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An evaluation of clinical stability of miniscrew with surgical guide using intraoral scan model and CBCT : Randomized clinical trial

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An evaluation of clinical stability of miniscrew with surgical guide using intraoral scan model and CBCT : Randomized clinical trial

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감사의 글

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마지막으로 언제나 변함없는 사랑과 헌신으로 저를 지지해 주신 부모님과 동생이지만 오빠처럼 저를 항상 챙겨주는 든든한 동생 용식이, 제가 힘들 때 마다 버팀목이 되어 준 강민 오빠와 부모님께도 이 글을 빌어 감사의 마음을 전합니다.

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Because the miniscrew is becoming more common in orthodontic treatment, achieving precision of miniscrew insertion, reduction of the risk of root damage, and improvement of the success rate of miniscrew insertion have become important. With the development of digital technology, it has become possible to create a dental model using an intraoral scanner rather than a plaster model, and as the clinical use of dental CBCT (cone beam computed tomography) increases, CBCT can be used to superimpose the tooth model and radiograph. Therefore, This study aimed to assess the use of surgical guides with computer-aided design and computer-aided manufacturing technology in achieving these ends.

A randomized clinical trial was conducted with 59 patients (100 miniscrews) who required miniscrew placement during orthodontic treatment. In each patient, a miniscrew (BMK, Korea, cylinder, 1.5x7 mm) was placed in the buccal interradicular space using panoramic radiography and dental CBCT. To evaluate the initial stability after miniscrew placement, the insertion torque (IT) and Periotest value (PTV) were measured twice. Periapical radiographs were obtained to assess root contact. Miniscrews maintained for more than 6 months were considered successful.

1. The success rate of the manual group was 80.9 % and the success rate of the surgical guide group was 88.9 %. There was statistically insignificant difference in the success rate using the surgical guide (p>0.05). In the Kaplan-Meyer survival analysis, miniscrews were failed early than 50 days in the manual group, whereas most of miniscrews were failed after 120 days in the guide group.

2. The root contact rate was 31.9 % in the manual group and 0.4 % in the surgical guide group, and the root contact rate was low when using the surgical guide, showing a statistically significant difference (p <0.001).

3. The insertion torque was 6.37 ± 2.64 Ncm in the manual group and 6.54 ± 2.90 Ncm in the surgical guide group, but the difference was not statistically significant (p> 0.05) and The PTV was 0.19 ± 2.86 in the guide group and 1.58 ± 2.13 in the manual guide group, which showed a statistically significant difference (p <0.05).

4. The insertion torque of was 6.56 ± 2.86 Ncm in the success group and 5.89 ± 2.18 Ncm in the failure group, but the difference was not statistically significant ($p > 0.05$) and The PTV was 0.57 ± 2.62 in the success group and 2.72 ± 1.45 in the failure group, which showed a statistically significant difference($p < 0.01$).

5. A total of five (10%) miniscrews were excluded due to the risk of the miniscrew guide itself. They were 4% of surgical guide slippage, 6% of adaptability problem.

The rate of miniscrew contact with the root was significantly lower in the surgical-guide group than in the manual group. The present study recommends the use of surgical guides for the stable placement of miniscrews in cases of anatomical limitations or the high possibility of root contact with the miniscrew.

Key words: Surgical guide, miniscrew, success rate, clinical stability, root contact

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Ⅰ. Introduction

In orthodontic treatment, the miniscrew has been used as an absolute anchor because it achieves predictable outcomes concerning sliding mechanics and efficient treatment by facilitating orthodontic tooth movement according to various directional forces. (Janssens, et al., 2002; Leung, et al., 2008; Park, 2003; Rungcharassaeng, et al., 2005). The success rate of miniscrew interventions was reported as 77.5-95.0% by several previous studies (Alharbi, et al., 2018; Schatzle, et al., 2009).Contributing factors associated with the success rate include bone quality, patient age, oral hygiene, skeletal patterns, insertion position, diameter and design of the screw, and operator skill (Jing, et al., 2016; Lee, et al., 2010; Miyawaki, et al., 2003; Morea, et al., 2011; Wiechmann, et al., 2007).

Used as a predictor of the success (Motoyoshi, et al., 2010; Yoo, et al., 2014), the initial stability of the miniscrew allows for new bone formation at the bone–implant interface and is closely related to the mobility of the miniscrew during orthodontic treatment. In particular, the initial stability is reportedly related to the thickness of the cortical bone in which the miniscrew is placed. (Cha, et al., 2010a; Cha, et al., 2010b; Cha, et al., 2010c). Initial stability can be evaluated by measuring insertion torque (IT) (Motoyoshi, et al., 2006; Motoyoshi, et al., 2010) and the Periotest value (PTV; Periotest, Simens, Bensheim, Germany) (Cha, et al., 2010a; Cha, et al., 2010b; Cha, et al., 2010c). Previous studies have reported that an IT of about 4-10 Ncm is sufficient to attain stable anchorage with favorable bone adaptation (Lim, et al., 2008; Motoyoshi, et al., 2006; Motoyoshi, et al., 2010). In addition, a PTV of between -3.2 and 4.8 indicated the clinical stability of the miniscrew at the site of high bone density and thick cortical bone (Cha, et al., 2010a; Cha, et al., 2010b; Cha, et al., 2010c).

The use of miniscrews is associated with risk of gingival inflammation, infection, edema, pain, agitation, and root damage at the site of insertion; among these risks, the root contact of a miniscrew is a major risk factor for intervention failure (Kuroda, et al., 2007). In most cases, the miniscrew is placed in the buccal alveolus, where interradicular spaces are very limited; hence, the possibility of root contact is high. The interradicular spaces of the maxilla and mandible were reported to be 2.4-4.9 mm (Poggio, et al., 2006). In general, the screw diameter is 1.2 mm-1.8 mm, rendering the placement of the miniscrew without root contact or proximity to the root difficult.

