment connection can demonstrate similar good results regarding bone levels as conical connections due to modifications of the implant design, e.g. platform switching. In recent years, there has been increasing scientific interest in the effect of platform switching on the maintenance of marginal bone (Gardner 2005, Prosper et al. 2009, Canullo et al. 2010).

Thus, the aim of the present study was to evaluate possible differences in the temporal pattern and in the extent of marginal bone-level alterations between submerged and open healing conditions at implants with a medium-rough surface including the implant collar, with a clearance-fit implant–abutment connection, and with platform switching. Additionally, the temporal patterns of bacterial contamination of the implant's inner cavity was monitored and correlated with marginal bone-level alterations.

Material and Methods

Experimental design

According to the sample size calculation, in total 21 subjects were included in this prospective, single-blinded, controlled clinical trial. Each patient received two implants in the lower posterior mandible, randomly assigned to two groups: either an open healing (OH) or submerged (SH) healing period of 3 months was maintained. Patients were examined at surgery [time point 1 (T_1): baseline], 1 and 2 months after surgery [time point 2 (T_2): 1 month; time point 3 (T_3): 2 months], at second-stage surgery (time point 4 (T_4): 3 months), at placement of the supra-structure [time point 5 (T_5): 4 months], at first recall [time point 6 (T_6): 8 months], at second recall [time point 7 (T_7): 12 months], and at third recall [time point 8 (T_8): 25 months]. Standardized radiographs were taken at T_1, T_4, T_5, T_7, and T_8 and microbiological samples from the implants' internal cavities were obtained at T_1, T_4, T_5, and T_7 (Fig. 1).

Subject population

Twenty-one patients (eight females, 13 males, aged 50.7 ± 10.5 years) were recruited at the Dental Clinic Bochum/University of Witten/Herdecke, Germany, who fullfilled the following inclusion criteria: good general health and the absence of infectious diseases, diabetes, and osteopathy. Other requirements included no periodontitis, no drugs influencing bone metabolism, no lactating or pregnant women. Furthermore sufficient bone was required to accommodate implants with 9.5 mm of length and 4 mm of diameter, 4 mm of keratinized mucosa in the prospective implant position in the bucco-lingual direction and a medium or thick soft-tissue biotype, i.e. thickness of the crestal mucosa of $\geqslant$2 mm (Fu et al. 2010). The extraction of the missing teeth dated back at least 6 months.

The patients were informed in detail about 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 in Edinburgh in 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 SICace® implant (SIC-Invent, Basel, Switzerland). This implant has an internal hex connection with an interlocking clearance fit (Zipprich et al. 2007) and a medium-rough, sand-

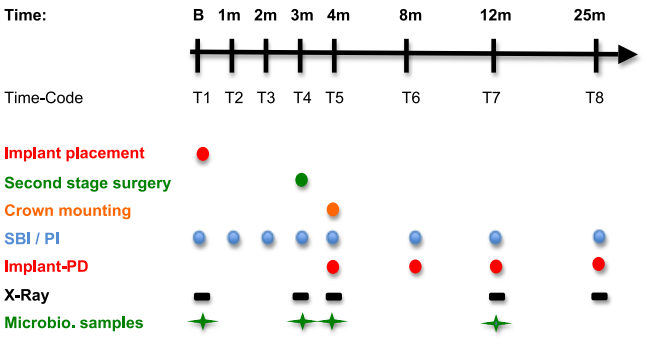

Fig. 1. Time schedule of the study: m, month; B, baseline; SBI, sulcular bleeding index; PI, plaque index; PD, probing depth.

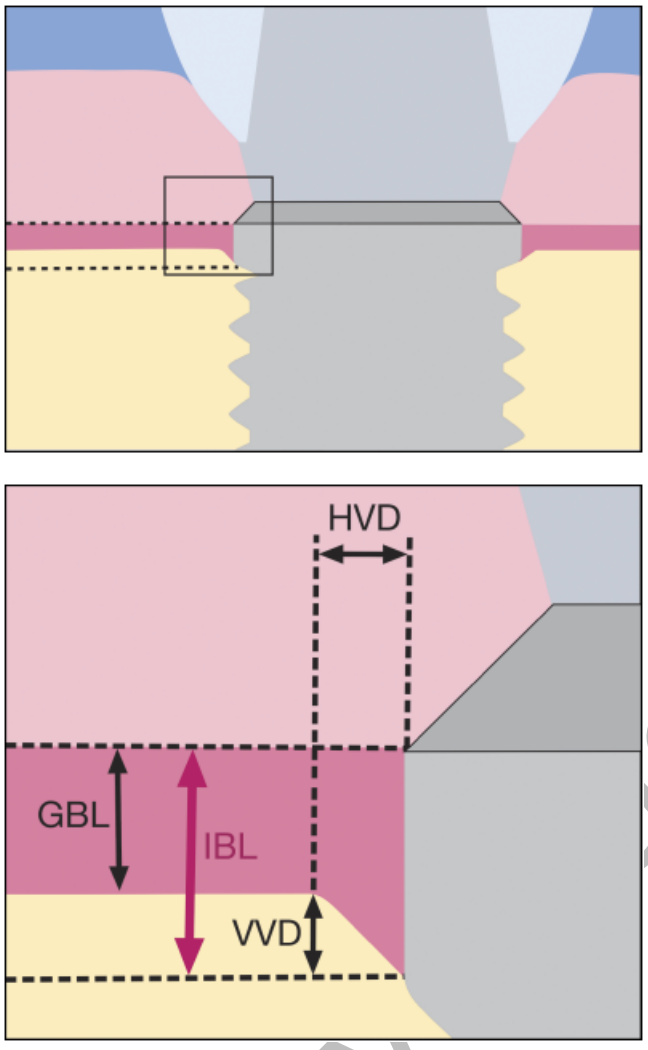

Fig. 2. Marginal bone-level alterations at the studied implants. The red area demonstrates the bone-level alteration 2 years after baseline (i.e. implant operation). Measured distances from reference points, mean of mesial and distal measurements; IBL, vertical bone level at the implant; reference point: microgap; HVD, horizontal aspect of the vertical bony defect at the implant; reference point: implant surface; VVD, vertical aspect of the vertical bony defect at the implant; calculated: VVD = IBL-GBL; GBL, general horizontal bone level; reference point: microgap.

