

## A prospective, split-mouth, clinical study of orthodontic titanium miniscrews with machined and acid-etched surfaces

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### ABSTRACT

**Objectives:** To determine whether the success rate and primary stability of surface-treated miniscrews differ from those of nontreated miniscrews.

**Materials and Methods:** Patients who required one or more miniscrews for the same reason in each quadrant were recruited into a single-blinded, split-mouth, randomized, controlled trial with a 1:1 allocation ratio. Self-drilling miniscrews with two surface types were used: those with no surface treatment, and those with an acid-etched surface treatment. The cumulative success rate and primary stability of each type of miniscrew were examined, and factors potentially affecting the success and failure of miniscrews were investigated.

**Results:** Forty patients were included in the study, with a total of 98 orthodontic miniscrews. The overall success rate was 88.8%, and the respective success rates for acid-etched and machined surface miniscrews were 91.8% and 85.7%. The respective mean insertion torques were  $13.62 \pm 5.95$  N·cm and  $13.38 \pm 4$  N·cm, and periotest values measured immediately after insertion were  $-0.50 \pm 2.77$  for acid-etched miniscrews and  $-0.28 \pm 3.36$  for machined surface miniscrews. There was no significant difference in the mean insertion torques and periotest values according to surface treatment and jaw.

**Conclusions:** Neither the success rate nor the primary stability of acid-etched surface miniscrews and machined surface miniscrews differed significantly. There is a high possibility that miniscrews will fall out in patients who have an open bite or those who require total distalization. (*Angle Orthod.* 2019;89:411–417.)

**KEY WORDS:** Acid-etched surface treatment; Orthodontic miniscrew; Primary stability; Prospective study; Success rate

### INTRODUCTION

Orthodontic miniscrews are a popular means of achieving skeletal anchorage control due to their simplicity of placement and removal, low cost, and capacity for immediate force loading.<sup>1,2</sup> Recently, the

failure rates of miniscrews have been reported to be approximately 10%–15%, indicating that their usefulness is clinically acceptable.<sup>1</sup> Nevertheless, previous studies reported that patients with high mandibular plane angle had higher miniscrew failure rates than

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those with normal and low mandibular angles.<sup>2,3</sup> There was a great risk of failure of miniscrews in adolescent patients, due to active bone metabolism and low maturation of the bone.<sup>4,5</sup> In addition to these host factors, several other factors affecting the success rate of miniscrews have been reported including screw design (taper or cylinder),<sup>1</sup> surface topography,<sup>6,7</sup> diameter,<sup>2,8</sup> and length.<sup>2</sup>

Various surface treatments for increasing miniscrew surface roughness or changing the nano-surface or topography to mimic that of natural bone have been developed to improve stability in patients with a high risk of miniscrew failure. Odontuya et al.<sup>7</sup> reported that resorbable blasting media (RBM) treatment supported the early stability of miniscrews in a rabbit model. This was because RBM-treated miniscrews had a rougher surface and were associated with less initial lamellar bone resorption than miniscrews that had not undergone surface treatment. Choi et al.<sup>6</sup> reported that anodic oxidized miniscrews exhibited modified surface topography, but their biomechanical stability was similar to that of non-treated miniscrews in a beagle model.

Few prospective studies have evaluated differences in success rates and stability depending on the type of surface treatment in actual clinical situations. To determine whether surface-treated miniscrews are clinically more cost-effective than non-treated miniscrews, well-controlled prospective clinical studies are necessary. The aim of this prospective clinical study was to determine whether the success rate and primary stability of surface-treated miniscrews differed significantly from those of nontreated miniscrews. Specifically, this study investigated whether surface treatment of miniscrews may be one of the key factors that contributes to the success of miniscrews in clinical situations. The null hypothesis was that there is no difference in the success rate or primary stability of miniscrews regardless of surface treatment.

