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Marginal bone level change during sequential loading periods of partial edentulous rehabilitation using immediately loaded self-tapping implants: a 6.5-year retrospective study

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PURPOSE. A large number of studies have suggested the practicability and predictability of immediate implant function, but few studies have reported marginal bone level changes during sequential loading periods. The purpose of this study was to evaluate the marginal bone remodeling of immediately loaded self-tapping implants both at each time point and during each loading period between two time points. **MATERIALS AND METHODS.** The patients included in this retrospective study were treated with immediately loaded NobelSpeedy Replace implants between August 2008 and July 2009. Differences in the marginal bone level (MBL) at each time point and the marginal bone level change (ΔMBL) between two time points were analyzed with Bonferroni correction ($P < .05$). **RESULTS.** Overall, 24 patients (mean age, 47.3 ± 12.8 years) with 42 immediately loaded implants and a median follow-up of 6.5 years (IQR, 67.8 months) were included. The cumulative survival rate after 10 - 12 years was 95.2%. Continuous but slow marginal bone loss was observed during long-term follow-up. MBL at both 7.5 years and 11 years was significantly lower than that at loading, 6 months, 2 years and 4 years ($P < .05$). No bone loss difference was found in any period before 4 years of follow up ($P > .05$). The loading period of 4 years to 7.5 years showed the largest ΔMBL compared to those of other time periods ($P < .05$). **CONCLUSION.** Slight bone loss occurred continuously, and more radical changes of marginal bone can be observed during the period of 4-7.5 years. Thus, long-term effective follow-up of immediately loaded implants is needed. [J Adv Prosthodont 2022;14:133-42]

KEYWORDS
Marginal bone level change; Immediate loading; Partial edentulous rehabilitation; TiUnite; Anodized implants

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INTRODUCTION

Dental implants have been successfully applied to restore edentulous patients based on osseointegration theory over the past few decades.[1-3] Peri-implant bone level preservation is the key to implant success in long-term observation.[4,5]

The original surgical protocol required implants to remain submerged for a 3- to 6-month osseointegration period and required individuals to undergo the second surgical procedure to expose the implant; this could cause patient discomfort and inconvenience.[6,7] These disadvantages of the traditional protocol prompted the need for research on new improved approaches.

Immediate and early implant loading have been used to reduce the treatment time and to place an implant-supported fixed prosthesis in the shortest time possible after implant placement.[8-11] In the majority of these studies, primary implant stability was vital for successful osseointegration.[12,13] Implants with improved macroscopic design and microtextured surfaces may help reach the preferred level of primary stability and reduce the micromotion to achieve reliable osseointegration.[14,15] One such newly designed implant is the NobelSpeedy™ Replace implant (Nobel Biocare, Gothenburg, Sweden), which is characterized by internal tri-channel connection with engaging threads and a TiUnite anodized surface.[16] The self-tapping feature may ensure adjustable and extended preparation for reinforced mechanical anchorage and accelerated implant osseointegration, thus favoring expanded indications for applying immediate function.[17]

Many studies have shown the feasibility and predictability of immediate implant function using the aforementioned implant and have reported the marginal bone loss of implants at each time point.[16,18-21] It was reported that there is continued trend of marginal bone loss over time; in addition, in a study with a follow-up period of 20 years, over ten percent of the implants show more than 3 mm bone loss, with progressive bone loss in the first year.[4,5,22] However, few studies have reported marginal bone level changes during sequential loading periods of long-term follow-up.

The purpose of this retrospective study was to evaluate the marginal bone level at each time point and marginal bone level change during each loading period between two time points.

MATERIALS AND METHODS

The present study was designed as a retrospective and noninterventional study and reported according to STROBE guidelines. The study was approved by the Medical Ethics Committee of Hospital of Stomatology, Sun Yat-sen University (KQEC-2020-71-01) and conducted in full accordance with the Helsinki Declaration of 1975, revised in 2013.