blasted, acid-etched surface including the implant collar. All implants used in the study had a length of 9.5 mm and a diameter of 4 mm. The platform of the abutment was shifted from 4–3.3 mm diameter, resulting in a circular step of 0.35 mm (Fig. 2). The surface of this circular step was machined. The diameters of the cover screw for the submerged healed implants and of the healing abutment for the open-healing procedure were 3.3 mm; hence the cover screw and the healing abutments had a platform-switched outline.

Radiographic examination and evaluation

The radiographic follow-up was performed by means of five standardized digital panoramic images (OPG): T_1, T_4, T_5, T_7, and T_8. For standardization, the patients' mandibles were fixed with a customized bite splint, and the panorex unit was individually re-adjusted to the respective patient position. Digital orthopantomographs were obtained with the Promax RPX 232574 (Planmeca, Helsinki, Finland). For analysis of the radiographs and measurements, the DIMAXIS Software 4.3.1 (Planmeca) with a measuring precision of 0.01 mm was used. The regions of interest on the radiographic images were magnified with the software tools to the highest possible level (× 20), and the bone height measurements were calibrated at the respective implant length of 9.5 mm.

The crestal bone level was assessed at mesial and distal sites of all implants with the implant shoulder as a reference point (Fig. 2). The following measuring units were defined: IBL (vertical implant bone level; reference point: microgap) is the vertical distance between the micro-gap and the most coronal bone-to-implant contact. HVD (horizontal aspect of the vertical bony defect; reference point: implant surface) and VVD (vertical aspect of the vertical bony defect) are horizontal- and vertical-measuring units to describe angular bony defects, whereby general horizontal bone level (GBL; reference point: micro-gap) is the horizontal level at which the angular defect begins. IBL − GBL is the vertical (= VVD), and HVD is the horizontal component of the angular defect. If the HVD value is 0, IBL and GBL are identical and no angular defect is present. Changes of the crestal bone level over time are expressed as differences of the measured values: ΔIBL, ΔGBL, and ΔHVD. For the statistical calculations, the means of the mesial and distal measurements were used. Three calibrated dentists experienced in oral radiology independently performed the radiographic evaluations, resulting in a total of 3780 measurements. If the differences in the 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-analysed the specific implant together to reach a consensus.

Microbiological analysis

Microbiological samples were harvested from each implant's internal cavity at surgery T_1, T_4, T_5, and T_7. At T_7, the crowns and abutments were removed. Before sampling, the selected implants and their adjacent regions were isolated with cotton rolls; great care was taken to avoid contamination of the implants during removal of the internal screw. After harvesting microbiological samples, 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 using three consecutively inserted sterile paper points (ISO #90, Roeko, Langenau, Germany), which were left in the internal cavity of the implant for 20 s and then immediately transferred into an anaerobic transport medium (Port-A-Cul, BD,

Heidelberg, Germany) for subsequent cultivation on selective and non-selective culture media as described previously (Jervøe-Storm et al. 2005). Quantitative and qualitative analyses of seven putative periodontopathogenic bacteria [*Aggregatibacter actinomycetemcomitans*, *Porphyromonas gingivalis*, *Prevotella intermedia/nigrescens*, *Tannerella forsythia*, *Campylobacter* spp., *Fusobacterium* spec. (*F. nucleatum and F. periodonticum*), and *Eikenella corrodens*] as well as of *Capnocytophaga* spp., *Propionibacterium* spp., *Hallela dentalis*, *Actinomyces odontolyticus*, *Actinomyces* spp., *Acinetobacter baumanii*, *Acinetobacter* spp., *Eubacterium* spp., *Prevotella* spp., *Veillonella* spp., and *Candida albicans,* were performed. Additionally, identification of two non-pathogenic bacteria, *Neisseria* spp. and *Streptococcus viridans*, was performed. Blinding of the laboratory was assured by consecutively numbering all samples.

Clinical procedure, randomization, and allocation concealment

After promotion of the study in the local press in January 2007, >200 persons were screened as potential study subjects (Fig. 1). Twenty-one patients were selected according to the inclusion and exclusion criteria; all subjects provided informed consent and were enrolled. In April 2007, all implant surgeries were performed by three calibrated oral surgeons experienced in implant dentistry within 1 week at the Dental Clinic Bochum/University of Witten-Herdecke, Germany. After a terminal injection with local anaesthetics (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 adjacent to each other at bone level. The minimum distance between the implants was 3 mm. Surgical re-contouring of the alveolar bone was not permitted. For each patient, the locations of the submerged and open healing conditions were randomized according to a computer-generated list. After the implant insertion and after the second-stage surgery the study patients were permitted to rinse with a 0.2% chlorhexidine gluconate mouthwash (Meridol perio, GABA, Therwil, CH) twice daily for 1 min. during 1 week until removal of the sutures. During the 6 weeks after implant insertion and during the 2 weeks after the second-stage surgery no mechanical cleaning at the implant sites was allowed for the patients.