## MATERIALS AND METHODS

### Study Design and Subjects

This prospective clinical study recruited patients who required the placement of miniscrews for orthodontic treatment at the Department of Orthodontics, Yonsei University Dental Hospital (Seoul, Korea) between April 2016 and November 2016. Inclusion criteria for the study were the requirement of one or more miniscrews for the same reason in each quadrant of the maxilla or mandible during orthodontic treatment, complete fixed appliance treatment with or without premolar extraction, and patients who were over 13 years and had all permanent teeth erupted with the exception of third molars. Exclusion criteria were

severe craniofacial deformities such as a cleft lip and palate, a history of bone disease such as osteoporosis or diabetes, and cases where there was a high expectation of failure due to anatomical limitations such as pneumatization of the maxillary sinus, narrow interproximal alveolar bone, or attached gingiva deficiency.

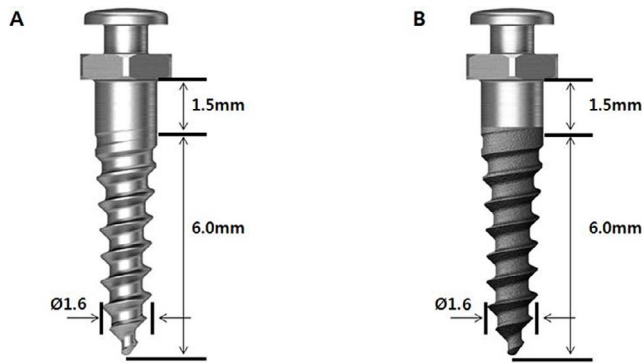
Written informed consent was obtained from all patients (and their legal guardians in the case of minors) prior to participating in this study. The study complied with the guidelines of the declaration of Helsinki and was approved by the ethics committee of Yonsei University Dental Hospital, Seoul, Korea (IRB No. 2-2015-0023).

The study was a single-blinded, split-mouth, randomized, controlled trial with a 1:1 allocation ratio. Self-drilling miniscrews (diameter 1.6 mm, thread length 6 mm) were used. Miniscrews with two different surface types were included: those with no surface treatment (machined surface, OSSH1606; Osstem Implant, Busan, Korea) and those with an acid-etched surface (OSSH1606HE; Osstem Implant, Busan, Korea) (Figure 1).

The patients did not know which type of miniscrew was placed at which location, which was determined via a random block design. Orthodontic miniscrews were placed bilaterally, mainly in the posterior buccal area between the second premolar and the first molar in the maxilla or mandible. Two miniscrews were symmetrically placed on each side for the same purpose. The miniscrews were used as skeletal anchorage for en masse retraction, total arch distal movement, and intrusion of maxillary posterior teeth. Both types of miniscrews were placed with a manual hand driver directly, without predrilling. All miniscrews in the study were inserted by the same orthodontic specialist. The orthodontic load applied to the miniscrews was estimated to be 100–200 g approximately 4 weeks after surgery. The direction of the force loaded onto each pair of miniscrews within each patient was the same and was perpendicular to the screw.

### Scanning Electron Microscopy

To evaluate differences in surface topography between the two types of miniscrews, their surfaces were observed via scanning electron microscopy at magnifications of 50x and 1000x (S3000N; Hitachi, Tokyo, Japan). They were coated with platinum by ion sputtering (IB-3, Eiko Engineering, Ibataki, Japan), 6 mA for 6 minutes, and were examined and photographed at 20 kV acceleration voltage. The middle thread was observed for each surface type.



**Figure 1.** Schematic diagrams of orthodontic miniscrews with (A) a machined surface and (B) an acid-etched surface.

**Success Rate**

The cumulative success rates of each of the two types of miniscrews were examined. Criteria for the success of miniscrews were absence of clinical detectable mobility (movement greater than 1 mm)<sup>6</sup> and capacity to sustain the anchorage function throughout the orthodontic treatment. Furthermore, success of miniscrews was defined as inserted miniscrews that were maintained for >6 months.<sup>9</sup>

**Primary Stability**

To evaluate the stability of a miniscrew, the maximum insertion torque was measured using a torque sensor (Mark-10, MGT 12, Copiague, NY, USA). Periotest value (PTV) was measured via the Periotest system (Siemens, Bensheim, Germany) in the form of mobility values immediately after insertion and 6 months after insertion.

**Statistical Analysis**

The cumulative survival of the miniscrews was analyzed using the Kaplan-Meier method. The Kolmogorov-Smirnov test was applied to assess data distribution and normality. A two-way analysis of variance (ANOVA) was used to compare the mean initial torque and PTV according to surface treatment and insertion site.

