1. Introduction

Maintaining peri-implant tissue health is necessary for the long-term success of implant treatment. Poor oral hygiene, smoking, and a history of periodontal disease have been reported as risk factors for peri-implantitis [1].

Previous research has discussed whether the presence of keratinized mucosa (KM) is required to keep peri-implant tissue healthy [2].

Peri-implant tissue health requires no clinical signs of inflammation, no bleeding and suppuration on gentle probing, no increase in probing depth compared with previous examinations, and no bone loss beyond crestal bone level changes resulting from initial bone remodeling [3].

Some evidence suggests implants with less than 2 mm of KM exhibit more bleeding on probing and supporting bone loss than those with more than 2 mm of KM [4]. Conversely, Roccuzzo et al. found that peri-implant tissue health could be maintained with good oral hygiene in spite of the width of KM [5]. It is important, therefore, to confirm the influence of KM on peri-implant tissue health. If the presence of KM is important for peri-implant tissue health, soft tissue grafting may be considered in cases with insufficient KM. Although many studies have investigated the influence of KM, a clear conclusion has not yet been reached.

One of the difficulties in reaching a consensus is the presence of confounders such as poor oral hygiene, smoking, and a history of periodontal disease in previous studies. Most previous studies did not consider factors affecting peri-implant tissue health that prevent accurate assessment of the effect of KM.

The purpose of our cross-sectional study was to confirm the association between peri-implant tissue health and the presence of KM using multivariate analysis to control for the confounding effects. We hypothesize that the presence of ≥ 2 mm of KM is related to improved peri-implant tissue health when compared with KM that is < 2 mm wide.

We built up the null hypothesis that the presence of ≥ 2 mm of KM is not related to improved peri-implant tissue health when compared with KM that is < 2 mm wide.

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2. Materials and methods

2.1. Study design

This study subjects were partially edentulous patients who had been treated with implants at a dental university hospital, Japan, and were recalled every 3 or 4 months between May 2013 and March 2016. The inclusion criteria of this study were: (1) implants with fixed prostheses inserted more than one year ago; and (2) implants placed without guided bone regeneration. Exclusion criteria were: (1) implants whose probing pocket depths were unable to be measured because of the contour of the prosthesis; (2) implants placed in totally edentulous jaws; and (3) patients with diabetes.

Our research was approved by the Ethics Committee at a university graduate school of dentistry (H25-E32).

2.2. Clinical parameters

According to the Consensus Report of the 2017 World Workshop, plaque accumulation, bleeding on probing, probing depth, and the supporting bone level should be evaluated regularly to check the peri-implant condition and to diagnose peri-implant lesions [6]. Two examiners were calibrated to the following clinical parameters: intra- and inter-examiner reliability was assessed until agreement was met [7]

Modified plaque index (mPI)

Plaque accumulation induced an inflammatory response characterized by increased proportions of T- and B-cells in the infiltrate of peri-implant tissue [8]. Plaque accumulation was assessed using the mPI (Table 1) [9].

Modified bleeding index (mBI)

Bleeding on probing is a sign of peri-implant tissue inflammation. The continued presence of bleeding on probing may result in supporting bone loss. Peri-implant tissue inflammation was assessed using the mBI (Table 1) [9].

Probing pocket depth (PPD)

Increase in the PPD over time is related to attachment loss. Conventional probing with weak force does not destroy the peri-implant tissue [10]. PPD was assessed on the buccal aspect with a contact probe (Nippon Shiken Corporation, Japan) with a standardized pressure of 0.2 N.

Bone loss (BL)

To assess the degree of bone loss, the bone level on dental X-rays taken at the last check-up was compared with the baseline bone level at the time of completion of the prosthodontic treatment. The magnification was compensated for by measuring the length of the placed implants on the dental X-ray; then the bone level at the mesial and distal aspects was measured and the mean value calculated [11].

Keratinized mucosa width

Using a Perio Probe (YDM Corporation, Japan), the width of the KM was measured from the buccal margin to the mucogingival junction, which was identified by the rolling technique [4].

2.3. Statistical analysis

The outcome variables of mPI, mBI, and PPD were assessed by multivariable regression analysis as a function of the set of independent variables at the patient level including age, sex, oral hygiene status, and cigarette smoking status, as well as at the implant level including the presence of KM, history of periodontitis, implant site, and time elapsed since prostheses delivery. Oral hygiene status was assessed by the O’Leary’s plaque control record. A history of periodontitis was recorded when medical records or patient inquiry indicated that the implant was placed at a site where tooth extraction occurred because of periodontitis.

