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Original Article

Implant stability and marginal bone level changes: A 2-year prospective pilot study

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KEYWORDS
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Marginal bone loss (MBL)

Abstract *Background/purpose:* Implant stability is crucial for successful osseointegration. Marginal bone level is considered an important indicator of long-term implant success and stability. The purposes of this study were to investigate 1) the effect of age, gender, bone density, implant length, and implant diameter on insertion torque (IT), primary implant stability quotient (ISQ), and secondary ISQ, 2) the impact of age, gender, bone density, implant length, implant diameter, IT, and ISQ on marginal bone loss (MBL).
Materials and methods: Ninety patients who needed implant therapy were enrolled and overall 156 implants were installed to support single crowns. IT and ISQ were recorded for all implants during surgery and ISQ measurements were performed at follow-up visits. Age, gender, bone density, implant length and diameter were also registered. Radiographic evaluation of MBL was performed postoperative immediate (baseline), 3, 6, 9, 12, 18, and 24 months using digital periapical radiographs.
Results: Age had little effect on IT and primary ISQ ($P > 0.05$). Generally, males had higher IT and primary ISQ, but no significant differences between genders were detected. Bone density

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showed significant effects on IT and primary ISQ. Correlation analysis revealed high positive correlations between IT/bone density and primary ISQ/implant diameter. Significant impacts of bone density and IT on MBL were found.
Conclusion: Implant diameter had a more profound impact than length on IT/primary ISQ. Bone density played a considerable role in IT/primary ISQ determination. Bone density and IT had more impacts than primary ISQ on MBL.

Introduction

Implant stability has been regarded as an important index to evaluate the extent of implant-bone anchorage and osseointegration. Achieving and maintaining adequate implant stability is critical to functional and satisfactory treatment outcomes. Implant stability is usually divided into two phases: primary stability and secondary stability. Primary stability originates from mechanical connection with bone. It may be influenced by bone density and quantity at the implant site, surgical techniques, implant geometry, implant length and implant diameter.[1] Secondary stability develops from regeneration and remodeling of peri-implant bone and tissue after implantation and is affected by primary stability, bone formation and remodeling.[2]

Previous methods for evaluating stability include histologic or histomorphometric analysis, tensional test, and reverse torque.[3,4] These methods, however, are destructive and may have ethical issues. Less invasive approaches such as percussion test,[5] insertion torque measurement,[6] and resonance frequency analysis (RFA)[1,2,4,6,7] have been proposed. The noninvasive, quantitative, repeatable, and reliable characteristics of RFA have greatly increased its popularity in clinical application.[8]

The currently most used methods to evaluate implant stability are insertion torque (IT) and implant stability quotient (ISQ). Researches have indicated that IT measures rotational stability while ISQ reflects axial stability. Therefore, combining these two measurements may increase their objectivity and accuracy in the determination of implant stability.[4,6,9]

Long-term follow-up of implants is essential to obtain information and analyze the reasons for implant success and failure. Implant marginal bone loss (MBL) is an important indicator for assessing the stability of peri-implant tissue.[10] Proper bone quality and quantity contribute to successful implant treatment. Stability of the peri-implant hard and soft tissues is crucial to long-term maintenance.[11] Marginal bone resorption, however, is common around two-piece implants exposed to the oral environment and has been explored extensively in the literature.[12] Untreated MBL may progress into advanced peri-implantitis and eventual implant loss.[13]

The exact etiology of peri-implant MBL remains unclear. Initial MBL has been ascribed to several possible causes, one of which is high mechanical stress generated during implant insertion (high IT).[10] Some studies have indicated that the height and density of peri-implant bone significantly affect ISQ measurements.[14,15] MBL may result in reduced ISQ values.[16] Previous studies have discussed the debate about several variables influencing MBL, but have not been conclusive.[17,18] Therefore, investigating the potential causes of MBL may help to clarify the issue, thereby reducing MBL for better esthetics and stable treatment outcomes.

This study aimed to explore implant stability measured as IT and ISQ and to investigate the effects of age, gender, bone density, implant diameter, and implant length on IT and ISQ measurements. The effects of age, gender, bone density, implant diameter, implant length, IT, and ISQ on MBL were also examined.