To investigate factors that contributed to miniscrew success in clinical situations, a multivariate regression model was used. The independent variables were divided into two categories; host-related variables and miniscrew-related variables. Host-related variables included age (<20 years, ≥20 years),<sup>10</sup> sagittal skeletal pattern (Class I, ANB 0–4°; Class II, >4°; Class III, <0°),<sup>11</sup> vertical skeletal pattern (high, SN-MP >37°; normal, SN-MP 27–37°; low, SN-MP <27°),<sup>12</sup> overjet (normal, 0–4 mm; excessive overjet >4 mm; crossbite <0 mm), and overbite (normal, 0–4 mm; deep bite >4 mm; open bite <0 mm).<sup>13</sup> Miniscrew-

Table 1. Characteristics of Patients<sup>a</sup>

Variables	
Sex	
Men	13 (32.5)
Women	27 (67.5)
Age (years) (mean ± SD)	22.16 ± 5.38
Sagittal skeletal pattern	
Class I	11 (27.5)
Class II	22 (55)
Class III	7 (17.5)
Vertical skeletal pattern (SN-MP)	
Normal (27°–37°)	15 (37.5)
High mandibular plane angle (>37°)	23 (57.5)
Low mandibular plane angle (<27°)	2 (5.0)
Overjet	
Normal overjet (0–4 mm)	27 (67.5)
Excessive overjet (>4 mm)	11 (27.5)
Crossbite (<0 mm)	2 (5.0)
Overbite	
Normal overbite (0–4 mm)	31 (77.5)
Deep bite (>4 mm)	2 (5.0)
Open bite (<0 mm)	7 (17.5)

<sup>a</sup> SN-MP indicates mandibular plane angle; unless otherwise noted, the right column means number (%).

related variables included surface treatment type (machined vs acid-etched), insertion site (maxilla vs mandible), and miniscrew purpose (en masse retraction anchorage, retraction; total arch distal movement, distalization; maxillary molar intrusion, intrusion). The model-building strategy involved the inclusion of any variable for which the bivariate test yielded a *P* value of <.05. A backward elimination was performed on any variable that did not contribute to the model on the grounds of the likelihood ratio test (logistic regression), using a *P* value cut-off of .05. Based on the dichotomized dependent variable, the adjusted odds ratios (OR) and 95% confidence intervals (CI) were calculated. All statistical analyses were performed using IBM SPSS software for Windows (version 23.0; SPSS, Armonk, NY, USA).

**RESULTS**

Forty patients (13 men and 27 women) were included in this study, with 98 orthodontic miniscrews (49 acid-etched and 49 machined surface), and their mean age was 22.16 ± 5.38 years. When the 40 patients were classified, 55% were skeletal class II, 57.5% exhibited a high mandibular plane angle, 67.5% had a normal overjet, and 77.5% had a normal overbite (Table 1); 63.3% of the miniscrews were placed in the maxilla; and en masse retraction was the most frequent purpose of placement (Table 2).

Scanning electron microscopy analysis revealed different surface topography of the two types of miniscrews, and acid-etching surface treatment evidently changed the surface morphology resulting in a

Table 2. Miniscrew Related Characteristics<sup>a</sup>

Variables	
Surface type of miniscrews	
Acid-etched surface	49 (50.0)
Machined surface	49 (50.0)
Insertion site	
Maxilla	62 (63.3)
Mandible	36 (36.7)
Purpose of miniscrew	
Retraction	56 (57.1)
Distalization	34 (34.7)
Intrusion	8 (8.2)

<sup>a</sup> The right column means number (%).

