



# Does operator experience affect the accuracy of guided palatal miniscrew insertion via surgical guide? An in-vitro study

Amedeo Salomone<sup>1</sup>, Mario Palone<sup>1</sup>, Francesca Cremonini<sup>1</sup>, Giuliano Maino<sup>1</sup>, Emanuele Paoletto<sup>2</sup>, Marta Cappelletti<sup>1</sup>, Luca Lombardo<sup>1</sup>

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1. Postgraduate School of Orthodontics, University of Ferrara, Via Luigi Borsari 46, Ferrara 44121, Italy
2. Lab Orthomodul, Thiene 36016, Italy

## Correspondence:

Mario Palone, Postgraduate School of Orthodontics, University of Ferrara, Via Luigi Borsari 46, Ferrara 44121, Italy.  
mario.palone88@gmail.com

## Keywords

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## Summary

**Introduction** > To compare the in-vitro accuracy of guided palatal miniscrew insertion comparing expert and inexperienced clinicians.

**Material and methods** > Twenty-one synthetic bone models, derived from a single master model, were acquired to simulate the clinical act of miniscrew insertion. Digital planning and CAD/CAM surgical guide manufacturing were executed by matching the CBCT of the master model with its corresponding STL file. The insertion of two palatal miniscrews in the anterior paramedian region was planned. The operators (mean age 35 years  $\pm$  5 years; 11 males and 9 females) were divided into two sub-groups (inexperienced and experienced), and the miniscrews inserted using a standardized procedure. Linear and angular discrepancies between planned and inserted miniscrew positions were then evaluated at the level of head and tip point by superimposing the reference model (derived from digital planning) with the 20 working models (derived from scanning after miniscrew insertion). Absolute accuracy and comparison between the sub-groups were assessed using a one-sample Wilcoxon test ( $P < 0.05$ ).

**Results** > Regardless of experience, a statistically significant difference in all investigated measurements was found. However, no statistically significant differences were detected between the two sub-groups, except for the sagittal discrepancy at the head, with the inexperienced group being less accurate ( $P = 0.002$ ).

**Conclusions** > The use of a CAD/CAM surgical guide ensures comparable accuracy between inexperienced and experienced clinicians, excepting some outlier discrepancies among the inexperienced subjects. Although there are differences in accuracy between the planned and achieved miniscrew position, these differences do not appear to be clinically significant.

## Introduction

The introduction of miniscrews was a turning point in the management of orthodontic anchorage. Although Cope raised the possibility of "*infinite anchorage*" [1], this has been disproved, as miniscrews can still migrate upon application of a force, whether orthopaedic or orthodontic [2]. Despite such limitations, miniscrews have greatly facilitated the management of orthodontic anchorage. Among the sites used, the palate is certainly the one most appreciated by clinicians. In fact, it has some characteristics, especially in the anterior area, which make it particularly suitable. These include the absence of tooth roots (rootless area) as long as there are no impacted teeth [3] and a paucity of noble vascular and nervous structures (with the exception of the nasopalatine nerve bundle) [4]. Furthermore, the palatal cortical invariably has a thickness greater than 1 mm [5] and it is covered only by keratinized gingiva [3], allowing the use of skeletal palatal anchorage for many appliances with different and various orthodontic purposes [6].

Although previous studies aimed to map palatal bone anatomy [3,4,7] and common trends have been found regarding the variation in total bone thickness (which diminishes towards the lateral and posterior areas) [8], Negrisoli et al. have shown that there is considerable inter-individual variability in total bone thickness according to various factors. Hence differences in the location of the measurement, the path of the miniscrew with respect to the palatal plane and the sex of the patient all need to be taken into account, planning palatal miniscrews insertion according to the anatomy to the patient's individual palate anatomy [9]. This can be achieved only by accurate matching of DICOM files generated via cone-beam computed-tomography (CBCT) with a digital model of the upper jaw.

Considering that a minimum bone thickness of 5 mm should always be sought for good miniscrew stability [4] and that the multicortical anchorage configuration (bi- or tricortical) is more effective than the monocortical one [10], the use of a computer-aided design/computer-aided manufacturing (CAD/CAM) surgical guide, derived from digital planning via CBCT, has been shown to be superior to freehand positioning in achieving these objectives [11]. Careful assessment of site suitability is especially important in the posterior areas, where the scarcity of bone thickness constrains the clinician to plan the insertion of miniscrews in the posterior palatal supra-alveolar insertion site (PPSAIS), where up to 2 mm of extra bone can be obtained and enables tricortical anchorage to be attained [12]. Moreover, the superior performance of the tricortical configuration has recently been confirmed in a finite element method (FEM) analysis by Brucculeri et al. [13]. Conceptually, this digital workflow makes it possible to comply with the principle of the "*bone-driven appliance*", which dictates that miniscrew position be conditioned primarily by the palatal bone anatomy, carefully choosing their length, inclination, depth and number of cortical involved, and not by the appliance design.

Achieving these factors is particularly crucial when selecting bone-borne appliances for orthodontic purposes or when performing the miniscrew-assisted rapid palatal expansion (MARPE) technique, especially in young/adults or adult patients, where high-intensity orthopaedic forces must be exerted. This is also essential when the clinician chooses to transition from a tooth-bone-borne to a purely bone-borne anchorage [14].

Guided miniscrew insertion also enables an appliance to be fitted during the same session as miniscrew placement, the so-called one-visit protocol [15], thereby optimizing chairside time, reducing the number of clinical appointments, and minimizing patient discomfort [6]. In such cases, precise execution of the guided placement procedure is essential.