The three-dimensional analysis of morphological and anatomical features of the surrounding structures and factors related to the operator should be considered for the stability of miniscrew. In the maxilla, the position of great palatine nerve must be considered when the miniscrew is inserted on the palatal side, and the vertical distance of the maxillary sinus from the alveolar crest must be measured to prevent sinus perforation. When placing a miniscrew in the mandible, the infra-alveolar canal should be avoided during insertion. (Kravitz and Kusnoto, 2007; Monnerat, et al., 2009). In addition, the abnormal shape and concavity of the root causes root damage during insertion of the miniscrew. In cases of the manual insertion of the miniscrew in patients with the aforementioned anatomical limitations, the skill of the operator is important to ensure the stability of the miniscrew. (Kuroda, et al., 2007; Monnerat, et al., 2009; Park, et al., 2010; Poggio, et al., 2006). Therefore, to prevent side effects during the insertion of the miniscrew, it is essential to evaluate bone quality and the anatomical features of surrounding structures using three-dimensional (3D) imagining. Finally, elucidation of the exact insertion position before the procedure allows for expected tooth movement during the insertion of the miniscrew to be simulated using computer-aided design and computer-aided manufacturing (CAD/CAM) software, thereby promoting the success of the orthodontic treatment.

Recently, dental CBCT has enabled the 3D characterization of the anatomical limitations of the maxillofacial complex and has helped clinicians to overcome the limitation of two-dimensional images by accurately visualizing structures of interest. In addition, the development of CAD/CAM has further allowed for the precise insertion of the miniscrew with a stereolithographic surgical guide based on 3D evaluation (Horwitz, et al., 2009; Morea, et al., 2011; Qiu, et al., 2012; Suzuki and Suzuki, 2008). However, most previous studies have only used the surgical guide with phantom models or cadavers (Bae, et al., 2013; Qiu, et al., 2012), and the majority of clinical studies on patients were retrospective or marred by small samples; hence, no previously published report has performed a randomized clinical trial to evaluate the efficiency and safety of surgical guides (Bae, et al., 2013; Liu, et al., 2010; Morea, et al., 2011; Qiu, et al., 2012).

Specific objectives

This study aimed to evaluate the success rate, initial stability, and root proximity of the miniscrew when using surgical guides informed by merged data derived from dental CBCT and the intraoral scanned model. Furthermore, the stability and safety of the surgical guide device were verified.

Ⅱ. Materials and Methods

1. Subjects, eligibility criteria, and settings

Subjects, inclusion and exclusion criteria

The participants for this randomized clinical trial were selected from patients who were receiving orthodontic treatment and were indicated for miniscrew insertion at the Department of Orthodontics, Yonsei University Dental hospital, Seoul, Korea. One hundred miniscrews (cylindrical; Biomaterials Korea, Seoul, Korea) were placed into the maxillary and mandibular buccal interradicular spaces of 59 patients (Mean age 23.2 years, 20 males, 39 females). Each screw was inserted by one of two orthodontic clinicians. The study was conducted after receiving the approval from the institutional review board (CRNo: 2-2018-0028), and informed consent was obtained from all study participants. This study was performed in accordance with the Declaration of Helsinki and its later amendments. The advantages and disadvantages of employing surgical guidance during the procedure were explained to all patients before they were enrolled in this trial.

The inclusion criteria were as follows:

Patients who have taken CBCT for the following reasons

(1) Skeletal discrepancy, asymmetry, or craniofacial anomalies

(2) Impacted third molar or impacted teeth

The exclusion criteria were as follows:

(1) Uncontrolled systemic disease

(2) Disease related to bone metabolism

Trial design and any changes after trial, randomization

Using the randomized number table generated by the clinician, N=100 (number of miniscrews) were randomly selected by a block randomized method according to the site of insertion, and the manual and the surgical-guide groups were populated. The methods were not changed after trial initiation.

Sample size calculation

Statistical significance, power, and effect size, were set to 0.05, 0.8, and 0.6 based on the number of samples used in previous studies. Since more than 90 samples were required and supposing that 1-2 miniscrews were placed in each patient, the target sample size was calculated to be 100 miniscrews.

Data processing, blinding

The cylinder-type miniscrews (BMK; Biomaterials Korea, Seoul, Korea) used in this study were of 1.5 mm in diameter and 7.0 mm in length for both groups. The miniscrews were placed in the maxillary and mandibular buccal interradicular spaces. The insertion sites were grouped into three areas as follows: from the anterior teeth to the first premolar, from the first premolar to the second premolar, and from the second premolar to the first molar. There was no statistically significant difference between the two groups in the $\chi2$-test. In the manual group, one miniscrew was excluded because it was difficult to follow up on account of the patient's not having visited the clinic for over 6 months after treatment, and two miniscrews were excluded on account of measuring errors. In the guide group, two miniscrews were excluded due to slippage error and three miniscrews were excluded because of adaptability problems; consequently, 47 miniscrews and 34 patients in the manual group and 45 miniscrews and 25 patients in the guide group were included in the data analysis (Figure 1). At the time of the insertion of a miniscrew, the orthodontist, and not the patient, was aware of the group to which the patient belonged.