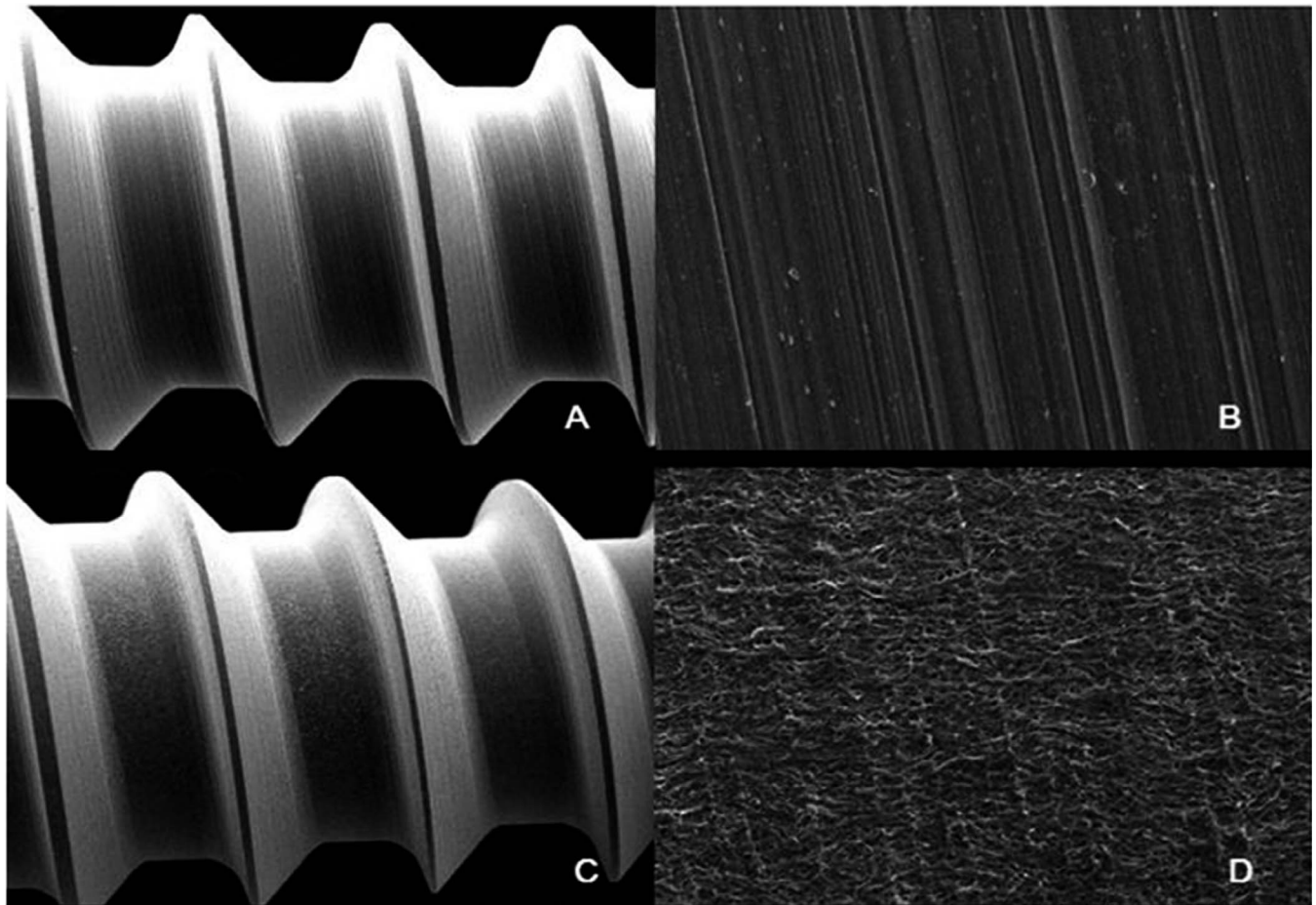
rough surface (Figure 2). The overall success rate was 88.8%, and the respective success rates for acid-etched and machined surface miniscrews were 91.8% and 85.7% (Figure 3). The difference in success rates was not statistically significant ( $P = .323$ ).

Mean insertion torques were  $13.62 \pm 5.95$  N-cm for the acid-etched miniscrews and  $13.38 \pm 4.0$  N-cm for the machined miniscrews. PTVs measured immediately after insertion were  $-0.50 \pm 2.77$  for the acid-etched

miniscrews and  $-0.28 \pm 3.36$  for the machined miniscrews. PTVs measured 6 months after insertion were  $4.58 \pm 5.15$  for the acid-etched miniscrews and  $6.42 \pm 5.6$  for the machined miniscrews. The differences between all measurements were not statistically significant ( $P = .733$ ,  $P = .647$ ,  $P = .066$ ). When the mean insertion torque and PTV were compared according to the surface treatment and jaw, no interaction between surface treatment and jaws was found using two-way ANOVA (Table 3).