However, except in the cases mentioned above, a 2D diagnostic image such as a cephalogram is considered suitable for planning guided miniscrew insertion for anterior paramedian palatal placement [16,17], especially in healthy young patients with no impacted teeth, as well as in mouth-breathers [18]. This approach allows for the achievement of hybrid anchorage in order to maximize skeletal expansion [19] or maxillary protraction [20], while adhering to the "*as low as diagnostically acceptable*" (ALADA) principle [21]. Above all, the clinical phase of miniscrew insertion is particularly crucial; of the entire workflow, it would seem to be the one capable of introducing the greatest amount of imprecision [6,22]. In fact, Migliorati et al. found an angular discrepancy between the planned and achieved miniscrew positions of about 6.22° (IQR: 4.35°, 9.08°), and that the final phase seems to have contributed to most of the error (4.57°) [6]. Pozzan et al. reached similar conclusions, with the clinical phase causing an average error of about 6.23° ± 3.75°, far higher than that introduced by the laboratory phases (about 2.12° ± 1.62°) such as the 3D-printing of the working model with holes for analogues and of the surgical guide for the one-visit protocol [22].

Although some studies have previously studied the accuracy of palatal miniscrew placement by means of surgical template both in-vitro [23,24] and in-vivo [6,22,25], none have related this to the clinical expertise of the operator. While Al-Gazzawi et al. hypothesized that the use of a surgical guide may lessen the impact of surgical skills and experience in placing miniscrews among the various clinicians [25], to the best of our knowledge there have been no studies investigating this aspect. Therefore, the primary aim of the following in-vitro study was to compare the placement accuracy of palatal miniscrews comparing two sub-groups of operators characterized by a marked difference in clinical experience. The research hypothesis was that guided miniscrew insertion would not obviate differences in clinical expertise, meaning it might not be a safe and reliable method for novice operators.

The secondary aim is to compare the accuracy of guided placement across the entire group, comprising individuals with

varying levels of experience of the procedure, against a hypothetical absolute precision defined by linear and angular deviations set at 0 mm and 0°.

## Material and methods

The study designed was evaluated and accepted by the post-graduate School of the University of Ferrara Ethics Committee as protocol n. 9/2022:

- Participants (P): two sub-groups with different levels of expertise in guided palatal miniscrew insertion (experienced vs. inexperienced);
- Intervention (I): use of a surgical guide for palatal miniscrew insertion;
- Comparison (C): for the primary aim, a direct comparison of insertion accuracy between the experienced and inexperienced groups, while for the secondary aim, a comparison of the entire group (both experienced and inexperienced operators) against a hypothetical absolute precision, defined by linear and angular deviations set at 0 mm and 0°, respectively;
- Outcomes (O): measurements of both linear (global, vertical, sagittal and transverse) and angular deviations (on the coronal plane) relative to the reference (digitally planned) miniscrew position;
- Study design (S): in-vitro study.

### Sample selection

Three synthetic bone models of the same maxillary arch were requested from the company Bone Models™ (Castellón, Spain) after sending an STL file of the latter (digital master model). The maxillary arch was characterized by the presence of a moderate degree of crowding (4.8 mm).

The synthetic bone of these three models replicated different human bone densities, thanks to the presence of a polyurethane mixture, whose exact composition has not been declared, and the addition of barium sulphate to mimic the radiopacity of human bone tissue. At the paramedian level and the third palatine ruga of each model requested, the thickness of the soft tissues (3 mm) was also replicated by means of a special mixture of silicones, simulating the clinical conditions [26].

In order to choose a synthetic bone density that was as close as possible to that clinically detectable at the level of the paramedian palatal site, after the performing of a pre-drilling hole the insertion of a miniscrew (Spider Screw Konic, HDC srl, Thiene, Italy) of 2 mm in diameter and 11 mm in length was simulated using the NSK Surgic Pro implant motor (Nakanishi INC, Kanuma, Japan) setting a speed of 20 rpm (rpm) and an initial torque of 5 N/cm. The torque was increased by intervals of 5 N/cm until the miniscrew was fully inserted. This preliminary procedure allowed the selection of the final study model, with a torque insertion value of between 10–15 N/cm in line with that reported in the literature during clinical application [27].

After this preliminary phase, 30 identical versions of the selected model were then requested with the same polyurethane synthetic bone mixture able to replicate an insertion torque value of between 10–15 N/cm.

Subsequently, STL files of these 30 models were acquired using a C4 benchtop scanner (3Shape, Copenhagen, Denmark), and then superimposed on the STL master file using Geomagic Control X software (Geomagic, Research Triangle Park, NC, USA) and the "best-fit" tool. Models with dimensional discrepancies greater than 0.1 mm were discarded, resulting in a total of 21 final physical models.

### Digital planning

The digital planning of the miniscrew insertions, with the related design and prototyping of the surgical guide (Miniscrew Assisted Palatal Application-MAPA protocol), was performed after 3D matching between the original STL file of the master model and DICOM files were obtained from a CBCT scan of the 10th physical model among the 21 models created. This model was randomly chosen.

DICOM data were obtained using a KAVO® OP 3D TM PRO tomograph (Kavo, Biberach, Germany). The settings used were: 13 cm × 15 cm FOV, 90 kV, 5.0 mA, 8.1 s exposure time, and 863 mGyXcm<sup>2</sup> emission.

The planning was performed by superimposing the STL and DICOM files using eXam Vision software (ExamVision ApS; Samsø, Denmark), integrated with the Rhinoceros software (Robert McNeel & Associates, Seattle, USA). The parallel insertion of two Spider Screw Konic miniscrews (HDC srl, Thiene, Italy) of length 11 mm and of diameter 2 mm was planned. The miniscrews were to be inserted 8.7 mm apart, with the distance between their heads and the median palatine raphe being 4.4 mm on the right and 4.2 mm on the left (*figure 1A*).