The patients included in this retrospective study had complete medical records and received NobelSpeedy Replace implants between August 2008 and July 2009 at the Department of Oral Implantology, Guanghua School of Stomatology, Sun Yat-sen University. Clinical and radiographic data were collected at implant placement/immediate loading and at annual visits up to 12.1 years after immediate loading.

Patients satisfying the following inclusion criteria were recruited: (1) partial edentulous rehabilitation with healed alveolar bone using immediately loaded NobelSpeedy Replace implants; (2) an implant with a diameter of $\geq$ 3.5 mm and a length of $\geq$ 10 mm; (3) a final tightening torque of 35 - 45 N·cm without further rotation; and (4) an implant site free from extraction remnants. The exclusion criteria were (1) malocclusion or an unstable occlusal relationship; (2) severe bruxism or other destructive habits; (3) bone augmentation performed less than 6 months prior to implant installation; (4) ongoing active infections or endodontic or periodontal problems in teeth adjacent to the implant; and (5) fixed bridges connected to natural teeth.

Patients underwent routine clinical and radiographic examinations before surgery. The surgical procedures were performed under local anesthesia with articaine with epinephrine 1:100,000 (Produits Dentaires Pierre Rolland, Merignac, France). The implant site was prepared and the implant was placed according to the manufacturer's recommendations (NobelSpeedy Replace; Nobel Biocare AB, Gothenburg, Sweden). An insertion torque of $\geq$ 35 N·cm was the goal at the time of implant placement for immediate loading. Screw tapping was used only when the torque exceeded 45 N·cm. The implant neck was inserted at the bone crest level under direct vision, and cortical anchorage was performed whenever possible. After surgery, cefradine (Yangtze River Pharmaceutical Group, Taizhou, China), 0.5 g four times per day for 7 days; acetaminophen (anti-inflammatory/analgesic drug), one tablet six times per day for 1 to 3 days after surgery; and chlorhexidine gluconate 0.12% mouthwash, twice daily for 2 weeks, were prescribed.

Immediately after the implant placement, the immediate temporary abutments were connected to the implants with 35 N·cm torque. A transitional composite resin was injected into a prefabricated vacuum-formed template to fabricate a provisional abutment-crown prosthesis. Screw-retained restorations were applied. Any protrusive and lateral contact was prevented when the implants were initially loaded, while a lightly acentric contact was applied in maximum intercuspation. An acentric contact was gradually applied for the healing period of 3 - 4 months as the foundation of the definitive restorations.

After a healing period of 3 - 4 months, the soft tissue was stable and healthy and then the provisional abutment-crown unit was removed and replaced by a definitive screw-retained porcelain-fused-to-metal (PFM) restoration. For continuously edentulous patients with 2 or more implants placed at the same site and time, splinted restorations were applied both in the provisional and definitive restorations.

All patients were provided health promotion and education after surgery and restoration. Patients were checked constantly to maintain the recommended oral hygiene protocol. Peri-implant maintenance was applied yearly after final restoration.

Data were collected and evaluated from the original medical records by two independent researchers. Clinical and radiographic evaluations were performed at immediate loading (baseline), the first month, 3 months, final prosthesis delivery, 6 months and yearly thereafter (Fig. 1). The variables described below were recorded as study variables.

For each patient, age, sex (F/M) and smoking habits (Y/N) were evaluated at baseline. For implants at

