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RESEARCH

Factors influencing the accuracy of guided palatal miniscrew insertion in young adults

Prospective in vivo study

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Abstract

Objective To evaluate the in vivo accuracy of guided palatal miniscrew insertion, focusing on the effect of insertion side, frontal insertion angle, and miniscrew length.

Materials and methods In all, 52 palatal miniscrews were inserted using computer-aided design/computer-aided manufacturing (CAD/CAM) surgical guides in 20 patients (average age: 19.74 years ± 6.83). Digital models were acquired after miniscrew insertion and scanbody application. Then, linear and angular discrepancies between planned and realized miniscrew positions were evaluated by superimposing the reference model with the final postinsertion model. Discrepancies are recorded and compared to absolute precision (hypothetical). The effect of side, frontal insertion angle, and miniscrew length on accuracy were investigated.

Results Mean linear total discrepancies were 1.10 ± 1.01 mm and 1.71 ± 1.10 mm at the miniscrew head and tip points, respectively. Mean angular discrepancies were 5.90 ± 6.06° in the transverse (XY), 2.65 ± 2.47° in the sagittal (YZ), and 3.02 ± 2.65° in the coronal (XZ) plane. All discrepancies were significantly different to absolute precision ($p < 0.001$), although not to an extent considered clinically relevant. Neither side nor frontal insertion angle (clinical factors), or miniscrew length (structural factor) significantly impacted accuracy.

Conclusion CAD/CAM surgical guides ensured clinically acceptable accuracy despite significant deviations from absolute precision. The insertion side, frontal insertion angle, and miniscrew length had minimal influence on accuracy, and therefore on outcome. Further studies should explore the effects of additional clinical, procedural, anatomical, and structural variables.

Keywords Palate · Surgical guides · Placement accuracy · Computer-aided design/computer-aided manufacturing · Maxillary-assisted rapid palatal expansion

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Faktoren, welche die Genauigkeit der geführten Insertion palatinaler Minischrauben bei jungen Erwachsenen beeinflussen

Eine prospektive In-vivo-Studie

Zusammenfassung

Zielsetzung Evaluierung der In-vivo-Genauigkeit der geführten Insertion palatinaler Minischrauben unter Berücksichtigung der Insertionsseite, des frontalen Insertionswinkels und der Länge der Minischrauben.

Materialien und Methoden Bei 20 Patienten (Durchschnittsalter: 19,74 Jahre ± 6,83) wurden 52 palatinale Minischrauben unter Verwendung computergestützter (CAD/CAM) chirurgischer Schablonen inseriert. Nach dem Einsetzen der Minischrauben und dem Scanbody-Anbringen wurden digitale Modelle erstellt. Anschließend wurden die linearen und winkligen Abweichungen zwischen den geplanten und den tatsächlichen Positionen der Minischrauben bewertet, indem das Referenzmodell mit dem endgültigen Modell nach dem Einsetzen überlagert wurde. Abweichungen wurden aufgezeichnet und mit der (hypothetischen) absoluten Präzision verglichen. Der Einfluss der Seite, des frontalen Einsetzwinkels und der Länge der Minischrauben auf die Genauigkeit wurde untersucht.

Ergebnisse Die mittleren linearen Gesamtabweichungen betrugen 1,10 ± 1,01 mm am Kopf und 1,71 ± 1,10 mm an der Spitze der Minischraube. Die mittleren Winkelabweichungen betrugen 5,90 ± 6,06° in der transversalen (XY) Ebene, 2,65 ± 2,47° in der sagittalen (YZ) Ebene und 3,02 ± 2,65° in der koronalen (XZ) Ebene. Alle Abweichungen unterschieden sich signifikant von der absoluten Präzision ($p < 0{,}001$), jedoch nicht in klinisch relevantem Ausmaß. Weder der seitliche noch der frontale Einführwinkel (klinische Faktoren) oder die Länge der Minischraube (struktureller Faktor) hatten einen signifikanten Einfluss auf die Genauigkeit.

Schlussfolgerung CAD/CAM-Bohrschablonen gewährleisteten trotz signifikanter Abweichungen von der absoluten Präzision eine klinisch akzeptable Genauigkeit. Die Insertionsseite, der frontale Insertionswinkel und die Länge der Minischrauben hatten nur minimalen Einfluss auf die Genauigkeit und damit auf das Ergebnis. In weiteren Studien sollten die Auswirkungen zusätzlicher klinischer, verfahrenstechnischer, anatomischer und struktureller Variablen untersucht werden.

Schlüsselwörter Gaumen · Chirurgische Schablonen · Platzierungsgenauigkeit · Computergestütztes Design/computergestützte Fertigung · Maxillär unterstützte schnelle Gaumenexpansion

Abbreviations

CAD/CAM	Computer-aided design/computer-aided manufacturing
CBCT	Cone-beam computed tomography
DPRI	Digital Planning Research Institute
FOV	Field of view
ICC	Intraclass correlation coefficient
MAPA	Miniscrew-assisted palatal application
MARPE	Maxillary-assisted rapid palatal expansion
PPSAIS	Palatal posterior supra-alveolar insertion site

Introduction

The palate is considered one of the most preferred insertion sites for miniscrews due to its easy access, paucity of noble structures, absence of roots (rootless area) [9], versatility in supporting various orthodontic mechanics, such as mesialization, distalization, intrusion, extrusion, and maxillary skeletal expansion, even in adult patients [12], and low risk of failure [13]. Regarding this latter aspect, Mohammed et al. reported an overall premature miniscrew failure rate of approximately 4.7% for the palate, with the lowest rates observed in the midpalatal region (1.3%), followed by the paramedian (4.8%) and parapalatal regions (5.5%) [13]. This reduced tendency to fail is attributed to the presence of keratinized gingiva, which is thinner in the midpalatal area [14], high cortical bone quality (typically > 1 mm) [1], and the absence of tooth roots. Indeed, contact with tooth roots increased the risk of early stability loss with a pooled risk ratio of 8.7 [13].

The process of guided palatal miniscrew insertion has significantly enhanced by the introduction of computer-aided design/computer-aided manufacturing (CAD/CAM) surgical guides, due to the fact that the risk of root involvement, nerve/vascular bundle injury, or penetration into the maxillary sinus or nasal cavity, can be minimized by digital planning miniscrew insertion. This involves precise three-dimensional (3D) matching of DICOM files obtained from cone-beam computed tomography (CBCT) scans with the digital maxillary model. This process ensures faithful reconstruction of the maxillary anatomy and therefore customized miniscrew insertion planning. Furthermore, guided insertion allows optimal bone engagement (involving a minimum of 5 mm of bone) [19], bi- [8] or tricortical anchorage [4], and proper inclination for each miniscrew. These factors are critical for achieving stability and minimizing miniscrew migration, especially under the heavy orthope-

dic forces exploited during miniscrew-assisted rapid palatal expansion (MARPE) procedures.

Although attempts have been made to improve the accuracy of guided miniscrew insertion, inaccuracies remained, particularly at the miniscrew tip and in angular values [11, 12, 16]. Quantifying linear error at the tip is crucial to maintaining a safe distance from roots and critical structures, thereby preventing iatrogenic complications. Angular deviations, on the other hand, can disrupt the immediate application of miniscrew-supported palatal appliances in a one-visit protocol [10].

While studies have examined the role of surgical guides in improving accuracy (in both in vitro and in vivo evaluations) [2, 12, 16], the individual factors contributing to inaccuracy remain underexplored, with only a few exceptions [2, 3]. Moreover, only the study by Pozzan et al. [16] has investigated the accuracy of miniscrew insertion involving a multicortical engagement (bicortical), which may hinder precise placement with respect to monocortical configuration.