After planning the miniscrew insertion, the surgical guide (Rhinoceros, Robert McNeel & Associates, Seattle, USA) was designed (CAD phase) and prototyped (CAM phase) using a DLP technology 3D printer (Everes Uno, SISMA spa, Piovene Rocchette, Italy), setting a resolution of 65 µm on the XY plane. The resin used was the Everes Functional model (SISMA Spa, Vicenza, Italy) with a Shore D Hardness of 85 and Young's modulus of 1681 Mpa. The MAPA surgical guide design completely covered the lingual and occlusal surfaces of the maxillary canine and premolar teeth on both sides, and one third of their vestibular surface, adapting to the palatal mucosa. Its thickness was 3 mm in order to ensure the greatest possible stability and stiffness. In the central portion, two complementary cylindrical recesses were incorporated to accommodate the two metal sleeves (HDC srl, Thiene, Italy) (*figure 1B*). A maximum of four surgical guides, each to be used a maximum of 5 times, were produced in order to obviate alterations due to wear.

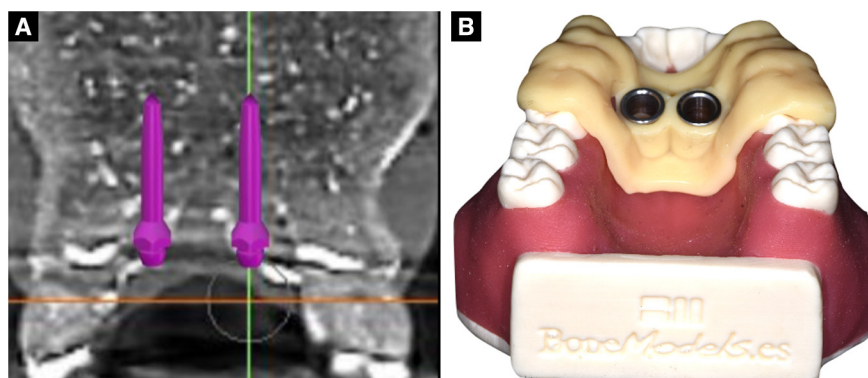


FIGURE 1  
**Digital planning of miniscrew insertion (A) and manufacturing of MAPA surgical guide (B)**

The main STL file, containing the maxillary model and the palatal miniscrews digitally positioned, was used as a reference model.

### Clinical Procedure

A total of twenty operators (mean age 35 years  $\pm$  5 years; 11 males and 9 females) were selected and subsequently divided into two sub-groups based on clinical experience with guided palatal miniscrew insertion as follows:

- **inexpert sub-group:** composed by 10 operators (mean age 24 years  $\pm$  2.8 years; 6 males and 4 females) with no clinical experience in the palatal guided miniscrew insertion by means of a surgical guide (< 5 palatal miniscrews). These were students at the University of Ferrara Postgraduate School of Orthodontics who had received only theoretical notions on the miniscrew insertion process;
- **expert sub-group:** composed by 10 expert orthodontic specialists (mean age 47 years  $\pm$  6.8 years; 5 males and 5 females) with ample previous clinical experience in the palatal guided miniscrew insertion by means of a surgical guide (>30 palatal miniscrews).

All operators were provided with a Surgic Pro implant motorized handpiece (Nakanishi INC, Kanuma, Japan), a maxillary model with a hardness of 10-15 N/cm (Bone Models™, Castellón, Spain), two Spider Screw Konic miniscrews (HDC srl, Thiene, Italy) with a length of 11 mm and a diameter of 2 mm, a 1.3 mm drilling bur for corticotomy (HDC srl, Thiene, Italy), a dedicated pick-up driver (HDC srl, Thiene, Italy) and the respective MAPA surgical guide. Each maxillary model was mounted on the special mannequin to simulate clinical miniscrew placement. The insertion protocol involved first corticotomy (700 rpm, 20 N/cm) and then the insertion of the orthodontic miniscrews using the appropriate pick-up driver (20 rpm, 20 N/cm). Both the corticotomy drilling bur and the pick-up driver bore a cylindrical body complementary to the metal sleeves inserted in the MAPA surgical guide.

After the insertion procedure, the operator (AS) placed the scanbodies (HDC srl, Thiene, Italy) on each head of the inserted miniscrew (*figure 2A*), and scanned the jaw models using the CS3600 intraoral scanner (Carestream Dental, Atlanta, USA), thereby obtaining the STL files of the corresponding working model.