Materials and methods

Subject selection

The present study was conducted at the Department of Dentistry, Kaohsiung Medical University Hospital, Kaohsiung, Taiwan. Ethical clearance was obtained and the study protocol was approved by the institute review board of Kaohsiung Medical University Hospital (KMUH-IRB-20140124). Patients who sought implant therapy were screened for this prospective study. Each eligible patient must be partially edentulous and meet the need for a single implant-supported crown.

Ninety participants were enrolled according to the following criteria: 1) age above 20 years, 2) no severe system diseases known to alter bone metabolism, 3) nonsmoker or no heavy smoking (<1 pack/day), 4) controlled periodontal diseases and good oral hygiene, 5) presence of ≧ 2 mm keratinized tissue. The exclusion criteria were: 1) active infection at implant sites, 2) severe bruxism or clenching habits, 3) uncontrolled periodontal diseases or poor oral hygiene, 4) drug or alcohol abuse, 5) pregnancy, and 6) need for bone augmentation. All subjects were informed of the study's aims and signed informed consent.

Preoperative radiographic evaluation

A panoramic radiograph, a periapical film, and cone beam computed tomography (CBCT) were collected for preoperative evaluation. CBCT scanning of the jaw was performed after placing a customized surgical template. Implametric software (NNT viewer®; NewTom, Verona, Italy) was applied to plan the implants on CBCT data (Fig. 1). The