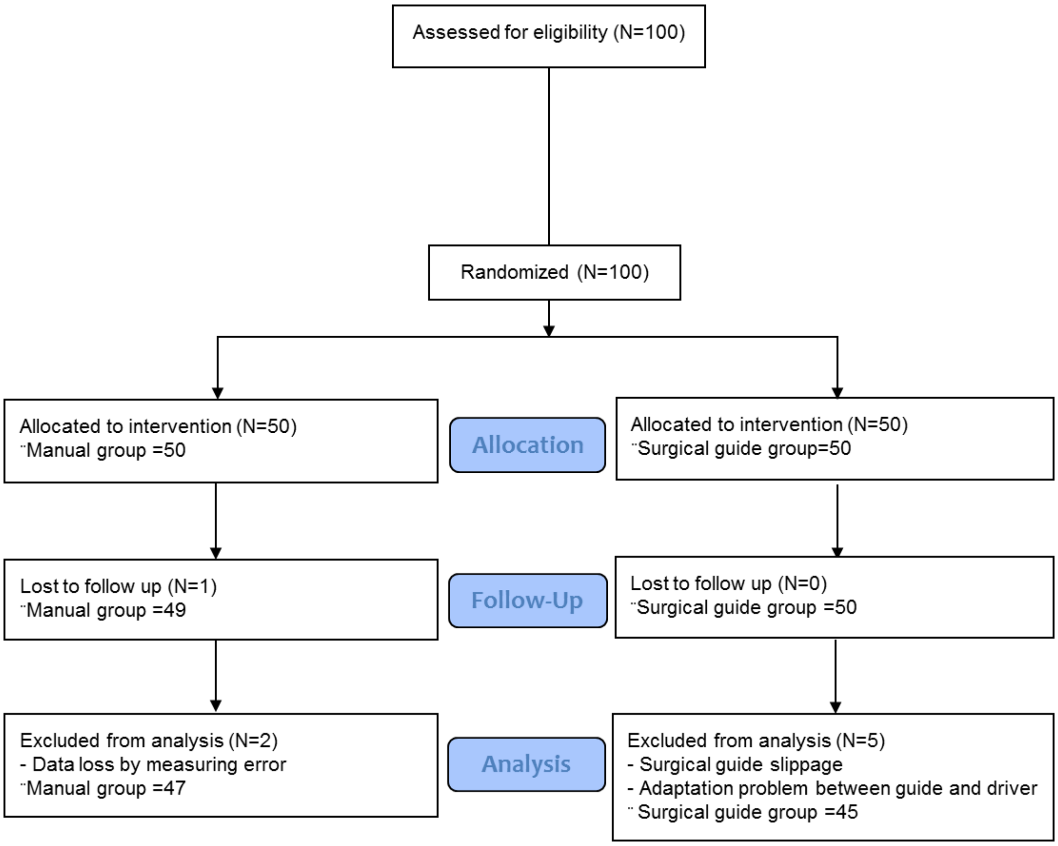

Figure 1. Flow chart of depicting the manual and surgical guide group

2. Methods

A. Production of miniscrew surgical guide

In the surgical-guide group, the digital model images were obtained from an intraoral scan (Trios 3, 3 shape, Copenhagen, Denmark) performed for initial diagnosis. CBCT-Rayscan (Raysacn α+, Ray Co., Ltd., Seoul, Korea) images which taken in P-mode (Default values, 400 µm, 17.0 sec, 80 kVp, 8 mA) for each patient. The digital images were merged with CBCT images using 3D software (OnDemand 3D, Cybermed, Daejeon, Korea), and after planning the miniscrew position, positional information was transferred to the software company (Cybermed, Daejeon, Korea). Miniscrew surgical guide was printed with polyjet-type 3D printer (Eden560v, Stratasys, Israel, Rehovot) (Figure 2). The surgical guide was composed of a 3D-printed base (Med610, Stratasys, Israel, Rehovot) and metal sleeves. The thickness of the surgical guide was 2.5 mm, and the margin of the surgical guide was 2.0 mm from the metal sleeves (Figure 2).

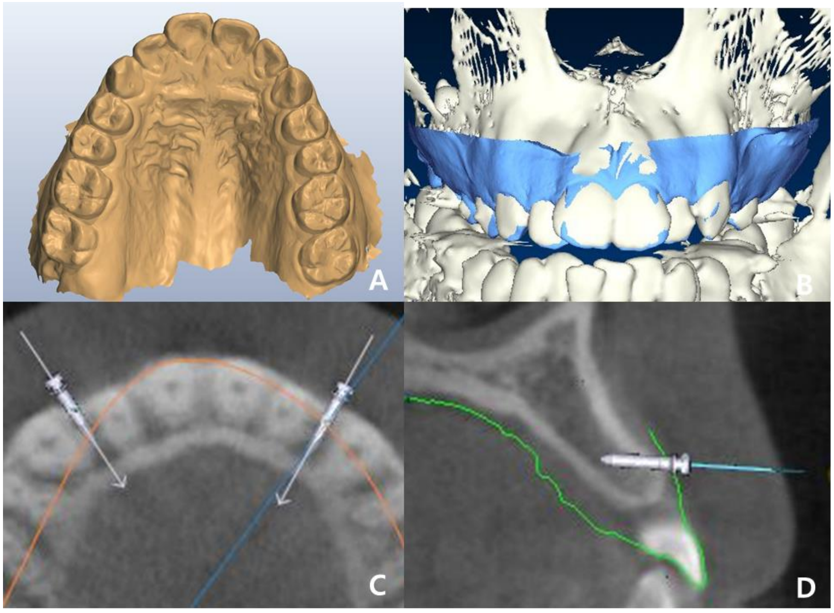

Figure 2. Planning procedure for miniscrew insertion: A, 3D digital model scanned with intra oral scanner; B, Merging of the CBCT and scanned model; C, Determination of site of miniscrew from axial views of reconstructed images; D, Determination of site of miniscrew from coronal views of reconstructed image.

B. Insertion methods (position, vertical height, etc.)

In the manual group, after determining the distance between the root and confirming the anatomical limitations of the projected insertion area with the CBCT and panoramic radiographs, the miniscrew insertion position was determined along the tooth contact surface through by eye with the assistance of an occlusal mirror. The miniscrew insertion height was planned after marking a distance of 4-6 mm from the cement-enamel junction (CEJ) using the dental probe, and the miniscrews were inserted while maintaining a positive angulation of 30-40˚ from the occlusal plane via a direct manual method (Bae, et al., 2013; Lee, et al., 2010; Shigeeda, 2014).

In the surgical-guide group, after confirming bone quality and quantity with the scan model merged with the CBCT images and measuring the distance between the roots, the placement was performed while allowing for the deviation of the insertion angle according to the slope of the alveolar bone and maintaining a positive angulation of 4-6 mm from the CEJ (Bae, et al., 2013; Lee, et al., 2010; Shigeeda, 2014). After placing the surgical guide on the target dentition and confirming its adaptability, the miniscrews were placed with a miniscrew driver that was guided by the metal sleeves of the surgical guide (Figure 3).