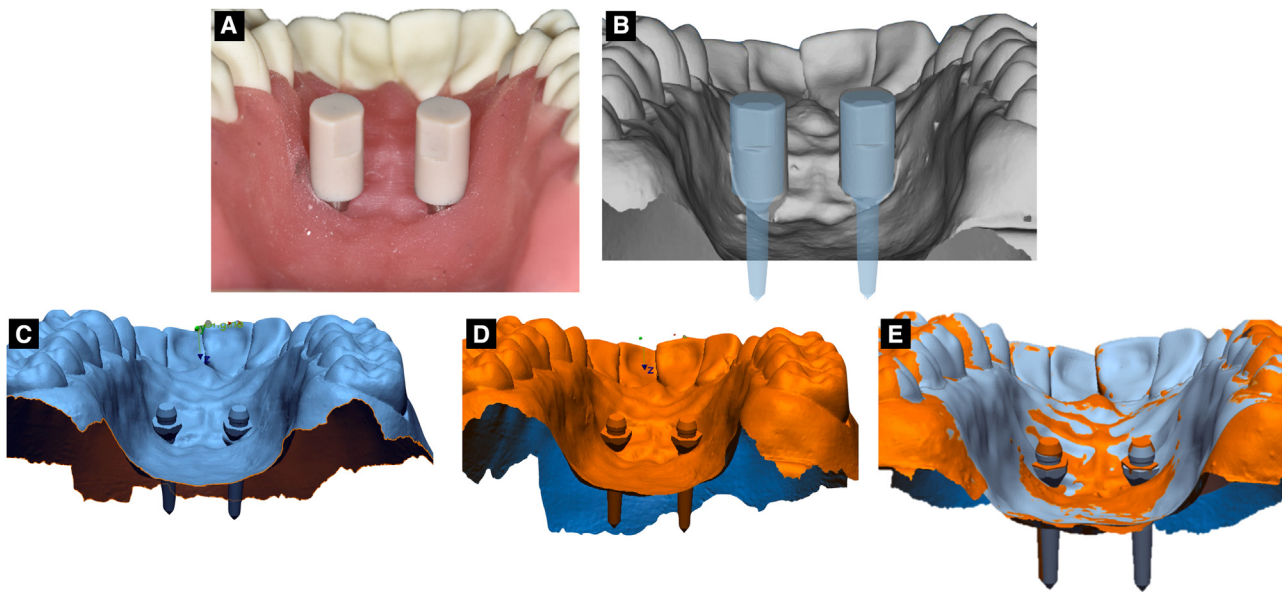


FIGURE 2

**Graphical representation of the digital workflow used for measurements. Positioning of scanbodies on miniscrew heads (A), superimposition of the model file thus obtained with the STL file with coupling of the digital scanbody and the palatal miniscrew (B) in order to achieve the working model with the spatial position of the miniscrew inserted (C). Subsequently, the latter is superimposed on the reference model, over the dental surfaces (D, E). After "hiding" the model, spatial discrepancies between planned and achieved miniscrew positions were measured**

### Measurements

Before proceeding with the digital measurements, the working model obtained was then superimposed with the STL file containing the scanbody/miniscrew spatial coupling (figure 2B) using Rhinoceros software (Robert McNeel & Associates, Seattle, USA) in such a way as to indirectly obtain the spatial position of the inserted miniscrews (final working model) (figure 2C).

The latter was digitally superimposed on the STL file of the reference model (figure 2D) at the level of all tooth surfaces using the Geomagic Control X software (Geomagic, Research Triangle Park, NC, USA) "best-fit" tool (figure 2E).

Once the reference model and the working model had been superimposed, they were oriented so that the Y-axis corresponded with the palatal raphe and the X-axis with the line tangent to the mesiolingual cusps of the first maxillary molars. After hiding the models, the spatial position of the inserted miniscrews in each working model was compared with those in the reference model (planned miniscrew).

To this end, the following reference points were identified on each miniscrew:

- head point: corresponding to the centroid of the miniscrew head;
- tip point: corresponding to the tip of the miniscrew;
- miniscrew axis: the line joining the Head and Tip points (figure 3).