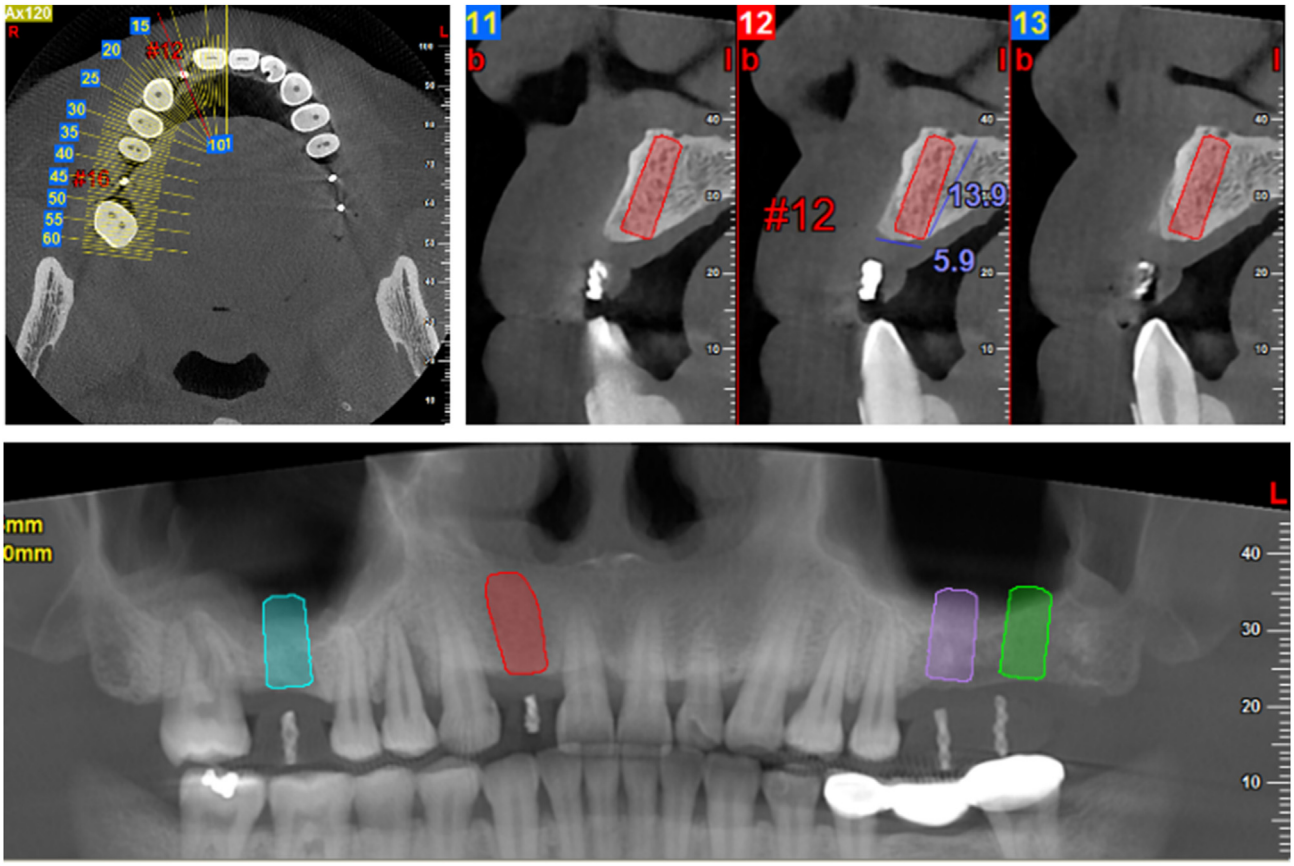

Figure 1 Cone beam computed tomography images and the preoperative planning.

software allows the clinician to select appropriate lengths and diameters of implants to be inserted and to measure the mean bone density at the implant sites in Hounsfield units.

Surgical procedures

Internal hex implants (Seven®; MIS, Shlomi, Israel) were installed at healed sites after a standard drilling protocol. The same dentist graded bone density (D1 to D4) according to the classification of Misch[19] via preoperative CBCT examination and placed all implants. Besides, the bone density was verified through drilling tactile during osteotomy according to the classification of Lekholm and Zarb.[20] The implants were placed using a surgical motor (MCU Control Unit, W&H Dentalwerk GmbH, Bürmoos, Austria) at a speed of 30 rpm.

Insertion torque measurements

The installation of implants was accomplished using a torque wrench (MIS, Shlomi, Israel), which allowed the record of the final insertion torque value. The implant platform was placed at an equal position to the buccal crest.

Implant stability quotient

RFA measurements were obtained immediately after implant placement (primary ISQ) and postoperative 2, 3, 4, 5, 6, 9, 12, 18, and 24 months (secondary ISQ) using the Osstell® Mentor (Integration Diagnostics AB, Göteborg, Sweden). A sensor called Smartpeg™ (Integration Diagnostics AB) was screwed onto the implant fixture for data analysis (Fig. 2). RFA values are expressed in a quantitative unit named the implant stability quotient (ISQ), which ranges from 1 to 100. A high ISQ value represents high stability, whereas a low value denotes low implant stability. Every implant was measured each time in four different directions (buccal, lingual/palatal, mesial, and distal) and the mean of the 4 values was recorded.

Figure 2 The Osstell® Mentor and Smartpeg™ transducer were used to measure implant stability quotient.

Definitive crowns fabrication

All implant-supported crowns were delivered postoperative 4 months—5 months. To facilitate ISQ measurements, screw-retained crowns or cement-retained crowns with lingual/palatal notches were fabricated for easier retrievability.

Marginal bone loss

Periapical radiographs were taken following implant placement and postoperative 3, 6, 9, 12, 18, and 24 months for evaluation of marginal bone loss (MBL). Standardized radiographs using a customized positioning jig for each participant and the paralleling technique were conducted to accurately assess MBL. Radiographic magnification was calibrated based on the ratio of image/actual length of the implant fixture installed. The distance between the implant platform and the marginal bone was measured (Fig. 3). An average of mesial and distal values for each fixture was regarded as the MBL at the scheduled follow-ups.

Statistical analysis

SPSS Statistics 22.0 (SPSS Inc., Chicago, IL, USA) was used for data analysis. T-test and analysis of variance (ANOVA) for multiple pairwise comparisons were performed to determine statistically significant differences. Pearson and Spearman correlation coefficients were used to determine the relationships between the parameters. P values ≤ 0.05 were considered to be significant.

Results

A total of 156 implants were installed in 90 patients (42 males and 48 females, mean age 55.8 ± 11.4 years, range 28—76 years) to support fixed single crowns. The distributions of the implants were as follows: 30 in maxillary anterior region (19.2%), 42 in maxillary posterior region (26.9%), 28 in mandibular anterior region (18%), and 56 in mandibular posterior region (35.9%). The distributions of implants according to bone density were as follows: D1 bone 10 (6.4%), D2 bone 51 (32.7%), D3 bone 67 (42.9%), and D4 bone 28 (18%). Implant lengths of 10, 11.5, and 13 mm and diameters of 3.3, 3.75, 4.2, and 5 mm were used. During the 2-year follow-up, neither mobility nor major complications (e.g., screw or fixture fracture) were found, which resulted in a 100% survival rate of the implants.

