Original Article

An in vitro study of a combined patient-specific device for safe and accurate insertion of infrazygomatic crest miniscrews

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ABSTRACT

Objectives: To develop and assess the efficacy of a novel combined patient-specific device (CPSD) for the accurate and safe insertion of infrazygomatic crest miniscrews in orthodontic procedures.

Materials and Methods: Twenty-eight miniscrews were placed in the infrazygomatic crest region of 28 cadaver maxillae using the direct manual method (n = 14) or the CPSD (n = 14) based on preset trajectories. The CPSD, designed based on the integration model, included a positioning guide, an insertion guide, and a depth-limiting groove. Deviations in the insertion site, tip location, insertion angle, and biting depth between the preset and real insertion trajectories were calculated to evaluate the accuracy of miniscrew insertion. Classification frequencies of root proximity, sinus penetration depth, and biting depth of the miniscrew after insertion were also calculated to evaluate the safety of miniscrew insertion.

Results: Regarding evaluation of accuracy, significant differences were observed in the deviation values of the insertion site, tip location, insertion angle, and biting depth between the CPSD and freehand groups ($P = .001$, $P < .001$, $P < .001$, $P = .039$, respectively). Regarding evaluation of safety, a significant difference was observed in the classification frequencies of root proximity between the two groups ($P = .016$).

Conclusions: Compared with manual insertion, CPSD could be a preferred method for safe and accurate insertion of infrazygomatic crest miniscrews for orthodontists. (*Angle Orthod*. 2025;95:43–50.)

KEY WORDS: Infrazygomatic crest miniscrew; Patient-specific device; Integration model

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INTRODUCTION

Infrazygomatic crest miniscrews are gaining popularity in modern orthodontic practice for their ability to facilitate tooth movement and provide strong primary stability.[1] Inserting the miniscrew at a steeper angle to prevent root contact and optimize bicortical anchorage using the maxillary sinus floor will help achieve these advantages in clinical practice.[2] However, challenges such as sinus penetration,[3] root damage,[4] and early loosening[5] may occur, owing to the complex anatomical features involving variations in the maxillary sinus and limited bone depth. Therefore, ensuring precise insertion of miniscrews is vital for orthodontists.

Devices using cone-beam computed tomography (CBCT) for accurate insertion have been proposed. Compared with conventional guides with two-dimensional (2D) radiography,[6,7] CBCT-guided surgical guides[8,9] offer precise site selection because of high-resolution imaging.[10] However, challenges such as inferior soft tissue contrast[11] and image noise[12] make accurate positioning difficult in the complex anatomy of the infrazygomatic crest region.

As highlighted in a previous study,[13] optimal insertion of an infrazygomatic crest miniscrew requires a specific tipping angle in the occlusogingival and mesiodistal directions. However, current CBCT-guided surgical guides can only control the insertion site of the miniscrew accurately,[8,9] with no guarantee of accurate insertion direction, owing to limitations in the surgical guide design. Therefore, accurately inserting the infrazygomatic crest miniscrew according to the recommended trajectory remains challenging.

To address this challenge, in the present study, we aimed to develop a novel combined patient-specific device (CPSD) for infrazygomatic crest miniscrews using an integration model fusing CBCT-acquired and scanner-acquired three-dimensional (3D) models. Considering the successful application of insertion guides based on the integration model in other regions of the maxilla,[14] the hypothesis was that CPSD would significantly enhance the safety and accuracy of infrazygomatic crest miniscrew insertion.

MATERIAL AND METHODS

Sample Description

Twenty-eight miniscrews, each measuring 10.0 mm in length and 2.0 mm in diameter (PT III plus; Zhejiang Protect Medical Equipment Co., Ltd., Zhejiang, China), and 28 cadaver maxillae with intact teeth, bones, and soft tissue, were assigned to two groups (CPSD group, n = 14; freehand group, n = 14). For each maxilla, only one miniscrew was inserted into the infrazygomatic crest region. This study was approved by the Medical Ethics Committee of the Seventh Affiliated Hospital, Southern Medical University.