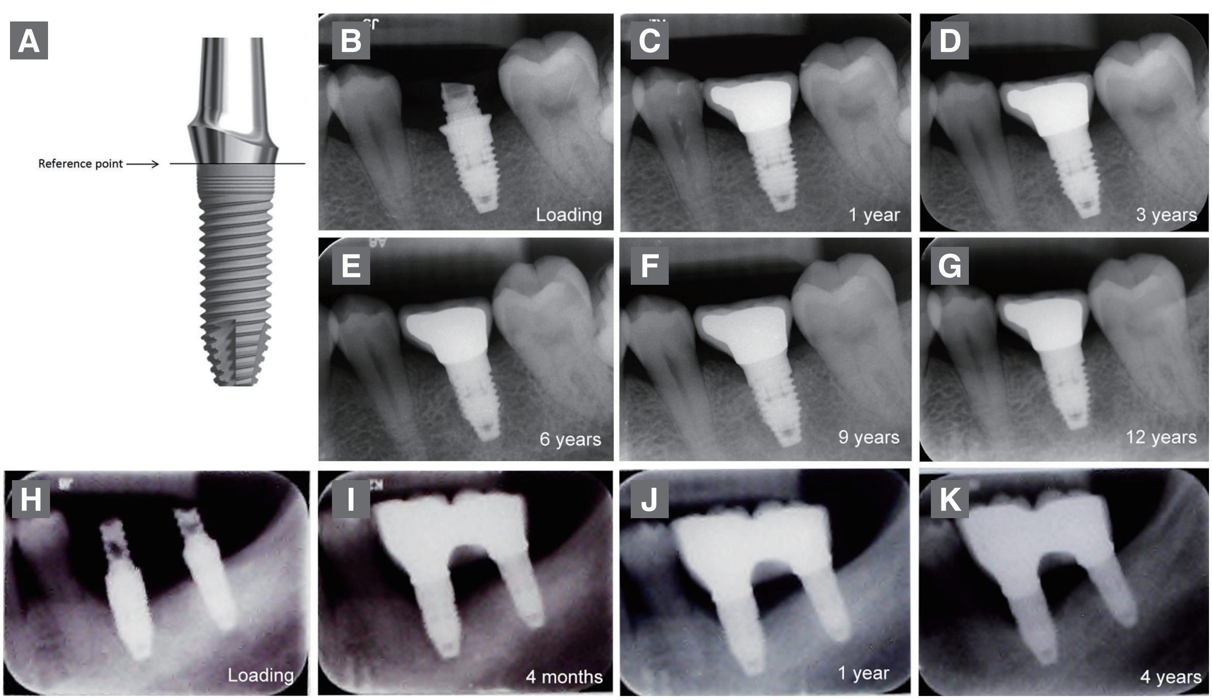

Fig. 1. Reference point and representative radiographic images. Implant-abutment connection for reference point (black arrow) (A). Radiographic evaluations of patient 1 at immediate loading (baseline) (B), 1 year (C), 3 years (D), 6 years (E), 9 years (F) and 12 years (G). Radiographic evaluations of patient 2 at immediate loading (baseline) (H), 4 months (I), 1 year (J), 4 years (K).

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baseline, the implant site (maxilla/mandible; anterior/posterior), implant type including implant length (mm) and diameter (mm), Lekholm & Zarb bone quality classification (Type I - IV), Lekholm & Zarb bone defect type (Type A - E), installation torque (N·cm) and implant stability quotient (ISQ) were examined.

At the follow-up visit, the implant stability quotient (ISQ) was also recorded at 3 months/final prosthesis delivery. An implant was considered to be surviving if the implant remained in the bone after prosthesis removal irrespective of clinical parameters. The Kaplan-Meier statistical method was used to calculate the survival rate.

Radiographic photos were obtained by Digora for Windows2.5 X-ray cone paralleling technique (Soredex, Helsinki, Finland). For the marginal bone level (MBL) at each time point and the marginal bone level change (ΔMBL) during sequential loading periods, radiographs were evaluated by calculating the mean distance of mesial and distal aspects of each implant ([mesial + distal]/2) from the implant/abutment junction (reference point, Fig. 1) to the first bone contact. Negative MBL numbers indicated that bone levels were apical to the reference point. Negative ΔMBL numbers indicated that marginal bone loss occurred during the loading period between two time points. Positive MBL and ΔMBL numbers signified bone gain.