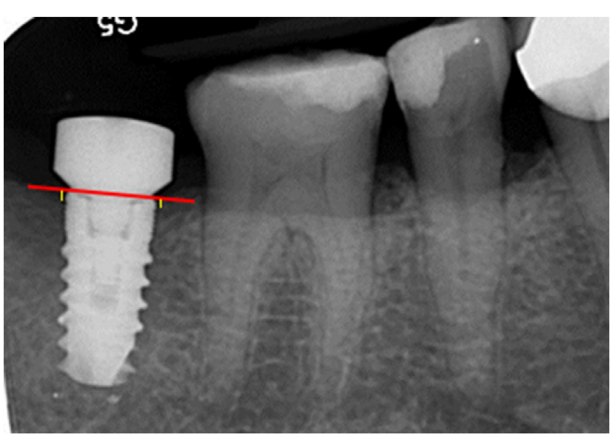

Figure 3 Radiographic measurement of marginal bone loss. The red line indicated the implant platform. Lengths of the yellow lines were averaged to represent the marginal bone loss.

The mean IT and primary ISQ of implants in different ages, genders, bone density, implant diameters, and implant lengths are shown in Table 1. Patients over 55 years of age had lower IT and primary ISQ values than younger subjects. However, the differences in mean IT and primary ISQ between the age groups were not statistically significant ($P > 0.05$).

The discrepancies in IT and primary ISQ between genders were insignificant. Males showed higher IT and primary ISQ values than females, but no significant differences between genders were found ($P > 0.05$).

The mean IT was 33.75 ± 6.82 Ncm (range, 20 to 50). Significant differences in IT were revealed between various bone types. Implants placed at sites with D1 or D2 bone density had significantly higher IT than those in D3 or D4 regions. Implants with larger diameters had significantly higher IT values. Implant length, however, had no significant impact on IT.

The mean ISQ for primary stability measurement was 65.06 ± 6.28 (range, 53 to 85). Obvious primary ISQ discrepancies were found between high bone density (D1 or D2) and D4 bone density. Significant differences in primary ISQ between the diameters were also noted ($P < 0.05$). Implants with larger diameters demonstrated higher primary ISQ. The primary ISQ did not differ significantly between the various implant lengths.

Fluctuations in the mean secondary ISQ values were noted postoperative 2 months—6 months (Table 2). No significant changes in secondary ISQ postoperative 6 months and thereafter were found. The differences in secondary ISQ for age, gender, bone density, and implant length were small postoperative 6 months—24 months. Implant diameter had more effect on secondary ISQ but the discrepancies were not significant and within 4 ISQ_S between the four diameters postoperative 9 months and thereafter.

Correlation analysis revealed high positive correlations between IT/bone density, and primary ISQ/implant diameter ($r = 0.836$ and 0.772, respectively). Moderate positive correlations between IT/implant diameter, IT/primary ISQ, and primary ISQ/bone density were observed ($r = 0.684$, 0.602, and 0.529, respectively). A weak correlation ($r = 0.438$) existed between primary ISQ and implant length. In addition, a very weak correlation ($r = 0.217$) between IT and implant length was found.

Marginal bone loss was measured at postoperative immediate, 3, 6, 9, 12, 18, and 24 months as shown in Fig. 4. Although a statistically significant difference was noted between the two time points 3 and 6 months, the amount of MBL during this period was so tiny that the difference might not be clinically significant. Besides, no significant differences in MBL postoperative 1 year could be detected.

Statistical analysis revealed no significant impact of age, gender, implant length, implant diameter, and primary ISQ on MBL. High positive correlations were observed between bone density/MBL and IT/MBL (r = 0.826 and 0.794,

Table 1 The insertion torque (IT) and primary implant stability quotient (ISQ) by age, gender, bone density, implant diameter, and implant length.