Construction of the Integration Model

CBCT images of each cadaver maxilla were captured and reconstructed into 3D models (Figure 1A) using Mimics 19.0 software (Materialise, Leuven, Belgium). Digitization of the plaster casts was performed using the HandySCAN BLACK Elite scanner (Creaform., Levis, Quebec, Canada; Figure 1B). The plaster casts for the cadaver maxillae were made by pouring dental stone (Shijiazhuang XinErLe Medical Equipment Co., Ltd., Shijiazhuang, China) into impressions using Type 0 Putty Hand-Mix and Type 3 Light Body (Huge Dental Material Co., Ltd., Shanghai, China). The integration model was formed in Geomagic Studio 2014 (3D Systems Inc., Rock Hill, SC) by aligning the CBCT-acquired 3D model with the scanner-acquired 3D model (Figure 1C).

Design of the CPSD

The preset insertion trajectory of the miniscrew was determined according to a previous study.[13] Subsequently, the corresponding positioning trajectory was defined, which maintained the same insertion angle as the preset insertion trajectory in the mesiodistal direction but was perpendicular to the bone surface in the occlusogingival direction.

The CPSD was designed according to the integration model and preset trajectories using Geomagic Design X 2019 (3D Systems Inc.). The CPSD comprised three components: a positioning guide (Figure 2A), an insertion guide (Figure 2B), and a depth-limiting groove (Figure 2B). The positioning guide was designed according to the preset positioning trajectory; it assisted the predrilling driver in locating the insertion site and penetrating the cortical bone perpendicularly. The insertion guide with the observation window was designed according to the preset insertion trajectory; it assisted the screwdriver in finishing the final insertion angle of the miniscrew without obstructing the view. The depth-limiting groove was designed to coordinate with the guide section of the insertion guide to ensure the insertion depth of the miniscrew. All were manufactured using a 3D printer Objet350 (Stratasys Ltd., Eden Prairie, MN, USA) with a biocompatible resin.

Cadaveric Miniscrew Insertion

As previously described,[15] in the freehand group, the dental explorer was initially used to determine the desired insertion site. Then the miniscrew was oriented perpendicular to the bone plate and penetrated the cortical

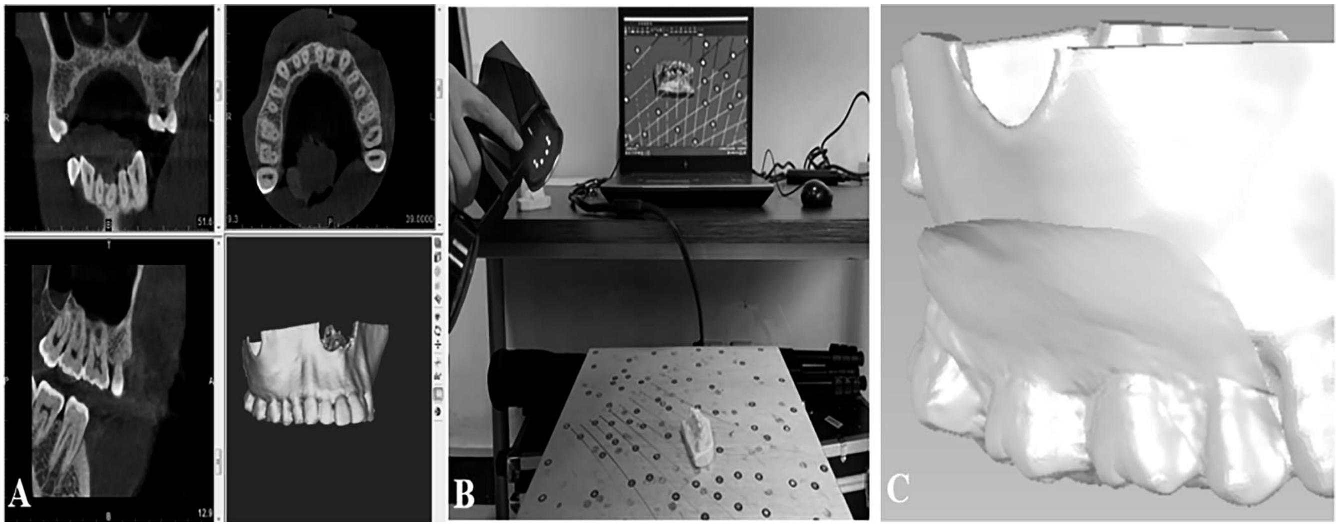

Figure 1. Construction of the integration model. (A) Three-dimensional (3D) reconstruction based on cone-beam computed tomography (CBCT). (B) Indirect digitization by the scanner. (C) The integration model was formed by fusing the CBCT-acquired 3D model and scanner-acquired 3D model.

plate. Finally, the screwdriver was gradually rotated to achieve the final angle and depth of the miniscrew.