Appointments for monitoring of wound healing and of gingival health [full-mouth sulcular bleeding index (SBI) (Muhlemann & Son 1971)] and for oral hygiene control [full-mouth plaque index (PI) (Silness & Loe 1964)] were scheduled at 1 and 2 months after surgery. The submerged implant was re-entered by elevating a mini full-thickness flap 3 months after implant insertion. Two weeks later, impressions were taken; another week later, a try-in of the casted crown frameworks was performed. Seven days later (4 months after implant operation), fully ceramic-veneered, casted single crowns were produced, SICace standard titanium abutments (SIC No. 936163) were tightened with 25 N cm on the implants, and the crowns were mounted on the abutments with provisional cement. Follow-up appointments were scheduled at 8, 12, and 25 months post-implant insertion for assessment of oral and implant health and hygiene based on full-mouth SBI and PI as well as peri-implant probing depths. Moreover, at the 16 appointments of the study, the oral hygiene of the test subjects was reinforced by hygiene re-instruction, or, if necessary, by professional plaque control.

Statistical methods

The primary outcome variable was changes of IBL at OH compared with SH implants. The following hypotheses were to be tested:

(i) A peri-implant crestal bone-level alteration occurs after implant operation regardless of healing conditions (open or submerged healing), resulting in a similar alteration of IBL values after 2 years (T_8).
(ii) The temporal patterns of IBL alteration are equivalent for implants under open and submerged healing conditions: equivalent IBL values occur for both healing types at T_4, T_5, T_7, and T_8.

Secondary outcomes to be tested were as follows:

(iii) Microbiological colonization of the implants' internal cavities increases within 1 year after implant placement.
(iv) Temporal patterns of microbiological colonization are dependent on the implant healing condition.
(v) Alterations in IBL values are correlated with the bacterial contamination of the implants' internal cavities.

To test (i) and (ii), a global test of the dependence of the IBL value on time and healing type using the non-parametric model of Brunner & Langer (2002) was performed. Additionally, an equivalence testing for IBL at T_4, T_5, T_7, and T_8 was performed using a two-sided Wilcoxon's test and an equivalence range of (-0.4 mm; $+0.4$ mm) (Astrand et al. 1999, Wellek 2003). To test (iii) and (iv), a global test of the dependence of the load of *S. viridans*, the bacteria species that was found most frequently at all time points, on time and healing type was performed using the non-parametric model of Brunner & Langer (2002). To test (v), the Pearson correlation coefficient between IBL and load of *S. viridans* was calculated and the Pearson product–moment correlation test was used. Spearman's rank-correlation coefficient was also calculated and led to similar results.

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 mandible 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 0.4 mm with an SD of 0.7 between OH and SH in this randomized split-mouth study design with 80% power and 21 patients. This estimate was based on a two-tailed test of matched pairs conducted at the 5% level of significance. According to the sample size calculation, 21 subjects were included in the study.

The SAS 9.2 software (SAS Institute, Heidelberg, Germany) was used. Graphs were prepared with the PRISM4 software (GraphPad Software Firma, La Jolla, CA, USA).

Results

All patients were available for all follow-up examinations. After 2 years, the implant survival rate was 100%. Patients presented with healthy peri-implant conditions, i.e. no bleeding on probing at the implants at any time, and adequate oral hygiene. However, gingival health and oral hygiene were slightly

impaired during the unloaded healing period (Table 1). The mean probing depth around the implants was 2.8 ± 0.5 mm for OH and 2.8 ± 0.7 mm for SH at the 2-year follow-up.

Table 2 gives an overview on the crestal bone-level changes at different time points. On an average, a slight bone loss was found over time. $n = 6$ (29%) OH implant sites and $n = 7$ (33%) SH implant sites exhibited angular defects. If angular defects were present, the horizontal and vertical component had approximately the same size, resulting in a 45° angle (Fig. 2). The Brunner and Langer model demonstrated that changes in IBL were significantly dependent on time ($p < 0.001$). Neither healing conditions alone (OH *versus* SH) ($p = 0.822$) nor the interaction of time and healing conditions ($p = 0.320$) had an influence on bone resorption. The main bone re-modelling occurred for all implants within the first 4 months after implant insertion, with approximately − 0.1 mm vertical bone loss per month. Between the crown placement and the 2-year follow-up, only a minimal additional vertical bone loss of approximately − 0.07 ± 0.39 mm was observed. The temporal progression of bone loss was similar for both healing types, so the mean intra-individual differences between the two treatment modalities were always < 0.1 mm (Table 3; Figs 3a and b, 4). Equivalence testing for hypothesis (ii) was statistically significant at every time point (all $p \leqslant 0.044$). Thus, hypotheses (i) and (ii) were accepted.

One year after implant placement, microorganisms were detected in the internal cavities of all tested implants. At T_7 $n = 32$ (76%) of the implants had internal contamination with *F. nucleatum* spp. in various combinations with *A. actinomycetemcomitans*, *P. gingivalis*, *P. intermedia/P. nigrescens,* and/or *T. forsythia*. Twelve months after implant insertion, $n = 10$ implants (24%) were negative for all of the five above-mentioned periodontopathogenic bacteria. Between T_1 and T_5 when the main percentage of bone loss occurred, almost no periodontopathogenic bacteria were detected in the implants' inner cavities. Additionally, at T_7 no specific pattern of contamination with periodontopathogenic bacteria could be seen in relation to implants with more or less bone loss. The most frequently detected species at all time points was *S. viridans* (Fig. 5). The Brunner and Langer model demonstrated a significant dependence of the load of *S. viridans* on time ($p < 0.001$), but not on healing mode ($p = 0.877$) or on the interaction of time and healing mode ($p = 0.998$). The microbiological contamination of the implants' internal cavities accelerated after crown mounting at T_5 (Table 4; Fig. 5). No significant correlation between bacterial load of the implants' inner cavities by *S. viridans* and IBL value alterations could be shown at any time (T_4: $r = -0.052$, $p = 0.742$; T_5: $r = 0.041$, $p = 0.797$; T_7: $r = -0.102$, $p = 0.521$). Therefore, hypothesis (iii) could be accepted but hypotheses (iv) and (v) could not be confirmed.

