Does the planned miniscrew position reflect the achieved one? A clinical study on the reliability of guided miniscrew insertion using lateral cephalogram and maxillary stereolithography file for planning

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Introduction: The anterior area of the palate is widely used as an insertion site for orthodontic miniscrews. These temporary anchorage devices can be placed either directly or using an insertion guide, and various kinds of digital planning and guides are currently available. This study aimed to verify if the guided procedure can guarantee the correct position of the miniscrews on the patient compared with the digital project. **Methods:** Twenty-five consecutively treated patients were included in the study. Angular and linear displacements of the miniscrews were evaluated among 3 groups: the planned position, the model position, and the achieved position. **Results:** The median achieved angle between 2 digitally planned screws was 6.22° (interquartile range: 4.35°, 9.08°) and the difference between the angles in the planning and the achievement groups was significant ($P < 0.001$). Lateral and vertical differences were also found among the 3 groups. **Conclusions:** Results show that the examined workflow is clinically efficient. Differences between the digitally planned position of the orthodontic miniscrews, the control position, and the achieved position were detected both for angular and linear measurements but were not clinically significant.

Since the introduction of miniscrews as anchorage reinforcement for orthodontic treatment, many applications have been published and realized. In addition, defined as temporary anchorage devices (TADs), they are widely used both for orthodontic and orthopedic purposes.

Several studies have been published to indicate the best insertion sites and the possible key factors to increase the success rate. This has been reported to be 70.3% for the mandibular arch, 93.4% for the maxilla, 98.0% for the anterior area of the palate, and 93.7% for the infrazygomatic zone. The buccal shelf had the lowest success and survival rates for 12 (31.3%) and 24 (20.8%) months, whereas Class III malocclusions had the lowest survival rate for buccal mini-implants (65.3% and 54.2%).[1-6]

The palatal area is considered a reliable and safe zone for many miniscrew-supported applications such as distalization, mesialization, or maxillary expansion, and it is used daily on a considerable portion of patients.

When an orthodontist plans a treatment that involves TADs supported mechanics in the palate, they can benefit from using insertion guides. Advantages rely on the possibility of reducing chair time (the so-called 1-visit protocol) and having full access and control of a digital workflow that includes miniscrews placement planning, device and guide design, and printing.

Guided insertion of miniscrews can be planned with different software, using a cone-beam computed tomography (CBCT) or a combination of a digital intraoral scan and lateral cephalogram. Although the latter is limited to

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median or paramedian insertion sites, both approaches include creating an insertion guide as the final step: these guides can be either fully 3-dimensional (3D) printed or realized with a combination of thermoforming material and resin.

A lateral cephalogram is generally part of the preliminary records possessed by the orthodontist, whereas CBCT represents an additional examination needed in specific clinical malocclusions or dental problems, such as impacted canines. In this perspective, the possibility of having a reliable digital workflow for miniscrews digital planning using only a lateral cephalogram can be useful. Moreover, using an insertion guide, even in a safe area such as the anterior palate, could result in a clinical advantage by allowing a 1-visit protocol, thus reducing chair time and appointments.

Different studies on CBCT-based planning were published,[7-12] but the scientific literature reports few data on the precision and reliability of the inserted miniscrews using a lateral cephalogram, intraoral scan, and thermoformed guide. Therefore, this study aimed to verify if this approach can guarantee the correct position of the miniscrews on the patient with respect to the digital project and the appliance fixation in the 1-visit protocol.

MATERIAL AND METHODS

This study included a sample of 25 patients (14 females, 11 males), with a mean age of 14.2 years, consecutively treated by the same operator (M.M.).

Orthodontic treatment consisted of a miniscrew-supported device in the anterior area of the palate, and the planned mechanics included distalization, mesialization, or maxillary expansion.

Exclusion criteria were as follows: systemic diseases, impacted teeth, use of drugs altering bone metabolism, cleft palate, and previous orthodontic treatment. All patients had a permanent dentition.