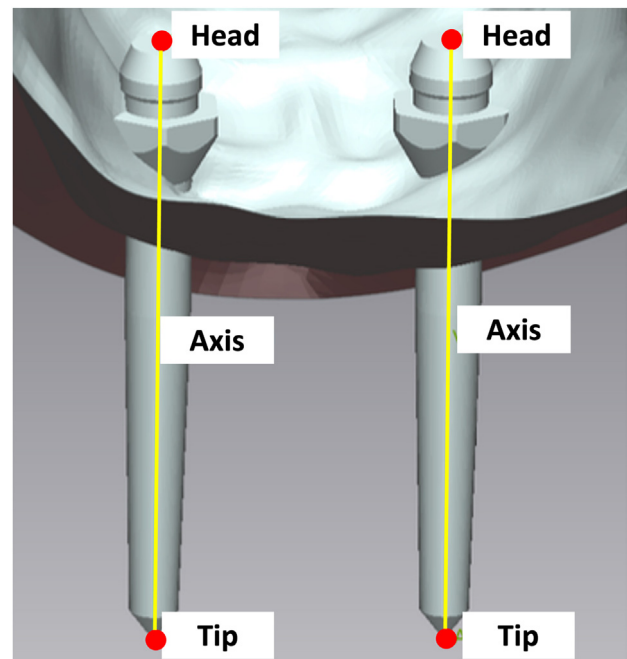


FIGURE 3

**Reference points on which measurements are performed**

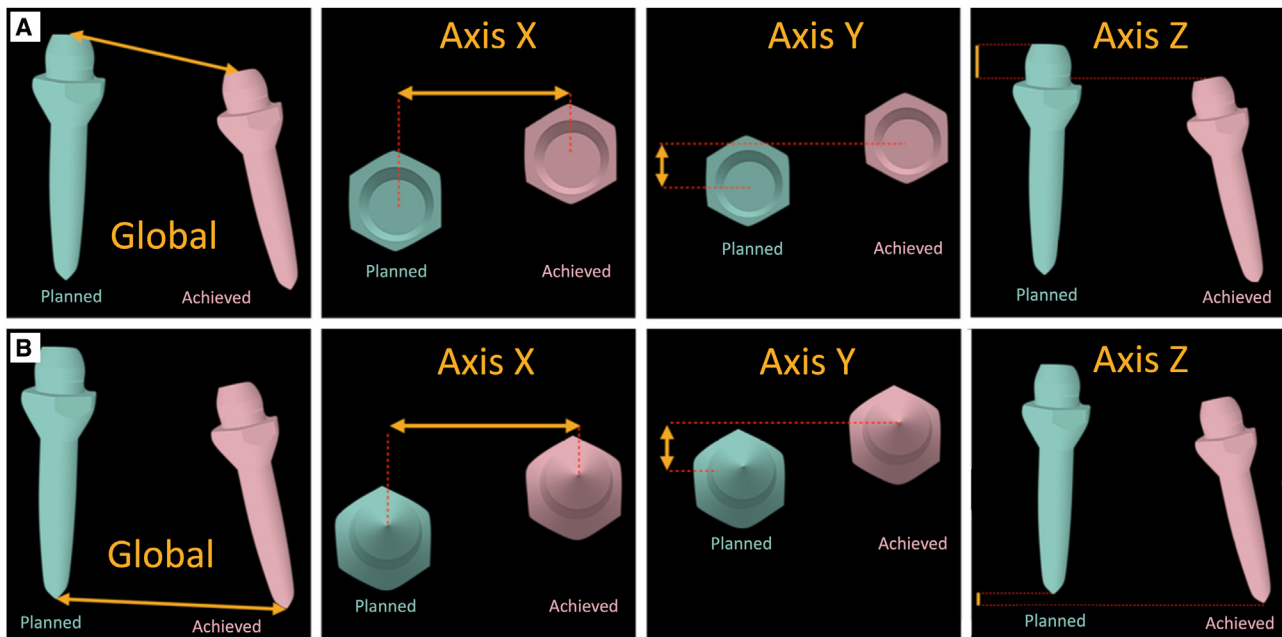


FIGURE 4

**Graphical representation of linear discrepancies between planned and inserted miniscrew positions at both miniscrew head (A) and tip (B)**

The following measurements were subsequently made:

- linear discrepancy (mm) at the level of both Head and Tip point, both globally and on each axis, as follows:
  - on the X-axis (transverse discrepancy),
  - on the Y-axis (sagittal discrepancy),
  - on the Z-axis (vertical discrepancy),
- yielding a total of 8 linear measurements (mm) (figure 4);
- angular discrepancy ( $^{\circ}$ ) between the inserted and planned miniscrew axes positions on the coronal YZ plane (figure 5).

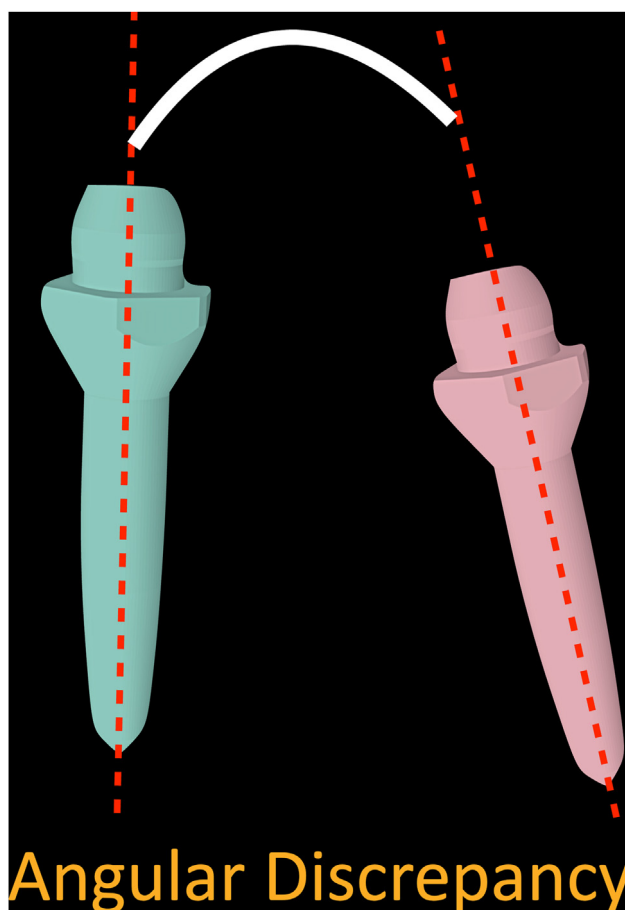


FIGURE 5

Graphical representation of angular discrepancies between planned and inserted miniscrew positions at both miniscrew head (A) and tip (B)

### Statistical analysis

The expected effect size between the two groups is 0.95. Based on this effect size and a significance level of 0.05, our sample size of 20 units per group provided a power greater than 80%. The normality of the data was assessed using the Shapiro-Wilk test ( $P < 0.05$ ). The normality test showed a statistically significant difference for each measurement examined, assuming the non-normal distribution of the data. Consequently, the measurements are reported using the median and the 25th and 75th percentiles. The accuracy of miniscrew insertion was analysed using the non-parametric one-sample Wilcoxon test applied to the median values, adjusted using the Bonferroni method to account for multiple comparisons ( $P < 0.05$ ). The degree of inaccuracy of each measurement investigated was compared against a value of 0, or absolute precision, first in the whole group (20 operators and 40 miniscrews analysed) and then

within each sub-group (expert and inexperienced). Subsequently, the spatial accuracy of the miniscrews inserted by the two sub-groups was compared for each measurement.

### Results

Table 1 shows the descriptive values (median, 25th and 75th percentiles, minimum and maximum values) for both the total sample and the respective sub-groups, inexperienced and expert (table 1). Considering the entire sample, the global linear discrepancies ranged from a minimum of 0.15 mm to a maximum of 1.75 mm, with a median value of 0.44 mm (0.31 mm; 0.57 mm) at the Head point and from a minimum of 0.18 mm to a maximum of 3.48 mm, with a median value of 0.76 mm (0.53 mm; 0.88 mm) at the Tip point. Both the highest linear deviations were recorded in the inexperienced sub-group. Considering the inaccuracy values on the three planes of space,

TABLE I

Median, 25th and 75th percentile and minimum and maximum inaccuracy values for each measurement investigated for miniscrew insertion by each sub-group and the total sample.