Hence, this study aimed to evaluate in vivo the degree of accuracy of guided miniscrew insertion with multicortical engagement, and to investigate the impact of side and frontal insertion angle (clinical factors)—taken as the angle between the miniscrews' long axis and the vertical axis on the coronal plane on the digital plan—and miniscrew length (structural factor). Identifying the relative importance of these variables may offer valuable insights for planning miniscrew insertion and improving placement accuracy, thereby making the clinician's work less difficult.

The null hypothesis was that these factors do not contribute to the accuracy of palatal miniscrew insertion in multicortical anchorage configurations, with differences relative to a hypothetical absolute precision remaining within a clinically acceptable range of 1.5 mm, as reported by Salomone et al. [17], and of 6.2°, as reported by Migliorati et al. [12].

Materials and methods

The protocol for this study was approved by the ethics Committee of the post-graduate school of Orthodontics of the University of Ferrara (protocol no. 5/2024). The study was conducted in accordance with the ethical principles of the Declaration of Helsinki and was designed following both the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines and PICOS terms:

- Participants (P): one group of young/adult patients undergoing orthodontic treatment involving the use of miniscrew-supported palatal orthodontic appliances.
- Intervention (I): use of a surgical guide for palatal miniscrew insertion.
- Comparison (C): direct comparison of insertion accuracy against a hypothetical absolute precision, defined by zero linear (0 mm) and angular (0°) deviations. The comparison will focus on the influence of variables such as side (left/right), frontal insertion angle, and miniscrew length.
- Outcomes (O): quantitative measurements of both linear deviations (including global, vertical, sagittal, and transverse) and angular deviations (in the coronal plane) from the digitally planned miniscrew position. Additionally, the study will assess the impact of the variables mentioned above on these deviations.
- Study design (S): an in vivo study.

Sample selection

Patients were recruited between March and October 2024 based on the following criteria.

Inclusion criteria

Patients undergoing orthodontic treatment using palatal skeletal anchorage to support various orthodontic mechanics aimed at overcoming skeletal resistance to palatal expansion and ensuring optimal anchorage management. These mechanics included molar distalization, mesialization of posterior teeth, and recovery of a maxillary canine.

Exclusion criteria

- Presence of systemic diseases,
- Use of medications affecting bone metabolism,
- Presence of craniofacial deformities or cleft palate, or
- Previous orthodontic treatment.

After application of the above-cited criteria, the collection of records and case analysis were acquired, and the final sample comprised 20 patients with a mean age of 19.74 years ± 6.83 years, of whom 13 were male (19.21 years ± 8.87 years) and 7 were female (20.02 years ± 5.86 years).

All subjects in the sample presented either a permanent dentition or a late mixed dentition (2 patients).

Digital planning

Palatal miniscrew insertion was digitally planned via the Miniscrew Assisted Palatal Application (MAPA) system, which is based on individualized placement of palatal miniscrews. This process involved matching DICOM files with a digital model of the maxilla acquired using a CS3600 intraoral scanner (Carestream Dental, Atlanta, GA, USA)

Fig. 1 Computer-aided design/computer aided manufacturing surgical guide used for guided palatal miniscrew insertion
Abb. 1 Computergestützte Konstruktion/computergestützte Fertigung einer chirurgischen Schablone für die geführte Insertion von Minischrauben in den Gaumen

for each patient. DICOM files were obtained via CBCT scans acquired using a KAVO® OP 3D TM PRO tomograph (Kavo, Biberach, Germany); the settings used were 10 cm × 10 cm field of view (FOV), 90 kV, 5.0 mA, 8.1 s exposure time, and 863 mGy × cm² emission. After matching, the planning was performed at the Digital Planning Research Institute (DPRI, Thiene, Italy) and approved by an experienced orthodontist specialized in digital planning for palatal miniscrew insertion (GBM).

The miniscrews were positioned to engage as much bone as possible (ensuring a minimum of 5 mm of anchorage support) [18] at an appropriate angle and achieving a multicortical (bi- or tricortical) anchorage. This configuration ensures high primary stability of the inserted palatal miniscrews [4, 8]. A total of 12 miniscrews were inserted planning a tricortical engagement, specifically the posterior miniscrews in patients treated with a 4-miniscrew-supported MARPE appliance, and the remaining ones planning bicortical engagement. The tricortical anchorage was achieved using the palatal posterior supra-alveolar insertion site (PPSAIS) described by Nucera et al., simultaneously engaging the cortical layers of the palate, nasal cavity, and maxillary sinus [15].

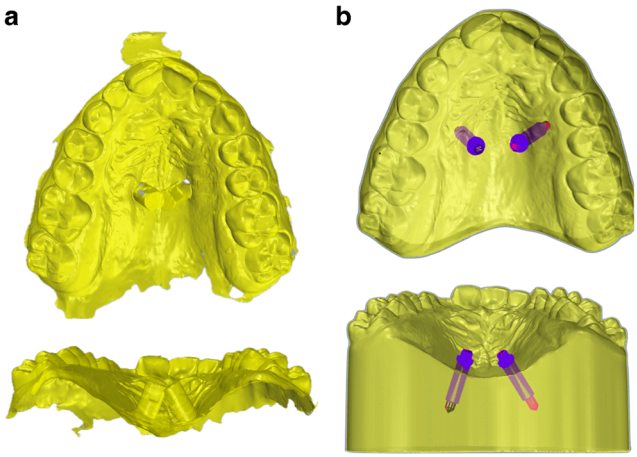

Fig. 2 Postinsertion in vivo digital model after scanbody positioning (**a**) and the reference model (**b**)
Abb. 2 Nach Einsetzen: digitales In-vivo-Modell nach Positionierung des Scanbodys (**a**) und das Referenzmodell (**b**)

Subsequently, a surgical guide (single or double) was designed (CAD phase) and prototyped (CAM phase) using a DLP technology printer (Everes Uno, SISMA Spa, Piovene Rocchette, Italy), with a resolution setting of 65 µm in the XY plane. The resin used was Everes Functional (SISMA Spa, Vicenza, Italy), with a Shore D hardness of 85 and a Young's modulus of 1681 MPa.

The surgical guide was designed to fully cover the lingual and occlusal surfaces of the maxillary dentition, along with one-third of the vestibular surface of at least three posterior teeth on each side. It was also adapted to the palatal mucosa and, in some cases, encompassed the canines. To ensure maximum stability and rigidity, the surgical guide had a thickness of 3 mm. In the central part of the core, two cylindrical recesses were incorporated to house metal sleeves (HDC srl, Thiene, Italy) designed to properly accommodate the cylindrical body of both the predrilling burs and the pick-up driver with a clearance fit of 0.05 mm and a length of interaction of 7 mm (Fig. 1). This minimal clearance fit, combined with the sleeve's extended to 7 mm contact length, limits the deviation angle between the sleeve and the pick-up driver to a maximum of 0.204°, ensuring precise guidance of both the predrilling burs and the pick-up driver, and facilitating clinical maneuvers.

Clinical procedure

A total of 52 palatal miniscrews (Spider Screw Konic, HDC, Thiene, Italy; Ø 2.0 mm, various lengths) were inserted using a surgical guide by two experienced operators (GBM and MP), each with experience in placing more than 30 guided palatal miniscrews. Following local anesthesia and field isolation, a pilot hole was prepared using a 1.3 mm predrilling bur (HDC, Thiene, Italy) at 600 rpm and 35 Ncm.