Data were reported using descriptive statistics (mean, standard deviation, median and interquartile range) and were analyzed by two independent researchers using the SPSS 25.0 software package (SPSS Inc., Chicago, IL, USA). The Kruskal-Wallis test was used to determine the level of significance. Differences in MBL and ΔMBL among the time periods were analyzed with Bonferroni correction. The level of significance was set at $P < .05$.

Table 1. Patient demographics and implant characteristics

Varibles		
Patient demographics (n = 24)		
Age (Mean ± SD [Range])	47.3 ± 12.8 [22 - 73]	
Female/Male n (%)	8 (33.3%) F	16 (66.7%) M
Smoking n (%)	3 (12.5%) Yes	21 (87.5%) No
Implant characteristics (n = 42)		
Implant site n (%)	Maxilla 10 (23.8%)	Mandible 32 (76.2%)
	Anterior 12 (28.6%)	Posterior 30 (71.4%)
Implant type n (%)	Speedy NP 3.5 × 10	2 (4.8%)
	Speedy NP 3.5 × 11.5	1 (2.4%)
	Speedy NP 3.5 × 13	1 (2.4%)
	Speedy RP 4 × 10	18 (42.9%)
	Speedy RP 4 × 13	13 (30.9%)
	Speedy WP 5 × 10	4 (9.5%)
	Speedy WP 5 × 13	3 (7.1%)
Lekholm & Zarb bone quality classification n (%)	Type I	7 (16.7%)
	Type II	25 (59.5%)
	Type III	8 (19.0%)
	Type IV	2 (4.8%)
Lekholm & Zarb bone defect type n (%)	Type A	5 (11.9%)
	Type B	34 (81.0%)
	Type C	3 (7.1%)
	Type D	0
	Type E	0
Implant stability (Mean ± SD [Range])	Installation Torque	42.0 ± 4.6 [35 - 50] N·cm
	ISQ*(Baseline)	72.5 ± 6.5 [49 - 84]
	ISQ*(3 month)	74.7 ± 5.3 [66 - 84]

*ISQ = implant stability quotient.

RESULTS

Table 1 shows the characteristics of the patients and implants included in the study. A total of 24 patients (8 females, 16 males, mean age of 47.3 ± 12.8 years) with 42 immediately loaded NobelSpeedy Replace implants who had a median follow-up period of 6.5 years (IQR, 67.8 months) were included. Of these 24 patients, 12.5% (3 patients) were smokers. Of the 42 implants that these individuals had, 76.2% (32 implants) were placed in the mandible, and 71.4% (30 implants) were placed in the posterior mandible. The most common bone quality classification and bone defect type were Type II (59.5%) and Type B (81.0%), respectively. The implant length ranged from 10 to 13 mm, and the implant diameter ranged from 3.5 to 5 mm. At baseline, the installation torque and implant stability quotient were 42.0 ± 4.6 N·cm and 72.5 ± 6.5, respectively. The implant stability quotient increased to 74.7 ± 5.3 at 3 months.

Twenty-seven implants were followed for a minimum of 5 years after loading. For each survival time interval, the initial implants were lost to follow-up after 1 year time point (6 implants), 5 year time point (3 implants) and 10 year time point (17 implants). One implant failed to integrate at 2 months after loading, resulting in a cumulative survival rate of 97.6% between 1 month and 10 years after immediate loading. After the 10 year follow-up period, another implant failed due to severe marginal bone loss at 134 months, resulting in a decreased cumulative survival rate of 95.2%; the other 9 implants were stable with no reported failure (Table 2).

Continuous but slow marginal bone loss was observed during long-term follow-up. The mean MBLs at both 7.5 years and 11 years were significantly lower than those at loading, 6 months, 2 years and 4 years (P < .05). No bone loss difference in each loading period was found before 4 years of loading (P > .05) (Fig. 2). The mean MBL were -0.22 ± 1.27 mm (n = 42) at baseline and -2.02 ± 0.60 mm (n = 9) at 11 years after loading. The frequency distribution of MBL showed that the MBLs of all the implants varied at baseline but concentrated at approximately 1 - 3 mm after 10 - 12 years (Table 3).

