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Multivariate analysis of the effect of keratinized mucosa on peri-implant tissues with platform switching: A retrospective study

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Abstract

Background: In recent years, platform switching implant treatment has been increasing, which is believed to minimize bone loss around the implant after placement. However, there have been no reports on the relationship between keratinized mucosa width (KMW) and bone loss and soft tissue recession in platform switching implants.

Objective: We evaluated the effect of the KMW on the amount of bone loss and soft tissue recession around a platform switching implant retrospectively using multivariate analysis.

Materials and Methods: This one-year retrospective study included 91 implants in 48 patients. Age, sex, a history of periodontitis, implant location, oral hygiene status, and the KMW were included as explanatory variables to evaluate bone loss (BL) and buccal gingival height (GH). Generalized estimating equations (GEEs) were used to evaluate the effect of the KMW on platform switching peri-implant tissues.

Results: The mean bone loss on the mesial (ΔBLm), distal (ΔBLd), and buccal (ΔBLb) sides of the implant were 0.16 ± 0.27 mm, 0.19 ± 0.34 mm, and 0.24 ± 0.50 mm, respectively, at 1 year after superstructure placement. The mean amount of change of GH (ΔGH) on the buccal side was 0.30 ± 0.47 mm. After correcting for confounders using GEEs, the results suggested that KMW < 1.5 mm was a significant factor ($P < 0.001$) for bone loss over time in ΔBLm , ΔBLd , and ΔBLb . In addition, for soft tissues on the buccal side, KMW < 1.5 mm was a significant factor for ΔGH reduction over time ($P < 0.001$).

Conclusions: Keratinized mucosa width ≥ 1.5 mm was associated with a higher probability less hard and soft tissue recession around the platform switching implant after 1 year from superstructure placement.

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KEYWORDS

bone loss, dental implants, generalized estimating equations, keratinized mucosa width, multivariate analysis, platform switching implant

Summary Box**What is Known**

- The effect of keratinized mucosa width (KMW) on peri-implant tissues has not been established, with some reports of an effect and others of no effect.
- Many studies group KMW by 2 mm, but the reason for this is not clear.

What this Study Adds

- The present study is a comprehensive analysis of KMW and peri-implant tissues, with a cut-off value for KMW established by statistical analysis.
- The results showed that KMW ≥ 1.5 mm resulted in less hard and soft tissue recession around the implant.

1 | INTRODUCTION

Implant treatment has become an effective option in prosthetic dentistry. Evaluation of circumferential bone loss around dental implants has been frequently used in routine clinical practice to prevent treatment failure and ensure favorable long-term prognosis. Thus, the accurate prediction of the change in bone level around the implant is crucial for predicting the prognosis of implant treatment.¹ Poor oral hygiene, lack of regular maintenance, and history of periodontitis have been reported to influence bone loss around implants.¹ On the other hand, the presence and keratinized mucosa width (KMW) on the buccal side of the implant have been reported to affect bone loss around the implant, while others have reported no effect.²⁻⁵ Kim and colleagues² & Perussolo and colleagues³ reported that bone loss was more significant in implants with KMW < 2 mm on the buccal side than those with KMW ≥ 2 mm. Buyukozdemir and colleagues⁵ reported no significant difference in bone loss between implants with buccal KMW < 2 mm and those with KMW ≥ 2 mm. The KMW was divided into two categories in these studies of platform matched (PM) implant: ≥ 2 mm and < 2 mm, but the rationale for setting 2 mm as the cut-off was not provided. Alberto Monje and colleagues⁶ also reported that KMW was critical to minimize the incidence of peri-implant mucositis and future bone loss in erratic maintenance compliers. However, further research is needed to determine the minimum amount of KMW required for long-term peri-implant health, function, and esthetics.

In recent years, platform switching implant treatment has been increasing, which is believed to minimize bone loss around the implant after placement.⁷ However, there have been no reports on the relationship between KMW and bone loss and soft tissue recession in platform switching implants.⁸

The primary objective of the study was to evaluate whether there is an association between KMWs and bone loss around platform switching implants, and the following studies were conducted. In this

study, we aimed to longitudinally evaluate the effect of the KMW on the amount of bone loss and soft tissue recession around platform switching implants. In addition to evaluating the bone loss on the mesial and distal sides of dental implants with the aid of dental radiographs, the amount of bone loss on the buccal side was evaluated by dental cone-beam CT (CBCT) images of platform switching implants, in which buccal KMW is most likely involved. In this study, we attempted to establish a cut-off value for the KMW on the buccal side of the implant by a receiver operating characteristic (ROC) curve. Using the cut-off value of the KMW obtained in the analysis, the effects of various factors, including the KMW, on the bone loss of the mesial, distal, and buccal sides of the implant and the soft tissue recession of the buccal side of the implant were investigated by a multivariate analysis, which excluded the effects of confounding factors.