Miniscrews were then inserted with a pick-up driver using an NSK Surgic Pro implant motor (Nakanishi Inc., Kanuma, Japan) at 20 rpm and 15–20 Ncm.

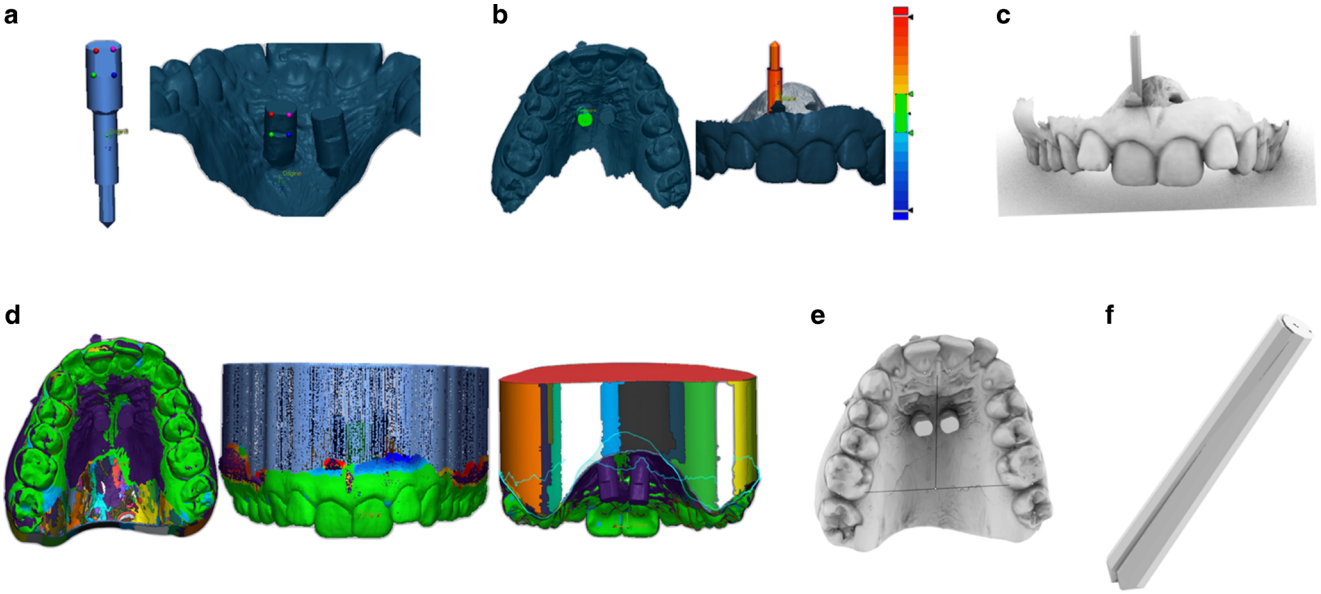

Fig. 3 Graphical representation of the digital measurement workflow. Superimposition of STL (Standard Triangulation Language) native files with the in vivo postinsertion model (**a**, **b**) to obtain the final postinsertion model (**c**). The reference model was then superimposed on the final postinsertion model (**d**), and both oriented accurately (**e**). Finally, both models were deleted, leaving only the miniscrews in their planned and inserted positions (**f**)

Abb. 3 Graphische Darstellung des digitalen Messablaufs. Überlagerung der nativen STL(Standard Triangulationssprache)-Dateien mit dem In-vivo-Modell nach Implantation (**a**, **b**), um das endgültige Modell nach Implantation zu erhalten (**c**). Das Referenzmodell wurde dann auf das endgültige Modell nach Implantation überlagert (**d**) und beide Modelle wurden genau ausgerichtet (**e**). Schließlich wurden beide Modelle gelöscht, sodass nur die Minischrauben in ihren geplanten und implantierten Positionen verblieben (**f**)

Digital superimposition procedure

After miniscrew insertion, digital scans were obtained with the scanbodies in place (HDC srl, Thiene, Italy) using an intraoral scanner (CS3600, 3Shape Trios, Copenhagen, Denmark) producing an in vivo postinsertion maxillary model (Fig. 2a). Additionally, STL (Standard Triangulation Language) files combining both the maxillary models and the digitally planned miniscrew positions were generated in the course of digital planning to serve as the reference model (Fig. 2b).

To determine the spatial position of each miniscrew body in the in vivo postinsertion maxillary model, native STL files were aligned with the postinsertion model using Geomagic Control X (3D Systems Inc., Rock Hill, SC, USA). Alignment was performed at the scanbodies by marking four reference points on the vertical groove of both the native and in vivo scanbodies (Fig. 3a). Accuracy was verified using a ± 0.2 mm tolerance, with green indicating acceptable deviations (Fig. 3b); manual adjustments were performed when required.

The aligned STL file was imported into Rhinoceros software (Robert McNeel & Associates, Seattle, WA, USA), where the scanbody was digitally removed to obtain the final postinsertion model, including the malocclusion model and the miniscrew body (Fig. 3c). This model and the reference model were then reimported into Geomagic Control X and aligned on dental surfaces and palatal mucosa not adjacent to the miniscrew site using an initial alignment followed by a best-fit algorithm (Fig. 3d). Accuracy was again verified with a ± 0.2 mm tolerance.

Both models were subsequently imported into Rhinoceros for orientation along the three Cartesian axes. Two reference lines were constructed: one tangential to the distal marginal crests of the maxillary first molars to define the transverse axis, and one connecting the palatal margins of the maxillary incisors. The median points of these lines were identified and connected to create the sagittal axis (Fig. 3e).

Both grouped models were oriented to the frontal (XZ), transverse (XY), and sagittal (YZ) planes as follows:

- The transverse axis corresponded to the X-axis.
- The sagittal axis corresponded to the Y-axis.
- The midpoint of the transverse axis coincided with the Cartesian origin (X = 0, Y = 0, Z = 0).
- The anterior midpoint was aligned with the Y-axis.
- The model was oriented to visualize the posterior region on the frontal plane (XZ), the palate on the transverse plane (XY), and the lateral aspect on the sagittal plane (YZ).

Subsequently, both models were digitally trimmed to include only the miniscrew body from the reference (planned)

and postinsertion (inserted) models, enabling direct comparison (Fig. 3f).

Measurements

All measurements were performed using Rhinoceros software. For both planned and inserted miniscrews, the centroid at the miniscrew head (head point) and the tip apex (tip point) were identified. The centroid was defined by placing two external points, connecting them with a line, and dividing it into two equal segments to obtain the reference point. A line connecting the head and tip points was then drawn along the long axis of each miniscrew. These points and axes served as landmarks for the subsequent measurements.

Linear discrepancy (mm) at both the head and tip points, analyzed as

- Total (Fig. 4a),
- X-axis (transverse discrepancy; Fig. 4b),
- Y-axis (sagittal discrepancy; Fig. 4c), and
- Z-axis (vertical discrepancy; Fig. 4d).

Angular discrepancy (°) between the long axes of the planned and inserted miniscrews in the

- Sagittal plane (YZ-plane; Fig. 4e),
- Coronal plane (XZ-plane; Fig. 4f), and
- Transverse plane (XY-plane; Fig. 4g)

Overall, 8 linear (mm) and 6 angular (°) measurements were obtained for comparison. In addition, the frontal insertion angle (defined as the angle between the vertical Z-axis and the long axis of the planned miniscrew on the coronal (XZ) plane) was measured as an indirect indicator of insertion difficulty (Fig. 4h).