The loading period of 4 years to 7.5 years showed the largest ΔMBL compared to those of other time periods (P < .05) (Fig. 3). ΔMBLs amounted to -0.33 ± 0.84 mm during implant insertion to 6 months (n = 41), 0.02 ± 0.58 mm during 6 months to 2 years (n = 35), 0.02 ± 0.67 mm during 2 years to 4 years (n = 30), -1.31 ± 0.94 mm during 4 years to 7.5 years (n = 26), and -0.24 ± 0.13 mm during 7.5 years to 11 years (n = 9). The frequency distribution results showed that 26.9% of the implants exhibited more than 1 mm bone loss from 4 to 7.5 years; hence, this period exhibited the most radical change (Table 4).

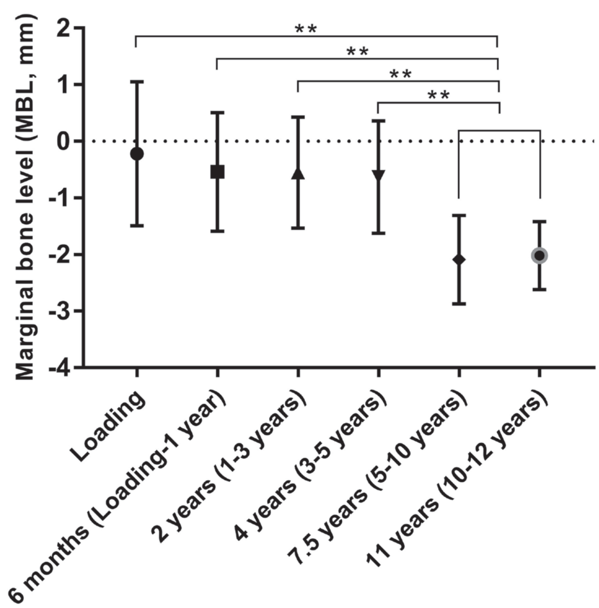

Fig. 2. Marginal bone level (MBL) at each time point including loading (n = 42), 6 months (n = 41), 2 years (n = 35), 4 years (n = 35), 7.5 years (n = 27) and 11 years (n = 9). (** P < .01, * P < .05)

Table 2. Cumulative survival rate for implants with an immediate function protocol

Survival time interval	Initial implants	Failed implants	Censored implants	Cumulative survival rate (%)
Loading - 1 month	42	0	0	100.0
1 - 3 months	42	1	0	97.6
3 months - 1 year	41	0	0	97.6
1 - 3 years	35	0	0	97.6
3 - 5 years	35	0	5	97.6
5 - 10 years	27	0	0	97.6
10 - 12 years	10	1	2	95.2

Table 3. Mean and frequency distribution of marginal bone level (MBL, mm) in relation to the implant/abutment junction at the different time intervals

	Loading		6 months (Loading - 1 year)		2 years (1 - 3 years)		4 years (3 - 5 years)		7.5 years (5 - 10 years)		11 years (10 - 12 years)	
Mean	-0.22		-0.54		-0.55		-0.63		-2.09		-2.02	
SD	1.27		1.05		0.98		0.99		0.78		0.60	
n	42		41		35		35		27		9	
	n	%	n	%	n	%	n	%	n	%	n	%
MBL ≥ 3.0	1	2.4	1	2.4	0	0	0	0	0	0	0	0
2.0 ≤ MBL < 3.0	1	2.4	0	0	0	0	0	0	0	0	0	0
1.0 ≤ MBL < 2.0	4	9.5	0	0	3	8.6	1	2.9	0	0	0	0
0 ≤ MBL < 1.0	12	28.6	9	21.9	5	14.2	11	31.4	0	0	0	0
-1.0 ≤ MBL < 0	14	33.3	19	46.3	17	48.6	9	25.7	1	3.7	0	0
-2.0 ≤ MBL < -1.0	5	11.9	8	19.5	7	20.0	10	28.6	11	40.7	5	55.6
-3.0 ≤ MBL < -2.0	5	11.9	4	9.9	3	8.6	4	11.4	12	44.5	4	44.4
MBL < -3.0	0	0	0	0	0	0	0	0	3	11.1	0	0

