# Immediate and Early Loading of Chemically Modified Implants in Posterior Jaws: 3-Year Results from a Prospective Randomized Multicenter Study

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#### ABSTRACT

*Background:* There is a lack of well-designed prospective, randomized clinical trials evaluating the efficacy of immediate and early loading of implants placed in the partially edentulous posterior maxilla or mandible.

*Purpose:* The aim of this study was to evaluate crestal bone level changes over 3 years following immediate or early loading of Straumann implants with a chemically modified surface (SLActive®, Institut Straumann AG, Basel, Switzerland) placed in the posterior maxilla and mandible.

*Materials and Methods:* Subjects received temporary restorations immediately or 28 to 34 days after surgery, with permanent restorations placed at 20 to 23 weeks. Bone level changes were measured by comparison of standardized radiographs taken on the day of implant placement and 5, 12, 24, and 36 months thereafter.

*Results:* Two hundred thirty-nine of two hundred sixty-six patients (89.9%) completed the trial. Implant survival rates were 97.4% and 96.7% in the immediate and early loading groups, respectively (p = not significant). Over 36 months, the mean bone level change for immediately loaded implants was  $0.88 \pm 0.81$  mm versus  $0.57 \pm 0.83$  mm for the early-loaded group (p < .001). After adjusting for a slight difference in initial placement depth, the time of loading had no significant influence on bone level change.

*Conclusions:* Changes in crestal bone level occurred mostly during the first 5 months postloading. After this bone remodeling period, crestal bone level was stable up to 36 months. Implants with a chemically modified surface are safe and predictable for immediate and early loading in the posterior maxilla and mandible.

KEY WORDS: bone level changes, early loading, immediate loading, implant survival, implants, multicenter, radiographs, randomized

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#### INTRODUCTION

The clinical success of oral implants is dependent upon interaction with surrounding bone ultimately resulting in the phenomenon of osseointegration. The inherent surface properties of the devices have a central role in mediating physical, chemical, and biological processes that occur during the early healing stages following implantation. Collectively, these events determine the characteristics of the bone/implant interface, which in turn influence the long-term outcomes and efficacy of the treatment.<sup>1–3</sup>

Modifications of the titanium surface topography and roughness can have a substantial effect on the host response to the implant. Thus, it should be feasible to create devices with properties that enhance both the quantitative and qualitative aspects of bone healing on the implant surface. It has been shown that this can lead to enhanced rates and extents of osseointegration.<sup>4–7</sup> Rough surface topography appears to generate firm contact with blood clots allowing for migration and differentiation of precursor osteogenic cells, which form bone directly at the implant surface.<sup>8,9</sup>

Modifications of the titanium surface chemistry influence surface charge and wettability. The latter is largely dependent on surface free energy and affects the degree of contact between the implant surface and the physiologic environment. Higher wettability enhances interaction between the biomaterial and host,<sup>10</sup> as can various surface chemistry modifications.<sup>6,11–15</sup>

A chemically modified titanium surface (SLActive® [SLA], Institut Straumann AG, Basel, Switzerland) has been developed, using the extensively documented sandblasted, large-grit, acid-etched (SLA, Institut Straumann AG) surface topography. The chemical modification is characterized by a hydroxylated/hydrated TiO<sub>2</sub> film, which creates a surface with high surface free energy, reduced atmospheric hydrocarbon contamination, and strong hydrophilicity (water contact angle of 0° compared with 139.9° for SLA).<sup>16,17</sup> Relative to SLA, data have shown that the chemical modification and increased surface energy increase cellular events in the host response to the implant: osteoblast differentiation is enhanced and expression of genes encoding factors involved in wound healing in general and osteogenesis in particular (e.g., osteocalcin, alkaline phosphatase, type I collagen, osteoprotegerin, Transforming growth factor 1 [TGF-1], and vascular endothelial growth factor [VEGF])<sup>18-20</sup> is increased. It has been reported that the osteoblast response is greater than what would be expected from the sum of individual surface energy and topography alterations, suggesting a synergistic effect.<sup>20</sup> In vivo studies demonstrated increased bone apposition to the chemically modified SLA surface in the early healing stages with 60% greater bone formation compared with the standard SLA surface. Additionally, there was earlier formation of more mature bone<sup>8,21</sup> and consistently higher mean removal torque values in the first 8 weeks.<sup>22</sup> Histological and immunohistochemical analysis of the bone response to the chemically modified SLA surface has also shown enhanced bone formation.<sup>23</sup> This suggests that the

chemically modified SLA surface may augment initial implant stability.