		Number	Global (mm)		Transversal (X-Axis) (mm)		Sagittal (Y-Axis) (mm)		Vertical (Z-Axis) (mm)		Angular discrepancy (°)
			Head	Tip	Head	Tip	Head	Tip	Head	Tip	
Inexpert sub-group	Median	20	0.43	0.73	0.06	0.41	0.21	0.40	0.34	0.26	2.75
	25th percentile	20	0.35	0.51	0.04	0.19	0.14	0.21	0.19	0.10	1.77
	75th percentile	20	0.52	0.90	0.17	0.66	0.31	0.58	0.43	0.42	3.60
	Min.	20	0.24	0.18	0.01	0.01	0.06	0.07	0.03	0.02	0.38
	Max.	20	1.75	3.48	0.91	3.47	1.49	1.97	1.69	1.46	13.57
Expert sub-group	Median	20	0.49	0.76	0.07	0.21	0.09	0.37	0.40	0.39	1.71
	25th percentile	20	0.26	0.54	0.03	0.09	0.03	0.15	0.24	0.22	0.82
	75th percentile	20	0.60	0.88	0.13	0.45	0.15	0.61	0.52	0.50	3.19
	Min.	20	0.15	0.24	0.01	0.00	0.00	0.04	0.11	0.08	0.39
	Max.	20	0.79	1.20	0.42	0.69	0.39	1.00	0.78	0.85	4.13
Total	Median	40	0.44	0.76	0.07	0.30	0.14	0.38	0.36	0.35	2.03
	25th percentile	40	0.31	0.53	0.04	0.15	0.08	0.18	0.20	0.17	1.00
	75th percentile	40	0.57	0.88	0.14	0.58	0.28	0.59	0.49	0.44	3.40
	Min.	40	0.15	0.18	0.01	0.00	0.00	0.04	0.11	0.02	0.38
	Max.	40	1.75	3.48	0.91	3.47	1.49	1.97	1.69	1.46	13.57

TABLE II

Comparison of absolute precision (discrepancy values = 0) for each measurement using the non-parametric one-sample Wilcoxon test ( $P < 0.05$  considered statistically significant), analysed across the entire sample, as well as in inexpert and expert sub-groups. To account for multiple comparisons,  $P$ -values were adjusted using the Bonferroni correction.

		Total	Inexpert sub-group	Expert sub-group
		$P$ -value	$P$ -value	$P$ -value
Global (mm)	Head	<0.001	<0.001	<0.001
	Tip	<0.001	<0.001	<0.001
Transversal (X-Axis) (mm)	Head	<0.001	<0.001	<0.001
	Tip	<0.001	<0.001	<0.001
Sagittal (Y-Axis) (mm)	Head	<0.001	<0.001	<0.001
	Tip	<0.001	<0.001	<0.001
Vertical (Z-Axis) (mm)	Head	<0.001	<0.001	<0.001
	Tip	<0.001	<0.001	<0.001
Angular discrepancy (°)		<0.001	<0.001	<0.001

TABLE III

Comparison of each measurement between inexperienced and expert sub-groups, analyzed using the non-parametric Wilcoxon test. To account for multiple comparisons, p-values were adjusted using the Bonferroni correction.

		Inexpert	Expert	P-value
		Median (25th and 75th percentile)	Median (25th and 75th percentile)	
Global (mm)	Head	0.43 (0.35; 0.52)	0.49 (0.26; 0.60)	>0.99
	Tip	0.73 (0.51; 0.90)	0.76 (0.54; 0.88)	>0.99
Transversal (X-Axys) (mm)	Head	0.06 (0.04; 0.017)	0.07 (0.03; 0.13)	>0.99
	Tip	0.41 (0.19; 0.66)	0.21 (0.09; 0.45)	>0.99
Sagittal (Y-Axis) (mm)	Head	0.21 (0.14; 0.31)	0.09 (0.03; 0.15)	0.018 <sup>a</sup>
	Tip	0.40 (0.21; 0.58)	0.37 (0.15; 0.61)	>0.99
Vertical (Z-Axys) (mm)	Head	0.34 (0.19; 0.43)	0.4 (0.24; 0.52)	>0.99
	Tip	0.26 (0.10; 0.42)	0.39 (0.22; 0.50)	>0.99
Angular discrepancy (°)		2.75 (1.77; 3.60)	1.71 (0.82; 3.19)	>0.99

<sup>a</sup>P < 0.05 considered statistically significant.

the inaccuracy at the Tip point tended to be greater than that at the Head point, with the exception of the vertical plane, on which discrepancies were largely similar. The greatest median inaccuracy at the Head point was recorded on the Z-axis [0.36 mm; (0.20 mm–0.49 mm)], while at the Tip point it was on the Y-axis [0.38 mm; (0.18 mm–0.59 mm)]. As for the angular measurements, there was a range of inaccuracy from 0.38° to 13.57°, with the median value being 2.03° (1°; 3.40°). The highest inaccuracy values in both linear and angular measurements were found for the inexperienced sub-group (table I). A comparison of the recorded inaccuracy values with respect to a hypothetical absolute precision (discrepancy equal to 0) is shown in table II. In all cases, there was a statistically significant difference from 0 in all the measurements investigated, both linear and angular (P < 0.001) (table II).