The procedure in the CPSD group also included insertion site determination, cortical plate penetration, and miniscrew final insertion. In the CPSD group, insertion site determination and cortical plate penetration were performed using a 1.2-mm-wide predrilling driver (Zhejiang Protect Medical Equipment Co., Ltd.) following the placement of the positioning guide (Figure 3A). Then a miniscrew was inserted using an insertion guide and a screwdriver equipped with a depth-limiting groove (Figure 3B). The screwdriver consistently pushed the miniscrew until the depth-limiting groove made contact with the guide section of the insertion guide, signaling the cessation of insertion (Figure 3C).

Evaluation of Accuracy and Safety

All specimens underwent a secondary CBCT scan after insertion. The accuracy and safety assessments were conducted by a postgraduate student who was unaware of which specimens belonged to each group.

Using Geomagic Studio 2014, a 3D model of the specimen was generated after insertion based on CBCT data and then registered with the preinsertion 3D model (Figure 4A). The real insertion trajectory of the miniscrew was determined, and the absolute deviations of the insertion site, tip location, insertion angle, and biting depth between the preset and real insertion trajectory were calculated using Geomagic Design X 2019 (Figure 4B). The safety of the insertion trajectory was evaluated for the root proximity, sinus penetration depth, and biting depth of the miniscrew after insertion. Based on root proximity, root damage occurred when the miniscrew contacted tooth roots, and potential root damage was characterized as a distance less than the 0.5 mm safety threshold between the miniscrew and the roots (Figure 5A, B).[4,16] Based on the sinus penetration depth, sinus damage was

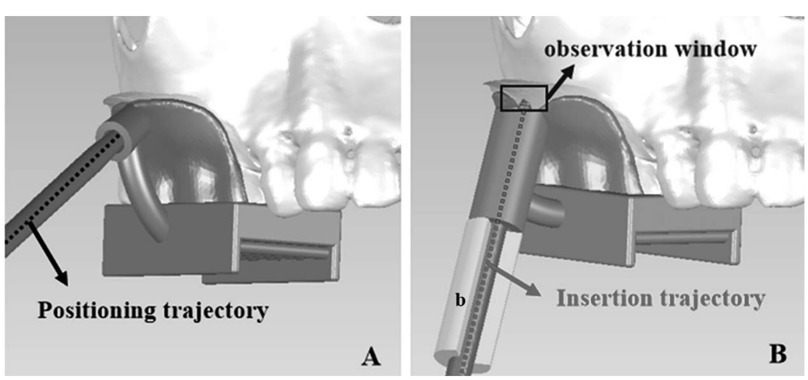

Figure 2. Design of the combined patient-specific device (CPSD). (A) Positioning guide. (B) Insertion guide with observation window and depth-limiting groove (b).

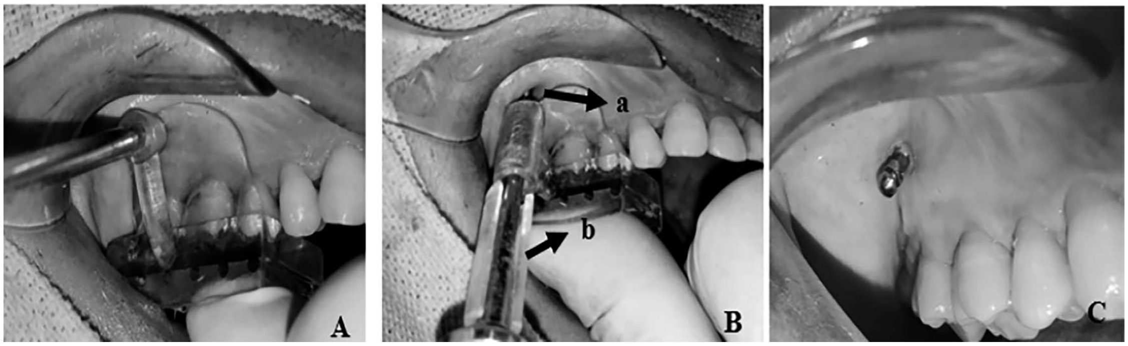

Figure 3. Insertion of the miniscrew using the combined patient-specific device (CPSD). (A) Predrilling using the positioning guide. (B) Insertion of the miniscrew using the insertion guide and depth-limiting groove. (a) Observation window; (b) depth-limiting groove. (C) Completion of miniscrew insertion using the CPSD.