Table 1. Full mouth plaque index (PI, Silness & Loe 1964) and sulcular-bleeding index (SBI, Muhlemann & Son 1971), categorized in time: T1 = 0 months (baseline), T2 = 1 month, T3 = 2 months, T4 = 3 months, T5 = 4 months, T6 = 8 months, T7 = 12 months, and T8 = 25 months. ($n = 21$)

Index	Time	Mean	SD	Minimum	Maximum
PI	T1	0.55	0.34	0.18	1.38
	T2	0.90	0.78	0.07	2.40
	T3	0.66	0.51	0.10	1.77
	T4	0.52	0.34	0.14	1.38
	T5	0.42	0.28	0.07	0.96
	T6	0.26	0.20	0	0.73
	T7	0.35	0.20	0.04	0.77
	T8	0.40	0.18	0.02	0.75
SBI	T1	0.35	0.28	0	0.90
	T2	0.60	0.56	0.04	1.86
	T3	0.43	0.43	0.04	1.67
	T4	0.55	0.42	0	1.50
	T5	0.33	0.25	0	0.90
	T6	0.23	0.20	0	0.80
	T7	0.24	0.22	0	0.79
	T8	0.34	0.24	0	0.93

Discussion

With the standardized operation procedure at comparable surgical sites in the

Table 2. Peri-implant crestal bone level alterations compared with baseline (0 months) for time and implant healing conditions (submerged *versus* open healing): mean of the mesial and distal measurements on the radiographs (mm) (see Fig. 2)

Time	Measuring point	Submerged healing						Open healing					
		mean	SD	median	minimum	maximum	95% CI	mean	SD	median	minimum	maximum	95% CI
3 months (T4)	ΔIBL	− 0.21	0.34	0	− 1.04	0.13	–0.37; –0.06	–0.29	0.41	–0.11	–1.22	0.30	–0.48; –0.11
	ΔHVD	0.11	0.29	0.00	0.00	0.95	–0.02; 0.24	0.15	0.29	0.00	0.00	1.03	0.02; 0.28
	ΔGBL	–0.11	0.23	0.00	–0.67	0.13	–0.22; –0.01	–0.14	0.23	–0.07	–0.72	0.3	–0.25; –0.03
4 months (T5)	ΔIBL	–0.42	0.33	–0.39	–1.32	0.03	–0.57; –0.27	–0.46	0.39	–0.53	–1.11	0.34	–0.64; –0.29
	ΔHVD	0.21	0.34	0.00	0.000	1.03	0.05; 0.36	0.18	0.31	0.00	–0.45	0.81	0.04; 0.32
	ΔGBL	–0.24	0.23	–0.23	–0.75	0.03	–0.34; –0.13	–0.23	0.28	–0.23	–0.71	0.34	–0.35; –0.10
12 months (T7)	ΔIBL	–0.47	0.34	–0.58	–1.02	0.00	–0.63; –0.32	–0.48	0.48	–0.55	–1.14	0.68	–0.70; –0.26
	ΔHVD	0.21	0.39	0.00	0.00	1.27	0.04; 0.39	0.25	0.37	0.00	0.00	1.03	0.07; 0.42
	ΔGBL	–0.31	0.33	–0.28	–1.02	0.00	–0.46; –0.16	–0.23	0.51	–0.24	–0.90	1.44	–0.46; 0.01
25 months (T8)	ΔIBL	–0.54	0.38	–0.61	–1.44	0.00	–0.71; –0.37	–0.47	0.46	–0.53	–1.16	0.60	–0.68; –0.26
	ΔHVD	0.23	0.39	0.00	0.00	1.27	0.05; 0.41	0.16	0.29	0.00	0.00	0.90	0.03; 0.29
	ΔGBL	–0.15	0.84	–0.25	–1.73	1.65	–0.53; 0.23	–0.23	0.50	–0.38	–0.90	1.44	–0.46; –0.01

ΔIBL, vertical bone level alteration at the implant compared with baseline (0 months); ΔHVD, horizontal component of the vertical bony defect at the implant, alteration compared with baseline (0 months); ΔGBL, general horizontal bone level alteration compared with baseline (0 months).

Table 3. Intraindividual differences ofΔIBL values between open and submerged healing conditions (mm) and statistical results of the equivalence tests.

Time after implant operation	Mean	SD	95% CI	IBL < 0.4 mm	IBL > 0.4 mm
3 months	0.08	0.55	–0.17; 0.33	$p = 0.044$	$p = 0.004$
4 months	0.05	0.41	–0.14; 0.24	$p = 0.002$	$p < 0.001$
12 months	0.01	0.5	–0.22; 0.23	$p = 0.007$	$p = 0.006$
25 months	– 0.07	0.55	–0.32; 0.18	$p = 0.004$	$p = 0.044$