The latter variable was taken into account according to the clinical experience of the operators (GBM and MP), who reported increased difficulty as the insertion angulation of posterior miniscrews increased.

The clinical success of one- and two-step orthodontic appliance delivery, supported by miniscrews, following their insertion was also assessed and reported.

However, a direct comparison of accuracy miniscrew insertion between bicortical and tricortical engagement could not be performed due to the limited sample size of the latter group.

Statistical analysis

The post hoc power analysis was based on the linear vertical discrepancy along the Z-axis measured at the miniscrew head, which exhibited the smallest effect size (0.87). Considering this value and a significance threshold set at 0.05, a sample size of 52 units would ensure a statistical power exceeding 0.99. Therefore, the investigated sample was deemed adequate.

Given the sample size, normality of the distribution of the measured discrepancies was assumed, in line with the central limit theorem, which is valid for sample sizes exceeding 30 observations.

Consequently, all measurements, both linear and angular, are reported as mean and standard deviation (SD), minimum and maximum values. After 2 months, the reproducibility of the measurements was assessed using the intraclass correlation coefficient (ICC), calculated on repeated measurements for 20% of the sample.

A one-sample t-test was used to compare the measured discrepancies against a hypothetical condition of absolute precision (0 mm for linear and 0° for angular measurements).

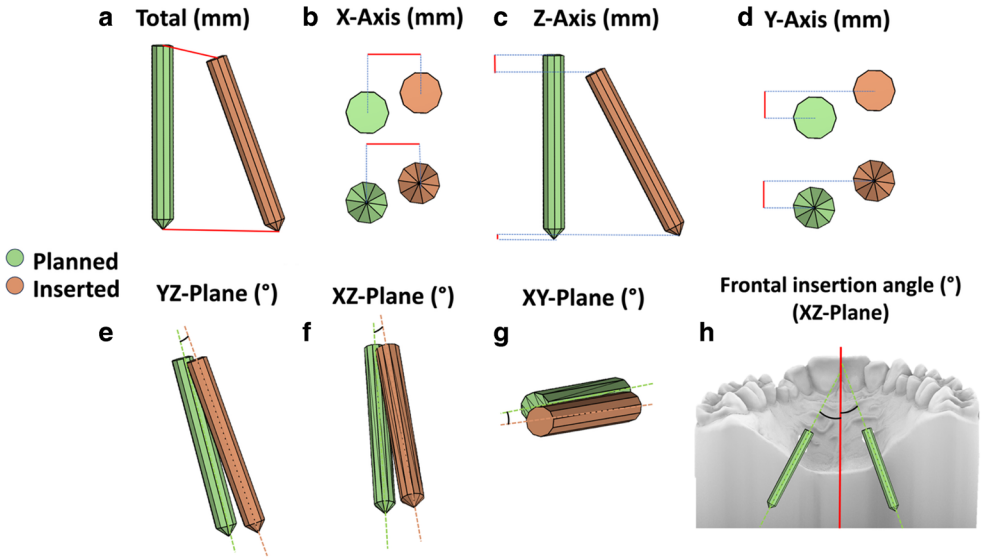

Fig. 4 Graphical representation of linear discrepancies (**a**–**d**), angular discrepancies (**e**–**g**), and the frontal insertion angle (**h**)
Abb. 4 Graphische Darstellung der linearen Abweichungen (**a**–**d**), der Winkelabweichungen (**e**–**g**) und des frontalen Insertionswinkels (**h**)

Table 1 Characteristics of the miniscrews inserted in the study, including their length, diameter, and type of appliance used, as well as demographic data of the patients enrolled (age and sex). A total of 12 miniscrews were inserted posteriorly in four-miniscrew-supported MARPE appliances, all with tricortical anchorage.

Tab. 1 Merkmale der in der Studie eingesetzten Minischrauben, einschließlich ihrer Länge, ihres Durchmessers und der Art der verwendeten Apparatur, sowie demographische Daten der teilnehmenden Patienten (Alter und Geschlecht). Insgesamt wurden 12 Minischrauben (posteriore MARPE-Minischraube, gestützt durch 4 Minischrauben) eingesetzt, um eine trikortikale Verankerung zu planen

Patient	Miniscrews, *N*	Length (mm)	Diameter (mm)	Age	Sex	Miniscrew-supported appliance
1	2	15	2	30 years 10 months	Male	Distal Jet and canine recovery
		15	2			
2	2	11	2	15 years 6 months	Male	Mesial slider
		12	2			
3	4	10	2	22 years 9 months	Female	MARPE (4 miniscrews)
		10	2			
		12	2			
		13	2			
4	2	8	2	15 years 10 months	Female	MARPE (2 miniscrews)
		10	2			
5	2	11	2	15 years 9 months	Male	MARPE (2 miniscrews), mesial slider and canine recovery
		12	2			
6	2	14	2	17 years 5 months	Female	MARPE (2 miniscrews) and distal jet
		14	2			
7	2	11	2	14 years 8 months	Female	MARPE (2 miniscrews)
		11	2			
8	4	15	2	17 years 9 months	Male	MARPE (4 miniscrews)
		15	2			
		12	2			
		12	2			
9	2	10	2	16 years 0 months	Male	MARPE (4 miniscrews)
		10	2			
10	2	12	2	25 years 6 months	Male	MARPE (4 miniscrews)
		12	2			
11	2	13	2	15 years 9 months	Male	T-Rex appliance
		13	2			
12	2	11	2	12 years 6 months	Female	MARPE (2 miniscrews) for SKAR III protocol
		10	2			
13	4	13	2	37 years 10 months	Female	MARPE (4 miniscrews)
		13	2			
		13	2			
		13	2			

Table 1 (Continued)
Tab. 1 (Fortsetzung)

Patient	Miniscrews, *N*	Length (mm)	Diameter (mm)	Age	Sex	Miniscrew-supported appliance
14	2	12	2	13 years 6 months	Female	MARPE (2 miniscrews) for SKAR III protocol
		12	2			
15	4	11	2	19 years 8 months	Male	MARPE (4 miniscrews)
		11	2			
		9	2			
		10	2			
16	2	12	2	14 years; 0 months	Male	MARPE (2 miniscrews)
		12	2			
17	4	15	2	18 years; 0 months	Male	MARPE (4 miniscrews)
		15	2			
		15	2			
		15	2			
18	2	13	2	16 years; 2 months	Male	Canine recovery
		11	2			
19	2	13	2	30 years; 4 months	Male	Canine recovery
		13	2			
20	4	14	2	25 years; 0 months	Male	MARPE (4 miniscrews)
		14	2			
		15	2			
		15	2			

MARPE miniscrew-assisted rapid palatal expansion, *N* number

Multiple linear regression models were then constructed to investigate whether the independent variables related to the clinical procedure, namely side (right or left) and frontal insertion angle (indirectly defined by the insertion angle with respect to the vertical Z-axis in the XZ-plane), influenced the accuracy of the guided miniscrew positioning. Simple linear regression was also performed with miniscrew length as the independent structural variable. The decision to use multiple and linear regression analyses, respectively, was made to avoid confounding, as the variables pertained to different aspects of the clinical procedure under investigation.

These regressions enabled quantification of the effect of the above mentioned variables on both the dependent variables (total linear discrepancies at both the head and tip points) and the angular discrepancy.

The statistical significance level was set at 0.05 ($p < 0.05$).