	Number	IT (Ncm) (mean ± SD)	Primary ISQ (mean ± SD)	IT *P* value	Primary ISQ *P* value
Age (year)				0.462	0.377
≥55	52	32.69 ± 4.06	64.04 ± 6.32		
<55	38	35.20 ± 5.18	66.46 ± 5.25		
Gender				0.257	0.162
Male	42	34.82 ± 8.16	66.48 ± 5.32		
Female	48	32.83 ± 6.51	63.85 ± 7.14		
Bone density[a]				0.014*	0.027*
D1	10	47.25 ± 6.92	78.47 ± 6.71		
D2	51	40.81 ± 7.63	68.49 ± 8.03		
D3	67	30.79 ± 4.61	63.95 ± 7.26		
D4	28	23.16 ± 8.20	56.68 ± 5.87		
Implant diameter (mm)				0.032*	0.029*
3.3	15	29.51 ± 7.59	60.18 ± 7.65		
3.75	57	31.62 ± 6.55	63.20 ± 8.52		
4.2	64	34.63 ± 5.24	65.14 ± 5.29		
5	20	40.17 ± 7.85	73.77 ± 4.23		
Implant length (mm)				0.575	0.186
10	61	32.06 ± 7.95	63.78 ± 6.88		
11.5	55	34.28 ± 6.91	64.86 ± 6.24		
13	40	35.60 ± 4.23	67.29 ± 7.81		

[a] According to the classification of Misch.[19]
Ncm, Newton centimeter; SD, standard deviation; *, statistical significance ($P < 0.05$).

respectively). A moderate negative correlation was found between secondary ISQ and MBL ($r = -0.581$).

Discussion

Proper implant stability contributes to osseointegration. Careful monitoring of implant stability with objective and qualitative methods helps clinicians to determine proper timing for loading.[21] Combining IT and RFA to assess primary implant stability may better reveal true implant stability.[6,22] Insertion torque has been an easy and inexpensive way to measure implant stability. However, it can only be used during implant placement and cannot evaluate secondary stability after bone growth and remodeling.[4,9]

Resonance frequency analysis (RFA) of implant stability was first proposed by Meredith in 1996.[23] It is a noninvasive and safe analytical tool for measuring implant stability at different time points with high reliability.[24] RFA has been introduced into many basic researches to improve devices and has attracted considerable scientific interest.[25,26] Application of RFA to assess implant stability during any period, to evaluate the effect of various types of loading, and to early diagnose implant failing can benefit clinical implant therapy and follow-ups.[8,24,27] Together with IT measurement, RFA may provide more accurate and valuable information about the status of bone-implant interface and real implant stability.[6,9,28]

One of the disadvantages of RFA is the need for an analyzer and transducers, which makes the method relatively expensive. Moreover, the transducer must be attached to the implant before performing RFA. Additional time is required to remove and reposition implant-supported restorations to monitor implant stability with the device.

Factors influencing the measurement of implant stability may include age, gender, bone density and volume, implant diameter, implant length, implant geometry, implant surface characteristics, and surgical technique.[1,2,23,27] Most researchers have agreed on some of the above factors, like bone density, bone quantity, and surgical technique.[2,6,14,29,30] However, the impact of implant length and diameter on stability measurement remains controversial.[18,25,26,31] Sim and Lang[25] found that ISQ values were influenced by bone structure and implant length. Han and colleagues[26] revealed that neither implant diameter nor implant surface modifications affected ISQ. Noaman and Bede[31] claimed that implant diameter had a favorable effect on implant stability, whereas implant length had no effect. This present study found a high positive correlation between implant diameter and primary ISQ, which is similar to the study by Noaman and Bede.

To date, there is no absolute ISQ cutoff value for all implant systems to distinguish implant failure and success. Variables influencing ISQ measurement may increase the difficulty and diversity in developing a critical value, which predicts long-term implant prognosis.[32] Tözüm et al.[33] and Glauser et al.[34] recommended that obvious and progressive decline in ISQ values is linked with failed implants. However, low ISQ values do not always lead to implant failure.[32] RFA measurements need to be repeated over longer periods for better monitoring and analysis of implant stability. Decreased stability of implants with low ISQ values may prompt clinicians to closely monitor and unload implants while looking for potential problems until stability is restored. Conversely, decreased stability in the first 3 months of healing for implants with high ISQ values is usually a common phenomenon and does not need changes in routine follow-ups.[2]

Table 2 The secondary implant stability quotient (ISQ) by age, gender, bone density, implant diameter, and implant length.