To evaluate the effect of KM on peri-implant tissue health, the implants were categorized into those with ≥ 2 mm of KM and those with < 2 mm of KM. Implants that come from a single patient behave similarly to each other compared with implants that come from different patients; this creates data clustering. Generalized estimating equations (GEE) were used to control for such data clustering; and the GEE model used a cumulative logit link function with a binomial distribution to accurately analyze ordered outcome variables [12]. Significance was established with a p value of less than 0.05. Statistical analysis was carried out using SPSS statistics 23.0 (IBM, USA).

3. Results

Three-hundred and eighty-one dental implants (Nobel Biocare, Sweden) placed in 120 participants met the inclusion criteria. Forty-seven dental implants were excluded by the exclusion criteria. A total of 334 implants placed in 111 partially edentulous patients (34 males and 77 females; mean age 59.5± 11.8 years) were included in the study.

The implants were restored with fixed prostheses, and the mean loading time was 56.2 ± 37.3 months. Of the 334 dental implants, 224 implants were found to have ≥ 2 mm of KM, whereas 110 implants had < 2 mm of KM (Table 2).

As shown in Table 3, the mPI, mBI, and PPD in the presence or absence of KM did not show any statistically significant differences. In contrast, The degree of BL (odds ratio 4.33, p = 0.034) was greater for implants without KM than those with KM even after adjusting for the other explanatory variables. These clinical parameters were assessed by two examiners. The results of the intraclass correlation coefficient (ICC) reached 0.95 for ICC (1, 1) and 0.98 for ICC (2, 1).

4. Discussion

The results of the present study showed that the presence of KM was related to reduced bone loss, although there was no significant difference in plaque accumulation, mucosal inflammation, or pocket probing depth.

Various factors are thought to influence peri-implant tissue health, including the presence of KM [2]. In a natural tooth, the keratinized gingiva contains free and attached gingiva, and the width of the keratinized gingiva is defined from the marginal gingiva to the mucogingival junction [13]. Previous research has investigated whether the presence of keratinized gingiva around a natural tooth influences the health of the periodontium. Provided with adequate oral hygiene, the health of the periodontium can be maintained even when keratinized gingiva is lacking [14]. However, the current consensus is that ≥ 2 mm of keratinized gingiva and ≥ 1 mm of attached gingiva is necessary around teeth [15].

It is not always possible to apply conclusions regarding natural teeth to implants because of differences in the anatomical structure between implants and teeth [16]. In natural teeth, the principal fibers run vertically to the root and insert into the root cementum, whereas around implants, the collagen tissue fibers run in a parallel or oblique direction to the implant surface and do not insert into the implant [17]. Because the peri-implant tissue has a weaker mechanical attachment than periodontium, resistance to bacterial infection is weaker, and tissue destruction may occur more easily [18].

Many clinical studies have shown the significance of KM in maintaining peri-implant tissue health [19, 20]. However, some studies reported that peri-implant tissue health could be maintained even in the absence of KM [21, 22]. Therefore, a consensus on the effect of KM on peri-implant tissue has not yet been reached.

Although peri-implant tissue health may be affected by various factors, few studies researching the effect of KM on peri-implant...
tissue took confounding factors into account. Therefore, the present study evaluated the influence of KM on peri-implant tissue health after compensating for confounding factors using multivariate analysis. Some studies reported that the presence of more than 2 mm of KM did not exert any meaningful influence on plaque accumulation [23, 24]. The results of the present study also found no association between the accumulation of plaque and the presence of KM, regardless of the patients’ oral hygiene status.

With regard to bleeding on probing, some studies reported that there was no relationship between the presence of KM and mucosal inflammation [23, 24]. Similar to these findings, the present study suggested that the presence of more than 2 mm of KM did not exert any meaningful influence on mucosal inflammation. Because bleeding on probing is associated with plaque accumulation, it is considered that there was no significant difference in bleeding on probe. In contrast, other studies have suggested that the presence of more than 2 mm of KM decreased plaque accumulation around implants [19]. Bouri et al. reported that implants with insufficient KM (< 2 mm) had a significantly higher chance of bleeding on probing than implants with sufficient KM (≥ 2 mm) [4], and other studies also had similar results [25–27]. There are differences between the results of these studies and those of the present study probably because of the way of statistical analysis and the maintenance protocol. Many of them used the Wilcoxon signed rank test and did not take confounding factors into account. In the present study, the maintenance interval was decided by various factor such as the patients’ periodontal condition and plaque control. Most of the maintenance interval were three or four months. Although the maintenance interval affect mPI and mBI, it is not specified in many of the other study.