Each patient's initial records were collected and included an intraoral scan (3Shape Trios; 3Shape, Copenhagen, Denmark), photographs, panoramic radiographs, and lateral cephalogram x-rays.

All patients were planned to receive 2 orthopal miniscrews 1.7 mm in diameter and 8 mm in length (OrthoEasy PAL; Forestadent, Pforzheim, Germany).

One operator imported the maxillary stereolithography (STL) file and lateral cephalogram on a dedicated software (OnyxCeph3; Image Instruments, Chemnitz, Germany) and matched them. Lateral cephalograms were calibrated using the ruler present on the acquisition image, while the maxillary STL file was automatically calibrated by the intraoral scanner. The superimposition procedure included selecting different points on the right view of the STL file (buccal side of central incisors, premolars, and molars) and selecting the same points on the lateral cephalograms. The segmented STL file on the sagittal view allowed a proper match with the x-ray (Fig 1).

Two miniscrews were then virtually added to the matched file and placed in the anterior area of the palate using the space between the second and third rugae as reference. The right inclination and position were checked using the STL file and the lateral x-ray. The lateral cephalograms were used to control the miniscrew-incisors distance and the depth of maxillary bone. Buccal-palatal miniscrew angulation was evaluated on the STL file using a mean interscrew distance of 9.0 mm. Once the project was completed, a new maxillary STL file was generated with holes corresponding to the miniscrews position, in which the laboratory analogs were successively positioned.

The STL file with the miniscrews position was 3D printed (DentaModel; Asiga, Alexandria, Australia). The first part of the guide was obtained by thermoforming 2.5-mm thick polyethylene terephthalate glycol discs (Erkodur freeze; Erkodent, Cologne, Germany). The thermoformed sheet was cropped in the middle to free the space of the screw positions. Afterward, miniscrews analogs were inserted, and the metal sleeves were placed on the analog's head together with the blade used to insert the miniscrews.

The last step included using resin (Leocryl; Leone, Sesto Fiorentino, Italy) to fix the metal sleeves and the thermoformed part (Fig 2).

The guide was first checked in the patient's mouth to assure precision and stability, and after local anesthesia injection, TADs were manually positioned using a surgical key torque (BIOMET 3i, Palm Beach Gardens, Fla).

After the miniscrews insertion, a new intraoral scan was taken covering the TADs' head with scan bodies to obtain the position of miniscrews. This step allowed the after superimposition procedure.

The 3D printed model used to create the guide was used as a control group. In all 3D printed models, miniscrews analogs were inserted, and scan bodies were placed over them. A model scan was then taken and imported as STL files (control group).

On the TADmatch module (OnyxCeph3, Image Instruments), the planned-model (Group P) was uploaded, and the position of the miniscrews was registered with the function "save current position" and exported on an Excel file. Successively, the second scan was uploaded, with the "achieved scan" from the patient's intraoral scan (group A) or the "control scan" from the 3D printed Molde (group C).