	n	Secondary ISQ									
		2 months	3 months	4 months	5 months	6 months	9 months	12 months	18 months	24 months	*P* value
Age (year)											0.631
≥ 55	52	66.17 ± 5.26	68.83 ± 6.81	69.12 ± 5.08	72.53 ± 5.75	73.22 ± 6.04	73.27 ± 5.12	73.96 ± 5.80	73.29 ± 5.47	74.55 ± 5.31	
< 55	38	67.52 ± 7.11	69.24 ± 6.92	71.08 ± 7.42	72.55 ± 6.24	74.46 ± 6.33	74.97 ± 5.47	74.54 ± 6.09	74.26 ± 5.72	75.27 ± 5.85	
Gender											0.482
Male	42	67.22 ± 4.05	69.16 ± 5.22	70.48 ± 5.81	72.29 ± 6.11	73.55 ± 6.40	74.82 ± 5.36	74.58 ± 6.12	75.80 ± 5.73	75.13 ± 4.05	
Female	48	65.19 ± 6.24	66.94 ± 7.05	68.53 ± 6.55	70.06 ± 4.24	70.92 ± 7.11	72.18 ± 6.58	73.25 ± 4.96	73.91 ± 6.47	74.36 ± 6.10	
Bone density[a]											0.239
D1	10	72.52 ± 7.01	72.31 ± 6.58	73.24 ± 7.17	74.22 ± 6.29	74.18 ± 5.73	73.81 ± 7.12	74.33 ± 5.39	73.87 ± 5.15	75.22 ± 5.48	
D2	51	70.65 ± 6.26	71.29 ± 7.21	72.66 ± 5.83	72.46 ± 6.02	73.35 ± 5.64	73.66 ± 6.26	74.25 ± 7.10	74.51 ± 5.60	73.89 ± 6.15	
D3	67	65.94 ± 5.82	69.27 ± 6.02	70.69 ± 6.10	71.04 ± 5.58	71.93 ± 6.35	72.54 ± 5.46	73.31 ± 6.09	74.12 ± 5.93	74.03 ± 6.12	
D4	28	60.17 ± 7.25	65.24 ± 5.27	67.44 ± 6.53	68.73 ± 7.09	69.27 ± 6.38	70.49 ± 6.23	71.57 ± 5.88	72.46 ± 6.49	72.84 ± 5.73	
Implant diameter (mm)											0.194
3.3	15	63.35 ± 5.81	64.28 ± 4.17	66.02 ± 6.24	69.24 ± 5.52	70.33 ± 6.05	72.16 ± 5.88	73.05 ± 6.21	73.28 ± 5.26	73.31 ± 6.04	
3.75	57	66.97 ± 7.55	67.32 ± 8.02	68.60 ± 6.51	70.22 ± 5.83	71.82 ± 6.32	72.87 ± 7.05	73.87 ± 5.92	74.07 ± 7.13	74.26 ± 6.23	
4.2	64	68.22 ± 7.03	69.75 ± 5.66	70.28 ± 5.73	71.97 ± 5.36	73.04 ± 6.11	74.29 ± 5.02	74.55 ± 6.28	74.42 ± 6.79	74.80 ± 5.65	
5	20	74.16 ± 6.71	75.47 ± 7.11	75.61 ± 7.38	77.25 ± 5.68	76.28 ± 5.73	76.02 ± 6.04	76.63 ± 5.95	76.58 ± 5.20	76.39 ± 5.28	
Implant length (mm)											0.461
10	61	64.55 ± 3.95	66.17 ± 5.38	68.35 ± 7.02	70.59 ± 6.68	71.36 ± 5.85	72.54 ± 4.87	73.11 ± 6.24	73.39 ± 5.59	74.28 ± 4.81	
11.5	55	66.28 ± 5.26	68.31 ± 6.42	69.83 ± 5.45	71.84 ± 6.33	72.77 ± 6.04	74.02 ± 5.72	74.48 ± 4.97	74.16 ± 6.18	74.19 ± 568	
13	40	66.63 ± 5.71	68.95 ± 5.27	70.11 ± 6.37	72.61 ± 5.36	73.08 ± 7.21	74.65 ± 6.63	74.59 ± 7.32	75.02 ± 6.22	74.87 ± 6.73	

[a] According to the classification of Misch.[19]