In recent years, immediate and early loading techniques have become more widely documented and accepted for situations ranging from single-tooth replacement to full-arch restorations.<sup>24-28</sup> Immediate and early loading can have several advantages over delayed protocols, most importantly it allows the patient to resume reasonably normal masticatory function as quickly as possible after surgery.<sup>29,30</sup> Immediate loading also avoids the requirement for an interim removable prosthesis, improves treatment efficiency, and immediately enhances the aesthetic appearance of the patient. Due to challenges associated with bone quantity and quality, there is a lack of well-designed prospective randomized clinical trials evaluating the use of these procedures in the partially edentulous posterior maxilla or mandible.

The overall goal of this multicenter randomized study was to determine the efficacy of immediate and early nonocclusal loading of implants with the chemically modified SLA surface when used to support single crowns or two to four unit fixed dental prostheses in the posterior maxilla and mandible. The primary objective of the study was to assess changes in crestal bone level of these implants over a 36-month period. The hypothesis was that there is no statistically significant difference between mean crestal bone level changes of the implants in the immediate versus early loading groups.

## MATERIALS AND METHODS

This is a final report from a prospective randomized 3-year study conducted at a total of 19 centers in 10 countries. The materials and methods are only outlined here; further details can be found in the two previous publications.<sup>31,32</sup>

# Patients and Implants

Patients were missing at least one tooth in the posterior maxilla or mandible and had healed implantation sites, adequate bone, and natural teeth or fixed prosthesis as the opposing dentition. Each patient received between one and four dental implants with a chemically modified SLA surface (SLA, Institut Straumann AG), either 4.1 (regular neck) or 4.8 mm (wide neck) in diameter and 8, 10, or 12 mm in length. All implants were the Standard type (2.8-mm machined-transmucosal collar), except for three Standard Plus implants (1.8-mm machined-transmucosal collar), which were placed in the immediate group.

All patient examination and radiographic and surgical procedures were agreed upon in investigator meetings and defined in a study protocol signed by all principal investigators. Study conduct and written informed consent (received from all patients) were in accordance with the "Declaration of Helsinki" (1964) and subsequent amendments and clarifications, and approval for the study was also obtained from relevant Ethics Committees. The first patient was enrolled in April 2004 and the last 3-year follow-up appointment was in August 2009.

# Randomization

Patients were randomized into an immediate or early loading arm via a sequential list in blocks of 10 generated for each center by an independent statistician and placed in sealed envelopes. Each numbered envelope was opened in chronological order immediately prior to surgery. Patients were therefore consecutively randomized, each assigned to a sealed treatment code envelope corresponding to their enrollment position.

## Surgical Procedures

Surgery was conducted in all centers by experienced implant surgeons, each with between 10 and 25 years of clinical experience. Routine surgical techniques for each center were used, following the standard Straumann one-stage surgery protocol.<sup>24</sup> Any patients with implants lacking primary stability or with inadequate bone at surgery were excluded from further study participation; such patients were subsequently offered implant treatment using the conventional protocol or another form of treatment. The day of surgery was defined as baseline (day 0).

# **Prosthetic Procedures**

Provisional restorations (single crowns or two to four unit fixed partial dentures) were placed on the day of surgery in the immediate loading group and after 28 to 34 days in the early loading group. All provisional restorations were placed out of occlusal contact. Permanent fixed restorations (porcelain, ceramic-metal, or acrylic resin on gold) were placed 20 to 23 weeks postsurgery.

## **Radiographic Evaluation**

Standardized periapical radiographs were taken at baseline and at seating of the permanent restoration. Radiographic and clinical evaluation was subsequently performed 12, 24, and 36 months postsurgery. Standardized radiographs were taken using the same customized film holder-beam aiming device (Figure 1) throughout the study. Implant threads (at least two) on each radiograph were used to calculate a magnification factor for analysis.