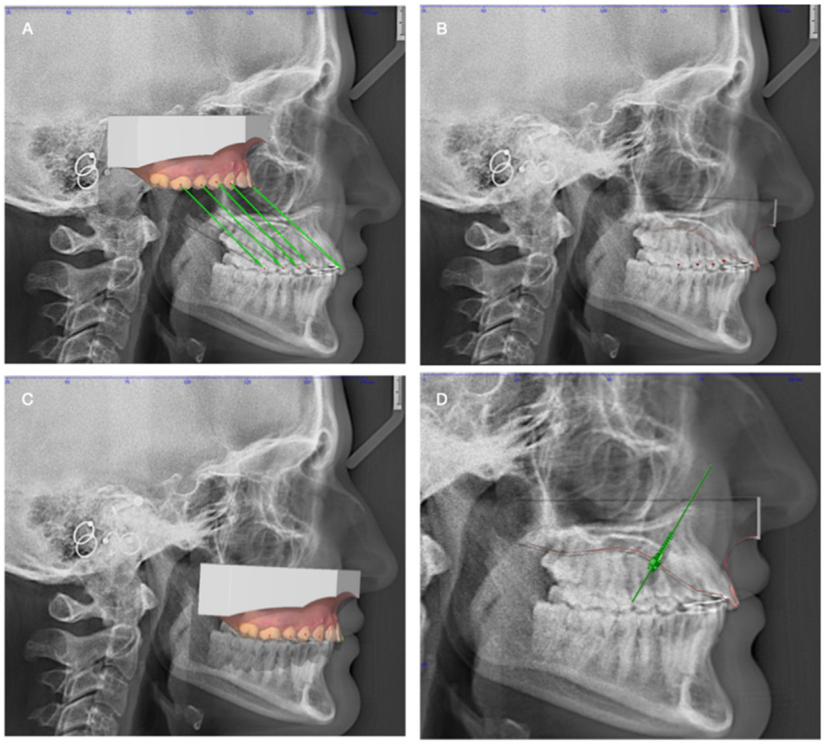

Fig 1. **A**, STL file and lateral cephalogram references point for alignment. **B,** The STL maxillary image sagittally segmented for incisor correspondence control in respect of the lateral cephalogram and evaluation of palatal mucosa correspondence to the palatal cortical line. **C,** STL file and lateral cephalogram superimposed. **D,** Planned miniscrew.

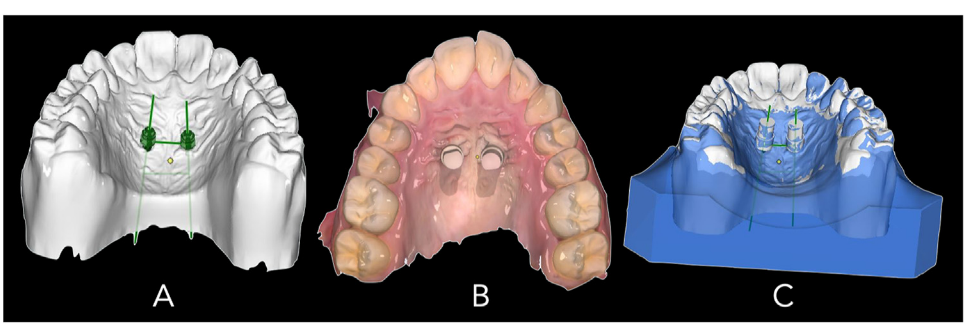

Fig 2. Insertion guide preparation.

The 2 maxillary scans were registered and superimposed as surface function. The position of the "A" miniscrews or "C" analogs were virtually inserted into the first model and then exported into a new Excel file.

The 3D position of each miniscrew was obtained and registered as XYZ coordinates of the head and tip of the screws. Linear and angular differences between planned miniscrews and achieved (P vs A), between planned and control (P vs C), and between achieved vs control (A vs C) were obtained with vectorial formulas.

A total of 75 superimpositions were performed (Fig 3).

Thirty superimpositions were re-evaluated by the same operator and compared with previously obtained data. The intraclass correlation coefficient was calculated for linear and angular values, and the results were 0.92 and 0.94, respectively.

Statistical analysis

Continuous variables are given as means $\pm$ standard deviations and medians with interquartile range (IQR),

Fig 3. A, STL file with planned miniscrew position. **B,** Intraoral scan with scan body. **C,** Superimposition. Second intraoral scans were generally obtained 4-6 weeks after digital planning.

whereas categorical variables are reported as the number and/or percentage of subjects. The normal distribution z-test was used to determine the power of the sample, and the null hypothesis was that the mean of paired differences was equal to 0. The power analysis found that a sample size of 8 achieves 95% power to detect a mean of paired differences of 3.00° with a known standard deviation of differences of 2.00 and with a significance level (α) of 0.05 using a 2-sided paired z-test. Differences in the angle determined by the mutual position of 2 screws in the space with respect to the 3 different settings were tested with the Wilcoxon's signed rank test adjusted using the Bonferroni method. Differences with a P value of <0.05 were selected as significant. Data were acquired and analyzed in R statistical software (version 2018; R Core Team, Vienna, Austria).

