

Predictors of initial stability of orthodontic miniscrew implants

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SUMMARY The purpose of this retrospective study was to elucidate potential confounding factors affecting initial stability of miniscrews inserted to enhance orthodontic anchorage. Four hundred and seven miniscrews inserted in 168 patients treated by 17 orthodontic residents were analysed in a consecutive chart review. The outcome variable was the stability of the miniscrew, measured as a dichotomous variable, 0 if the miniscrew loosened during a 1 week period after insertion to the time of orthodontic force application and a value of 1 otherwise. Potential confounding variables examined were gender, age, jaw, insertion site, tissue type, length and diameter of the miniscrew, and number of previous insertions. Generalized estimating equations (GEE) methods were used to estimate the influence of each factor on stability for the correlated binary outcomes of each patient. A weighted analysis for the GEE approach was also performed for the convergence calculation of the estimation procedure due to a value of 0 in one of the cells. Crude odds ratio (cOR) and adjusted odds ratio (aOR) and their 95 per cent confidence intervals (CI) were calculated for this purpose.

The overall success rate after 1 week was 93.1 per cent (379/407). The screws inserted by more experienced clinicians (more than 20 miniscrews) were found to have approximately a 3.6-fold higher success rate of initial stability compared with those inserted by less experienced clinicians after adjusting for the insertion site (aOR = 3.63, $P = 0.015$). The results of the present study suggest that the initial stability depends on insertion site and clinician experience.

Introduction

Anchorage control plays an important role in orthodontic treatment. In the past, extraoral headgear, elastics, and a number of other appliances have been suggested as effective forms of orthodontic anchorage. However, the main drawback of these appliances is that they all rely on patient compliance to be successful. For this reason, other alternatives for anchorage have been developed for intraoral appliances, such as osseointegrated implants used in the replacement of missing teeth (Roberts *et al.*, 1984, 1989, 1990; van Steenberghe *et al.*, 2004). In recent years, new bone anchors have been developed for orthodontic treatment. These devices include osseointegrated implants (Wehrbein *et al.*, 1996), zygomatic ligatures (Melsen *et al.*, 1998), miniplates (Umemori *et al.*, 1999), and miniscrews (Kanomi, 1997; Costa *et al.*, 1998).

Compared with osseointegrated implants that provide very high success rates, miniscrew stability, with its simple mechanical retention, is not as high as would be expected. To this end, Miyawaki *et al.* (2003), Cheng *et al.* (2004), Tseng *et al.* (2006), and Park *et al.* (2006) examined several confounding factors affecting miniscrew stability for orthodontic anchorage. Lim *et al.* (2009) also examined the initial stability of 378 miniscrews in 154 patients. Generalized estimating equations (GEE; Zeger and Liang, 1986) analysis of the data detected significant associations between initial stability and the confounding variables. However, no significant association of any factor was

observed based on the various types of miniscrews used. In the present study, one type of miniscrew was included to obtain more meaningful information with more appropriate statistical methods, as a means of better detecting reliable confounding factors affecting initial stability.

In order to increase the success rate of miniscrew stability, it is necessary to assess stability after stratifying the pre- and post-orthodontic force application. There is a need to consider the potential that clinician-related factors can be more responsible for stability prior to the application of orthodontic force and that patient-related factors such as oral hygiene are potentially more responsible for stability after orthodontic force application. Consequently, initial miniscrew stability, i.e. the time of orthodontic force application, has received more attention than post-orthodontic force application (Lim *et al.*, 2009). Thus, the purpose of this study was to evaluate potential confounding factors affecting initial stability when a tapered type miniscrew is placed for orthodontic anchorage, with the primary intention being to increase the success rate prediction.

Subjects and methods

This study protocol was approved by the Chonnam National University Hospital Institutional Review Board. A retrospective chart review of patients was consecutively

conducted at the Graduate Orthodontic Clinic of Chonnam National University Hospital from 2003 to 2005. A total of 407 tapered miniscrews of various sizes (Orlus; Ortholution Inc., Seoul, Korea) in 168 patients (51 males and 117 females; mean age \pm SD = 23.0 \pm 8.7 years) were included in this study. This type of miniscrew tapers from a larger head diameter to a smaller diameter at its tip; the screw diameter is measured at the midpoint from the neck to the tip of the screw. The miniscrews were placed directly with a hand-driven screwdriver without pre-drilling. For this study, detailed patient information was obtained from lateral cephalometric films, panoramic radiographs, and photographs.