The standardized radiographs were used to determine the mean change in crestal bone level (mesial and distal) between the implant shoulder and the first visible bone-to-implant contact.<sup>33</sup> Radiographic measurements accounted for possible distortion based



Figure 1 Customized film holder-beam aiming device (A) and position relative to the x-ray cone beam in a mandible situation (B).

on changes from the true implant dimensions. Magnification factors were calculated by the known thread distance of 1.25 mm divided by the measured thread distance. All radiographic analyses were performed by the same independent x-ray reader, who was blinded to the loading protocol.

# Primary and Secondary Objectives

The primary study objective was evaluation of the radiographic change in bone level from baseline to 36 months. Differences between the immediate and early loading groups were compared; bone loss >0.3 mm was deemed to be detectable and was used as a nonin-feriority margin for comparison of the two treatment groups.

Secondary objectives included evaluations of implant survival and success. Criteria for success of individual implants included lack of mobility, absence of peri-implant radiolucency, recurrent peri-implant infection, continuous or recurrent pain or structural failure of the implant, and bone loss >2 mm between any two consecutive appointments.

## Statistical Methods

Baseline characteristics were reported descriptively. For continuous variables, means and standard deviations were calculated. Mean mesial and distal bone level measurements were used to determine the overall crestal bone level change for each implant. Data were analyzed using descriptive statistics and two generalized linear models where the patient was included as a random variable. The Kenward-Roger method<sup>34</sup> was used to calculate the degrees of freedom in the denominator, and type II tests were used to calculate *p* values and confidence intervals. All independent parameters were included as fixed effects to assess significance, and several were analyzed for a possible significant impact on bone loss.

For the difference in bone loss between the groups, all identified significant effects were included as fixed effects and observed distributions were used as coefficients to evaluate adjusted means and the difference between the groups. The risk for bone loss was compared between the treatment groups by a generalized estimating equation (GEE) model with treatment groups and jaw as fixed effects. Possible within-patient correlations were considered as a repeating effect. The same correlation was used for both groups.

#### RESULTS

#### Patients and Implants

The study enrolled a total of two hundred sixty-six patients, one hundred thirty-eight and one hundred twenty-eight in the immediate and early loading groups, respectively. A total of three hundred eighty-three implants were placed, one hundred ninety-seven and one hundred eighty-six in the immediate and early loading groups, respectively. The mean age of patients at baseline was  $46.3 \pm 12.8$  years. Most patients (64.3%) received a single implant; two, three, and four implants were placed in 30.1%, 3.0%, and 2.6% of patients, respectively. A total of two hundred sixty implants (67.9%) and one hundred twenty-three implants (32.1%) were placed in the mandible and maxilla, respectively; the first molar position (World Dental Federation position 36/46; American Dental Association positions 19/30) was the predominant site (44.1% of implants). There were no relevant differences between the groups for implant number or position.

## Implant Survival and Success

A total of two hundred thirty-nine patients (89.9%) completed the 3-year follow-up visit; the number of treated patients at each center is shown in Table 1. Three hundred forty implants were placed in these subjects, one hundred seventy-eight and one hundred sixty-two in the early and immediate loading groups, respectively. The discontinuation rates were 10.1% (14 of one hundred thirty-eight patients) and 10.2% (13 of one hundred twenty-eight patients) in the immediate and early loading groups, respectively. Reasons for discontinuations were complications (one and three patients in the early and immediate loading groups, respectively) and compliance issues (e.g., subject did not show up, subject could not be located, and subject refused to continue). There were 11 implant failures (five and six in the immediate and early loading groups, respectively); all occurred within 90 days of implant placement except one in the immediate group that occurred 458 days after implant placement. Details of each failure can be found in a previous publication.<sup>32</sup> The overall survival rate was therefore 97% (97.4% and 96.7% in the immediate and early loading groups, respectively). None of the 22 implants placed in type IV bone failed after 3 years, resulting in a 100% survival rate for implants placed in bone of low quality. Overall implant success rates were 96.9% and 96.7% in the immediate and early loading groups, respectively (one implant in the immediate group was classified as unsuccessful due to the presence of continuous peri-implant radiolucency based on radiographic findings).