2 | MATERIALS AND METHODS

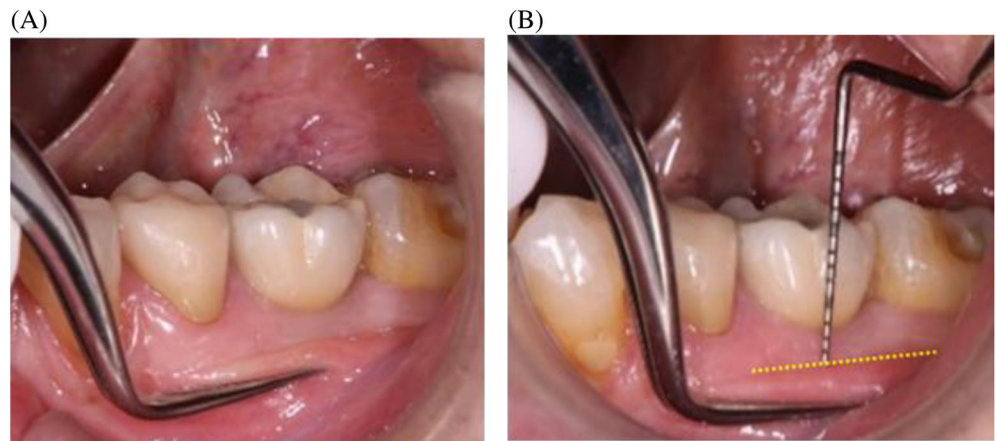
2.1 | Study design and sample selection

This study retrospectively examined patients who underwent implant treatment at Osaka University Dental Hospital between December 2015 and August 2020 and visited the hospital for one-year maintenance. The inclusion criteria of this study were: (a) 20 years old or older, presented at least one implant-supported fixed dental prostheses in function for ≥ 1 year, (b) placement of a platform switching implant (Nobel Biocare, Switzerland or Straumann, Switzerland), (c) placement at bone level, and (d) CBCT and dental radiographs were obtained at the time of implant superstructure placement (T1) and 1 year after placement (T2). The exclusion criteria were: (a) patients with diabetes, (b) patients with smoking, (c) implants placed in totally edentulous jaws.

All implants were placed according to manufacturer-specified protocols.

FIGURE 1 Rolling technique.

(A) The alveolar mucosa was pulled up with dental tweezers to clarify the mucogingival junction. (B) The shortest distance from the mucogingival junction to the labial marginal gingiva of the implant was measured.



This research was approved by the Ethics Committee of Osaka University Graduate School of Dentistry and Dental Hospital (H29-E44, R1-E33).

2.2 | Clinical parameters

2.2.1 | Keratinized mucosa width

The KMW at T1 was measured using a rolling technique (Figure 1), as reported by Bouri and colleagues.⁹ The alveolar mucosa was pulled up with dental tweezers to clarify the mucogingival junction. Next, the shortest distance from the mucogingival junction to the mid-buccal marginal gingiva of the implant was defined as the KMW.

2.2.2 | Plaque control record

O'Leary's plaque control record (PCR) was used to assess the oral hygiene status at T1 and T2.¹⁰

2.2.3 | A history of periodontitis

A history of periodontitis^{11,12} was recorded when medical records or patient inquiries indicated that the implant was placed at a site where tooth extraction occurred because of chronic periodontitis. The definition of periodontitis conformed to that reported by Papapanou and colleagues.¹³

2.3 | Radiographic examination and measurements

2.3.1 | Bone loss on the mesial and distal sides

Dental radiographs were taken using a photographic indicator (CID-III, JAPAN), positioned so that the platform was centered and the threads were clear. The distance from the platform level (PL) to the alveolar bone on the mesial side of the implant (mesial bone level, BLm) and the distance

from the PL to the alveolar bone on the distal side (distal bone level, BLd) were measured using an image processing software program (SYNAPSE, Japan) (Figure 2A). The actual implant length was used for calibration of the measurements (BLm and BLd). The BLm and BLd values at T2 minus the value at T1 were calculated as the bone change on the mesial side (Δ BLm) and the bone change on the distal side (Δ BLd), respectively.

2.3.2 | Bone loss and amount of change of buccal gingival height on the buccal side

CBCT imaging was performed using a CBCT imaging system (Alphard 3030, Japan). For CBCT data reconstruction and CBCT image measurement, the coDiagnostiX™ (Dental Wings, Canada) software program. The implant model (IM) was displayed on the CBCT data at the same position as the actual implant body. The horizontal section, including the IM platform, was termed the axial section. On the axial section, the section perpendicular to the tangent to the dental arch passing through the center of the IM was termed the cross-sectional section for measurement. The cross-sectional section for measurement was used to measure the distance from the buccal PL of the implant to the alveolar bone (buccal bone level, BLb) (Figure 2B).

The distance from the PL to the top of the soft tissue on the buccal side of the implant (buccal gingival height, GH) was measured using the same section used to measure bone loss (Figure 2B). The amount of bone change on the buccal side of the implant (Δ BLb) was calculated as the value of BLb at T2 minus the value at T1. The value of GH at T2 minus the value at T1 was calculated as the amount of change of GH on the buccal side (Δ GH).

CBCT images were performed by inserting a roll of cotton into the oral vestibule at the time of imaging¹⁴ to exclude the lips and buccal mucosa in contact with the gingival soft tissue so that the boundary between the gingival soft tissue and oral vestibule could be distinguished.