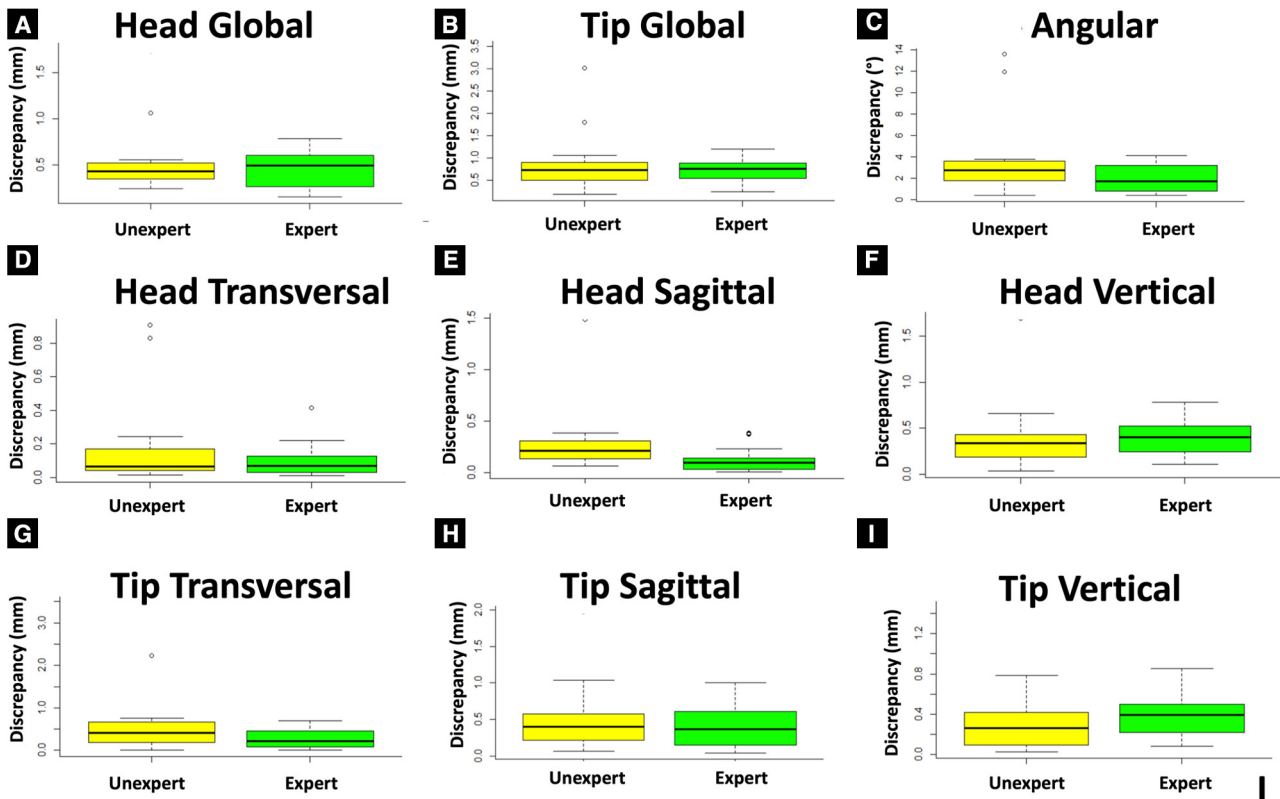
A direct comparison between the two sub-groups shows no statistically significant difference (P > 0.05), with the exception of the inaccuracy on the Y-axis (P = 0.018) recorded at the Head point, being less precise in the inexperienced group [0.21 mm; (0.14 mm–0.31 mm)] compared to the expert group [0.09 mm; (0.03 mm–0.15 mm)]. For differences that did not reach statistical significance, the median values did not display a common trend, except for a small angular discrepancy found at the level of the expert group (table III).

The respective comparison box-plots are shown in figure 6.

## Discussion

The primary objective of this study was to investigate the respective accuracy of miniscrew placement in the anterior

paramedian area of the palate by two sub-groups of operators (expert and inexperienced) guided by surgical guide. Indeed, although the accuracy of guided insertion of palatal miniscrews has previously been investigated, there is no such comparison in the literature. A direct comparison between the planned and inserted miniscrew position in the three planes of space in all cases shows that it is not possible to faithfully replicate the digital plan, although the discrepancy in median differences found in this study is very small and probably not clinically significant. That said, there were notable positional discrepancies recorded in the inexperienced group for two individual operators, suggesting that the possibility of outliers should not be overlooked. The presence of these two outliers may be attributed to inaccuracies during the miniscrew insertion procedure. Palatal miniscrews are self-drilling and feature a highly aggressive tip. If the operator fails to properly align the tip with the previously prepared cortical hole or fails to recognize the tactile feedback from the characteristic "snap" upon entry, the subsequent rotation of the miniscrew may result in a slightly divergent pathway compared to the one created by the drilling bur. This is particularly likely if rotation is begun before the tip fully engages with the pre-prepared entrance. In terms of median values, though, no differences were found between the expert and inexperienced sub-groups for any of the measurements investigated, with the exception of the position of the head of the miniscrews on the sagittal plane, which was more precise in the expert group. It should be added, however, that that difference was far from being clinically significant, and therefore likely to be irrelevant.



**FIGURE 6**  
**Box-plots representing the comparison between expert and inexpert sub-groups for each angular (C) and linear measurement investigated at both miniscrew head (A, D, E, F), miniscrew tip (B, G, H, I).**

The possibility of reducing the differences in clinical experience is probably largely thanks to the construction method used for the surgical guide. In fact, in order to increase the stability and rigidity of the same, a very rigid resin (Shore D Hardness of 75) was used, which had an average thickness of about 3 mm, extending at the level of the premolars and canines up to a third of their vestibular surface, also contacting the palatal mucosa.