## Bone Level at Implant Placement

Initial implant depth at baseline was significantly different between the treatment groups; implants in the immediate loading group were placed deeper into the bone than in the early loading group. The mean distance from implant shoulder to bone level was  $1.23 \pm 0.73$  and  $1.52 \pm 0.67$  mm in the immediate and early loading groups, respectively (Table 2). The difference between the groups (0.29 mm) was statistically significant (p < .001).

Mean implant depths were  $1.33 \pm 0.70$  and  $1.51 \pm 0.65$  mm in the immediate and early loading groups, respectively, in the mandible, and  $1.04 \pm 0.77$  and  $1.54 \pm 0.71$  mm in the immediate and early loading groups, respectively, in the maxilla (see Table 2). The difference between the groups was higher (but not significant) in the maxilla compared with the mandible.

Considering the length of the machined collar, the initial mean dimension of the bone contact zone along

TABLE 1 Number of Patients Evaluated per Center					
Center	No. of Patien	ts			
1	11				
2	11				
3	6				
4	12				
5	50				
6	14				
7	5				
8	10				
9	9				
10	6				
11	20				
12	22				
13	17				
14	10				
16	16				
17	4				
18	6				
19	8				
20	2				
Total	239				

#### TABLE 2 Implant Depth at Baseline Measured from the Implant Shoulder to First Visible Bone Contact (mm)

Jaw	Treatment Group	n	Mean	SD
Maxilla	Immediate	62	1.04	0.77
	Early	47	1.54	0.71
	Total	109	1.26	0.78
Mandible	Immediate	116	1.33	0.7
	Early	115	1.51	0.65
	Total	231	1.42	0.68
Both jaws	Immediate	178	1.23	0.73
	Early	162	1.52	0.67
	Total	340	1.37	0.71

SD = standard deviation.

the collar (2.8 mm – mean initial implant depth) was 1.57 and 1.28 mm in the immediate and early loading groups, respectively (Figure 2, time 0).

The analysis of the implant depth at baseline by an analysis of variance model revealed highly significant center effects, significant differences between the treatment groups, significant effects of the jaw, significant jaw  $\times$  center interactions, significant treatment  $\times$  jaw interactions, and nonsignificant treatment  $\times$  center interactions (Table 3).

#### Change of Crestal Bone Level

For both treatment groups, significant changes in crestal bone level over the 36-month study period occurred during the first 5 months postimplantation (Figures 2 and 3). A strong correlation between bone loss and initial implant depth was apparent (Figure 4), that is, deeper placement of the SLA/machined interface increased the likelihood of crestal bone loss. Mean unadjusted changes from baseline to 5 months postimplantation visit were  $0.82 \pm 0.88$  mm in the immediate group and  $0.56 \pm 0.73$  mm in the early group ( $p < .05^{32}$ ). After the initial bone remodeling phase, no further statistically significant bone loss was observed from 5 up to 36 months postimplantation (Figures 2 and 5 and Table 4). Mean unadjusted bone level changes between two consecutive follow-up visits varied between -0.01 and 0.06 mm in the immediate loading group and between -0.03 and 0.04 mm in the early loading group (negative values represent bone gain; see Table 4). The overall bone loss from 5 up to 36 months postimplantation was 0.076 and 0.006 mm for immediate and early



**Figure 2** Depth in millimeter of the SLActive/machined-surface interface relative to the proximal bone crests, from implant placement (baseline; time 0) up to 3 years. The bone remodeling period is visualized by gray background; the period from final restoration up to the 3-year follow-up visit is visualized by white background.

TABLE 3 Statistical Modeling of the Implant Depth at Baseline				
Effect	p Value			
Treatment group	.0001			
Center	<.0001			
Treatment $\times$ center interaction	.0947			
Jaw	.0001			
Treatment × jaw interaction	.0199			
Jaw $\times$ center interaction	.007			

loading groups, respectively. The dispersion of the changes in crestal bone level was close to a normal distribution. In the immediate loading group, this distribution seems to be slightly more inconsistent (see Figure 5). Furthermore, the relative frequency for clinically relevant bone loss (>2 mm) was nonsignificantly higher in the immediate compared with the early loading group at all points in time.