Ten implants were randomly selected from the 91 implants studied for clinical measurements, and the reliability was checked using the interclass correlation coefficient. Measurements were performed three times for each implant by one measurer, and intra-rater reliability was verified using a measurement interval of 1 week. Intra-rater reliability exceeded 80%, indicating high reliability.

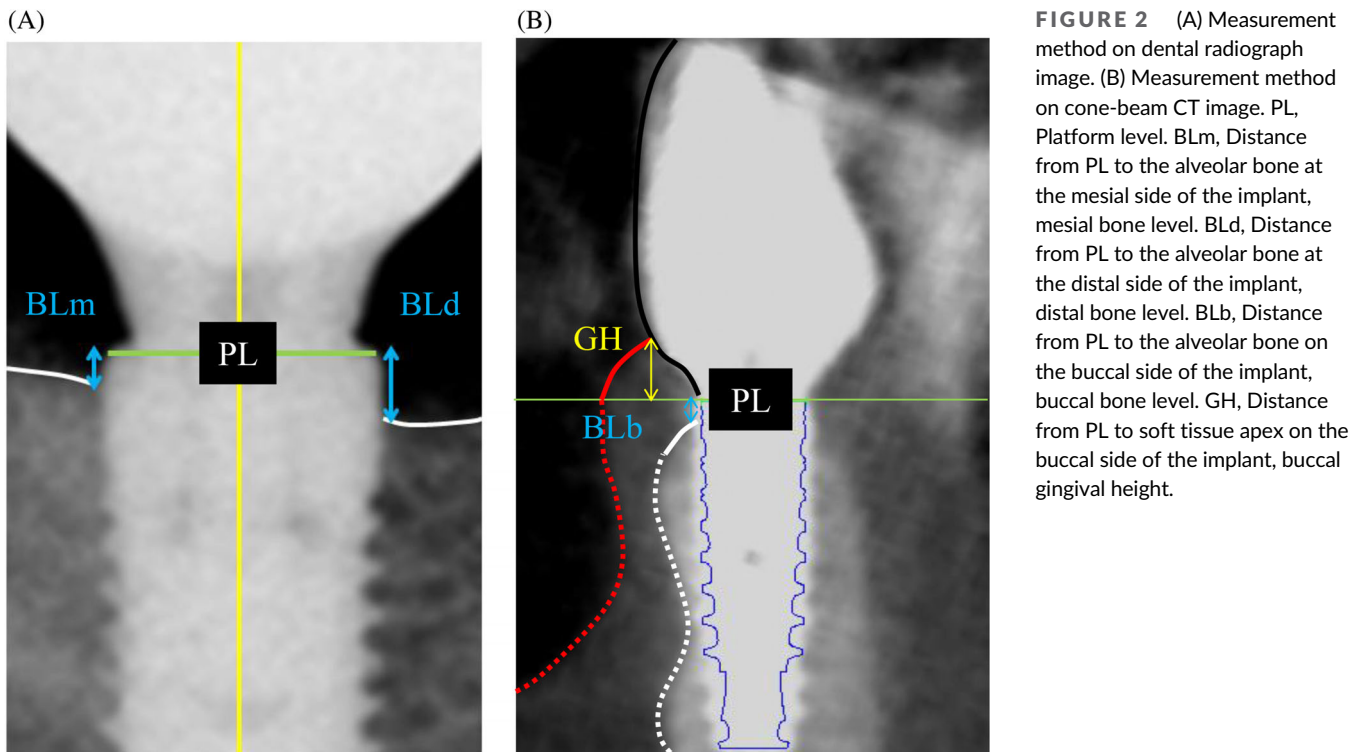


FIGURE 2 (A) Measurement method on dental radiograph image. (B) Measurement method on cone-beam CT image. PL, Platform level. BLm, Distance from PL to the alveolar bone at the mesial side of the implant, mesial bone level. BLd, Distance from PL to the alveolar bone at the distal side of the implant, distal bone level. BLb, Distance from PL to the alveolar bone on the buccal side of the implant, buccal bone level. GH, Distance from PL to soft tissue apex on the buccal side of the implant, buccal gingival height.

2.4 | Statistical analysis

2.4.1 | Setting a cut-off value for the KMW

In this study, an ROC analysis, a method that examines the usefulness of diagnostic tests in clinical research, was used to establish an appropriate cut-off value.

In this analysis, bone loss (≥ 0.3 mm) from the time of superstructure placement to 1 year after placement was treated as a dichotomous variable, and bone loss (< 0.3 mm) was treated as no bone loss.¹⁵ A receiver operating characteristic (ROC) curve was used to examine the cut-off value of the KMW. The ROC curves for Δ BLm, Δ BLd, and Δ BLb were drawn using the KMW at the time of superstructure placement as a continuous variable. The presence of bone loss around the implant over time was used as a dichotomous variable. The Youden index (the point of maximum sensitivity and specificity) and area under the curve (AUC) calculated from the ROC analysis were used as a reference to determine the cut-off value for the KMW. The AUC value is used as an indicator to determine the diagnostic ability of a parameter.¹⁶