characterized as the penetration of the miniscrew into the sinus beyond 1 mm (Figure 6A, B).[3] Regarding biting depth of the miniscrew, the ineffective insertion was defined as a biting depth below the 3.8-mm minimum required depth for primary stability (Figure 7A, B).[17]

Statistical Method

Statistical analysis was performed using SPSS version 20.0 (SPSS, Chicago, IL, USA). Normal distribution was assessed using the Shapiro-Wilk test. The Satterthwaite *t*-test was used to analyze deviations in the insertion site, tip location, and insertion angle between the CPSD and freehand groups. The Mann-Whitney *U*-test was used to analyze deviations in biting depth and compare the classification frequencies of root proximity between the two groups. Fisher's exact test was used to compare the classification frequencies of maxillary sinus penetration depth and biting depth between the two groups.

RESULTS

As shown in Table 1, significant differences were found in the deviation values of the insertion site, tip location, insertion angle, and biting depth between the CPSD and freehand groups ($P = .001$, $P < .001$, $P < .001$, $P = .039$, respectively).

As shown in Figure 8, a statistically significant difference in the classification frequencies of root proximity between the two groups was observed ($P = .016$). The rates of root damage and potential damage were 21.43% and 14.29% in the freehand group, respectively, while no root damage or potential damage occurred in the CPSD group. Although no significant differences were found in the classification frequencies of sinus penetration depth and biting depth between the two groups (both $P = .481$), the CPSD group exhibited lower rates of sinus damage (0%) and ineffective insertion (0%) for miniscrews than the freehand group, for which both rates were 14.29%.

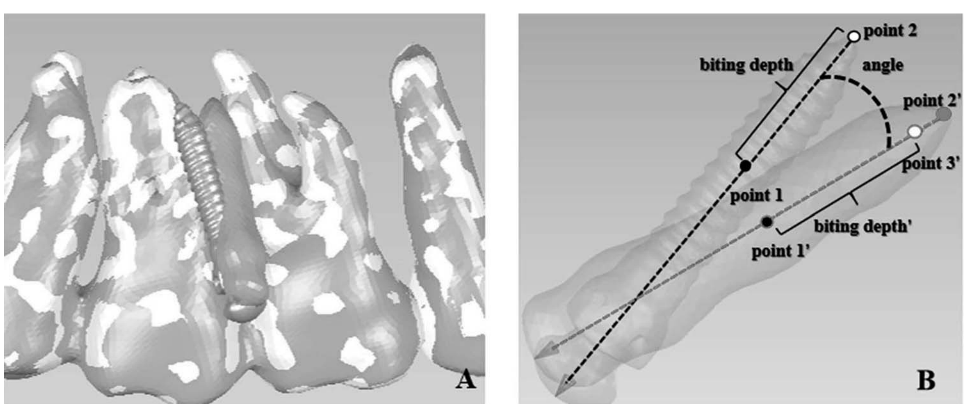

Figure 4. Accuracy evaluation of the miniscrew insertion trajectory. (A) Three-dimensional (3D) model registration before and after insertion. (B) Measurement of accuracy evaluation indicators. Points 1 and 1′ are the preset and real insertion sites of the miniscrew. The linear distance between them is the deviation in the insertion site. Points 2 and 2′ are the preset and real tip points of the miniscrew. The linear distance between them is the deviation in tip location. Point 3′ is the intersection of the real insertion trajectory and maxillary sinus. The difference in length between biting depth and biting depth′ is the deviation in biting depth. The grey and black dotted lines represent the real and preset insertion trajectories and the angle between them is the deviation in insertion angle.