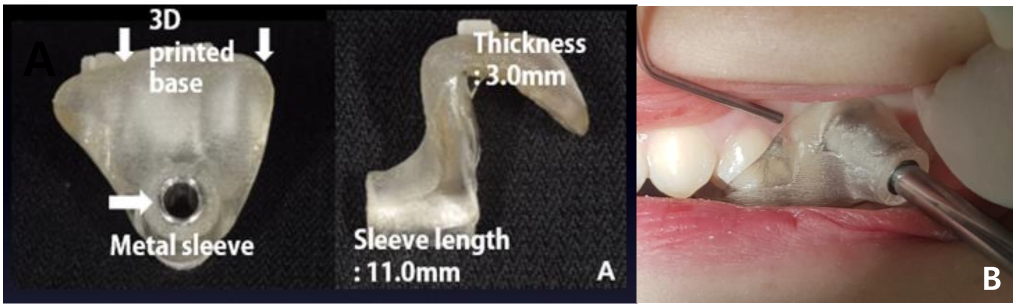

Figure 3. Composition of surgical guide and try in the dentition: A, Surgical guide is composed of the metal sleeves and 3D printed base and thickness of the surgical guide is 3.0 mm and sleeve length is 11.0 mm; B, Surgical guide try in the maxilla dentition.

C. Evaluation factors and methods

(1) Measuring the insertion torque (IT) and Periotest value (PTV)

After completion of the miniscrew placement, the maximum IT for the final 1/4 rotation was measured using a torque sensor (Mark-10, MGT50, CA, USA). The IT was measured twice and converted to Ncm. PTVs (Siemens, Bensheim, Germany) were recorded twice as mobility values in the same position while maintaining the measuring head horizontal to the ground and perpendicular to the miniscrew head. Pearson's correlation values were obtained to measure the reliability between the two measurements; those of IT and PTV were 0.973 and 0.977, respectively. Therefore, only the first measurement was used for subsequent analyses.

(2) Root proximity in the periapical radiograph

After placement of the miniscrew, the periapical radiographs were taken horizontally, parallel to the screw. Periapical radiographs were retaken if there parallelism was not achieved. The periapical radiographs were divided into three categories based on the contact surface of the two adjacent teeth and the tangents at the root (Figure 4).

(1) Center of the root: screw head was on the contact plane.

(2) Close to the root: screw head was close to the root but did not contact the root.

(3) Contact the root: screw contacted any point of the adjacent root.

The category of root proximity was assessed by two orthodontic clinicians. The Pearson's correlation value between the two clinicians' assessments was 0.999. Therefore, only the value of the one clinician was used for the analysis.

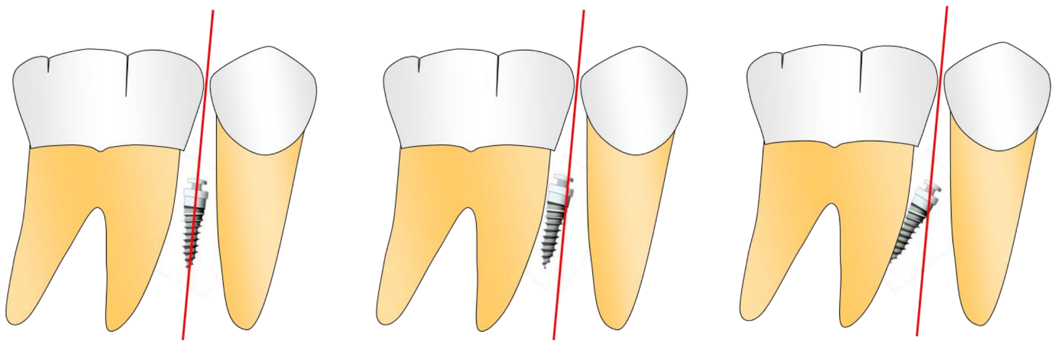

Figure 4. Classification of the root proximity: A, Center of root: screw head on the contact plane; B, Close to root: screw head close to the root but not contact the root; C, Root contact: screw contact any point of the root.

(3) Evaluation of interradicular space using CBCT

Linear measurements were made at depths of 4 mm with the proximal CEJ as the reference point by using a radiograph viewer program (INFINITT PACS, Infinitt Healthcare, Seoul, Korea) with the CBCT axial images (Figure 5). The mesio-distal distance was measured parallel to the mean arch forms connecting the mid-root portion of each root at each vertical level.

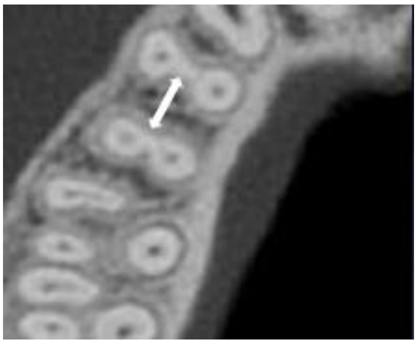

Figure 5. Measurements of interradicular space in a maxillary axial view: arrow indicates interradicular distance.

(4) Evaluation of success rate and presence of inflammation

The miniscrews were checked at intervals of 4 weeks to determine the failure and mobility in both groups. Success of the miniscrew placement was defined as the maintenance of the inserted miniscrews for over 6 months; and clinically stable miniscrew placement, as less than 1 mm of mobility without screw thread exposure. Procedures were considered successful if the required tooth movement was completed within 6 months and the miniscrew was removed.

D. Statistical analysis

All measurements were performed by two clinicians. To confirm the intra- and inter-class errors, all measurements of the 92 miniscrews were analyzed twice; the Pearson's correlation value was greater than 0.97.

The Kaplan-Meier survival analysis was performed to compare the success rates between the two groups. The Shapiro-Wilk test was performed to test the normality between the manual and surgical guide groups. The normal distribution was confirmed, and the measured values were divided according to whether they were associated with the use of the surgical guide and with successful placement as determined by an independent t-test.

Correlations among the use of the surgical guide, success or failure, and root proximity were evaluated using the χ^2-test. All statistical analyses were performed using SPSS (version 23; SPSS, Chicago). The significance level α was set at 0.05.