2.4.2 | Analysis of factors affecting peri-implant bone level and gingival height using GEEs

A multivariate analysis was used to correct confounding factors and evaluate the effects of various factors, including the KMW, on peri-

implant bone level and gingival height. The objective variables were Δ BLm, Δ BLd, Δ BLb, and Δ GH. In addition, there were seven explanatory variables: four patient-related factors (age, sex, and plaque control record at T1 and T2) and four implant background factors (KMW, whether periodontitis was the reason for tooth extraction at the implant position, and whether the implant position was maxillary or mandibular, anterior or posterior). The KMW was classified into two groups: above and below the cut-off value obtained from the ROC analysis. All analyses were performed using the SPSS Statistics 23 (IBM Japan, Japan) software. Generalized estimation equations (GEEs) were used for the statistical analysis, and the significance level was set at $\alpha = 0.05$. GEEs requires an explanatory variable \times 10 number of samples.¹² In this study, since there were eight explanatory variables, GEE can correct for correlations within the same individual, which required a sample size of 80. In this study, the statistical analysis results were differentiated by the implants the patients had, and the results were adjusted to avoid a substantial effect on patients at high risks, such as those with periodontal disease.

This study was performed following the STROBE guidelines.

3 | RESULTS

Among 54 participants who met all the inclusion criteria, 6 participants excluded according to the exclusion criteria. Thus, a total of 91 implants placed in 48 partially edentulous patients (18 males and 30 females; mean age 60.5 ± 13.0 years) were included in this study.

TABLE 1 Background information of patients (A) and details of implants (B).

(A) Background of patients	
Age (years)	
Mean ± SD	60.5 ± 13.0
Gender	
Male	18
Female	30
Oral hygiene status (PCR at T1, %)	
Mean ± SD	41.6 ± 21.4
Oral hygiene status (PCR at T2, %)	
Mean ± SD	34.7 ± 17.0
(B) Details of implants	
History of periodontitis (number of implants)	
Yes	13
No	78
Implant position (number of implants)	
Maxillary	43
(Anterior)	(8)
(Posterior: premolars and molars)	(35)
Mandibular	48
(Anterior)	(1)
(Posterior: premolars and molars)	(47)

Abbreviation: PCR, plaque control record.

TABLE 2 Amount of change in keratinized mucosa width and hard and soft tissue.

	Mean ± SD	Range	Median value
KMW (mm)	2.62 ± 1.85	0–9.0	3.0
ΔBLm (mm)	0.16 ± 0.27	0–1.35	0
ΔBLd (mm)	0.19 ± 0.34	0–2.15	0
ΔBLb (mm)	0.24 ± 0.50	0–3.0	0
ΔGH (mm)	0.30 ± 0.47	0–3.0	0.1

Abbreviations: KMW, keratinized mucosa width; SD, standard deviation; ΔBLb, buccal bone loss; ΔBLd, distal bone loss; ΔBLm, mesial bone loss; ΔGH, amount of change of GH.

The mean follow-up time was 14 ± 1.6 months. The baseline data of the study subjects are shown in Table 1.

3.1 | KMW, ΔBL, and ΔGH

The amount of change in keratinized mucosa width and hard and soft tissue are shown in Table 2. The average KMW was 2.62 ± 1.85 mm. The mean ΔBLm was 0.16 ± 0.27 mm. The mean ΔBLd was 0.19 ± 0.34 mm. The mean ΔBLb was 0.24 ± 0.50 mm. The mean ΔGH was 0.30 ± 0.47 mm.

3.2 | Setting a cut-off value for the KMW

ROC curves were drawn to determine the cut-off values using the ΔBLm, ΔBLd, and ΔBLb parameters and KMW as continuous variables. Youden Index is the point at which the value of Sensitivity – (1 – Specificity) is maximum. One of the criteria for setting the cutoff value one of the criteria to set the cutoff value for evaluation using ROC curve.

The ROC curves of ΔBLm and the KMW are shown in Figure 3A, and the Youden index of the ROC showed 1.5 mm (sensitivity 0.611, specificity 0.781, AUC value 0.725) (Table 3A).

The ROC curves of ΔBLd and the KMW are shown in Figure 3B, and the Youden index of the ROC showed 1.5 mm (sensitivity 0.632, specificity 0.792, AUC value 0.735) (Table 3B).

The ROC curves of ΔBLb and the KMW are shown in Figure 3C, and the Youden Index of the ROC curve showed 1.5 mm (sensitivity 0.74, specificity 0.829, AUC value 0.743) (Table 3C).

The cutoff value for KMW was set at 1.5 mm because all Youden Indices indicated 1.5 mm based on the above ROC analysis.

3.3 | Analysis of factors affecting peri-implant tissue using GEEs

The results of the multivariate analysis are presented with correction for confounding factors using GEEs. On the mesial side of the implant, KMW <1.5 mm was suggested to be a significant factor for bone loss over time ($P < 0.001$, odds ratio [OR] = 10.691) (Table 4A). On the distal side, KMW <1.5 mm was suggested to be a significant factor for bone loss ($P < 0.001$, OR = 10.494) (Table 4B). On the buccal side, KMW <1.5 mm was suggested to be a significant factor for bone loss ($P < 0.001$, OR = 11.103) (Table 4C). For the soft tissues on the buccal side, KMW <1.5 mm was also suggested to be a significant factor for ΔGH ($P < 0.001$, OR = 3.728) (Table 4D).