The potential confounding variables examined were divided into three categories: patient, miniscrew, and operator-related. Patient factors were related to gender, age (less than 15, more than 15 and less than 20, more than 20 and less than 25, and more than 25 years), jaw (maxilla or mandible), insertion sites, and tissue type (keratinized or non-keratinized). The miniscrews were inserted into the following areas: maxillary buccal (mostly between the second premolar and first molar), palatal slope (between the maxillary second premolar and first molar or between the first and second molar), midpalatal (the midline of the palate corresponding to the area between the maxillary second premolar and first molar), mandibular buccal molar (between the second premolar and first molar or between the first and second molar), mandibular buccal canine (distal to canine), or other (between the mandibular incisors or mandibular retromolar area). The palatal mucosa and attached gingiva were classified as keratinized tissue, whereas the buccal mucosa was classified as non-keratinized tissue. Miniscrew factors included diameter and length of the miniscrew: diameters 1.6 and 1.8 mm and lengths 6, 7, 8, and 10 mm. Operator factor referred to the number of previous insertions conducted by the 17 orthodontic residents.

Stability of the miniscrews was assessed 1 week after placement because drill-free type screws are always firm immediately after insertion compared with pre-drill type screws. No load was applied to the screws after placement, before assessment of stability. While the initial stability was the outcome variable of this study, each response variable for initial stability was measured as dichotomous, i.e. using a value of 0 if the miniscrew loosened (failed) during the 1 week period and a value of 1 otherwise.

The overall and success rates for potential confounding factors were calculated. The number of miniscrews inserted in one subject's mouth ranged from 1 to 8 (Table 1). Over 80 per cent of the patients (137/168) had two or more miniscrews inserted. It can be seen from Table 2 that the number of patients with successful initial placement was 144 (86 per cent), with three (2 per cent) all failures. Thirteen patients (7 per cent) had a skewed distribution of initial stability. Over 90 per cent of the initial stability of the miniscrews in each patient was highly correlated. Thus, within a single patient, the outcomes were not independent.

Table 1 Number of miniscrews implanted for each patient.

Number of miniscrews	Number of patients (%)
1	31 (18.5)
2	82 (48.8)
3	26 (15.5)
4	20 (11.9)
5	4 (2.4)
6	3 (1.8)
8	2 (1.1)
Total	168 (100)

Table 2 Stability of miniscrews for each patient.

Stability of miniscrews	Number of patients (%)
All success	144 (86)
All failure	3 (2)
Skewed	13 (7)
Equally distributed	8 (5)
Total	168 (100)

Both univariate and multivariate GEE (Zeger and Liang, 1986) approaches were used to estimate the influence of each factor on the stability for the correlated outcomes of each patient. However, due to a value of 0 in one of the cells, based on the 0 per cent failure rate of the midpalatal area, not all parameters could be estimated. To overcome this, a weighted analysis using the GEE approach with a relatively small weight of 0.01 instead of 0 was used to calculate the convergence for the estimation procedure. The backward elimination variable selection process of model building began with a univariate analysis of eight potential confounding variables, with each variable whose univariate test had a value of $P < 0.25$ being included in the multivariate test (Mickey and Greenland, 1989). After the selection of suitable candidates, the adjusted odds ratios (aORs) and their 95 per cent confidence intervals (CIs) were then calculated. The GEE goodness-of-fit statistic was subsequently used to evaluate how well a final model fitted a set of observations (Horton *et al.*, 1999). The null hypothesis of the goodness-of-fit test was that the model is a good fit to the data; a value of $P > 0.05$ also indicated that the final model also fitted the data. All statistical computations were performed using SAS software Release 9.1 (SAS Institute, Inc., Cary, North Carolina, USA), with the significance level set at 0.05 for a two-tailed test. In addition, SAS macro language was used for the GEE goodness-of-fit test and the GENMOD procedure in SAS for GEE analysis.

Results

The overall success rate was 93.1 per cent for all miniscrews (379/407). The success rates for initial stability were observed with respect to the following potential confounding factors.

The success rates were comparable in females (93.6 per cent) and males (92.1 per cent) and the four age categories had similar success rates of over 90 per cent. Miniscrews implanted in the maxilla (93.1 per cent) and mandible (93.2 per cent) were also found to have similar success rates. A 100 per cent success rate was shown in the midpalatal area, but the other areas had success rates of around 90 per cent. Notable was that clinicians who had performed miniscrew insertions more than 20 times had a 7.1 per cent higher success rate than those who had undertaken less than or equal to 20 insertions (Table 3).