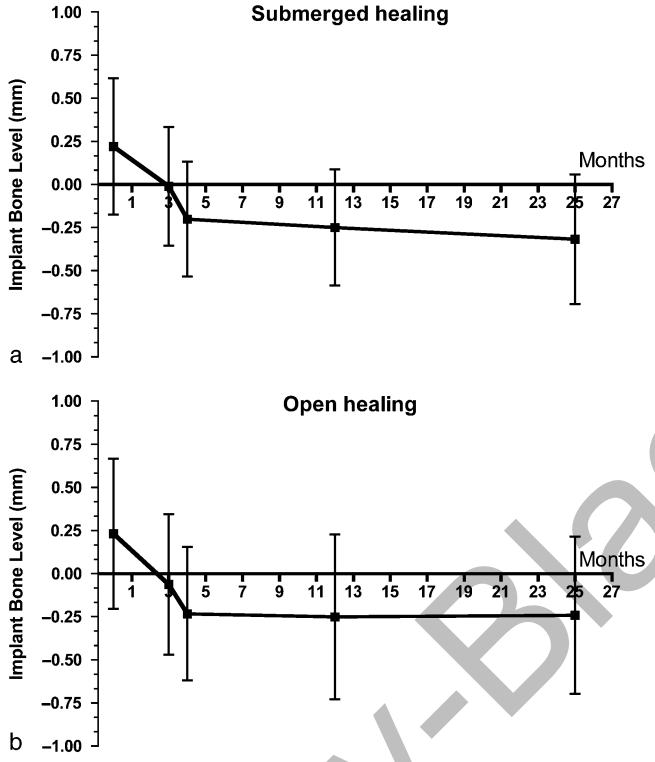

Fig. 3. Means ± SD of the vertical implant bone level (IBL) for submerged and open healed implants (data presentation adapted from Astrand et al. 2004). The bone level was measured immediately after implant surgery (baseline = 0 months), immediately before re-entry (3 months post-operatively), immediately after crown insertion (4 months post-operatively), at the second recall (12 months post-operatively), and at the third recall (25 months post-operatively). A negative value at the *y*-axis indicates that the most coronal bone-to-implant contact was more apical than the reference point (i.e. implant–abutment microgap), and *vice versa*. (a) IBL for submerged healing (b) IBL for open healing.

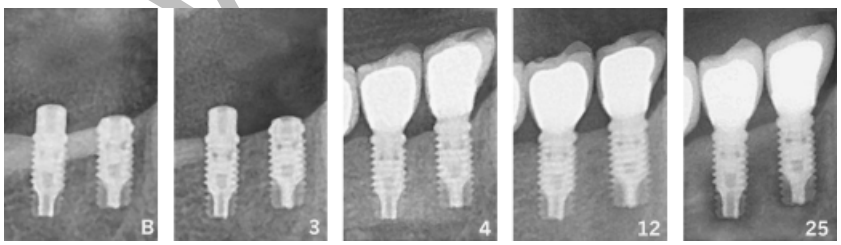

Fig. 4. Study patient with two implants placed in the position of the first (region 44) and second right premolar (region 45): region 44 submerged healing, region 45 open healing. Region of interest of the panoramic images at baseline (B), 3 months (3), 4 months (4), 12 months (12), and 25 months (25) after implant insertion.

posterior mandible and with strict oral hygiene control, possible confounding factors should have been minimized. Plaque control and the gingival health of the patients were adequate (De Boever & De Boever 2006, Theilade et al. 1966, Van Der Weijden et al. 1994). Only during the unloaded healing period (T_2–T_4), as mechanical cleaning at the implant-sites was not allowed for 6 and 2 weeks plaque control and gingival health were slightly impaired. After crown mounting (T_5–T_8) full-mouth SBI and PI scores improved to the baseline level. Peri-implant mucosal health was good throughout the study as probing depths were shallow and no bleeding on probing was present (Ericsson & Lindhe 1993, Esposito et al. 2010). In the present study, for mounting the ceramic veneered metal crowns on the implant–abutments, provisional cement was used following recommendations in the relevant literature (Mehl et al. 2008, Michalakis et al. 2003, Wolfart et al. 2006).

Two years after implant placement, similar mean marginal bone-level alterations of < 0.6 mm were found at platform-switched implants, independent of their respective healing mode. Compared with the criteria for implant success with 1.5 mm vertical bone-level alteration for two-piece implants within the first year, which is generally accepted (Albrektsson & Isidor 1994), the measured size of IBL was small and comparable with the results of implants with platform-switching and a tight inner cone connection (Astrand et al. 2004). In a clinical multi-centre study, the use of platform-switched implants with a clearance-fit connection and submerged healing led to significantly less bone resorption compared with implants with conventional matching abutments ($p < 0.001$) 1 and 2 years after implant placement (Prosper et al. 2009). Open and submerged healing conditions at platform-switched implants were not investigated, but matching abutments were randomly tested under submerged and open healing conditions; 1 and 2 years after implant installation, no differences regarding peri-implant bone-level alterations were found. The mean extent of vertical bone loss after 2 years was with 0.27 mm at submerged and 0.23 mm at non-submerged healed implants, smaller than some published bone loss rates of implants with platform switching (Astrand et al. 2004, Norton 2006). This means that the aetiology of bone- alterations is multifactorial and implants with matching abutments can also demonstrate very good results regarding bone-level alterations. Significant peri-implant bone-level alterations were observed over time, and occurred primarily in the first