Among the patient-related factors, age, plaque control record, whether the reason for extraction was periodontitis or not, and implant position (maxillary or mandibular, anterior or molar) were not found to be significant factors for bone loss or ΔGH.

4 | DISCUSSION

Kim and colleagues² & Perussolo and colleagues³ reported that bone loss in implants with buccal KMW <2 mm was significantly greater than those with KMW ≥2 mm. On the other hand, Wennström and colleagues⁴ & Schou and colleagues¹⁷ reported that good oral hygiene could maintain the health of peri-implant tissues with or without the KMW, and no consensus has been reached. Most of these studies evaluated only inflammatory parameters and did not discuss bone loss around implants, which might be why there is no agreement on the influence of KMW. Therefore, it is

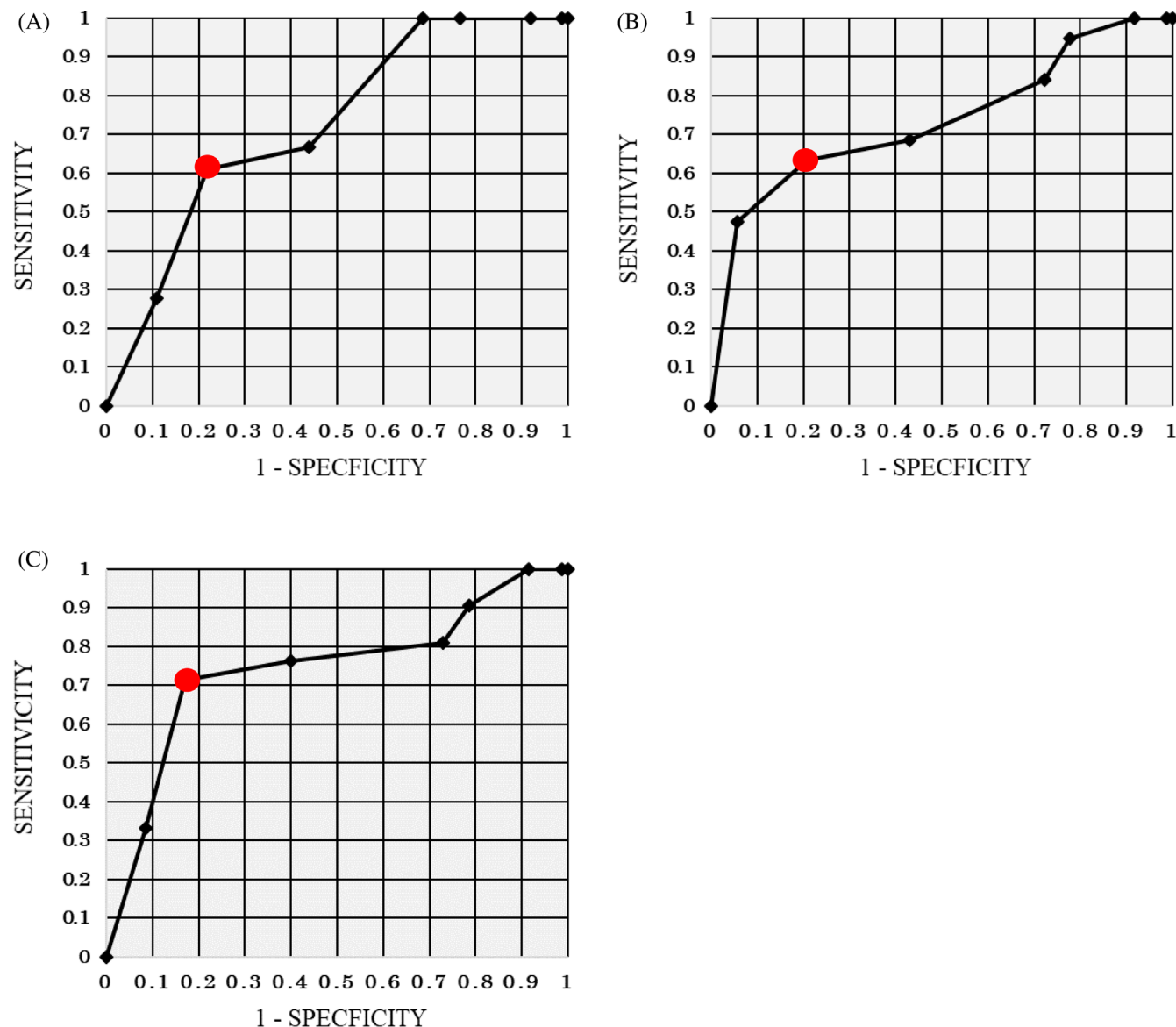


FIGURE 3 ROC curve showing the relationship between KMW and the presence of bone loss of the implant 1 year after the installation of the superstructure (A), in the mesial side (B), in the distal side (C), and the buccal side. The red point is the Youden index (the point of maximum sensitivity + specificity) on the ROC curve.

significant to focus on the effect of KMW on bone loss around implants.