In terms of the univariate analysis performed using the GEE method for detecting significant risk indicators, the midpalatal area [crude odds ratio (cOR) = 19.90, 95 per cent CI: 12.20–32.45] was found to have a significantly higher success rate than the maxillary buccal area. The mandibular buccal molar area (cOR = 1.82, 95 per cent CI: 0.48–6.83) tended to have a higher success rate than the maxillary buccal area, but there was no significant trend. The maxillary buccal area was used as a reference group in the comparison of the success rates of the insertion sites; the category with the largest sample size or most frequently inserted area was used as the reference group. In addition, insertions involving a clinician with experience in performing more than 20 insertions (cOR = 4.06, 95 per cent CI: 1.40–11.87) were

found to have significantly less loosening than when the clinician had only performed up to a maximum of 20 insertions. No significant comparative differences were found between groups according to age, gender, jaw involved, tissue type, length, or diameter of the inserted miniscrews (Table 4).

Based on the results of the multivariate analyses, the preliminary model included variables whose univariate test had a value of $P < 0.25$. From this preliminary model, the final model included the variables, insertion sites, and clinician experience, obtained using the backward elimination variable selection method. After adjusting for insertion site, it was found that the more experienced clinicians (more than 20 miniscrews) were found to have a 3.63 fold higher success rate of initial stability compared with less experienced clinicians (less than or equal to 20 miniscrews; aOR = 3.63; $P = 0.015$). The GEE goodness-of-fit statistic was 13.61 with a value of $P = 0.14$. The magnitude of this result in conjunction with a large P -value (greater than 0.05) indicates that the final model fits the data well (Table 4).

Discussion

This study evaluated factors affecting initial miniscrew stability with regard to their use as orthodontic anchorage, to

Table 3 Success rate and number of miniscrews according to the selected variables.

Variables	Insertion (<i>n</i>)	Success (<i>n</i>)	Success rate (%)
Gender			
Male	126	116	92.1
Female	281	263	93.6
Age (years)			
25 and over	128	120	93.8
≤20 to <25	104	97	93.3
≤15 to <20	86	81	94.2
Under 15	89	81	91.0
Jaw			
Maxilla	319	297	93.1
Mandible	88	82	93.2
Insertion site			
Maxillary buccal area	224	205	91.5
Palatal slope	30	28	93.3
Midpalatal area	53	53	100.0
Mandibular buccal molar area	44	42	95.5
Mandibular buccal canine area	32	30	93.8
Other	24	21	87.5
Tissue type			
Keratinized	267	257	96.3
Non-keratinized	35	34	97.1
Diameter of miniscrews (mm)			
1.6	22	21	95.5
1.8	385	358	93.0
Length of miniscrews (mm)			
6	4	3	75.0
7	108	100	92.6
8	269	253	94.1
10	26	23	88.5
Number of insertions			
≤20	250	226	90.4
>20	157	153	97.5
Total	407	379	93.1

Table 4 The crude odds ratio (cOR), adjusted odds ratio (aOR), and their 95 per cent confidence intervals (CIs) for the contributing factors for the stability through general estimating equations analysis.

Variables	Univariate	Multivariate
	cOR (95% CI)	aOR (95% CI)
Gender		
Male	1.00	
Female	1.26 (0.53–3.00)	
Age (years)		
25 and over	1.00	
≤20 to <25	0.92 (0.28–3.02)	
≤15 to <20	1.08 (0.30–3.86)	
Under 15	0.68 (0.25–1.84)	
Jaw		
Maxilla	1.00	
Mandible	1.01 (0.40–2.55)	
Insertion site		
Maxillary buccal area	1.00	1.00
Palatal slope	1.26 (0.39–4.07)	1.14 (0.37–3.50)
Midpalatal area	19.90 (12.20–32.45)**	17.09 (10.04–29.07)**
Mandibular buccal molar area	1.82 (0.48–6.83)	1.83 (0.49–6.80)
Mandibular buccal canine area	1.32 (0.35–4.95)	1.03 (0.29–3.71)
Other	0.65 (0.18–2.36)	0.51 (0.14–1.89)
Tissue type		
Keratinized	1.00	
Non-keratinized	1.32 (0.16–10.85)	
Diameter of miniscrews (mm)		
1.6	1.00	
1.8	1.58 (0.21–11.73)	
Length of miniscrews (mm)		
6	1.00	
7	0.19 (0.02–2.33)	
8	0.79 (0.29–2.15)	
10	0.48 (0.13–1.80)	
Number of insertions		
≤20	1.00	1.00
>20	4.06 (1.40–11.87)*	3.63 (1.38–9.52)*

GEE goodness-of-fit $X^2 = 13.61$ ($P = 0.14$) for final model.