Ⅲ. Results

1. Reliability of measurements

A. Reliability of insertion torque and Periotest value

The reliability between the two measurements of IT and PTV, as indicated by Pearson's correlation values, were 0.973 and 0.977, respectively (Table 1).

Table 1. Reproducibility of insertion torque (IT) and Periotest-value (PTV) with Pearson's correlation values based on absolute agreement

Measurements	Pearson correlation coefficient
Insertion torque (IT)	0.973***
Periotest value (PTV)	0.977***

Pearson's correlation test, ***p<0.001

IT, insertion torque

B. Reliability of root proximity

The reliability of the measurement over twice times of root proximity by two clinicians was 0.999 of Pearson's correlation values (Table 2).

Table 2. Reproducibility of root proximity in intra-examiners with Pearson's correlation values based on absolute agreement

Measurements	Pearson correlation coefficient
Root proximity	0.999***

Pearson's correlation test, ***p<0.001

IT, insertion torque

2. Analysis of success rate by each variables

The overall success rates were 80.9% and 88.9% for the manual and surgical-guide groups, respectively; the difference between these rates was not statistically significant (Table 3). However, according to the Kaplan-Meier survival analysis, when 6 months were converted to 180 days to confirm the day of miniscrew removal, the graph plotting the cumulative success rate of the manual group against that of the surgical-guide group revealed that miniscrews were removed earlier than 50 days and after 120 days in the manual and surgical-guide groups, respectively (Figure 6). Although eight miniscrews were excluded from the manual and surgical groups, there was no statistically significant difference in numbers of miniscrews inserted into the three sites between the two groups (Table 4). There were no significant differences in success rate according to sex, jaw placement, side of insertion, site of insertion, and purpose of miniscrew. For example, the success rates were 89.4 and 77.1 percent for the maxilla and the mandible, respectively, indicating that interventions involving the maxilla were more successful than those involving the mandible. The difference in success rate according to variables is presented in Table 3.

Table 3. Success rates and number of miniscrews according to variables

	Success miniscrew/ total miniscrews (N)	Success rate (%)	*p value*
Type of miniscrew insertion			
Manual method	38/47	80.9	.245
Surgical guide method	40/45	88.9	
Gender			
Male	25/31	80.6	.545
Female	53/61	86.9	
Jaw of placement			
Maxilla	51/57	89.4	.127
Mandible	27/35	77.1	
Side of insertion			
Right	41/48	85.4	.542
Left	36/44	81.8	
Site of insertion			
Incisor to PM1	11/13	84.6	.857
PM1 to PM2	9/10	90.0	
PM2 to M1	58/69	84.1	
Purpose of miniscrew			
Intrusion	20/21	95.2	.379
Protraction	11/13	84.6	
Retraction	23/27	85.2	
Distalization	24/31	77.4	

N, number of miniscrew, %, percentage

PM1, first premolar; PM2, second premolar; M1, first molar

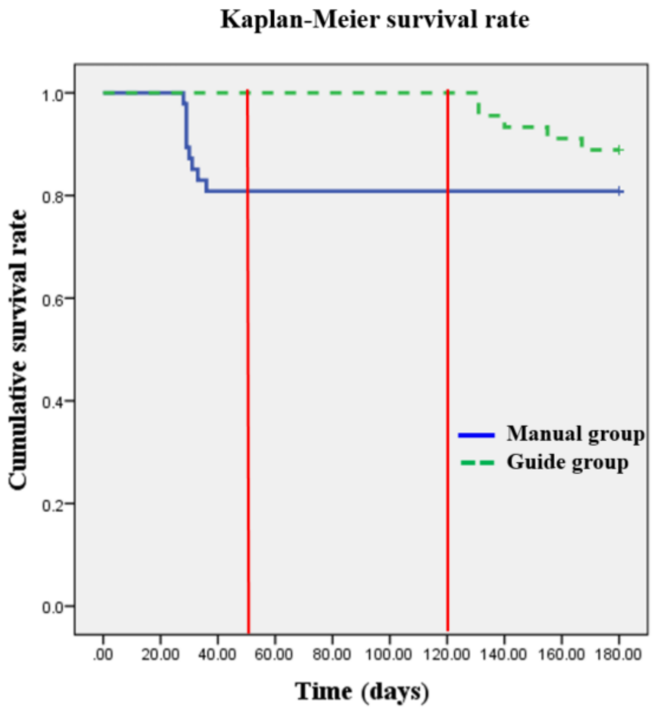

Figure 6. Kaplan-Meier survival estimates by presence of surgical guide: the y-axis shows cumulative success survival ratio and the x-axis shows time by days. The duration of survival was measured from miniscrew placement of failure or to the last follow up or completion of treatment. The cumulative survival of the guide group (dot line) was higher than those in the manual group (straight line). The manual group showed failure of miniscrew before 50 days but the guide group was dropped after 120 days.

Table 4. Success rates of two different miniscrew insertion methods for the jaw and site of insertion.

	Manual group %(success N/total N)	Guide group %(success N/total N)	*p value*
Jaw of placement			
Maxilla	86.9 (20/23)	91.2 (31/34)	
Mandible	75.0 (18/24)	81.8 (9/11)	.010
Site of insertion			
Incisor to PM1	85.7(6/7)	83.3(5/6)	
PM1 to PM2	80.0(4/5)	100.0(5/5)	
PM2 to M1	80.0(28/35)	86.9(30/34)	.976
Total	80.9(38/47)	88.9(40/45)	.245

χ^2 test , N, number of miniscrew, %, percentage

3. Comparison of the results between the manual group and the guide group

The χ^2-tests were used to compare the differences in variables between the manual and the surgical-guide groups (Table 5). Success rates were 80.9% and 88.9% for the manual and surgical-guide groups, respectively, but there was no statistically significant difference between these rates. The root contact rates were 31.9% and 0.4% for the manual and surgical-guide groups, respectively; the difference between these two rates was statistically significant (p < 0.001). Inflammation was observed at a rate of 33.3% in the manual group and 22.2% in the surgical-guide group; the difference between these rates was no significant.