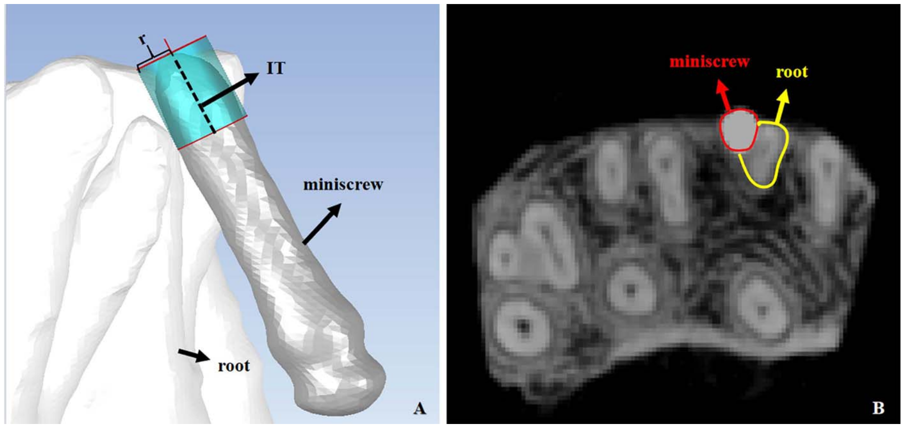

Figure 5. Safety evaluation of root damage. (A) Root damage ($r \leq 1.0$ mm) or potential damage (1.0 mm $< r < 1.5$ mm). IT indicates insertion trajectory; r, the radius of the cylinder tangent to the root with the insertion trajectory as the axis. (B) Cone-beam computed tomography (CBCT) image of root damage. Red area: miniscrew; yellow area: root.

DISCUSSION

In this study, a novel device, CPSD, based on an integration model was developed specifically for infrazygomatic crest miniscrew insertion. Compared with manual insertion, significantly lower deviation values of the insertion site, tip location, insertion angle, and biting depth were observed using the CPSD. Also, lower rates of sinus damage, root damage, and ineffective insertion were observed.

Establishing an accurate digital model is crucial for designing a high-precision guide for miniscrew insertion.[18] Although CBCT is commonly used in clinical practice, the virtual model reconstructed from CBCT data does not display the occlusal surface and soft tissue accurately enough for manufacture of a guide.[19] Therefore, integrating a scanner-acquired 3D model is necessary to overcome such CBCT-related issues.[14] Scanner-acquired 3D model images can be obtained via direct and indirect methods, and both have been demonstrated to exhibit acceptable accuracy in clinical practice.[20] Considering alveolar mucosa movement in the infrazygomatic crest region, in the present study, we used indirect digitization by scanning plaster casts.[21] The functional impression used to obtain a plaster cast could better replicate the compressed state of the alveolar mucosa, which may have increased the match between the insertion guide based on this integration model and the gingival surface of the corresponding part of the infrazygomatic crest region.

The comprehensive design of the insertion guide is another key aspect in the design of a high-precision insertion guide. The traditional design of an insertion guide focuses solely on controlling the insertion site.[8,9,22] However, this may not be adequate for infrazygomatic crest miniscrews. The infrazygomatic

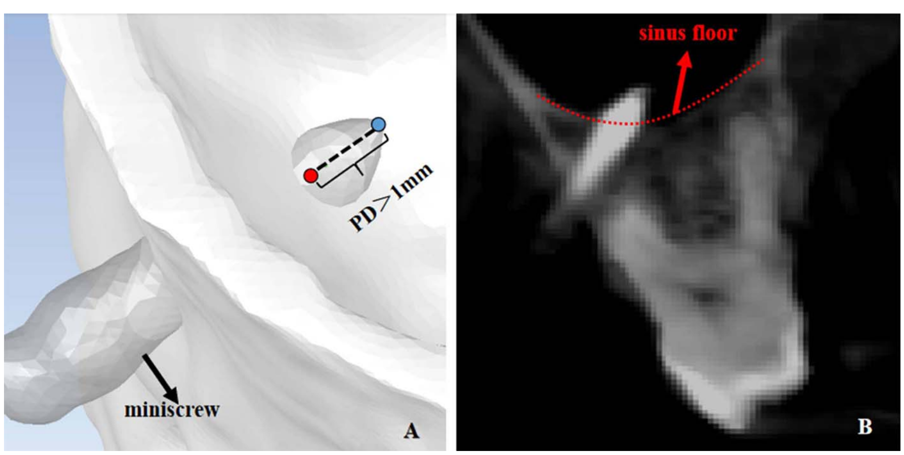

Figure 6. Safety evaluation of sinus damage. (A) Sinus damage. PD indicates penetration depth. Blue circle: tip point of miniscrew; red circle: intersection point of miniscrew and sinus floor. (B) Cone-beam computed tomography (CBCT) image of sinus damage.