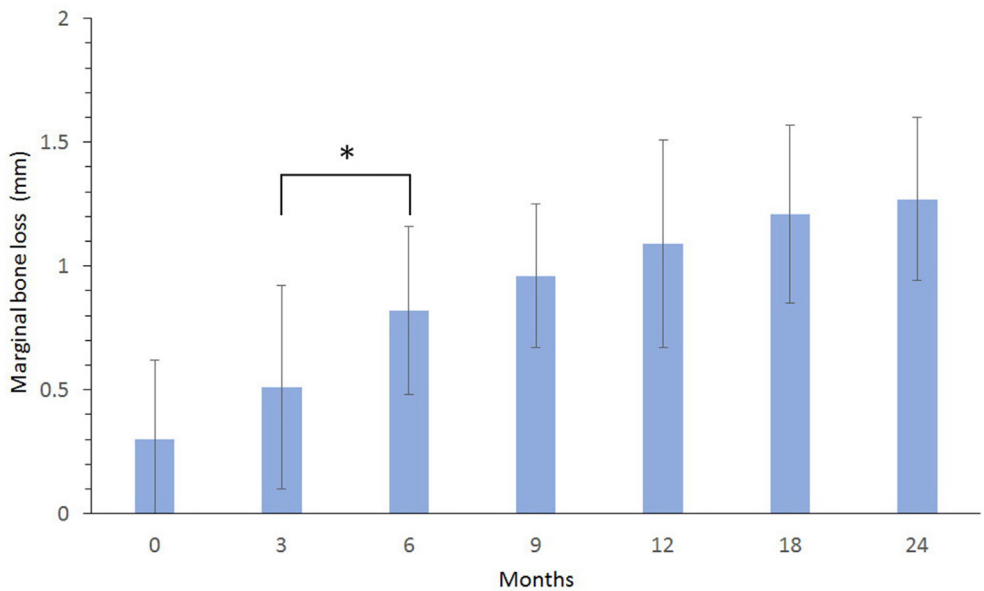

Figure 4 Marginal bone loss immediately, 3, 6, 9, 12, 18, and 24 months postoperatively. *: statistical significance ($P < 0.05$).

Maintenance of peri-implant bone level is important for function, esthetics, and long-term implant success. Because the marginal bone level determines the gingival level, implant replacement in patients with high smile line is challenging, particularly in the esthetic zone.

The exact etiology of MBL around implants is unknown and multiple factors have been hypothesized to explain this phenomenon. The kind of implant (single piece or two pieces),[12] the location and type of the implant—abutment junction (IAJ) and the solidity of the IAJ,[35] the implant design (machined smooth neck versus rough threaded neck),[36] the abutment design (whether there is a platform switch),[37] screw loosening or residual cement left in peri-implant soft tissue have been linked with MBL.[38]

Controversies exist regarding the effects of several variables such as age, gender, implant length, implant diameter, platform design, and insertion torque on MBL.[17,18,39] More long-term studies investigating factors influencing MBL are needed to better understand and clarify this issue.

Mumcu[17] found that age, gender, and cantilevers influenced MBL, but implant length or diameter had no significant effect on MBL. Sennerby[7] indicated an inverse correlation between MBL and ISQ. Tözüm and colleagues[33] claimed a negative correlation between increased MBL and decreased ISQ within postoperative 6 months. The correlation was not observed postoperative 6—12 months. The authors proposed that increased interface stiffness compensates for the effects of bone loss due to bone formation and remodeling at 6—12 months. This present study found a moderate negative correlation between secondary ISQ and MBL, and no significant differences in MBL postoperative 1 year, which is consistent with the research by Tözüm et al.

Previous studies have investigated whether a high insertion torque incurs more MBL.[10,39] It was hypothesized that as insertion torque increases, the bone compression increases, which may cause "bone necrosis by pressure". However, there is no consensus on the relationship between insertion torque and MBL till now.[40]

Clinical measurement of implant stability can be easily performed via insertion torque and resonance frequency analysis. The results of this study suggest that implant diameter and bone density played considerable roles in IT/primary ISQ determination. Bone density and IT had more impacts than primary ISQ on MBL. Further studies with larger samples, a wider range of implant sizes, and long-term follow-ups are necessary to better understand their effects on insertion torque and resonance frequency analysis in assessing implant stability, and to investigate other factors that may influence implant stability and marginal bone level.

Declaration of competing interest

The authors have no conflicts of interest relevant to this article.

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