Of the implants that were analyzed at the 36-month follow-up visit, those in the early loading group (n = 23, 14.2%) were more frequently placed in type 1 bone, according to the Lekholm and Zarb criteria,<sup>35</sup> compared



**Figure 3** Digital radiographs from a patient treated with a single implant in the mandible in position 36 (World Dental Federation) and immediate loading. Bone remodeling was greatest up to 5 months postimplant placement, followed by stability of the crestal bone level over the ensuing 27 months. (A) Surgery. (B) Five months postimplant placement (insertion of final restoration). (C) One-year follow-up. (D) Two-year follow-up. (E) Three-year follow-up. (F) Intra-oral photograph of the same clinical case at 3-year follow-up.



**Figure 4** Correlation between implant depth at baseline and bone loss after 36 months. Negative bone loss implies bone gain. Negative depth of the SLActive/machined-surface interface implies bone contact to the machined neck of the implant.

with those in the immediate loading group (n = 11, 6.2%, Table 5). Implants placed in type IV bone were more frequent in the immediate loading group (n = 14, 7.9%) in contrast to the early loading group (n = 8, 4.9%). However, bone quality had no significant effect on crestal bone level change, indicating that bone quality seems not to be a major predictor of future bone loss (Table 6).

Clinically relevant bone loss (>2 mm) was more often observed in the maxilla (13%) compared with the mandible (3.6%). In addition, the difference in bone level change between the treatment groups was higher in the maxilla compared with the mandible at all points in time (Table 7). A GEE for clinically relevant bone loss with implant depth, jaw, and treatment group as independent variables showed a significant effect for the jaw only at the 12-month (p = .019) and 36-month (p = .012) follow-up visits, but at all visits for the implant depth (p < .001).

#### DISCUSSION

#### Implant Survival and Success

The present study confirms the results from previous clinical investigations that good outcomes can be obtained with immediate and early loading protocols in the posterior maxilla and mandible.<sup>36–40</sup> Implant survival rates 3 years after placement of implants with a chemically modified SLA surface were 97.4% and 96.7% in the immediate and early loading groups, respectively. Implants generally failed during the critical period

of osseointegration (within 90 days), except for one implant in the immediate loading group, which failed after the 1-year follow-up visit. One implant in the immediate loading group continuously exhibited periimplant radiolucency. Thus, the implant success rates were 96.9% and 96.7% in the immediate and early loading groups, respectively.

The results of this prospective study revealed no significant difference in implant survival and success rates between the two protocols up to 36 months following implant placement. These findings are in agreement with previous published reports showing no significant differences in implant failure rates between immediate and early loading protocols at least 1 year after placement.<sup>41–45</sup> However, possibly due to small sample sizes, the results of other studies showed a trend toward a higher risk of failures with early loading.<sup>46</sup> Another study comparing the long-term success of immediate occlusal versus early loading of implants placed in the posterior mandible of partially edentulous patients reported a survival rate of 85% for the immediate loading group versus 100% for the early loading group 3 years after implant placement.<sup>47</sup> The current study, one of the largest randomized, controlled clinical trials of its kind, involving over two hundred sixty patients and over three hundred eighty placed implants suggested that both loading protocols can be applied with equivalent predictability. Furthermore, implant survival and success rates could be maintained up to 3 years after placement, suggesting long-term success for both loading protocols. These findings are supported by



Figure 5 Distribution of crestal bone level changes in immediate and early treatment group at all assessment visits. SD = standard deviation.

after Remodeling between Serial Follow-Up Visits and in Total					
Time Spread	Treatment Group	n	Mean		
5- to 12-month	Immediate	167	0.06		
follow-up	Early	155	0.04		
12- to 24-month	Immediate	157	0.02		
follow-up	Early	149	0.00		
24- to 36-month	Immediate	155	-0.01		
follow-up	Early	140	-0.03		
Total bone loss (between	Immediate	155	0.076		
5- and 36-month	Early	140	0.006		
follow-up)					

**TABLE 4 Unadjusted Bone Level Changes (mm)** 

TABLE 6 Statistical Modeling of the Change in Crestal Bone Level from Baseline up to 36 Months – Analysis for Possible Significant Independent Parameters Using the Kenward-Roger Method