In addition, the rationale for setting the KMW cut-off value at 2 mm, which was used in many studies, was not provided. Considering all these points in this study, we conducted a longitudinal study to identify the factors that influence the prognosis of tissues surrounding the platform switching implant, including the KMW. First, the amount of bone loss on the buccal side was assessed by CBCT images. In contrast, bone loss on the mesial and distal sides was evaluated by dental radiographs. The cut-off value of the KMW on the buccal side of the implant was investigated using a ROC analysis. Next, based on the cut-off value of the KMW, a multivariate analysis was performed to investigate the factors related to bone loss.

4.1 | Bone loss of platform switching implants up to approximately 1 year after superstructure placement

Using platform switching implants instead of PM implants has recently become mainstream. Although platform switching implants have been reported to improve the stability of the hard and soft tissues around the implant, there are very few reports on the significance of the KMW in this type of implant.⁸ The amount of bone loss in PM implants is reported to be approximately 1.0 mm 1 year after superstructure installation.^{18–20} This is due to the micro-movement of the implant-abutment interface caused by the superstructure, the associated micro-leakage of bacteria, or biological width establishment.²¹

TABLE 3 Sensitivity and Specificity values of keratinized mucosa width by the cut-off value.

(A)		
KMW (mm)	Sensitivity	1 - specificity
-1	0	0
0.5	0.278	0.11
1.5	0.611	0.219
2.5	0.667	0.438
3.5	1	0.685
4.5	1	0.767
5.5	1	0.918
7.5	1	0.986
10	1	1
(B)		
KMW (mm)	Sensitivity	1 - specificity
-1	0	0
0.5	0.474	0.056
1.5	0.632	0.208
2.5	0.684	0.431
3.5	0.842	0.722
4.5	0.947	0.778
5.5	1	0.917
7.5	1	0.986
10	1	1
(C)		
KMW (mm)	Sensitivity	1 - specificity
-1	0	0
0.5	0.333	0.086
1.5	0.714	0.171
2.5	0.762	0.4
3.5	0.81	0.729
4.5	0.905	0.786
5.5	1	0.914
7.5	1	0.986
10	1	1

Note: A, On the mesial side; B, On the distal side; C, On the buccal side.
Abbreviation: KMW, keratinized mucosa width.

On the other hand, in the case of platform switching implants, there is no clear consensus on the amount of bone loss during the first year after installation of the superstructure. Still, it is believed that the amount of bone loss is also lower than that of PM implants because there is much less micro-movement and micro-leakage.⁸ Therefore, when setting a cut-off value for bone loss in studies of platform switching implants, it is necessary to set a different standard from that for PM implants. Twelve studies²²⁻³³ of platform switching implants were selected from previous meta-analyses,¹⁵ and their data on bone loss during the first year after superstructure placement was used as a

reference to establish criteria for the presence of transitional bone loss. Gultekin and colleagues²⁸ reported a bone loss of 0.35 mm 1 year after superstructure placement. Pozzi and colleagues³³ reported a bone loss of 0.28 mm, Cristalli and colleagues²⁶ reported a bone loss of 0.33 mm, and Yamada and colleagues²⁵ reported a bone loss of 0.32 mm. Therefore, in this study, the criterion for bone loss over time was set at 0.3 mm 1 year after superstructure attachment. To determine the cut-off value, 0.3 mm or more bone loss from the time of superstructure placement to approximately 1 year after placement was treated as a dichotomous variable in this analysis, and bone loss <0.3 mm was treated as no bone loss.

4.2 | Setting the cut-off value for the KMW

The Youden index was 1.5 mm for each of these parameters. The calculated AUC values indicated that all values showed moderate diagnostic ability.¹⁶ These results suggest that a cut-off value of 1.5 mm for KMW at the time of superstructure placement is appropriate for predicting bone loss in patients with platform switching implants during the first year.

4.3 | Analysis of factors affecting peri-implant tissue using GEEs

In addition to oral hygiene, regular maintenance, and history of periodontitis, peri-implant tissues may be influenced by various factors, such as KMW, diabetes mellitus, smoking, the occlusal relationship, and the design of the prosthetic device.^{1,34} Few studies have considered these confounding factors in analyzing the effects of the KMW on peri-implant tissues. Thus, a multivariate analysis is needed to examine the individual impact of each factor. In addition, since multiple implants placed in the same patient were analyzed in this study, variation in data within the same subject is expected to exist. GEEs can evaluate the effect of each factor on the outcome, taking into account the variability of the data due to the effects of repeated data hierarchies within the same subject or longitudinal surveys.¹⁶

Post hoc power analysis was performed on each covariate using R and the packages gee and lmpower.^{35,36} Table 5 shows the power analysis when the sample size is approximately 91. The detection power was 0.9 or above with respect to KMW and implant position (anterior or posterior). For other factors, increasing the sample size may be necessary to obtain larger statistical powers to detect effects on the objective variable. Although, our power analysis suggests that the KMW results are correctly evaluated.