Higher success rates were associated with skeletal Class I, normal mandibular plane angle, and normal overjet. When considering miniscrew-related variables, acid-etched surface and en masse retraction anchorage were associated with better success rates (Table 4). Notably however, there was no significant difference in the success rates in each group.

To investigate the individual factors affecting miniscrew failure statistically, multivariate regression analysis was performed. On the basis of the adjusted analysis, if the purpose of the miniscrew was distalization (OR 7.49, 95% CI 1.23–45.75,  $P < .05$ ) and if the



**Figure 2.** Scanning electron microscopy images of the lateral sides of orthodontic miniscrews. (A) Machined miniscrew at 50 $\times$  magnification. (B) Machined miniscrew at 1000 $\times$  magnification. (C) Acid-etched miniscrew at 50 $\times$  magnification. (D) Acid-etched miniscrew at 1000 $\times$  magnification.

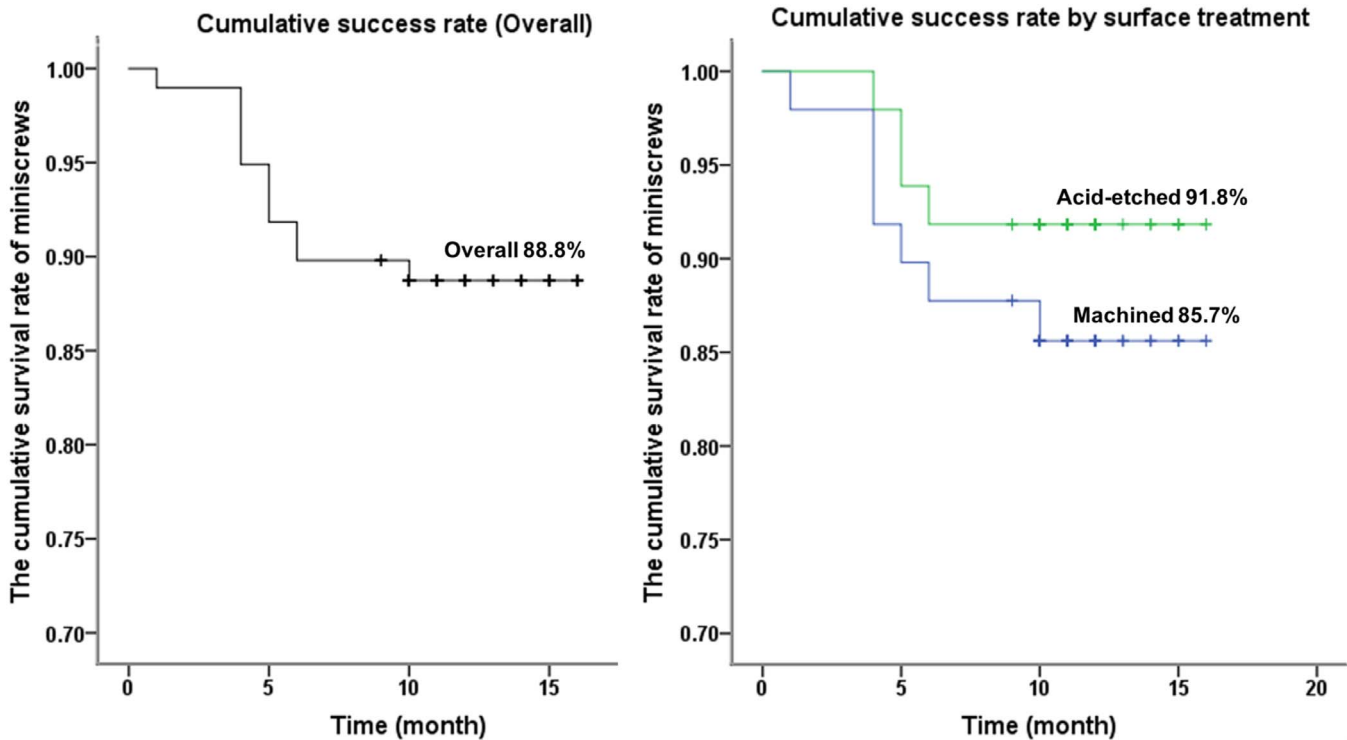


Figure 3. Kaplan-Meier survival function curve (overall and by surface treatment).

overbite was an open bite (OR 4.76, 95% CI 1.78–63.39,  $P < .05$ ), the possibility of miniscrew failure was high (Table 5).