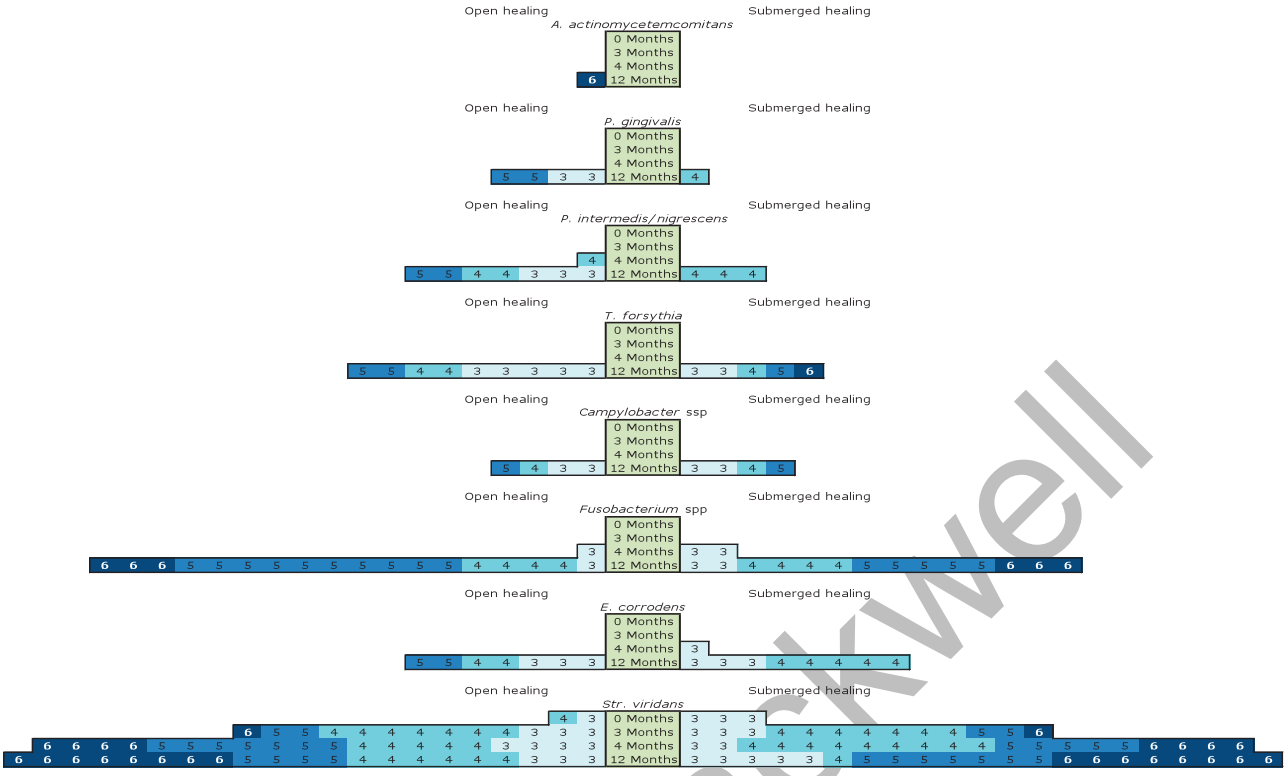

Fig. 5. Bacterial contamination of the implant inner cavities by the seven monitored putative periodontopathogenic bacteria and *S. viridans* – the marker used for bacterial contamination; grouped for open *versus* submerged healing. The colour of the rectangles depicts the magnitude of bacterial counts. The darker the rectangle, the higher the bacterial counts. Each number represents one positive sample. Numbers 3–6 indicate the order of bacterial counts: 3 indicating a range $\geqslant 10^3$ but $<10^4$ bacteria/sample, 4 indicating a range $\geqslant 10^4$ but $<10^5$ bacteria/sample, 5 indicating a range $\geqslant 10^5$ but $<10^6$ bacteria/sample, and 6 indicating a range $\geqslant 10^6$ bacteria/sample. The data are not linked to any specific site. Data presentation adapted from Mombelli et al. (1995).

4 months (i.e. between implant operation, re-opening, impression taking, framework try-in, and crown mounting: the period when the peri-implant mucosa was frequently manipulated) (Abrahamsson et al. 1997). From the 4- to the 25-month follow-ups (i.e. during the loading period), only a minimal change of -0.07 ± 0.39 mm occurred. This time-related pattern of crestal bone-level change is typical of implants, and has been reported for other implant systems (Manz 2000, Astrand et al. 2004). The additional disconnection and re-connection of the crowns and abutments at T_7 was probably a certain trauma for the peri-implant mucosa and could have induced further bone-level alterations. Thus the study was planned to disconnect the implant crown and abutment only once during the loading period in order to reduce artificially induced bone-level alterations due to the study design. The bone-level alteration (ΔIBL) between T_7 and T_8 was with a mean of -0.04 mm and a median of -0.005 mm close to 0 and therefore this trauma at T_7 did not have a long-term negative impact on peri-implant bone levels. At all time points in the study, the mean intra-individual difference of vertical bone loss between both healing types was <0.1 mm. Using 0.4 mm of difference in bone-level alterations as the minimum value for clinical relevance, as proposed previously (Astrand et al. 1999), for the definition of the equivalence range, equivalent IBL values for both healing conditions could be demonstrated statistically for all time points. Thus, our findings do not agree with published data of animal studies about the temporal difference in bone-level alterations comparing submerged or open healing conditions of implants with a clearance-fit implant–abutment connection and matching abutments: implants under open healing conditions initially demonstrated more peri-implant bone loss than did submerged healed implants. However, after second-stage surgery, the bone loss around the submerged healed implants accelerated so that 6 weeks after re-entry, the total amount of peri-implant vertical bone loss was ca. 1–2 mm, regardless of whether an open or a submerged healing mode was used (Hermann et al. 1997, Fiorellini et al. 1999). On the other hand, our results of very limited marginal bone-level alterations and no differences in temporal patterns of bone loss between healing modes are in agreement with a clinical study on implants with an inner cone implant–abutment connection and non-matching abutments (Cecchinato et al. 2004). Also, more recent animal studies using implants with an inner cone implant–abutment connection and platform switching did not show different temporal patterns of peri-implant bone-level alterations. The measured bone loss was significantly less than the current implant success criteria. These studies demonstrated an enhanced crestal bone resorption when placing the implant shoulder more apically (Jung et al. 2008, Cochran et al. 2009). Whereas, this bone loss was less than shown in studies with matching implant–abutment configurations (Hermann et al. 2000). Hence, the bone resorption protective effect of platform

Table 4. Microbiological contamination of the implant inner cavities, categorized in healing conditions (open and submerged): count of positive tested implants (maximum possible count: $n = 21$ in each group) and load of the positive tested implants (log units).