4.3.1 | Bone loss

For Δ BLm, Δ BLd, and Δ BLb, KMW <1.5 mm was a significant factor for bone loss over time (Tables 3 and 4A). This result is consistent with the longitudinal study by Perussolo and colleagues³ and the

TABLE 4 Results of analysis by GEEs.

(A)				
		P value	Adjusted OR	95% confidence interval
Sex	Male	0.0115*	0.266	0.092–0.776
	Female		1	
Age		0.737	1.007	0.967–1.048
Oral hygiene status	PCR at T1	0.272	1.014	0.989–1.040
	PCR at T2	0.198	1.018	0.991–1.045
History of periodontitis	No	0.170	2.930	0.630–13.632
	Yes		1	
Implant position	Maxillary	0.925	0.956	0.375–2.493
	Mandibular		1	
Implant position	Anterior	0.277	1.870	0.604–5.788
	Posterior		1	
Keratinized mucosa width	<1.5 mm	<0.001 [†]	10.691	4.034–28.330
	≥1.5 mm		1	
(B)				
		P value	Adjusted OR	95% confidence interval
Sex	Male	0.797	0.895	0.386–2.075
	Female		1	
Age		0.310	0.982	0.947–1.017
Oral hygiene status	PCR at T1	0.089	1.022	0.997–1.049
	PCR at T2	0.718	0.995	0.968–1.023
History of periodontitis	No	0.686	0.769	0.216–2.739
	Yes		1	
Implant position	Maxillary	0.813	1.119	0.440–2.845
	Mandibular		1	
Implant position	Anterior	0.999	0.998	0.181–5.506
	Posterior		1	
Keratinized mucosa width	<1.5 mm	<0.001 [†]	10.494	3.974–27.709
	≥1.5 mm		1	
(C)				
		P value	Adjusted OR	95% confidence interval
Sex	Male	0.042*	0.355	0.131–0.965
	Female		1	
Age		0.389	1.017	0.978–1.058
Oral hygiene status	PCR at T1	0.052	1.033	1.000–1.067
	PCR at T2	0.485	1.012	0.979–1.046
History of periodontitis	No	0.408	2.190	0.343–13.995
	Yes		1	
Implant position	Maxillary	0.114	0.439	0.158–1.219
	Mandibular		1	
Implant position	Anterior	0.131	2.676	0.745–9.615
	Posterior		1	
Keratinized mucosa width	<1.5 mm	<0.001 [†]	11.103	4.257–28.959
	≥1.5 mm		1	

TABLE 4 (Continued)

(D)		P value	Adjusted OR	95% confidence interval
Sex	Male	0.584	1.284	0.524–3.146
	Female		1	
Age		0.315	1.012	0.988–1.037
Oral hygiene status	PCR at T1	0.702	1.005	0.981–1.028
	PCR at T2	0.204	1.019	0.990–1.050
History of periodontitis	No	0.823	1.119	0.416–3.010
	Yes		1	
Implant position	Maxillary	0.800	1.127	0.447–2.843
	Mandibular		1	
Implant position	Anterior	0.182	2.362	0.669–8.342
	Posterior		1	
Keratinized mucosa width	<1.5 mm	0.003*	3.728	1.542–9.012
	≥1.5 mm		1	

Note: A, mesial bone loss (Δ BLm). B, distal bone loss (Δ BLd). C, buccal bone loss (Δ BLb). D, amount of change of GH. (Δ GH).

Abbreviations: OR, odds ratio; PCR, plaque control record.

* $P < 0.05$. † $P < 0.001$.

TABLE 5 Post hoc power analysis.

gee.implant.n91.	Power
Sex	0.02794
Age	0.03028
Plaque control record at T1	0.02717
Plaque control record at T2	0.02875
History of periodontitis	0.07035
Implant position (maxillary or mandibular)	0.076
Implant position (anterior or posterior)	0.9958
Keratinized mucosa width	0.9

cross-sectional studies by Shimomoto and colleagues¹¹ & Mameno and colleagues,³⁷ which mainly used multivariate analyses to evaluate PM implants. The studies suggested that KMW ≥ 2 mm was an important factor in bone loss. When the peri-implant KMW was < 1.5 mm, the peri-implant hard and soft tissues may be weakly resistant to and strongly affected by the movement of the movable mucosa of the cheek and lip. Considering that the patients in the present study were observed until approximately 1 year after installing the superstructure when the amount of bone loss attributed to initial bone remodeling was considered the greatest, it is highly likely that bone loss will not progress if the KMW is ≥ 1.5 mm.

This study suggests that even PS implants, which are considered to have low bone loss, may cause bone loss around the implant with a KMW < 1.5 mm. Therefore, if the KMW < 1.5 mm, aggressive KMW augmentation is recommended. Oh and colleagues reported less bone loss and mucosal recession in the group with free gingival grafts (FGG) around implants with a KMW < 2 mm compared to implants without increased KMW.³⁸ In a study by Lim and colleagues in which patients

with KMW < 2 mm underwent FGG, apically positioned flap (APF), and collagen matrix (CM) surgery, they reported that the FGG group had less KMW contraction up to 12 months than the APF and CM groups, suggesting that FGG should be applied to obtain sufficient KMW when KMW is < 2 mm.³⁹

In this study, female sex was resulted as a significant factor for Δ BLm and Δ BLb. Negri and colleagues⁴⁰ reported a trend toward greater bone loss in women > 50 years of age. He stated that this might be correlated with osteoporosis associated with the onset of menopause. We believe that Δ BLm and Δ BLb may have been resulted as factors because many of the subjects in this study were older women. In the multivariate analyses of Perussolo and colleagues³ & Wang and colleagues,³⁷ reported that sex was not a significant factor. Based on these results, we could not conclude that sex differences were a risk factor in this study.