Effect	p Value
Treatment group	.2308
Center	<.0001
Number of implants per patient	.0797
Jaw	.4653
Treatment × bone quality interaction	.8128
Bone quality (categorial)	.8678
Jaw × treatment interaction	.1791
Implantation depth	<.0001
Time point	.5194
Treatment × time interaction	.6356

other comparable studies, such as that by Testori and colleagues,<sup>42</sup> where the 1-year survival rate in immediate nonocclusal versus early loading in edentulous patients could be maintained up to 5 years with no significant differences between the two protocols,<sup>48</sup> and that by Calandriello and Tomatis,<sup>49</sup> which showed similar results from a 5-year trial on immediate occlusal loading of single mandibular molars.

Primary implant stability is a prerequisite for the success of any loading protocol but is particularly critical for immediately and early-loaded implants.<sup>50,51</sup> Implant stability is thought to be partly dependent on the bone quality of the recipient site. However, of the 11 failures that occurred during this study, none occurred

in sites with type IV bone, yielding a 100% survival rate for implants placed in low-quality bone. Similar shortterm results, using the same chemically modified SLA implants, were obtained by Bergkvist and colleagues,<sup>52</sup> who showed no apparent differences in survival rates between immediately loaded implants in bone tissue of different densities. This is in contrast to results obtained with machined-surface implants, where lower survival rates have been observed in type IV bone.<sup>53,54</sup> This suggests that low bone density may not be a critical factor influencing long-term implant survival and success in immediate or early loading. Moreover, the novel surface

TABLE 5 Distribution of Implants According to Bone Quality (Divided for Maxilla and Mandible and Subdivided for Treatment)									
		I = Almost Homogenous Compact Bone		II = A Thick Layer of Compact Bone Surrounding a Core of Dense Trabecular Bone		III = A Thin Layer of Compact Bone Surrounding a Core of Dense Trabecular Bone		IV = A Layer of Compact Bone Surrounding a Core of Low-Density Trabecular Bone	
Jaw	Group	n	%	n	%	n	%	n	%
Maxilla	Immediate	1	1.6	27	43.5	27	43.5	7	11.3
	Early	3	6.4	20	42.6	22	46.8	2	4.3
	Total	4	3.7	47	43.1	49	45.0	9	8.3
Mandible	Immediate	10	8.6	63	54.3	36	31.0	7	6.0
	Early	20	17.4	59	51.3	30	26.1	6	5.2
	Total	30	13.0	122	52.8	66	28.6	13	5.6
Total	Immediate	11	6.2	90	50.6	63	35.4	14	7.9
	Early	23	14.2	79	48.8	52	32.1	8	4.9
	Total	34	10.0	169	49.7	115	33.8	22	6.5

TABLE 7 Unadjusted Change in Crestal Bone Levels from Baseline to 36 Months (mm)						
Visit	Jaw	n	Mean	SD		
5 months postimplantation	Maxilla	107	0.82	1.04		
	Mandible	214	0.64	0.69		
12-month follow-up	Maxilla	107	0.82	1.01		
	Mandible	215	0.71	0.78		
24-month follow-up	Maxilla	93	0.96	0.99		
	Mandible	213	0.63	0.8		
36-month follow-up	Maxilla	100	0.86	0.96		
	Mandible	195	0.67	0.77		

SD = standard deviation.

characteristics of chemically modified SLA may allow it to overcome the drawbacks of type III and IV bone. Although information about surgical technique modifications was not collected in this study, it is possible that some occurred in sites with poorer bone quality including underdrilling the osteotomies and no thread tapping.

#### Bone Level at Implant Placement

In this study, implant depth at baseline unexpectedly correlated with the type of loading protocol and the location within the jaw. One drawback of the study was that randomization into the immediate or early loading groups occurred before implant placement, potentially allowing biased implant placement by the clinicians depending on the loading group. Indeed, this resulted in implants being placed deeper for immediate and the maxilla compared with early loading and mandible, possibly aiming for maximum primary stability. Consequently, the interface between the rough surface and the machined collar of the implant was also placed deeper, which can have a negative impact on bone loss.55-58 However, as this bias effectively reflects the normal clinical setting, where a loading protocol is generally decided before surgery, any clinical significance of this observation is unlikely. This is further supported by the finding that survival as well as success rates obtained for both loading protocols were similarly high in this study.