	Month 0 = T1						Month 3 = T4					
	open healing			submerged healing			open healing			submerged healing		
	positive (*N*)	mean of positive	SD	positive (*N*)	mean of positive	SD	positive (*N*)	mean of positive	SD	positive (*N*)	mean of positive	SD
Aggregatibacter actinomycetemcomitans	0			0			0			0		
Porphyromonas gingivalis	0			0			0			0		
Prevotella intermedia/P. nigrescens	0			0			0			0		
Tannerella forsythia	0			0			0			0		
Campylobacter spp.	0			0			0			0		
Fusobacterium sp.	0			0			0			0		
Elkenella corrodens	0			0			0			0		
Capnocytophaga spp.	0			0			0			0		
Propionibacterium spp.	0			0			2	4.5	0.7	0		
Hallela dentalis	0			0			0			0		
Actinomycesodontolyticus	0			0			2	3	0	0		
Actinomyces spp.	0			0			0			0		
Acinetobacter baumanii	3	3	0	2	3	0	2	6	0	2	5	1.4
Acinetobacter spp	0			0			0			0		
Eubacterium spp.	0			0			0			0		
Prevotella spp.	0			0			1	3	0	0		
Veillonella sp.	0			0			0			0		
Aerobic spore-developing microorganisms	2	4	1.4	0			0			0		
Candida albicans	0			0			1	4	0	0		
Neisseria spp.	0			0			0			1	4	0
Streptococcus viridans	2	3.5	0.7	3	3	0	13	4.1	0.9	14	4	0.9

	Month 4 = T5						Month 12 = T7					
	open healing			submerged healing			open healing			submerged healing		
	positive (*N*)	mean of positive	SD	positive (*N*)	mean of positive	SD	positive (*N*)	mean of positive	SD	positive (*N*)	mean of positive	SD
Aggregatibacter actinomycetemcomitans	0			0			1	6	0	0		
Porphyromonas gingivalis	0			0			4	4	1.2	1	4	0
Prevotella intermedia/P. nigrescens	1	4	0	0			7	3.9	0.9	3	4	0
Tannerella forsythia	0			0			9	3.7	0.9	5	4.2	1.3
Campylobacter spp.	0			0			4	3.8	1	4	3.8	1
Fusobacterium sp.	1	3	0	2	3	0	18	4.8	0.8	14	4.6	1
Elkenella corrodens	0			1	3	0	7	3.9	0.9	8	3.6	0.5
Capnocytophaga spp.	0			0			9	3.6	0.7	9	3.3	0.5
Propionibacterium spp.	4	3.3	0.5	6	3.2	0.4	6	3.3	0.5	3	3.7	0.6
Hallela dentalis	0			0			0			1	4	0
Actinomyces odontolyticus	2	3	0	3	3	0	9	3.7	0.7	9	3.3	0.5
Actinomyces spp.	5	3.2	0.45	2	3.5	0.7	19	3.7	0.7	16	3.8	0.8
Acinetobacter baumanii	4	5	1.4	6	4.3	1.2	0			0		
Acinetobacter spp.	2	4.5	2.1	3	5	1	0			0		
Eubacterium spp.	0			0			0			0		
Prevotella spp.	0			0			12	4	0.7	3	4	1.7
Veillonella sp.	0			0			0			0		
Aerobic spore-developing microorganisms	12	4.8	0.8	9	4.9	0.9	0			1	4	0
Candida albicans	0			1	5	0	0			1	6	0
Neisseria spp.	0			0			5	3.8	0.8	2	4	0
Streptococcus viridans	20	4.5	1.1	20	4.6	0.9	21	4.8	1.1	21	4.9	1.2

switching might be more apparent when positioning the impant shoulder more sub-crestally. In the present study, following the drilling protocol of the SICace implant, the implant shoulder was placed epicrestally. This epicrestal location also minimized the confounding effect of different bone-crest-related implant shoulder positions. In the present study, 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 panoramic images as inferior to that of intra-oral images (Benn 1990). Nevertheless, in vitro studies have shown that panoramic images of the posterior mandibular region offer a quality that is comparable to intra-oral films (De Smet et al. 2002, Rockenbach et al. 2003, Deserno et al. 2009).