Table 2 Descriptive analysis reporting mean, standard deviation (SD), minimum and maximum values for each linear (mm) and angular (°) measurement investigated

Tab. 2 Deskriptive Analyse mit Angabe von Mittelwert, Standardabweichung (SD), Minimal- und Maximalwerten für jede untersuchte lineare (mm) und anguläre (°) Messung

Measurements			Observations, *N*	Mean	SD	Minimum	Maximum
Linear (mm)	Head	Total	52	1.10	1.01	0.03	3.69
		X-Axis	52	0.39	0.42	0.01	1.87
		Y-Axis	52	0.51	0.47	0.01	1.85
		Z-Axis	52	0.81	0.92	0.01	3.45
	Tip	Total	52	1.71	1.10	0.17	4.29
		X-Axis	52	0.93	0.71	0.05	2.77
		Y-Axis	52	0.97	0.82	0.01	3.68
		Z-Axis	52	0.89	0.89	0.04	3.32
Angular (°)		XY-Plane (transverse)	52	5.90	6.06	0.06	25.55
		YZ-Plane (sagittal)	52	2.65	2.47	0.02	10.2
		XZ-Plane (coronal)	52	3.02	2.65	0.01	13.04

N number; *SD* standard deviation

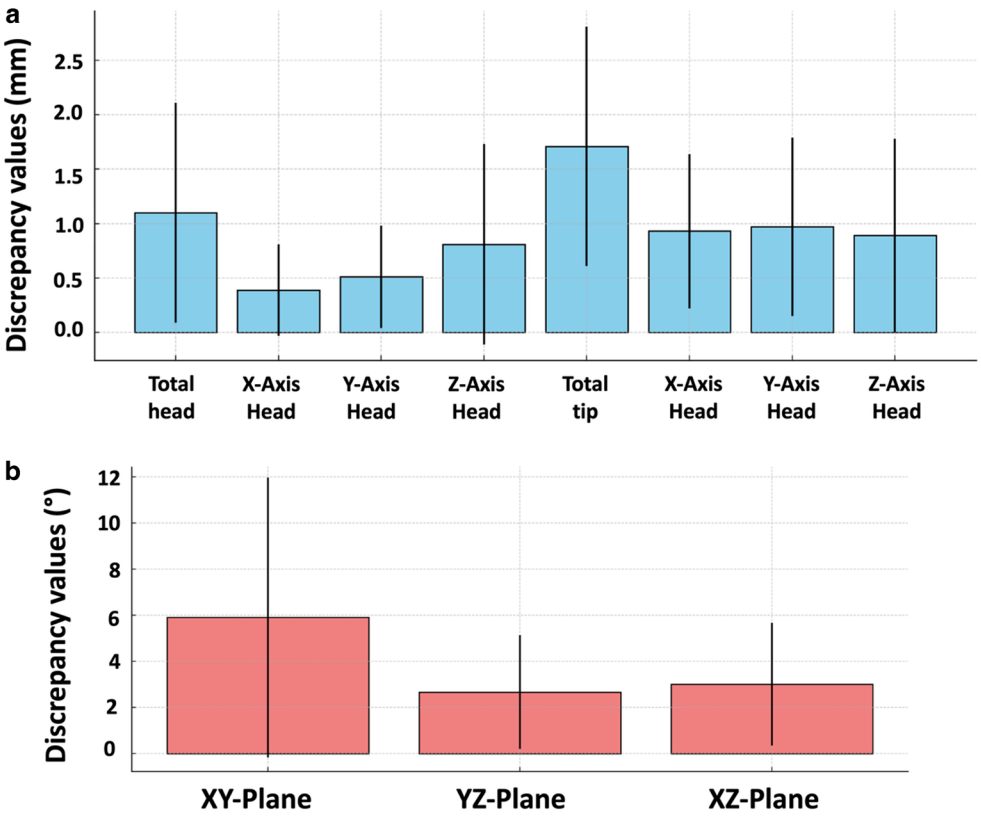

Fig. 5 Graphical representation of the methods of measuring mean linear (**a**) and angular discrepancies (**b**)

Abb. 5 Graphische Darstellung der Methoden zur Messung der mittleren linearen Abweichungen (**a**) und Winkelabweichungen (**b**)

Table 3 Statistical comparison of both linear and angular discrepancies between planned and inserted miniscrew positions with respect to absolute precision (0 mm for linear and 0° for angular measurements) using the parametric one-sample t-test ($p < 0.05$ considered significant)
Tab. 3 Statistischer Vergleich der linearen Abweichungen und der Winkelabweichungen zwischen den geplanten und den eingesetzten Minischraubenpositionen hinsichtlich der absoluten Präzision (0 mm für lineare und 0° für anguläre Messungen) unter Verwendung des parametrischen t-Tests für eine Stichprobe ($p < 0{,}05$ als signifikant angesehen)

Measurements			Observations, *N*	Mean	SD	p-value
Linear (mm)	Head	Total	52	1.10	1.01	<0.001
		X-Axis	52	0.39	0.42	<0.001
		Y-Axis	52	0.51	0.47	<0.001
		Z-Axis	52	0.81	0.92	<0.001
	Tip	Total	52	1.71	1.10	<0.001
		X-Axis	52	0.93	0.71	<0.001
		Y-Axis	52	0.97	0.82	<0.001
		Z-Axis	52	0.89	0.89	<0.001
Angular (°)		XY-Plane (transverse)	52	5.90	6.07	<0.001
		YZ-Plane (sagittal)	52	2.66	2.47	<0.001
		XZ-Plane (coronal)	52	3.00	2.66	<0.001

N number; *SD* standard deviation

The ICC values ranged from 0.758 (angular discrepancy on the XY plane) to 0.997 (total linear discrepancy at the head point), with a mean ICC value of 0.913 across all measurements. In all cases, the reproducibility of the measurements was considered acceptable.

Results

The geometric characteristics of the miniscrews, including their length (mm) and diameter (mm), are presented in Table 1, which also reports demographic data (age and sex), the type of palatal appliance, and the number of miniscrews inserted per patient (Table 1).

The clinical success of miniscrew-supported orthodontic appliance delivery was always achieved, irrespective of whether it involved a one-visit (two miniscrews) or two-visit procedure (four miniscrews).

Table 4 Descriptive analysis of frontal insertion angle intended as the angulation of the planned miniscrew with respect to vertical Z-axis on the coronal plane (XZ plane)
Tab. 4 Deskriptive Analyse des frontalen Insertionswinkels, definiert als die Angulation der geplanten Minischraube in Bezug auf die vertikale Z-Achse auf der koronalen Ebene (XZ-Ebene)

Measurements	Insertion difficulty
Observations (*N*)	52
Mean (°)	13.19
SD (°)	12.92
Median (°)	9.24
25th percentile (°)	0.76
75th percentile (°)	24.30
Minimum (°)	0.00
Maximum (°)	39.90

SD standard deviation

Hence, mean and standard deviation (SD) were calculated for all the investigated measurements (Table 2). The total linear discrepancies ranged from 0.03 to 3.69 mm at the head (mean 1.10 ± 1.01 mm) and from 0.17 to 4.29 mm (mean 1.71 ± 1.10 mm) at the tip. When examining the Cartesian axes individually, the greatest inaccuracies at the head point were observed along the vertical axis (0.81 ± 0.92 mm), whereas at the tip the greatest inaccuracies were found along the sagittal axis (0.97 ± 0.82 mm). Comparing the linear discrepancies at the head and the tip, greater inaccuracies were consistently observed at the tip, although minimal differences for both were noted along the Z-axis (0.81 ± 0.92 mm and 0.89 ± 0.89 mm, at the head and tip respectively). Angular measurements ranged from 0.06 to 25.55°, with the largest mean discrepancy value was found in the transverse plane (XY) with a mean value of 5.90 ± 6.06°. On the other hand, comparable mean discrepancies were observed in both the sagittal (YZ) plane, with a mean value of 2.65 ± 2.47°, and the coronal (XZ) plane, with a mean value of 3.02 ± 2.65° (Table 2).