The degree of bone loss was greater for implants without KM than those with KM in our study, and this is in accordance with the results of previous studies [20]. It is suggested that although no significant difference was found in plaque accumulation and bleeding on probing between implants with and without KM, the degree of bone loss may be significant because the resistance against brushing pressure, the force of mastication, and movement of the buccal mucosa is weaker in the absence of KM around implants [4].

There was no significant difference in the PPD between implants with and without KM. This finding is supported by those of multiple previous studies [19]. In the present study, although the degree of bone loss was greater for implants without KM, no significant difference was found in PPD between implants with and without KM. This phenomenon can be explained by examining mucosal recession. It is considered that deepening of the pocket does not occur because of mucosal recession with bone loss. In fact, most studies evaluating gingival recession reported that the absence of KM was associated with gingival recession [24].

In cases in which the lack of keratinized mucosa is expected on the buccal side of the implant, it may be desirable to make an incision nearer the lingual side or to perform surgical augmentation of the keratinized mucosa during secondary surgery.

Most studies investigating the significance of KM are cross-sectional studies using univariate analysis. In our study, the significance of KM was assessed by multivariable analysis in order to control the confounding effects such as risk factors for peri-implantitis and time elapsed since prosthesis delivery. KM: keratinized mucosa, mPI: modified plaque index, mBI: modified bleeding index. PPD: probing pocket depth, BL: bone loss, OR: odds ratio, CI: confidence interval

### Table 1. mPI and mBI assessment.

| Score | Description                                                                 | mPI             | mBI             |
|-------|------------------------------------------------------------------------------|-----------------|-----------------|
| 0     | No detection of plaque                                                        | 0               | 0               |
| 1     | Plaque only recognized by running a probe across the smooth marginal surface | 1.240 (0.760 - 2.025) | 0.389          |
| 2     | Plaque can be seen by the naked eye on mucosal margin                         | 77              | 4.330 (2.520 - 7.442) |
| 3     | Abundance of soft matter                                                       | 0.109           | <0.01           |

### Table 2. Patient level and implant level explanatory variables.

**On patient level**

| Age ( years ) | Overall ± SD | Sex | Male | Female |
|---------------|--------------|-----|------|--------|
| Overall ± SD  | 59.5 ± 11.8  |     | 34   | 77     |

| Oral hygiene status ( PCR*, % ) | Overall ± SD | Oral hygiene status ( PCR*, % ) |
|---------------------------------|--------------|----------------------------------|
| Overall ± SD                   | 26.7 ± 17.4  |                                  |

| Cigarette smoking status | Overall ± SD |
|--------------------------|--------------|
| Non-smoker               | 98           |
| Smoker                   | 13           |

***: Plaque Control Record by O’Leary, SD: Standard Deviation.

**On implant level**

| Presence of KM | Overall ± SD |
|----------------|--------------|
| < 2 mm         | 110          |
| ≥ 2 mm         | 224          |

| History of periodontitis | Overall ± SD |
|-------------------------|--------------|
| No                      | 229          |
| Yes                     | 105          |

| Implant site | Overall ± SD |
|--------------|--------------|
| Maxillary    | 128          |
| Mandibular   | 206          |
| Anterior     | 36           |
| Posterior    | 298          |

| Elapsed time since prosthesis delivery ( months ) | Overall ± SD |
|-------------------------------------------------|--------------|
| Overall ± SD                                   | 56.2 ± 37.3  |

KM: keratinized mucosa, SD: Standard Deviation.

### Table 3. Effect of the presence of KM on mPI, mBI, PPD and BL after adjustment for the potential confounders.

| Variable | Adjusted OR* (95% CI) | p-value |
|----------|-----------------------|---------|
| mPI      | 1.692 (0.867 - 3.304) | 0.123   |
| mBI      | 1.525 (0.910 - 2.555) | 0.109   |
| PPD      | 1.240 (0.760 - 2.025) | 0.389   |
| BL       | 4.330 (2.520 - 7.442) | <0.01   |

*Adjustment was made for age, sex, oral hygiene status, cigarette smoking status, presence of KM, history of periodontitis, implant site and time elapsed since prosthesis delivery. KM: keratinized mucosa, mPI: modified plaque index, mBI: modified bleeding index. PPD: probing pocket depth, BL: bone loss, OR: odds ratio, CI: confidence interval

### 5. Conclusion

The results of the present study suggest that the presence of KM reduces the risk of bone resorption and can help to maintain peri-implant tissue health.

### Conflicts of interest

All authors have no conflicts of interest.
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