* $P < 0.05$; ** $P < 0.01$.

identify factors that could enable greater miniscrew stability. From a previous investigation that assessed factors affecting the clinical success of screw implants, it was found that when a patient had two or more miniscrews implanted, instances of stabilities could be clustered (Lim *et al.*, 2009). The effect of the increased variability due to clustering is to increase the standard error of the effect measure, widen the CI, and thus flatten the type I error rate. Conversely, failing to account for clustering in the analysis will result in CIs that are falsely narrow and P -values that are falsely small (Shoukri and Chaudhary, 2007). Whereas this clustering was not considered in previous research (Miyawaki *et al.*, 2003; Park *et al.*, 2006), multivariate GEE analysis, after adjusting for confounding factors affecting the initial stability of tapered type miniscrews, was performed on the correlated outcomes of each patient in the present study.

A 100 per cent success rate was shown in the midpalatal area with the miniscrews in this area remaining the most stable after insertion to the time of orthodontic force application. The reasons for this stability might be due to contributions from the

compact bone and thin gingival tissue in this area. Miniscrews could therefore be inserted in the area without the potential for loosening as it was shown that miniscrew insertions in this area were the most effective and stable (Chen *et al.*, 2007).

In this study, clinicians who had performed more than 20 insertions were found to have a higher success rate than those with no more than 20 insertions. The reason for operator-induced loosening was thought to be due to 'wobbling' i.e. the miniscrew wobbles on its axis; it may damage the bone tissue supporting the fastening of the miniscrew, caused by screwdriver rotation during insertion. These non-axial rotations mainly occur when using a drill-free type of screw. Since pre-drilling was not performed in this study, the screwdriver was rotated under pressure along the axial direction during insertion; this pressure is required to penetrate the cortical layer. However, once the cortical layer is penetrated, only rotation should be continued as there is potential to cause non-axial rotations when pressure is added to the rotation after penetration. These are not caused by pure axial pressure and a clinician's skill would

increase with repeated insertions. Consequently, non-axial rotations were diminished based on the skill of the clinician, enabling the success rate to increase.

Another possible reason why experienced clinicians showed higher stability of miniscrew placement than inexperienced clinicians may be that experienced clinicians are able to insert a screw with an adequate angle and therefore reduce the possibility of root proximity, which is known to cause screw loosening. Kuroda *et al.* (2007) in a sample of 216 miniscrews in 110 patients reported that the proximity of a miniscrew to the root is a major risk factor for the failure of screw anchorage. A vertical angle of insertion is recommended to be an oblique 20–40 degrees, to the horizontal plane in an apical direction, whereas the horizontal angle should be perpendicular to the bone surface to avoid root contact or perforation (Hwang and Hwang, *in press*). That study considered that experienced clinicians are able to decide an adequate angle of insertion, maintain the angle during screw insertion, and avoid or reduce the possibility of root proximity, which is known to be a major factor in screw loosening.

No significant relationship was found in this study as the age of patients increased, but Chen *et al.* (2007) reported that growing patients had a higher possibility of loosening than adults as they had a thinner shell of cortical bone and a lower degree of bone density. One possible reason for the difference is that stability was checked 1 week after insertion in this study whereas late stability during treatment was evaluated in the investigation of Chen *et al.* (2007). The results also showed that tissue type was not associated with stability. This finding might be because initial stability was assessed in this study. While non-keratinized tissue, such as movable mucosa, has a high risk of infection, which is a source of loosening compared with keratinized tissue, this problem rarely occurs at the beginning of screw placement. Consequently, tissue type did not influence initial stability.

Since miniscrews should remain clinically stable after orthodontic force is applied, the success rates of both pre- and post-orthodontic force application are important. Miniscrews could loosen after orthodontic force application, though they are initially stable. Accordingly, further studies are needed to evaluate potential confounding factors affecting stability after orthodontic force application.

Conclusions

1. The overall success rate for miniscrews after 1 week was 93.1 per cent.
2. The midpalatal area was the most suitable for initial stability.
3. Clinicians that had performed more than 20 miniscrew insertions had a higher success rate than those with less than or equal to 20 insertions, even after adjusting for insertion site.

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