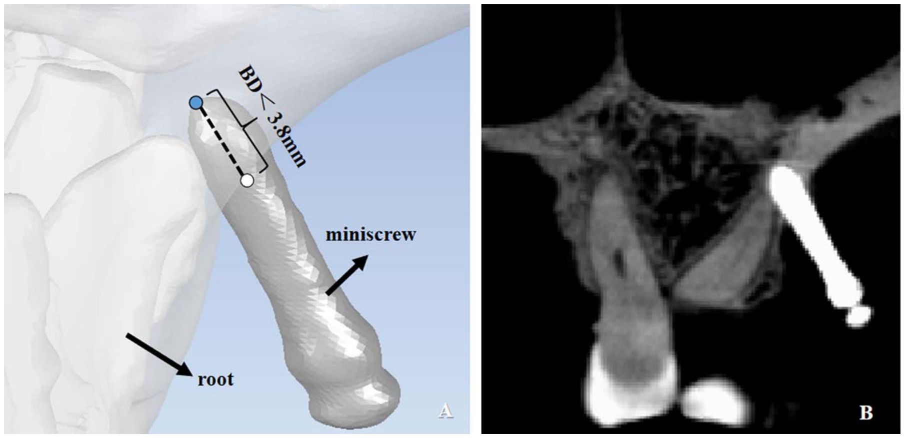

Figure 7. Safety evaluation of ineffective insertion. (A) Ineffective insertion. BD indicates biting depth. Blue circle: tip point of miniscrew; white circle: insertion point of miniscrew. (B) Cone-beam computed tomography (CBCT) image of ineffective insertion.

crest comprises two cortical plates: the buccal cortical plate and the sinus floor, which could achieve bicortical fixation.[2] However, achieving bicortical fixation in the infrazygomatic crest region also requires careful consideration of adjacent anatomical structures, such as the roots and sinus.[3,13] Typically, miniscrews should be inserted at a steeper angle with limited insertion depth to achieve bicortical fixation without causing root or sinus damage.[2] Therefore, in addition to controlling the insertion site, strict control of the insertion angle and depth is also key for guides in the infrazygomatic crest region.

A novel CPSD that included a positioning guide, an insertion guide, and a depth-limiting groove was designed to fulfill this requirement. These three components of the CPSD work together to facilitate safe and accurate insertion of the miniscrew. Specifically, the positioning guide of the CPSD was designed to locate the insertion site precisely and prevent the miniscrew from slipping during subsequent insertion.[23] The significantly lower deviation of the insertion site in the CPSD group validated the effectiveness of the positioning guide. Additionally, the combination of an insertion guide and a depth-limiting groove was designed to achieve strict control of the insertion angle and depth. In the present study, we show significantly lower deviations in tip location, insertion angle, and biting depth, along with a reduced rate of root damage in the CPSD group, demonstrating the effectiveness of these two components.

Table 1. Deviation Values of Insertion Site, Tip Location, Insertion Angle, and Biting Depth Between CPSD and Freehand Groups[a]

Metrics	CPSD Group (n = 14)	Freehand Group (n = 14)	*P* Value
Insertion site (mm)	0.89 ± 0.52	2.34 ± 1.29	.001
Tip location (mm)	1.12 ± 0.52	3.27 ± 1.15	<.001
Insertion angle (°)	5.67 ± 1.77	16.68 ± 8.13	<.001
Biting depth (mm)	0.29 (0.47)	0.84 (1.73)	.039

[a] CPSD indicates combined patient-specific device. Data are expressed as mean ± SD or median (interquartile range).

Insertion accuracy and safety are the two important aspects of evaluating the production and design of insertion guides. Bae et al.[14] developed a guide for miniscrew insertion in the maxilla. However, that guide lacked control over biting depth, making their surgical guide not entirely applicable in the infrazygomatic crest region. Su et al.[18] manufactured templates with a limit ring for miniscrew insertion in the infrazygomatic crest region, but the absence of a slipping prevention device resulted in higher deviation of the insertion angle of the miniscrew in the vertical direction. This underscores the limited angle control of the miniscrew guide in their study. It may be concluded that these insertion guides had design defects, leading to the poor performance. In the current study, the CPSD showed acceptable accuracy in insertion site, tip location, insertion angle, and biting depth of miniscrew and excellent safety in avoiding root damage, sinus damage, and ineffective insertion, highlighting the clinical usefulness of the CPSD. This may have been because of the efficiency of the positioning guide, insertion guide, and depth-limiting groove in controlling the insertion site, insertion angle, and biting depth.