A direct comparison of the measured linear and angular discrepancies with the hypothetical condition of perfect precision (discrepancies equal to 0 mm or 0°) revealed a statistically significant difference in all cases ($p < 0.001$; Table 3). The discrepancies are graphically represented in Fig. 5.

Multiple linear regressions were thus performed, considering total linear discrepancies at the head and tip points and the angular discrepancy in the transverse plane (XY), as this variable exhibited the largest divergence. Descriptive values for the independent variable frontal insertion angle are reported in Table 4. Table 5 presents a summary of the multiple linear regression analyses, including the coefficients of determination (R^2), which indicates the explanatory power

Table 5 Regression analysis results for the dependent variables of total linear head and tip discrepancy, and XY-plane angular discrepancy considering the independent variables of side and insertion. Model details, including R, R^2 statistics, and coefficients associated with the analyzed predictors are summarized

Tab. 5 Ergebnisse der Regressionsanalyse für die abhängigen Variablen der gesamten linearen Abweichung zwischen Kopf und Spitze sowie der Winkelabweichung in der XY-Ebene unter Berücksichtigung der unabhängigen Variablen Seite und Insertion. Mit den analysierten Prädiktoren verbundene Modelldetails, einschließlich R-, R^2-Statistiken und Koeffizienten, sind zusammengefasst

Total linear head discrepancy	*Model summary*	–	*R*	R^2	*Adjusted* R^2	*Estimated SE (mm)*	
		–	*0.132*	*0.018*	*–0.023*	*1.02*	
	Coefficients	–	*B*	*SE (mm)*	*Beta*	*t*	*p-value*
		(Constant)	1.067	0.247	–	4.327	<0.001
		Side	–0.156	0.282	–0.078	–0.553	0.583
		Frontal insertion angle	0.008	0.011	0.107	0.758	0.452
Total linear tip discrepancy	*Model summary*	–	*R*	R^2	*Adjusted* R^2	*Estimated SE (mm)*	
		–	*0.241*	*0.058*	*0.02*	*1.09*	
	Coefficients	–	*B*	*SE (mm)*	*Beta*	*t*	*p-value*
		(Constant)	1.593	0.264	–	6.028	<0.001
		Side	–0.253	0.303	–0.116	–0.836	0.407
		Frontal insertion angle	0.018	0.012	0.212	2	0.132
XY plane angular discrepancy	*Model summary*	–	*R*	R^2	*Adjusted* R^2	*Estimated SE (mm)*	
		–	*0.221*	*0.049*	*0.01*	*6.04*	
	Coefficients	–	*B*	*SE (mm)*	*Beta*	*t*	*p-value*
		(Constant)	7.656	1.462	–	5.237	<0.001
		Side	–0.976	1.675	–0.081	–0.582	0.563
		Frontal insertion angle	–0.096	0.065	–0.205	–1.470	0.148

p value <0.05 considered as statistically significant

R correlation coefficient; R^2 determination coefficient; *B* regression coefficient; *SE* standard error

Table 6 Regression analysis results for the dependent variables of total linear discrepancy at the head and tip, and XY-plane angular discrepancy by the independent variable miniscrew length. Model details, including R, R^2 statistics and coefficients associated with the analysed predictors ($p < 0.05$ considered statistically significant) are summarized

Tab. 6 Ergebnisse der Regressionsanalyse für die abhängigen Variablen der gesamten linearen Diskrepanz an Kopf und Spitze sowie der Winkelabweichung in der XY-Ebene in Abhängigkeit von der unabhängigen Variablen Minischraubenlänge. Mit den analysierten Prädiktoren verbundene Modelldetails, einschließlich R-, R^2-Statistiken und Koeffizienten, sind zusammengefasst ($p < 0{,}05$ als signifikant angesehen)

Total linear head discrepancy	*Model summary*	–	*R*	R^2	*Adjusted* R^2	*Estimated SE (mm)*	
		–	0.178	0.032	0.012	1.001	
	Coefficients	–	*B*	*SE (mm)*	*Beta*	*t*	*p-value*
		(Constant)	2.312	0.959	–	2.411	0.020
		Length	–0.098	0.077	–0.178	–1.278	0.207
Total linear tip discrepancy	*Model summary*	–	*R*	R^2	*Adjusted* R^2	*Estimated SE (mm)*	
		–	0.087	0.008	–0.012	1.109	
	Coefficients	–	*B*	*SE (mm)*	*Beta*	*t*	*p-value*
		(Constant)	2.354	1.063	–	2.214	0.031
		Length	–0.052	0.085	–0.087	–0.617	0.540
XY plane angular discrepancy	*Model summary*	–	*R*	R^2	*Adjusted* R^2	*Estimated SE (mm)*	
		–	0.150	0.023	0.003	6.055	
	Coefficients	–	*B*	*SE (mm)*	*Beta*	*t*	*p-value*
		(Constant)	12.062	5.803	–	2.079	0.043
		Length	–0.499	0.464	–0.150	–1.074	0.288

R correlation coefficient; R^2 determination coefficient; *B* regression coefficient; *SE* standard error