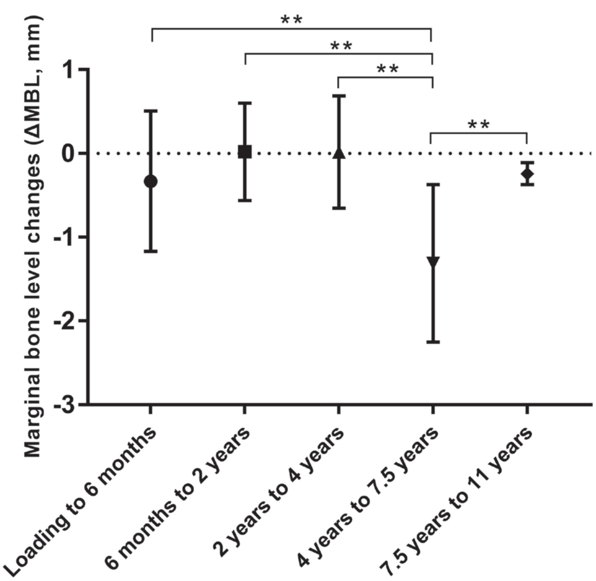

Fig. 3. Marginal bone level change (ΔMBL) based on paired baseline and follow-up radiographs including loading to 6 months (n = 41), 6 months to 2 years (n = 35), 2 years to 4 years (n = 30), 4 years to 7.5 years (n = 26) and 7.5 years to 11 years (n = 9). (** *P* < .01, * *P* < .05)

DISCUSSION

The present study evaluated the marginal bone remodeling of 42 immediately loaded implants both at each time point and during each loading period between two time points; the median follow-up time was 6.5 years. One implant failed to integrate at 2 months, and another implant failed due to severe marginal bone loss after 10 - 12 years, resulting in a decreased cumulative survival rate of 95.2%. The initial implants were lost to follow-up after multiple time points; thus, the aforementioned cumulative survival rate may be lower in view of the possible implant failure for those missed follow-up. Continuous but slow marginal bone loss was observed during long-term follow-up. The mean marginal bone levels at both 7.5 years and 11 years were significantly lower than those at loading, 6 months, 2 years and 4 years ($P < .05$). No bone loss difference of each loading period was found before 4 years of follow-up ($P > .05$). The loading period of 4 years to 7.5 years showed the largest marginal bone change compared to other time periods ($P < .05$).

The present study indicated that implant restorations that underwent the immediate loading protocol showed the same clinical outcomes as those that underwent the staged loading protocol.[23,24] In this study, the early implant failure rate was 2.4%, and

Table 4. Mean and frequency distribution of marginal bone remodeling (ΔMBL, mm) calculated from paired baseline and follow-up radiographs after sequential loading periods