**DISCUSSION**

The acid-etching surface treatment method has been shown to facilitate osteogenic cell and blood cell retention and allows for cell migration at the miniscrew surface. As a result, it improves the biocompatibility and stability of titanium miniscrews.<sup>14</sup> Several animal studies have shown that acid-etched surface treatment improved the stability and success rate of miniscrews. However, most previous in vivo studies have been conducted in animals such as dogs or rabbits. In many cases, force was not applied to the miniscrew, and the cortical bone thickness of dogs and rabbits differs from that of humans. Additionally, most human studies have

been retrospective. For these reasons, this controlled, split-mouth, human clinical study represents a timely addition to the knowledge base.

The primary stability of miniscrews is regarded as mechanical retention at implantation and is one of the important factors pertaining to clinical success. Primary stability was assessed by maximum insertion torque and PTVs in the current study, and mean insertion torque was 13.62 N·cm for the acid-etched miniscrews and 13.38 N·cm for the machined miniscrews. Motoyoshi et al.<sup>15</sup> reported that a maximum insertion torque between 5 N·cm and 10 N·cm is appropriate. According to this criterion, the insertion torque in the current study was somewhat large. However, other studies have reported that there was no evidence on which to base specific recommendations of maximum insertion torque levels to obtain higher orthodontic miniscrew success rates.<sup>16,17</sup> In addition, maximum insertion torque report-

Table 3. Mean and Standard Deviation of the Insertion Torque Value and Periotest Value (PTV) According to the Surface Treatment and Jaw<sup>a</sup>

Variables	Jaw	Surface Treatment		Surface Treatment × Jaw
		Machined	Acid-etched	
Insertion torque (N·cm)	Mx	12.91 ± 4.52	13.4 ± 6.11	0.818
	Mn	14.18 ± 2.85	14.12 ± 5.79	
PTV immediately after insertion	Mx	-0.93 ± 3.24	-1.26 ± 2.82	0.862
	Mn	0.92 ± 0.81	0.81 ± 2.16	
PTV 6 months after insertion	Mx	6.26 ± 6.78	3.83 ± 4.34	0.871
	Mn	7.99 ± 6.37	5.13 ± 5.8	

<sup>a</sup> Surface treatment x jaw means  $P$  value calculated with two-way ANOVA. Mx indicates maxilla; Mn, mandible.

Table 4. Success Rate of Miniscrew According to Variables<sup>a</sup>

Clinical Variables	Success/Total (n)	Success Rate (%)
Age (years) (Mean ± SD)		
<20	23/26	88.5
≥20	64/72	88.9
Sagittal skeletal pattern		
Class I	27/28	96.4
Class II	44/50	88
Class III	16/20	80
Vertical skeletal pattern (SN-MP)		
Normal (27–37°)	34/36	94.4
High mandibular plane angle (>37°)	48/56	85.7
Low mandibular plane angle (<27°)	5/6	83.3
Overjet		
Normal overjet (0–4 mm)	58/64	90.6
Excessive overjet (>4 mm)	26/30	86.7
Crossbite (<0 mm)	3/4	75
Overbite		
Normal overbite (0–4 mm)	68/74	91.9
Deep bite (>4 mm)	7/8	87.5
Open bite (<0 mm)	12/16	75
Surface type of miniscrews		
Machined surface	42/49	85.7
Acid-etched surface	45/49	91.8
Insertion site		
Maxilla	55/62	88.7
Mandible	32/36	88.8
Purpose of miniscrew		
Retraction	52/56	92.9
Distalization	29/34	85.3
Intrusion	6/8	75

<sup>a</sup> SN-MP indicates mandibular plane angle.