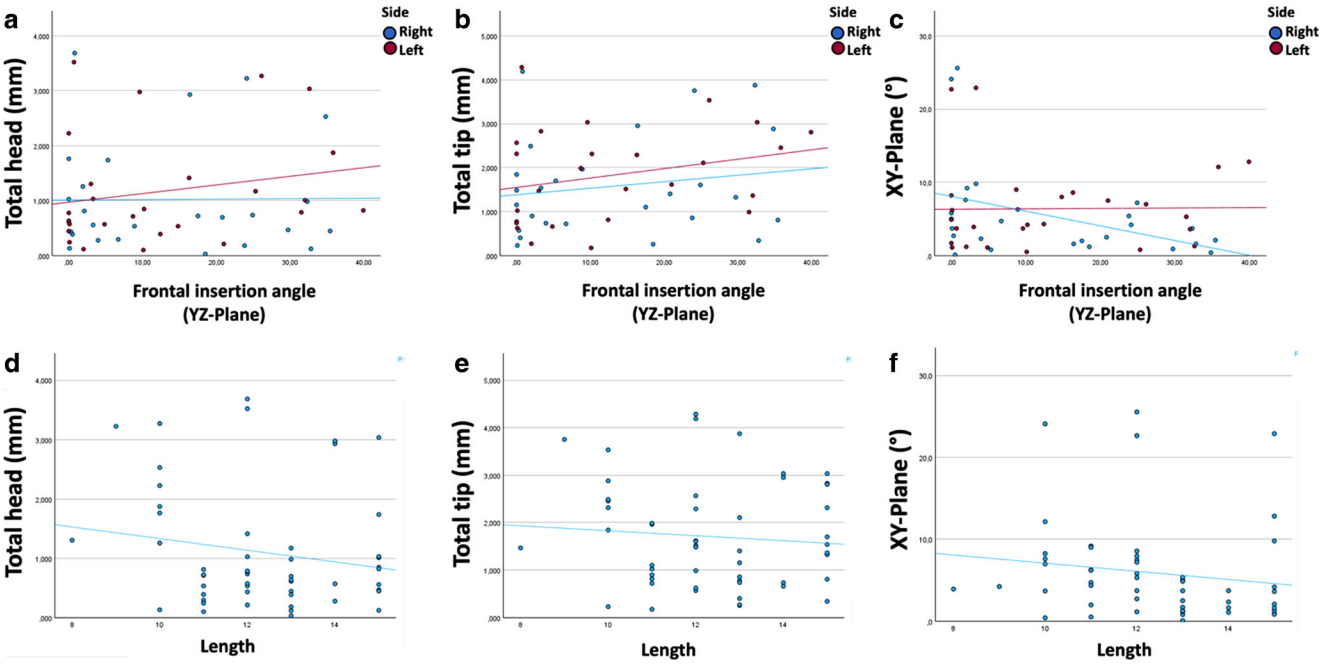

Fig. 6 Scatterplots of the multiple linear regression models showing total linear discrepancy at the head (**a**) and tip (**b**), and angular discrepancy in the transverse plane (XY; **c**), with side and frontal insertion angle as independent variables. Scatterplots of simple linear regression models showing total linear head discrepancy (**d**), total linear tip discrepancy (**e**), and angular discrepancy in the transverse plane (XY; **f**), with miniscrew length as the independent variable

Abb. 6 Scatterplots der multipel linearen Regressionsmodelle mit Darstellung der linearen Gesamtabweichung am Kopf (**a**) und an der Spitze (**b**) sowie der Winkelabweichung in der Transversalebene (XY; **c**) mit seitlichem und frontalem Insertionswinkel als unabhängigen Variablen. Scatterplots einfacher linearer Regressionsmodelle mit Darstellung der gesamten linearen Diskrepanz am Kopf (**d**), der gesamten linearen Diskrepanz an der Spitze (**e**) und der Winkelabweichung in der Transversalebene (XY; **f**) mit der Länge der Minischraube als unabhängiger Variable

of the independent variables in the overall model. None of the independent variables reached statistical significance ($p > 0.05$) in any of the three regression analyses performed (Table 5).

For the dependent variable *total linear discrepancy at the head*, the model explained only 1.8% of the total variability of the phenomenon ($R^2 = 0.018$), with neither side ($p = 0.583$) nor frontal insertion angle ($p = 0.452$) exerting a significant influence. For the dependent variable *total linear discrepancy at the tip*, the model explained only 5.8% of the total variability of the phenomenon ($R^2 = 0.058$), with neither side ($p = 0.407$) nor frontal insertion angle ($p = 0.132$) significantly affecting the outcome. As for the dependent variable *angular discrepancy on the transverse plane (XY)*, the model explained only 4.9% of the total variability of the phenomenon ($R^2 = 0.049$), with neither side ($p = 0.563$) nor frontal insertion angle ($p = 0.148$) being a significant factor (Table 5).

Simple linear regressions for the same dependent variables with miniscrew length as the independent variable are presented in Table 6. In this case, the resulting model explained only 3.2% of the total variability in the dependent variable *total linear discrepancy at the head* ($R^2 = 0.032$), with miniscrew length ($p = 0.207$) not being significant. For the dependent variable *total linear discrepancy at the tip*, on the other hand, the model explained only 0.8% of the total variability ($R^2 = 0.008$), with miniscrew length ($p = 0.540$) not having a significant influence. As for the dependent variable *angular discrepancy in the transverse plane (XY)*, the model explained only 2.3% of the total variability of the phenomenon ($R^2 = 0.023$), with miniscrew length ($p = 0.288$) once again not being significant (Table 6).

Scatter plots of both multiple and simple linear regression models are provided in Fig. 6.

Discussion

The introduction of modern CAD/CAM technologies has enabled digital planning of palatal miniscrew insertion. These technologies also allow the design of a CAD/CAM surgical guide that adheres to the digital plan. This digital workflow results in significant laboratory time savings, reduces production costs, and is less dependent on the technician's skill. Literature on the prototyping of medical devices has demonstrated their great accuracy, which ranges from 0.13 to 0.57 mm, thereby validating their use [5–7, 18].

The findings from this study are largely consistent with the null hypothesis. Although all observed discrepancies were statistically significant as compared to the hypothetical absolute precision, the linear discrepancies were generally below 1 mm on average, except the total discrepancy values, which were 1.10 mm at the head and 1.71 mm at the tip. However, from a clinical perspective, all miniscrew-supported orthodontic appliances were successfully fitted after guided miniscrew insertion, irrespective of whether a one-visit procedure (two miniscrews) or two-visit procedure (four miniscrews) was adopted.

Considering the respective Cartesian axes, the greatest discrepancies at the head were found along the vertical axis, similar to findings by Migliorati et al. [12]. On the other hand, no clear trend was observed at the tip. The discrepancies at the head were comparable to, though more pronounced than, those reported by Mang De La Rosa et al. [11] and Al-Gazzawi et al. [2]. Nonetheless, the latter authors did not identify a similar trend of greater inaccuracy along the vertical axis [2].

The greater vertical inaccuracy observed in this study is noteworthy as it could affect the delivery of bone-supported orthodontic device in the same appointment after miniscrew insertion (one-visit protocol). However, in the cases in which a one-visit protocol was scheduled, appropriate fitting of the bone-borne appliances was always achieved. This suggests that the level of inaccuracy at the head falls within an acceptable range. Another potential explanation is that intraoral scanning with a scanbody might not accurately reproduce the vertical position of the miniscrew, especially when the scanbody is very close to the mucosa, causing its compression [12]. Another possible reason could be improper fitting of the scanbody, although the operators ensured its positioning by applying vertical pressure and testing the mobility. An indirect confirmation of correct placement is that the two-visit appliance delivery was always successful in the cases treated with a 4-miniscrew-supported MARPE (6 patients), confirming accurate acquisition of the intraoral scans.

If the vertical discrepancies observed at the head indeed fall within an acceptable range, it is important to note that these values are only applicable to devices supported by two miniscrews. For devices supported by four or more miniscrews (the cases in this study were not scheduled for a one-visit protocol), it could be hypothesized that the tolerance range for linear discrepancies would be significantly lower [16].

A clear trend that emerged from this investigation is the greater degree of inaccuracy at the tip compared to the head of the miniscrews, which is consistent with previous studies on the topic [11, 12]. The data suggest that during digital planning a safety margin of approximately 1.71 mm should always be maintained from the apex of adjacent teeth. It is worth noting, however, that in our study about 40% of measurements exceeded this average value, making a safety margin of 2 mm preferable (only 17.7% of values exceeded this threshold). This threshold is higher than that reported by Salomone et al., who recommend a 3.5 mm safety mar-

gin at the tip for less experienced clinicians, reduced to 1.5 mm for more experienced ones. However, although the miniscrews in our study were placed by experienced clinicians, it was an in vivo study, which inherently presents greater clinical challenges due to the presence of saliva, patient movement, limited mouth opening, and general fatigue, as well as obstacles created by the tongue, cheeks, and soft tissues, respectively.

Regarding angular discrepancies, those observed in this study are comparable to those reported by Pozzan et al. [16] and Migliorati et al. [12], but were higher than those reported by Mang de la Rosa et al. [11]. Specifically, the greatest discrepancies in this investigation occurred in the transverse plane, whereas Migliorati et al. observed greater discrepancies in the sagittal plane [12]. That being said, Mang de la Rosa et al. highlighted varying angular discrepancies, depending on the surgical guide used [11].