	Implant insertion to 6 months		6 months to 2 years		2 years to 4 years		4 years to 7.5 years		7.5 years to 11 years	
Mean	-0.33		0.02		0.017		-1.31		-0.24	
SD	0.84		0.58		0.67		0.94		0.13	
n	41		35		30		26		9	
	n	%	n	%	n	%	n	%	n	%
ΔMBL ≥ 1	2	4.9	1	2.9	3	10	3	11.5	0	0
0 ≤ ΔMBL < 1	12	29.3	20	57.1	11	36.7	6	23.1	0	0
-1.0 ≤ ΔMBL < 0	20	48.8	12	34.3	14	46.7	10	38.5	9	100
-2.0 ≤ ΔMBL < -1.0	6	14.6	2	5.7	2	6.6	7	26.9	0	0
-3.0 ≤ ΔMBL < -2.0	0	0	0	0	0	0	0	0	0	0
ΔMBL < -3.0	1	2.4	0	0	0	0	0	0	0	0

the later implant failure rate was 4.8% after 10 years. Higher primary stability, nonocclusally loaded temporary restorations during a 3-month healing, splinted implants, and biocompatible prosthetic materials may reduce the risk of implant failure.[25-28] For partial prostheses, implants were splinted to support a preferable force distribution to the bone-implant interface under functional occlusion. The lateral forces were reduced by restricting working side contacts to the canines to retain implant micromotions.[29] Considering loading protocols of dental implants, varied clinical outcomes of immediately loaded implants were reported with higher failure rates in individuals with single-tooth replacement[30] or positive results were reported for immediately loaded single-tooth implants.[31,32]

An ISQ of 60 has been demonstrated to be a lower limit for successful implementation of immediate loading implants.[13,33] In the present study, the resonance frequency measurements revealed a high mean insertion ISQ value of 72.5 (range 49 to 84), which was slightly higher at the 3 month follow-up. There was another increase in ISQ that commonly occurred during the months immediately following loading, after which the ISQ value then remained steady.[34] A linear correlation between torque and insertion ISQ value was found, indicating that RFA measurements are consistent with other means of primary stability parameters, such as insertion torque.[13,35] ISQ and insertion torque during implant insertion were both sufficient to reach a conclusive decision to evaluate immediate loading in the present study.

The mean marginal bone loss was observed during long-term follow-up period. To our surprise, we found that bone gain was found in the period from 6 months to 2 years and from 2 years to 4 years. Many studies have shown the accumulated mean marginal bone loss of implants,[36-38] but few data on the accumulated mean marginal bone gain are available. A previous study evaluated the 10 year clinical results of TiUnite immediate loading implants in both post-extracted and healed sites and showed that the mean marginal bone loss was 0.93 mm, 1.26 mm, and 1.36 mm at the 1 year, 2 year, and 3 year follow-ups, respectively.[39] However, a mean marginal bone level increase was detected in the present study and in a study evaluating the success rate of immediately loaded single-tooth ITI solid plasma-sprayed implants. The study revealed an average increase of 0.53 mm (-0.83 to +1.54 mm) from implant placement to the final examination.[40] In a study of immediate functional loading for a single-tooth implant, bone gain occurred in over half of all implants during the follow-up from 1 to 5 years,[41] which is consistent with our research. The most pronounced bone loss was observed during 4 years to 7.5 years, the first 6 months, and 7.5 years to 11 years in the present study. Most relevant studies evaluated early bone loss of implants,[42,43] but bone remodeling progress changes from implant insertion to the time of osseointegration establishment.

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Thus, immediate loading may influence early bone change alone, and subsequent bone loss may occur after final restoration. TiUnite implants showed greater first-year crestal bone loss than the other modern implants but reached a relatively steady state without further notable bone loss on an annual basis.[44,45] In the present study, pronounced bone loss was also observed from 4 years to 7.5 years, and a stable mean bone level of 2 mm, which may be coordinated with biological width, was ultimately achieved. Further study is needed to discover the causes of these findings. Hence, a controlled clinical study design with different initial biological widths will be necessary to substantiate the present data.

CONCLUSION

Within the limitations of the study, partial edentulous rehabilitation using immediately loaded self-tapping implants has been shown to be a successful treatment. However, slight bone loss occurred continuously, and more radical changes of marginal bone could be observed during the period of 4 - 7.5 years. Thus, long-term effective follow-up of immediately loaded implants is needed.

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