Table 5. Frequency analysis for each variable of manual group and surgical guide group

	Manual group %(N/total N)	Guide group %(N/total N)	*p value*
Success	80.9(38/47)	88.9(40/45)	.386
Root contact	31.9(15/47)	0.4(2/45)	.000*
Inflammation	31.9(15/47)	22.2(10/45)	.353

N, number of miniscrew, %, percentage, χ^2 test, * p<0.001

4. Comparison of insertion torque and Periotest value

A. Comparison based on presence of surgical guide

The mean difference between the measurements of the 47 miniscrews in the manual group and the 45 miniscrews in the surgical-guide group were compared using an independent t-test (Table 6). The IT was higher in the surgical-guide group, but the difference was statistically insignificant. PTV was significantly lower in the surgical-guide group ($p < 0.05$).

Table 6. Mean difference of insertion torque (IT) and Periotest value (PTV) of manual group and surgical guide group

	Manual group (N = 47) (Mean±SD)	Guide group (N =45) (Mean±SD)	Mean difference	95% CI of the mean difference		*p value*
IT	6.37 ± 2.64	6.54 ± 2.90	-0.17	-1.34	0.99	.768
PTV	1.58 ± 2.13	0.19 ± 2.86	1.39	0.34	2.44	.011*

SD, standard deviation, IT, insertion torque PTV, Periotest value; CI, Confidence interval, Independent *t*–test, *p<0.05

B. Comparison based on success

Of the total 92 miniscrews, 78 miniscrews were successful and 14 miniscrews failed. An independent *t*–test was to analyze the mean difference in the measurements between the success and failure groups (Table 7). The insertion torque was higher in the success group, but this difference was not statistically significant. PTV was significantly lower in the success group ($p < 0.05$).

Table 7. Mean difference of insertion torque (IT) and Periotest value (PTV) of success group and failure group

	Success group (N = 78) (Mean±SD)	Failure group (N =14) (Mean±SD)	Mean difference	95% CI of the mean difference		*p value*
IT	6.56 ± 2.86	5.89 ± 2.18	-0.67	-2.26	0.93	.408
PTV	0.57 ± 2.62	2.72 ± 1.45	2.15	1.16	3.15	.001*

SD, standard deviation, IT, insertion torque PTV, Periotest value; CI, Confidence interval,
Independent *t*–test, *p<0.01

5. Comparison of interradicular space between the groups

The interradicular space was larger in the failure group however there was no statistically significant difference also manual group showed larger interradicular space than guide group and it was statistically insignificant (Table 8).

Table 8. Mean difference of interradicular space of success group and failure group

	Success group (N = 78) (Mean±SD)	Failure group (N =14) (Mean±SD)	Total	*p value*
Manual group	2.98 ± 0.64	3.10 ± 0.67	3.00 ± 0.64	.926
Guide group	2.52 ± 0.56	2.58 ± 0.45	2.53 ± 0.55	.720
p value			.052	

SD, standard deviation, Independent *t*–test, **p*<0.01

6. Risk during miniscrew insertion with surgical guide

Five miniscrews inserted with surgical-guide assistance were excluded from the analysis. The risk of the slippage and adaptability of the surgical guide was 10% (Table 9).

Table 9. Risk encountered during miniscrew insertion with surgical guide.

Classification	Number of miniscrews (%)	Details
Slippage	2(4%)	deterioration of retention severe slope of the buccal bone
Adaptability problem	3(6%)	large amount of removal force tightening between guide and driver removal before full engage of miniscrew, then miniscrew insertion with manual method

%, percentage

Ⅳ. Discussion

The purpose of this study was to evaluate the effectiveness of the miniscrew surgical guide and to compare the success rate and stability of miniscrew placement according to the manual and guide method. Validation of miniscrew position using surgical guides by retaking a CBCT scan was not performed in this study owing to ethical issues.

Analysis of the success rate by variables revealed that the overall success rate for the maxilla (89.4%) was higher than that for the mandible (77.1%). In addition, in the manual group, the success rate was 86.9% for the maxilla and 75.0% for the mandible; in the guide group, it was 91.2% for the maxilla and 81.8% for the mandible. Miniscrews are usually placed in the attached gingiva but the posterior mandible has a narrow gingiva and small oral vestibule. Thus, access for the screw driver and placement of the miniscrew are likely to be limited in the mandible. Furthermore, the mandibular cortical bone is thicker than the maxilla. Therefore, the reason for the lower success rate in the mandible than in the maxilla is surgical difficulty caused by the anatomic features of the mandible. (Kuroda, et al., 2007; Monnerat, et al., 2009). However, gender, side of insertion, site of insertion, and jaw in which the miniscrew was placed showed no significant differences in success rate.

The success rate was 80.9% in the manual group and 88.9% in the guide group. A systemic review of the success rate of miniscrew placement reported an average success rate of 86.5% (Alharbi, et al., 2018). In addition, the success rate of miniscrew placement ranged from 77.5% to 95.0%; while varied results have been shown in other previous studies, the success rate was within the aforementioned range in the present study (Alharbi, et al., 2018; Schatzle, et al., 2009). In the guide group, the success rate was higher as the miniscrew was placed on the planned position for each patient through the assessment of bone quality and assessment of anatomic limitations using CBCT. In the Kaplan-Meier survival analysis, miniscrews failed after 120 days in the guide group; however, in the manual group, miniscrews failed before 50 days. The overall success rate was not statistically significant between the two groups, but the initial success rate was higher in the guide group. Therefore, it is a clinically significant finding.

Periapical radiographs were taken to evaluate the root proximity of the miniscrew after the placement of the miniscrew. In the previous studies, evaluation by 3D CBCT was found to be useful, but periapical radiographic examination is simpler, is cheap, and is associated with a lower exposure dosage compared with 3D CBCT. The root contact rate was 31.9% in the manual group and 0.4% in the guide group, and the difference was statistically significant. In the previous review, the root contact rate ranged from 47.4% to 48.3%; therefore, the root contact rate reported in this study was lower than reported in the previous studies in the manual group, which had a relatively higher root contact rate than the guide group (Chen, et al., 2008; Kuroda, et al., 2007; Shigeeda, 2014; Shinohara, et al., 2013).