Despite the angular differences observed, with the maximum discrepancy in the transverse plane reaching 25.55° and two additional values exceeding 20°, these findings suggest that such angular deviations do not significantly affect the fitting of orthodontic devices, provided that the linear discrepancies between the miniscrew heads remain within an acceptable range. This tolerance is likely attributable to the conical geometry of the miniscrew head. Nonetheless, it remains crucial to minimize these discrepancies as much as possible to prevent potential misfitting between bone-borne orthodontic appliances and the miniscrew heads [16].

A certain degree of inaccuracy was attributable to the geometric characteristics of the metal sleeve, the pick-up driver, the miniscrew length, and the respective clearance fits, both between the sleeve and the pick-up driver and between the pick-up driver and the miniscrew head. Taking all these factors into account, the resulting angular inaccuracy should range from approximately 0.3° for a miniscrew length of 8 mm to about 0.4° for a length of 15 mm, corresponding to tip deviations between roughly 0.12 mm and 0.18 mm. However, this aspect accounts for only a part of the overall inaccuracy, and miniscrew length did not seem to affect miniscrew insertion accuracy to any greater extent, as demonstrated in this study. Additional contributing factors may include the clearance fit between the predrilling bur and the metal sleeve, bone density, mucosal thickness, patient movement during clinical procedure, and the aggressiveness of the self-drilling miniscrew tip, which may cause it to deviate slightly from the planned insertion path.

Another aspect investigated was whether the side, frontal insertion angle (degree of angulation in the coronal plane with respect to midsagittal plane) and miniscrew length influenced the accuracy of miniscrew placement. Considering total linear discrepancies at the head and tip and angular discrepancies in the transverse plane, these variables had minimal influence, collectively explaining only 5% of the overall variability of total linear discrepancy values at the head, 6.6% of those at the tip, and 7.4% of angular discrepancies in the transverse plane. This analysis suggests that other factors could impact the accuracy of miniscrew placement. These may include surgical procedures (torque and speed during corticotomy and miniscrew insertion), patient anatomy (palate height and width) [3], amount of mouth opening, cortical and mucosal thickness, various diameters of palatal miniscrew, factors related to digital planning (degree of angulation on the sagittal and transverse planes and according to different orientation, depth of insertion, and sagittal and transverse positioning of the miniscrews) and those related to the surgical guide (number of anchorage teeth involved, width, length, rigidity of surgical guide, and the use or not of metal sleeves).

The findings of this study align with those of Al-Gazzawi et al. regarding the minimal influence of the insertion side [2] and with those by Brilli et al. regarding the side and miniscrew length [3]; as a matter of fact, the latter found greater angular discrepancies in those patients with steep and high palatal vaults [3].

De La Rosa et al. investigated the accuracy of indirect positioning of palatal miniscrews by comparing five surgical guides, three of which were 3D-printed and two conventional. The authors found that the highest accuracy was achieved using a conventional surgical guide made of GC Pattern Resin LS (GC Europe N.V., Leuven, Belgium), although the 3D-printed guides exhibited comparable accuracy. It is noteworthy that the least accurate guide was also conventional (Memosil 2, Kulzer, Hanau, Germany). Thus, the authors concluded that, beyond the production method (conventional or 3D-printed), the fabrication material played a crucial role [11]. GC Pattern Resin LS has a Shore D hardness of 62, offering an excellent balance between rigidity and minimal elasticity, while the less accurate guides made of silicone were more deformable. Depending on the resin used, the design of surgical guides should be adjusted: opting for a bulkier design for less rigid resins and a more minimal design for more rigid resins [11]. In light of these considerations, the surgical guide investigated in this study was manufactured using a resin material featuring a Shore D hardness of 85 and a thickness of approximately 3 mm. This provided high rigidity and resistance to deformation. Additionally, its extension over three posterior elements on each side reduced the possibility of tilting during its positioning.

Furthermore, as in the study by Pozzan et al. [16], all miniscrews in this study were positioned to achieve multicortical (bi- or tricortical) anchorage. Achieving these configurations, which is particularly advantageous clinically, may reduce the accuracy of miniscrew insertion. This might occur through a mechanism hypothesized by previous authors, in which engagement with the nasal cortex and, in

this study, the maxillary sinus, could create a "sliding effect" along the insertion path [16].

A procedural limitation of this study was the fact that comparisons were performed using pre- and postinsertion scans rather than pre- and postinsertion CBCT exams. Moreover, future studies should ensure analysis of the aforementioned variables to fully elucidate their variability across the phenomenon and, thus, increasing the explanatory power of the regression models, involving also operators with varying levels of clinical experience. Regarding this latter issue, a previous study by Salomone et al. highlighted that the use of a surgical guide can minimize the influence of operator experience. However, these conclusions were drawn from an in vitro study [17] and also require validation in an in vivo setting.

As for the decision to include two experienced operators, it is true that this may limit the generalizability of the study's findings. However, it also improves the consistency and reliability of the results. Although involving operators with varying levels of experience could have affected the accuracy of miniscrew placement, in this study both operators had a similar level of experience. An indirect confirmation of this is that no clinical complications were observed during the fitting of the miniscrew-anchored palatal appliances.

Moreover, future studies with larger numbers of inserted miniscrews achieving tricortical anchorage should be encouraged, as a direct comparison between bi- or tricortical anchorage was not feasible in this study due to the insufficient number of miniscrews achieving the latter (12 miniscrews in total). Moreover, further investigation is warranted if such a surgical guide is to be used for interradicular miniscrew insertion, due to the presence of adjacent teeth and limited interradicular spaces. Although the accuracy observed in this study may be suboptimal, the use of smaller, shorter miniscrews and a minimally challenging monocortical insertion procedure could help mitigate this issue.

Conclusion

- The use of the surgical guide allowed for the insertion of palatal miniscrews with multicortical anchorage with clinically acceptable accuracy.
- Although the linear and angular mean inaccuracies recorded were statistically significant, when the one-visit protocol was scheduled, the delivery of the two-miniscrew-supported palatal appliance was always successful, suggesting an acceptable level of clinical precision, likely ensured by the conical geometry of the miniscrew head.
- Since the greatest positional inaccuracy was observed at the tip of the miniscrews, the findings of this study might suggest adopting a minimum safety margin of 3 mm. However, considering the mean total discrepancy of 1.71 mm at the tip, a minimum safety margin of 2 mm could still be considered appropriate.
- Variables such as side, frontal insertion angle, and miniscrew length did not appear to influence the degree of inaccuracy in guided palatal miniscrew insertion. Consequently, additional clinical factors may contribute to this inaccuracy and should be explored in future research.

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Data Availability The data that support the findings of this study are not openly available due to reasons of sensitivity and are available from the corresponding author upon reasonable request. Data are located in controlled access data storage at postgraduate School of the University of Ferrara.

Declarations

Competing interests Maino B. Giuliano is among the inventors of MAPA system and the owners of the registered international patent (WO2016034973). None of the authors has financial interests that are directly or indirectly related to the work submitted for publication or give information about existing conflict of interests.

Ethical standards The protocol for this study was approved by the Ethical Committe of the postgraduate School of Orthodontics of the University of Ferrara (protocol no. 5/2024). The study was conducted in accordance with the ethical principles of the Declaration of Helsinki and was designed following both the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines and PICOS terms.

Written Informed Consent to Participate A written informed consent was obtained from each participant in the study. For underage participants, written consent was obtained from their parents or legal guardians.

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