Study Limitations

This study had certain limitations. First, the effect of the CPSD on the biomechanical properties of the miniscrews was not analyzed. Second, clinical validity of the CPSD needs to be evaluated in future studies.

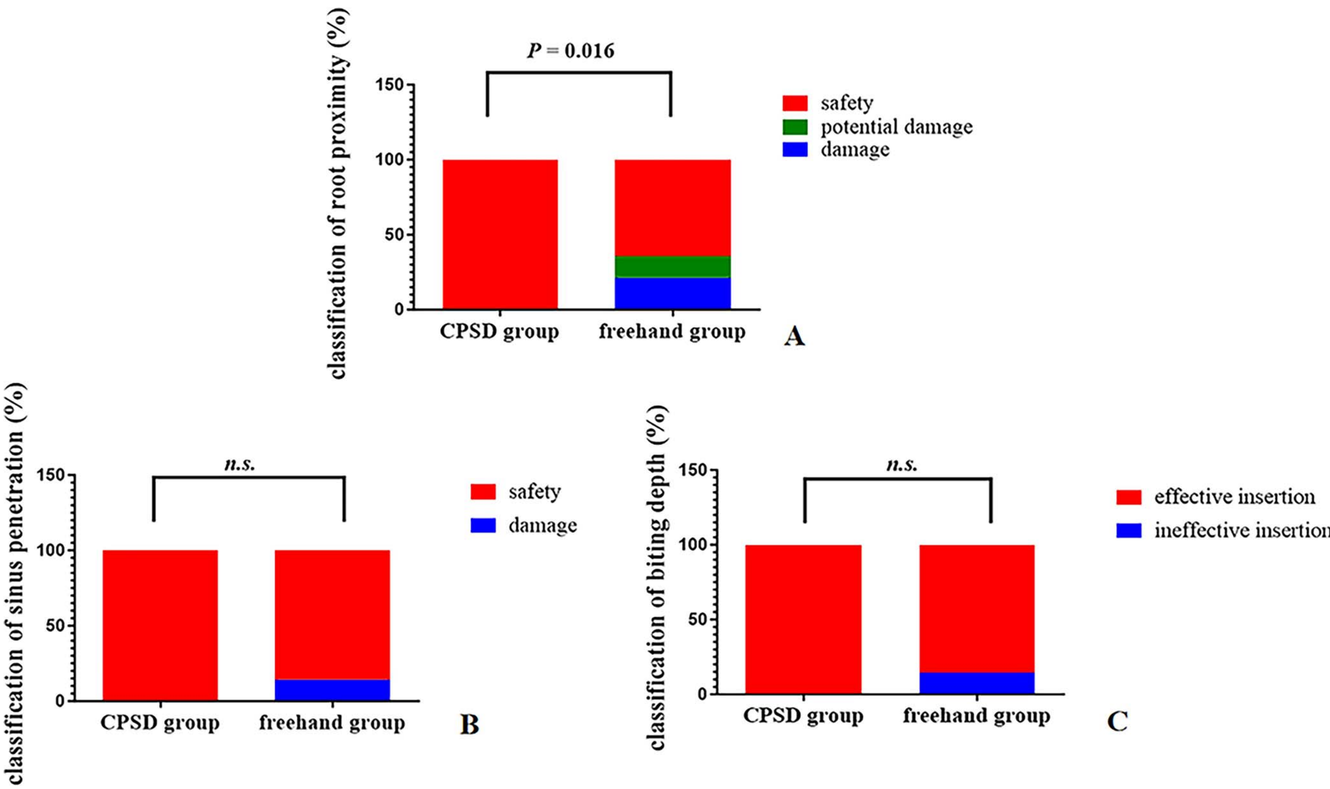

Figure 8. Safety comparison between the combined patient-specific device (CPSD) and freehand groups. (A) Classification frequencies of root proximity. (B) Classification frequencies of sinus penetration. (C) Classification frequencies of biting depth. n.s. indicates no significant difference was found between the two groups.

CONCLUSIONS

- Insertion with the CPSD could be preferred over manual insertion for the safe and accurate insertion of infrazygomatic crest miniscrews.

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