The post-operative bone-level alterations at two-piece implants are a result of surgical trauma (Fiorellini et al. 1999, Gomez-Roman 2001) and the establishment of the abutment ICT as a consequence of the bacterial contamination of the implant–abutment micro-gap (Ericsson et al. 1995, 1996, Broggini et al. 2003, 2006). Regarding bacterial contamination of the implants' internal cavities during the first 12 months of the present study, the number of positive implants as well as the number of the various species increased, although without significant differences between groups. All implants, regardless of the mode of healing, were not colonized by any of the seven analysed putative periodontopathogenic bacteria until the 4-month examination time point (T_5), where only a few implants (two in each group) were found to be positive. After 12 months (T_7), *Fusobacterium* spp. was the most frequently found periodontopathogenic bacteria. This finding is supported by an earlier in vivo study, where bacterial samples were taken around implants and underneath their supra-structures (Keller et al. 1998). This comparison, however, is complex due to differences between the two studies. In the previous study, bacterial contamination of screwed supra-structures was investigated: in the present study, the internal cavity of the implant was covered with a screwed abutment and a cemented crown. The colonization with *S. viridians* increased during the 12 months of microbiological monitoring. Twelve months after surgery all implant's internal cavities in both groups were contaminated with *S. viridans*. Thus, our clinical findings are in accordance with an in vitro study where microbiological leakage at the implant–abutment interface was tested during dynamic loading in a two-axis chewing simulator (Steinebrunner et al. 2005). Five different clearance-fit implant–abutment connections were studied and statistically significant differences of the time until leakage were measured. At the end of the study, after 1,200,000 chewing cycles, all tested implants demonstrated a bacterial leakage. To our knowledge, no other in vivo study has reported the colonization of implant internal cavities over 12 months. Interestingly, the temporal pattern of colonization was similar for both healing modes. The implant system used in the present study had an interlocking clearance-fit internal implant–abutment connection with a micro-gap that may become wider under extra-axially applied forces (Zipprich et al. 2007). Thus, the implant has a configuration that is prone to an increased internal bacterial contamination, possibly resulting in more crestal bone resorption than a one-piece implant or a two-piece implant with a rigid inner cone connection (Hermann et al. 1997, 2000, Buser et al. 1999, Enkling & Jervøe-Storm 2010). However, the internal connection of the SICace implant system even of the healing abutment showed a sufficient sealing when no load was applied. No statistically significant difference in bacterial load of the inner cavities could be shown between OH and SH at any time point in this study. The re-tightening procedure of the abutment screws at T7 might have sealed the micro-gap, additionally (Gross et al. 1999). During the healing period (T_1–T_4), the implants contained a very limited bacterial load, regardless of healing conditions, which was probably caused by contamination during implant surgery. Between re-entry and crown mounting when the implant was opened and closed six times (T_4–T_5), contamination of the implants' internal cavities increased. After functional loading (T_5–T_7), the contamination accelerated and even periopathogens were detected (Table 4; Fig. 5). Although bacterial contamination accelerated after functional loading, no further clinically relevant bone-level alteration occurred and no correlation between bacterial load of the implant inner cavities (tested with the load of *S. viridans*, the marker used for bacterial contamination) and bone loss was found. Thus, the progressive colonization of the internal implant cavities was not found to be associated with further bone loss. This means, that the implant bone-level alteration due to the surgical trauma could have reached an extent that no further bone resorption was necessary for the establishment of the biological width and of the abutment ICT: The implant bone-level alteration was 0.47 mm at time of crown mounting. This bone-level alteration combined with the circular step of platform-switching of 0.35 mm had an extent to house the abutment ICT that has a mean radial extent of 0.5 mm coronally, laterally, and apically to the micro-gap (Ericsson et al. 1995, Ericsson et al. 1996). Thus, the further change of quality and quantity of microbial contamination of the implant inner cavity might not have induced further bone resorption as the abutment ICT was already established. On the other hand, the quality and quantity of bacterial contamination of the implants inner cavity might only have a limited influence on bone-level alterations if the patients show adequate plaque control and healthy peri-implant soft tissues: A prospective clinical study with implant installations in periodontitis-susceptible patients demonstrated that putative periodontopathogenic bacteria can be present in the peri-implant mucosa sulcus without any negative impact on peri-implant soft- and hard-tissue health and do not necessarily induce bone-level alterations (De Boever & De Boever 2006). Also, in a clinical study with Brånemark implants being in function between 1 and 8 years, no correlation between quality and quantity of the colonization of the implant's inner cavity and bone-level alterations was found (Persson et al. 1996). Further clinical trials are necessary to study the impact of bacterial colonization of the implants inner cavity on bone levels and on peri-implant mucosa health.

At implants with a conical implant–abutment connection and with platform switching a very limited crestal bone-level alteration was found with no influence of the healing mode (open or submerged) on temporal patterns of bone-level change (Cecchinato et al. 2004). In the present study, implants with platform switching and a non-rigid clearance-fit connection demonstrated similar results regarding the temporal patterns and the total extent of bone-level alterations as implants with an inner cone connection and platform switching. Besides, platform switching other parameters of the implant design also have an influence on marginal bone-level alterations (Manz 2000, Lang & Jepsen 2009). In this respect, the rough implant collar of the implant under study may have also contributed to the measured limited peri-implant crestal bone-level alteration (Alomrani et al. 2005). To investigate differences

regarding bone-level alterations between various implant–abutment connections, further randomized clinical trials are necessary using platform-switching implants of the same design that only differ in the internal connection: rigid inner cone connection *versus* non-rigid clearance-fit connection.

Acknowledgements

The authors would like to acknowledge the support for the statistical evaluation of the study data by Dr. Claudia Weiss (KKS Köln, Coordinating Centre for Clinical Trials, Cologne, Germany) and the support for the evaluation of the radiographs by Prof. Dr. rer. nat. Thomas M. Deserno (né Lehmann) [Department of Medical Informatics, Aachen University of Technology (RWTH), Aachen, Germany]. The analyses of the microbiological samples with cultivation were performed by Dipl.-Biol. Wolfgang Falk (Laboratory for Oro-Dental Microbiology, Kiel, Germany). Statistical analysis using the Brunner and Langer model and calculations of the equivalence testings were performed with the support of Mr. Yves Bartels and Mr. Niki Zumbrunnen [Institute of Mathematical Statistics and Actuarial Science (IMSV), University of Bern, Switzerland]. Additionally, the authors would like to thank Dr. med. dent. Victoria Klimberg, Dr. Jens Rathje, Mrs. Martina Popovic, and Mrs. Sabine Sieverding (Dental Clinic Bochum/University of Witten/Herdecke, Witten/Herdecke Germany) for their excellent support in organizing the study appointments.

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Clinical relevance

Scientific rationale for study: Different temporal patterns of marginal bone-level alterations have been reported in conventionally restored implants and depended on healing mode (open *versus* submerged). No information from randomized clinical trials is available on the effect of the healing mode on bone levels at platform-switched implants with a clearance-fit implant–abutment connection.

Principal findings: Two years after implant insertion, implants with platform-switching and internal hex implant–abutment connections showed very limited marginal bone-level alterations, which did not differ between implants with open or submerged healing. After 1 year, the inner cavities of all implants harboured bacteria: however, no correlation between the microbial load and the extent of bone loss was found.

Practical implications: The study results indicate that bone levels at platform-switched implants were independent of the healing mode and could be well maintained over 2 years.