In order to determine implant depth, radiographic analyses were performed at the mesial and distal aspects of each implant. Although standardized radiography is a sensitive and direct method for peri-implant bone level measurement, radiographs only reflect a twodimensional situation of the real situation in the patient and no information on the buccal and lingual aspects of an implant can be elucidated from the radiographs. Therefore, it could not be exactly concluded whether the implants were really placed deeper or whether this was required to account for correct implant placement at the buccal and lingual aspects. However, this possibility is unlikely given the high occurrence of implants placed deeper only in one loading group.

Even though all 19 centers that participated in the study faced a similar surgical treatment, the clinical situation was evaluated differently, causing a significant center effect. Deeper implant placement was centerdependent, and certain individual interpretations of the treatment protocol were evident, that is, some centers clearly distinguished between loading protocols and/or maxillary and mandibular implants, while others did not adapt their treatment method. Furthermore, differences in center-specific patient populations, despite well-defined inclusion/exclusion criteria, cannot be ruled out.

Overall, this complex pattern of effects on the implant depth (see Table 2) indicates that several independent factors were weighted individually by the physician in planning implant placement. Nevertheless, final treatment success was not dependent on the initial center-specific approach. This strongly supports the reliability of the system for immediate and early loading, allowing the clinicians flexibility in successful treatment of individual patients. In general, the depth of implant placement should follow the philosophy "as shallow as possible, as deep as necessary" as a compromise between primary stability and minimal bone resorption (see Figure 3).

## Change of Crestal Bone Level

The overall mean change in crestal bone level from implant placement to 36 months was  $0.88 \pm 0.82$  mm in the immediate loading group and  $0.57 \pm 0.84$  mm in the early loading group. The first few months after implant placement are the most active period in terms of bone remodeling and hence the most critical in regard of crestal bone level changes.<sup>59,60</sup> This is also evident from the current study where the greatest change in crestal bone levels occurred during the first 5 months after implant placement, with only minimal, nonsignificant bone loss of 0.076 and 0.006 mm for immediate and

early loading groups, respectively. Because the rough/ smooth interface of the implant was placed deeper in the bone in the immediate loading group, primary stability was further increased; however, the change in crestal bone level from baseline to 36 months was also significantly increased. Nevertheless, the average bone level in both groups remained above the rough/smooth interface and stabilized at similar heights above the rough/ smooth interface (see Figure 2). All values were well within the acceptable range for a clinically successful treatment outcome.

Bone loss of 2 mm or more occurred in only 7.2% of all cases and was slightly higher in the immediate group and in the maxilla; however, this was not statistically significant. Furthermore, bone quality had no impact on bone loss; an observation already previously reported by others.<sup>52</sup> Importantly, changes in bone levels were only apparent in the first 5 months after implant placement, with no further changes after final restoration (see Figures 2 and 3 and Table 4). A recent 5-year follow-up study with immediate occlusal loaded implants reported similar marginal bone level changes at 6 months after implant placement.<sup>49</sup> However, unlike in the present study, further marginal bone remodeling was apparent up to 3 years after implant placement. Similar observations on long-term bone loss up to 3 years after implant placement were also reported in a comparative study for immediately occlusal and earlyloaded implants.47

# CONCLUSIONS

The results demonstrated that implants with a chemically modified SLA surface are safe and predictable when used in immediate and early nonocclusal loading procedures in the posterior maxilla and mandible. Even in poor quality bone, the high survival and success rates were comparable with those achieved using conventional or delayed loading protocols at 3-year follow-up. The differences in bone level changes between immediate and early loading, although clinically insignificant, were influenced by implant depth at baseline. It appears that several independent factors are weighted individually by the physician in the planning of implant placement. Regardless of the loading protocol applied, the change in crestal bone level occurred mostly during the first 5 months after implant placement; after this bone remodeling period, crestal bone is stable at least until the 3-year follow-up visit.

# CONFLICT OF INTEREST STATEMENT

The authors have no conflicts of interest to declare.

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