If the contact between the miniscrew and the root is limited to the cementum and dentin, damaged root surfaces can be repaired in 2-3 months, forming the periodontal ligament, cementum, and new bone. (Ghanbarzadeh, et al., 2017; Lv, et al., 2018). In patients with root fractures, pulp necrosis or apical periodontitis occurs, and finally, root canal treatment or surgical intervention may be necessary. Furthermore, in some cases, extraction of the teeth may be inevitable. (Lim, et al., 2013). Therefore, avoiding root contact is crucial to the success of miniscrew placement and prevention of damage to the root damage. (Asscherickx, et al., 2008; Chen, et al., 2008) When the interradicular space is narrow or there is a possibility of causing damage to the surrounding structures owing to anatomic limitations, insertion of the miniscrew with the surgical guide is recommended for reducing root contact rate and improving the success rate of miniscrew placement.

Comparison of the average insertion torque revealed that the insertion torque was 6.37 ± 2.64 Ncm in the manual group, which was lower than the 6.54 ± 2.90 Ncm in the guide group, but the difference was not statistically significant. According to the previous reports, the miniscrew remains stable when the insertion torque ranges from 4 Ncm to 10 Ncm. (Cha, et al., 2010a; Motoyoshi, et al., 2006; Motoyoshi, et al., 2010) Therefore, miniscrews of both groups in this study were placed within a stable range. The insertion torque was higher in the success group than in the failure group; however, there was no statistically significant difference. This result is similar to previous studies that showed statistically insignificant differences in initial torque between the success group and failure group. (Cha, et al., 2010c).

Comparison of the PTV revealed that PTV was 1.58 ± 2.13 in the manual group, which was lower than the 0.19 ± 2.86 in the guide group, and the difference was statistically significant. Measuring PTV is one of the methods to evaluate the initial stability of the miniscrew; by using this method rather than assessing the osseointegration of the bone and implant, which is used in the field of prosthodontics, it is possible to estimate the mechanical connection between the surrounding bone and the miniscrew. (Cha, et al., 2010c; Jing, et al., 2016). When the miniscrew is placed with the surgical guide, insertion site is determined by evaluation of the bone quality and quantity through CBCT images. Therefore, PTV might be relatively low in the guide group because the primary stability was strong at the bone-miniscrew interface. PTV was lower in the success group than in the failure group, and the difference was statistically significant.

In the present study, the success rate of the guide group was higher than the average success rate reported in previous systematic reviews (Alharbi, et al., 2018; Schatzle, et al., 2009) and showed lower root contact. Therefore, placing the miniscrew with the surgical guide is recommended when the interradicular space is narrow, when anatomic limitations are present, or if miniscrew has to be placed intentionally in a specific position instead of the general interradicular space.

Limitations

This study included 100 miniscrews, so the number of miniscrews was relatively larger than that included in previous studies that used the surgical guide (Bae, et al., 2013; Liu, et al., 2010; Morea, et al., 2011; Qiu, et al., 2012). Although the difference in success rate was 8%, this difference was not significant. In the analysis, eight of the 100 miniscrews were excluded; three miniscrews were from the manual group and five miniscrews were from the guide group.

Two miniscrews were excluded owing to a significant measurement error and one miniscrew was excluded from the analysis because the patient, who was enrolled in the manual group, did not visit the clinic for over 6 months. Five miniscrews were excluded owing to miniscrew slippage during insertion and adaptability problem of the surgical guide. In the case of adaptability problem, as the friction between the screw driver and the mental sleeve was too high, when the driver was removed, the clinician had to pull the driver forcefully, which resulted in the screw falling out. As a result, the risk of the surgical guide itself was 10%, and risk management of the surgical guide is needed. First, before insertion of the miniscrew, clinicians have to confirm the tightness of the sleeve and screw driver before clinical application. Second, when the miniscrew insertion position is planned with CBCT, the angulation of the miniscrew and slope of the buccal alveolar bone have to be considered to prevent miniscrew slippage during initial insertion.

Even though the evaluation of contact between the miniscrew and the root by 3D CBCT is accurate, 2D periapical radiographic examination is applied owing to lower radiation dosage compared to CBCT. Reducing the radiation exposure dosage is currently becoming an ethical issue, so our method is a proper way to assess root contact after miniscrew insertion. However, the contact between the root and the miniscrew could not be detected, although a contact was noted in some cases (Kuroda, et al., 2007). Therefore, periapical radiographs were taken for maintaining the parallelism to the long axis of the miniscrew, reducing the error of 2D images, and periapical radiographs were retaken if the angulation of the direction of radiation was improper.

Suggestions for a follow-up study

In this study, the miniscrew surgical guide was planned by superimposing the scanned data using intraoral scanning and CBCT. Intraoral scanning has shifted the paradigm of orthodontic diagnosis (Yoon, et al., 2018), indirect bonding of the bracket, manufacture of orthodontic appliances, and it was clinically acceptable as much as generating a cast model. (Anh, et al., 2016; Reuschl, et al., 2016). Considering that the conventional method was preceded by taking an impression, making a cast model, and scanning the cast model with a model scanner, intraoral scanning can improve the efficiency of the process for fabricating surgical guides. In conclusion, in follow-up studies, the accuracy of planned miniscrew insertion position can be evaluated by performing intraoral scanning of the screw's head. We can then validate the accuracy of the surgical guide without radiation exposure. In addition, adaptability between the printed base of the surgical guide and the dentition is important, which is influenced by the accuracy and resolution of 3D printers (Kim, et al., 2018). Therefore, various types of 3D printers and printing materials need to be evaluated for validating the accuracy of the surgical guide.

Generalizability

These result indicate that the surgical guide can be used for miniscrew insertion in patients who have anatomic limitations or narrow interradicular spaces. However, this cannot be generalized because the study duration was only 6 months. Moreover, the study was undertaken by two clinicians in a single center at a university.

Ⅴ. Conclusion

The following results were obtained by statistical analysis of manual group and surgical guide group.