RESULTS

The median achieved angle between 2 digitally planned screws was 6.22° (IQR: 4.35°, 9.08°) degrees and the difference between the angles in the planning and the achieved groups was significant (P <0.001).

The median angle between 2 parallelly planned screws in the 3D printed model (control) group was 1.65° (IQR: 1.17°, 12.76°), and the difference between angles in the planning and the 3D printed model was significant (P <0.001).

No significant differences in the same angle were detected between the achieved result and the 3D printed model (P = 0.315), nor in its projections onto the planes generated by the Cartesian axes, except for the projection of the angle on the plane YZ (P <0.001, Table I).

Inserted miniscrews showed an angle of 3.74° (IQR: 2.41°, 6.74°) and 4.68° (IQR: 3.38°, 6.51°) with respect to their digitally planned position and an angle of 4.31° (IQR: 3.15°, 6.58°) and of 4.55° ± 3.00° with respect to the 3D printed model (Table II).

The linear displacement of screws in each setting is described in Table III.

DISCUSSION

This study focused on the digital planning of orthodontic miniscrews inserted in the anterior area of the maxilla. In particular, we analyzed the reliability of the workflow from the virtual planning to the clinical phase, in which the miniscrews are positioned, and the appliance is delivered in the same appointment (1-visit protocol).

Optimizing chair time and the procedure efficiency benefits the clinician, the patient, and the office agenda.

The use of digitally planned insertion guides for miniscrews in the anterior area of the palate has already been proposed and published and is currently considered a reliable alternative clinical procedure.[13-15]

Therefore, this procedure should guarantee adequate precision and reliability to avoid clinical and laboratory inconvenience. Several aspects and steps should be evaluated and must guarantee sufficient precision.

The small dimension of the retaining screws entails a high precision among all the working steps with limited

Table I. Angle determined by the mutual position in the space of a couple of screws in a patient with respect to 3 different settings

Variables	*Planning (n = 25)*	*Achieved (n = 25)*	*Model (n = 25)*	P *value*	
Angle XYZ	0.00 (0.00, 0.02)	6.22 (4.35, 9.08)	1.65 (1.17, 12.76)	P vs A	<0.001
				P vs M	<0.001
				M vs A	0.315
Angle XY	0.00 (0.00, 0.00)	4.24 (1.51, 7.14)	1.64 (0.84, 12.07)	P vs A	<0.001
				P vs M	<0.001
				M vs A	0.941
Angle YZ	0.00 (0.00, 0.02)	4.43 (2.00, 6.34)	0.96 (0.50, 2.00)	P vs A	<0.001
				P vs M	<0.001
				M vs A	<0.001
Angle XZ	0.00 (0.00, 0.00)	8.59 (3.08, 14.49)	2.36 (1.57, 21.01)	P vs A	<0.001
				P vs M	<0.001
				M vs A	0.482

Note. Values in degrees. Measurements are read in the plane containing both screw directions (Angle XYZ) or between the projections of the directions on the planes generated by the Cartesian axes X, Y, and Z (Angle XY, Angle YZ, Angle XZ, respectively). Results are expressed as median (IQR); *P* value determined by Wilcoxon's signed rank test *P* value adjusted by using Bonferroni method.
P, planning; *A*, achieved; *M*, model.