The oral hygiene status (plaque control record), which has been reported to be a risk factor in several previous reports, was not resulted as a significant factor in this study. Berglundh and colleagues¹ reported that patients with a history of severe periodontitis, inadequate plaque control, and a lack of regular maintenance after implant treatment are at increased risk. The present study included subjects who received initial periodontal treatment before surgery and underwent regular maintenance after implant treatment. The patients' oral hygiene in this study was well controlled, which may have prevented plaque control record from being identified as a significant factor.

4.3.2 | Gingival height

KMW < 1.5 mm was suggested to be a significant factor for Δ GH over time (Table 4D). Our results agree with previous studies, which used

univariate analyses, including cross-sectional studies by Kim and colleagues² & Adibrad and colleagues⁴¹ and a longitudinal study by Crespi and colleagues,⁴² which showed an association between a lack of KMW and soft tissue recession. In the peri-implant tissue, collagen fibers run obliquely or parallel to the implant. Therefore, the mechanical adhesion between the implant and the surrounding soft tissues is weaker than that of natural teeth. The resistance to external forces and bacterial infection is weak; thus, the destruction of the soft tissues around the implant is more likely to occur than in natural teeth.^{43,44} When the KMW was narrow, the thickness of the soft tissues became relatively thin, increasing the possibility of soft tissue recession.⁴⁵

4.4 | Limitations

There are several limitations in this study. This study is not a randomized controlled trial, and can therefore, not evaluate treatment interventions, because it was difficult to collect and evaluate all clinical parameters because of this retrospective study. Only participants who satisfied the inclusion criteria were targeted in this study, which may have resulted in selection bias. Clinical parameters such as PPD and mBI are items that assess the health of the peri-implant tissue. Albrektsson and colleagues⁴⁶ reported that periodontal indices such as bleeding on probing and probing depth are irrelevant diagnostic tools in the evaluation of implants and should be avoided as they cause unnecessary trauma to the peri-implant tissues. In addition, we did not evaluate these clinical parameters in this study because we wanted to primarily evaluate the relationship between KM and bone loss. However, we understand that evaluating these clinical parameters is very important and meaningful in evaluating the peri-implant tissues as reported by Berglundh and colleagues.¹

Regarding selecting explanatory variables in the multivariate analysis, plaque control record and whether periodontitis was the reason for extracting the tooth at the implant position were selected based on the importance of factors other than the five basic requirements: age, sex, whether the implant position was maxillary or mandibular, anterior or posterior, and the KMW. Other factors that may affect the peri-implant tissue include diabetes, smoking, the occlusal relationship, and prosthetic device design.³⁴ Therefore, we could not clarify the effects of the presence or absence of diabetes or smoking.^{47,48} In the future, adding factors, such as the presence or absence of diabetes mellitus and smoking, would be desirable because increasing the sample would allow us to add more factors to the analysis.

Since dental radiographs cannot measure the amount of bone loss on the buccal side, CBCT was used in this study to measure the amount of bone loss on the buccal side. However, CBCT cannot measure the amount of bone loss on the mesial and distal sides due to artifacts, so dental radiographs were also used. The fact that the measurement method could not be standardized due to possible differences in measurements is considered a limitation of this study.

Another limitation is that we were unable to make reference to soft tissue thickness, which is thought to influence bone stability.

Kobayashi and colleagues reported that thicker peri-implant soft tissue reduce the amount of tissue recession over time compared to thinner labial tissue.⁴⁹ Yamada and colleagues reported that differences in peri-implant phenotype affect the amount of hard and soft tissue resorption on the labial/buccal side of the implant.⁵⁰ Since it is very difficult to measure the thickness of soft tissue in molars, we consider the failure to consider soft tissue thickness to be a limitation of this study.

Based on the above, we believe that larger sample size, measurement of mucosal thickness, and continuous prospective longitudinal observation for more than 1 year are necessary to evaluate the long-term effects of the KMW on bone loss.

5 | CONCLUSION

This study was conducted to evaluate the effect of the KMW on the amount of bone loss around implant with platform switching. The results showed that KMW ≥ 1.5 mm was a significant prognostic indicator after platform switching implant placement, indicating little recession of the hard and soft tissue around the implant 1 year after superstructure placement.

AUTHOR CONTRIBUTIONS

Suzuki Azusa; study conception, data collection, data analysis, and interpretation, writing the article. Inoue Masaki; data collection, data analysis, and interpretation, significant revisions to the article. Ishigaki Shoichi; study conception, significant revisions to the paper. Nakano Tamaki; study design, significant revisions to the article. All authors approved the final draft.

CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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