1. The success rate of the manual group was 80.9 % and the success rate of the surgical guide group was 88.9 %. There was no statistically significant difference in the success rate using the surgical guide (p>0.05). In the Kaplan-Meyer survival analysis, miniscrews were failed early than 50 days in the manual group, whereas most of miniscrews were failed after 120 days in the guide group.

2. The root contact rate was 31.9 % in the manual group and 0.4 % in the surgical guide group, and the root contact rate was low when using the surgical guide, showing a statistically significant difference (p <0.001).

3. The insertion torque was 6.37 ± 2.64 Ncm in the manual group and 6.54 ± 2.90 Ncm in the surgical guide group, but the difference was not statistically significant (p> 0.05) and The PTV was 0.19 ± 2.86 in the guide group and 1.58 ± 2.13 in the manual group, which showed a statistically significant difference (p <0.05).

4. The insertion torque of was 6.56 ± 2.86 Ncm in the success group and 5.89 ± 2.18 Ncm in the failure group, but the difference was not statistically significant (p> 0.05) and The PTV was 0.57 ± 2.62 in the success group and 2.72 ± 1.45 in the failure group, which showed a statistically significant difference (p <0.01).

5. A total of five (10%) miniscrews were excluded due to the risk of the miniscrew guide itself. They were 4% of surgical guide slippage, 6% of adaptability problem.

The rate of miniscrew contact with the root was significantly lower in the surgical-guide group than in the manual group. The present study recommends the use of surgical guides for the stable placement of miniscrews in cases of anatomical limitations or the high possibility of root contact with the miniscrew.

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국문 요약

CBCT와 구강내 스캔 모델을 활용하여 식립 가이드(surgical guide)를 이용한 미니스크류의 임상적 안정성 : 무작위 임상시험

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김다소미

미니스크류를 이용한 교정치료가 보편화 되고 있기 때문에 미니스크류를 예측 가능한 위치에 식립하고 치근 손상 등의 위험을 줄이며 성공률을 높이는 것이 중요하다. 디지털 기술의 발달로 석고 모형이 아닌 구강 내 스캐너를 이용하여 모형을 채득하는 것이 가능해 졌으며 Dental cone beam computed tomography(CBCT)의 보급률이 높아짐에 따라 치아모델과 CBCT의 중첩이 가능해 졌다. 따라서 computer-aided design/computer-

aided manufacturing (CAD/CAM) 기술을 활용하여 제작된 미니스크류 식립 가이드를 이용하여 치근의 손상 위험을 줄이고, 미니스크류 식립의 부작용을 최소화 하면서 성공률을 높일 수 있는 방법에 대한 임상적 안정성의 평가가 필요하다.

교정 치료 중 미니스크류 식립이 필요한 환자 59명, 미니스크류 100개를 대상으로 무작위 임상 연구를 진행하였다. 각각의 환자에서 파노라마와 CBCT를 이용하여 협측 치근 사이에 미니스크류 cylinder type의 직경 1.5 mm 길이 7 mm (BMK, Biomaterials Korea, Seoul, Korea)를 식립하였다. 식립 후에 안정성을 평가하기 위해 식립 토크(IT)와 periotest value(PTV)를 2회씩 측정하였다. 치근단 방사선 사진을 촬영하여 치근 접촉도를 평가하였다. 6개월 이상 탈락 하지 않는 경우 성공으로 판단하였다. 이후 수동 식립군과 가이드 식립군에 대한 통계 분석을 시행하여 다음과 같은 결과를 얻었다.

1. 수동 식립군의 성공률은 80.9%, 가이드 식립군의 성공률은 88.9%로 미니스크류 식립 가이드를 이용한 경우 성공률이 높았으나 통계학적으로 유의한 차이는 없었다($p > 0.05$). 카플란-마이어 생존 분석에서 수동 식립군은 50일 이전 조기 탈락이 많았던 반면 가이드 식립군은 120일 이후 탈락이 많았다.

2. 치근 접촉률은 수동 식립군 31.9%, 가이드 식립군은 0.4 %로 미니스크류 식립 가이드를 이용할 경우 치근 접촉률이 낮았으며 통계학적으로 유의한 차이를 보였다($p < 0.001$).

3. 식립토크는 수동 식립군에서 6.37 ± 2.64 Ncm, 가이드 식립군에서 6.54 ± 2.90 Ncm 로 가이드 식립군에서 높았으나 통계적으로 유의한 차이는 없었고(p >

0.05) PTV는 수동 식립군이 1.58 ± 2.13 가이드 식립군이 0.19 ± 2.86로 가이드 식립군이 낮은 수치를 나타내었으며 통계적으로 유의한 차이를 보였다($p < 0.05$).

4. 성공한 군에서 식립토크 값이 6.56 ± 2.86 Ncm로 실패한 군이 5.89 ± 2.18 Ncm 를 나타낸 것 보다 높았으나 통계적으로 유의미한 차이는 없었으며($p > 0.05$) PTV는 성공한 군이 0.57 ± 2.62로 실패한 군 2.72 ± 1.45 보다 낮은 수치를 나타내었으며 통계적으로 유의한 차이를 보였다($p < 0.001$).

5. 미니스크류 식립 가이드 자체의 위험요소로 (10%)의 미니스크류가 제외되었다. 가이드의 미끄러짐(2개, 4%), 가이드와 스크류 드라이버간의 적합도 문제 (3개, 6%)이다.

미니스크류 성공에 중요한 요인이며 치근 손상 또는 파절에 영향을 줄 수 있는 치근과의 접촉도에서 미니스크류 식립가이드를 이용할 경우 치근 접촉도가 유의하게 낮게 나타났다. 따라서 치근과의 접촉 가능성이 높은 부위나 해부학적 한계가 있는 부위에서 미니스크류의 안정적인 식립을 위해서 미니스크류 식립 가이드를 활용하여 임상적으로 안정적인 미니스크류 식립이 가능할 것으로 생각된다. 하지만 미니스크류 식립 가이드의 위험요소가 10%에서 발생하였기 때문에 가이드 제작의 개선을 통한 임상적 정확성을 높여야 할 것이다.

핵심이 되는 말: 미니스크류 식립 가이드, 스크류 성공율, 임상적 안정성, 치근 접촉