edly varied depending on whether pilot drilling was utilized, the diameter and length of the miniscrews, and the thickness of the cortical bone at the placement site.<sup>16,18</sup>

PTVs have been used to evaluate the initial stability of mini-implants in terms of mobility, and it has been reported that PTVs immediately after insertion correlated significantly with insertion torque.<sup>19</sup> In that study, values between –8 and +9 indicated that the miniscrew was stable. In the current study, the initial mean PTVs were –0.5 for acid-etched miniscrews and –0.25 for machined miniscrews. At 6 months after insertion, mean PTVs were 4.58 for acid-etched miniscrews and 6.42 for machined miniscrews, indicating that they were relatively stable.

When host factors affecting the success rates of miniscrews were examined in this study, the dominant factors were overbite and miniscrew purpose. Patients with an open bite had a high failure rate. All patients with an open bite were in the high mandibular plane angle group in this study. Several previous studies have also shown that miniscrew success rates were low in patients with high mandibular plane angle.<sup>2,3</sup> The reason is that the thickness of buccal cortical bone in subjects with a high mandibular plane angle is thinner than that in

Table 5. Summary of Adjusted Multivariate Regression Analyses Predicting Failure of Miniscrews<sup>a</sup>

Clinical Variables	OR	Logistic Regression 95% CI	P Value
(constant)	0.013		
Purpose of miniscrew			
Retraction	1 (reference)		
Distalization	7.49	1.23–45.75	.029*
Intrusion	4.43	0.59–33.50	.149
Overbite			
Normal overbite (0–4 mm)	1 (reference)		
Deep bite (>4 mm)	4.76	0.37–61.07	.231
Open bite (<0 mm)	10.62	1.78–63.39	.010*

<sup>a</sup> OR indicates odd ratio; CI, confidence interval; \**P* < .05.

subjects with a low or normal mandibular plane angle.<sup>4</sup> In the current study, the purpose of miniscrew placement was classified as retraction anchor, distalization, or intrusion, and the distalization group exhibited a lower success rate than the other groups. As distalization progresses, the miniscrew contacts the root of the tooth and the bone density around the miniscrew is reduced. For this reason, the failure rate within 6 months was higher in the distalization group, although initial torque and mobility were good.

One of the limitations of this study was the small number of participants, particularly with regard to assessing risk factors related with success of Miniscrews. Logistic regression analysis yielded a rather broad 95% CI. Regarding vertical pattern, the success rate of the high mandibular plane angle group was 85.7%, which was a lower success rate than that of the normal group of 94.4%. Nevertheless, caution must be used when drawing conclusions. In the skeletal Class III group, which had a lower success rate than the skeletal Class I or II groups, approximately 70% of the patients belonged to the high mandibular plane angle group. In the open bite group, which exhibited a statistically significantly lower success rate, all patients belonged to the high mandibular plane angle group. If there had been a large number of patients in each group, logistic regression analysis would have resulted in narrower 95% CI than were obtained in the current study, and potential risk factors could have been investigated more thoroughly. Additionally, the removal torque of miniscrews was not examined in the current study. Secondary stability and osseointegration of miniscrews can be assessed by measuring removal torque. Of all the miniscrews used in the current study, 34.7% were used as anchors for distalization. As mentioned earlier, it was decided that it was meaningless to examine the removal torque of miniscrews because they could contact the root, and the bone density around the miniscrews changed during the distalization process.

In the future, to apply the results of this study more generally, larger sample sizes are needed to assess associations between skeletal pattern and miniscrew success rate. Furthermore, to evaluate associations between the secondary osseointegration of miniscrews and different surface treatments, it would be better to recruit subjects based on more restricted criteria regarding the purpose of the miniscrews; for example, anterior teeth en masse retraction cases where the relationship between the tooth and the miniscrew remains relatively unchanged over time.

## CONCLUSIONS

- The success rate of acid-etched surface miniscrews was 91.8% and that of machined surface miniscrews was 85.8% in the current study, but this difference was not statistically significant.
- There was no significant difference in primary stability according to surface treatment and jaw.
- Patients with an open bite or those who require distalization of the total dentition are predicted to have a high possibility of miniscrew failure.

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