As a matter of fact, the design of the surgical guide and the physical characteristics of the resins used for its manufacture are fundamental. Mang de la Rosa et al. compared the accuracy of different surgical guides with an emphasis on the physical characteristics (Shore A-D hardness values) of the various materials used, which should be known by the clinician as well as some printing settings (orientation on the build platform and post-processing phases) [24].

Since it seems that a good template design can smooth out differences between two groups with different clinical

experience in this regard, the discrepancies obtained can be evaluated on the global sample. The results of this analysis show that the median linear discrepancies found at the level of the heads are always smaller than 0.5 mm, similarly to that reported by Al-Gazzawi et al. [25]; it should be added that the latter did not experience significant differences between horizontal and vertical discrepancies, while in this study greater discrepancies were found on the vertical plane. Mang de la Rosa et al. [24] and Migliorati et al. [6] recorded slightly larger millimetric discrepancies in some cases, although it should be noted that this difference would be of little clinical relevance as these were always less than 1 mm, except in the linear measurement at the level of the vertical plane in the study of Migliorati et coll. [6].

The positional discrepancies at the level of the miniscrew tip are generally greater than those present at the level of the head; only by investigating these discrepancies on the vertical plane do we see similar discrepancies between the miniscrew head

and tip. A similar trend was also noted by Migliorati et al.; in fact, they also found minimal differences between head and tip on the vertical axis, although slightly greater than in this study [6]. Mang de la Rosa et al. reported greater linear discrepancies at the level of the miniscrew tip, although the largest were present at the sagittal level and not vertically [24].

As for the angular measurements, we found median discrepancies of about  $2.03^\circ$  ( $1.00^\circ$ ;  $3.40^\circ$ ) on the coronal plane (YZ), significantly lower than those detected in similar studies considering the same reference plane [6,22,24]. These differences could be attributable to the different measurement protocol as well as to the different surgical guide manufacturing protocols investigated. Indeed, Mang de la Rosa et al. found similar angular measurements when the surgical guide was constructed with Pattern Resin LS (GC Europe N.V., Leuven, Belgium), which has a Shore hardness value of 65, similar to that used in this study [24].

On the other hand, Migliorati et al. used a thermoformed surgical guide made from 2.5 mm thick polyethylene terephthalate glycol discs, whose metal sleeves were positioned and then stabilized to the thermoformed part by means of hard resin using the perforated model with the inserted analogues; in this case, the inaccuracy of the printing procedures of the perforated model and the manual insertion of the analogues would also have to be considered [6]. Similar angular discrepancies were also found with the study by Pozzan et al., although the authors did not specify the characteristics of the resin used, the thickness of the template and the design [22]. It should be emphasized that these last two studies are in-vivo and not in-vitro studies, so the differences are very likely explained by clinical difficulty [6,22].

Mang de la Rosa et al. found the greatest discrepancies with conventional surgical guides made from less rigid and elastic material like Memosil 2 (conventional SG; Kulzer, Hanau, Germany), which can be distorted by excessive finger pressure during the act of insertion; on the other hand, fewer discrepancies were found with more rigid manufacturing materials, such as 3D printed surgical guides with the exception of the one manufactured with V-Print resin (VOCO, Cuxhaven, Germany) and the conventional one produced with the GC Pattern Resin LS material (GC Europe NV, Leuven, Belgium) [24].

Regarding the clinical implications of this study, it can be concluded that, when planning miniscrew insertion digitally, the operator should ensure a safe distance between the tip of the miniscrew and the apex of the incisors in the anterior paramedian palatal region. If that were based on the median value found in this study, the safety margin would be about 0.76 mm. However, approximately 50% of measurements exceeded this

threshold, so 1.5 mm would seem a more appropriate target for expert clinicians, as only 7.5% of deviations exceed this value. To account for the possibility of outliers (such as we recorded among less experienced clinicians) we suggest novices adhere to a safe distance of 3.5 mm, gradually reducing this to 1.5 mm as they gain greater confidence in their technique.

The main limitation of this study is that it was conducted in vitro. However, the corresponding in-vivo procedure could be considered similar, as the palatal region involved in this study is easily accessible clinically. Therefore, to a certain extent, the results of this study may be clinically generalizable. Regarding the in-vitro design, it should be noted, however, that this was an obligatory choice to test the positioning accuracy between two sub-groups with different clinical experience on a single clinical case that presented the same clinical difficulty, in order to standardize the protocol. A further aspect to consider is that regular planning with the miniscrews parallel to each other in the anterior area of the palate was considered, so it is not certain that the same results would be obtained more angulated miniscrews positioned in the posterior palate. Further in-vitro studies will need to be performed to test for this.

Future studies involving free-hand palatal miniscrew insertion by expert versus novice operators may also prove interesting, although beyond the scope of the present study.

## Conclusions

Although a statistically significant difference between planned and positioned sagittal positions of the miniscrew at both head and tip was detected, this would not seem to be clinically impactful and therefore the research hypothesis was not confirmed.

In general, using a surgical guide to insert miniscrews appears to obviate differences in clinical expertise, although outliers among inexperienced operators cannot be completely ruled out.

**Authors' contributions** : Concept and study design: Giuliano B. Maino and Amedeo Salomone

Acquisition of data: Amedeo Salomone

Measurements: Amedeo Salomone

Analysis and/or interpretation of data: Mario Palone, Amedeo Salomone

Drafting the manuscript: Mario Palone and Marta Cappelletti

Revising the manuscript critically for important intellectual content: Luca Lombardo, Giuliano Maino, Cremonini Francesca and Emanuele Paoletto

Approval of the version of the manuscript to be published: Mario Palone, Amedeo Salomone, Giuliano Bortolo Maino, Marta Cappelletti, Emanuele Paoletto, Francesca Cremonini, Luca Lombardo.

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