Table II. Angles defined by each screw direction by performing pairwise observations in different settings

Variables	*Angle XYZ (n = 25)*	*Angle XY (n = 25)*	*Angle YZ (n = 25)*	*Angle XZ (n = 25)*
Planning vs achieved				
Screw 1	3.74 (2.41, 6.74)	2.54 (1.05, 3.68)	2.61 (1.22, 5.12)	3.44 (2.23, 6.25)
Screw 2	4.68 (3.38, 6.51)	2.85 (2.08, 4.09)	3.79 ± 2.54	6.79 (3.61, 8.94)
Planning vs model				
Screw 1	1.61 (0.95, 5.16)	0.83 (0.42, 4.48)	1.12 (0.81, 2.04)	1.61 (0.75, 6.06)
Screw 2	1.75 (1.12, 4.79)	1.69 (0.61, 4.44)	0.89 (0.52, 1.44)	2.10 (1.08, 8.43)
Model vs achieved				
Screw 1	4.31 (3.15, 6.58)	2.89 (0.63, 6.28)	2.14 (0.72, 3.80)	3.88 (1.18, 11.79)
Screw 2	4.55 ± 3.00	3.11 ± 2.23	2.45 (1.29, 5.08)	5.87 (2.30, 8.27)

Note. Values in degrees. Measurements are read in the plane containing both the observed directions (Angle XYZ) or between the projections of the directions on the planes generated by the Cartesian axes X, Y, and Z (Angle XY, Angle YZ, Angle XZ, respectively). Results are expressed as mean ± standard deviation or median (IQR).

error tolerance both from a vertical and angular point of view.

All the structures used in the study were partially or completely laser melted; this must be considered another important aspect of the method. The computer-aided design and manufacturing procedure allows an accurate production of the structure but can also lead to a few imprecisions in the printing process. Furthermore, the metal alloy used is more rigid, so fewer errors are allowed, and fewer adaptations are possible at chairside.

Previously published articles that evaluated stereolithographic insertion guides concluded that using CBCT and STL files for planning allows for accurate orthodontic miniscrews insertion and is more precise than a direct method.[9,10,16]

Most of the articles published used a CBCT for the planning step and a stereolithographic insertion guide. In this study, we evaluated virtual planning that includes a 2-dimensional x-ray instead of a 3D image and a thermoformed guide. Even though the guide is realized on a 3D printed model, this differs from a direct 3D printed insertion guide and relies substantially on the technician's ability and expertise. This approach is adequate when all the permanent dentition has completely erupted and is easy to achieve because most orthodontic patients already have a lateral cephalogram as an initial record. Furthermore, the literature showed how the bone thickness available 3-4 mm laterally to the midpalatal line assumes the same values as those visible in the lateral cephalogram.[17]

From previously published articles, differences between surgical and direct insertion were evaluated, but there are no analyses between planned and achieved positions, and this is fundamental to make the 1-visit protocol dependable in daily practice. We found differences in angular and linear measurements. The statistical

Table III. Linear displacement of each screw by performing pairwise observations of it in different settings

Variables	*X (n = 25)*	*Y (n = 25)*	*Z (n = 25)*
Planning with respect to achieved			
Screw 1 tip	0.20 ± 0.75	0.76 (0.49, 1.21)	1.04 ± 0.76
Screw 1 top	0.08 (−0.07, 0.32)	0.91 (0.75, 1.43)	0.59 (0.29, 0.87)
Screw 2 tip	0.49 ± 0.87	0.87 (0.59, 1.13)	1.16 ± 0.86
Screw 2 top	−0.00 ± 0.51	1.16 ± 0.56	0.55 ± 0.46
Planning with respect to model			
Screw 1 tip	0.02 (−0.19, 0.10)	0.56 (0.20, 0.84)	0.47 (0.25, 0.77)
Screw 1 top	0.11 (0.04, 0.76)	0.54 (0.31, 0.82)	0.43 ± 0.56
Screw 2 tip	0.23 ± 0.42	0.58 (0.37, 0.97)	0.51 (0.37, 0.87)
Screw 2 top	−0.10 (−0.38, −0.04)	0.68 ± 0.52	0.44 ± 0.45
Achieved with respect to model			
Screw 1 tip	−0.30 ± 0.86	−0.45 ± 0.75	−0.48 ± 0.68
Screw 1 top	0.01 (−0.17, 0.24)	−0.59 (−0.98, −0.18)	−0.04 ± 0.50
Screw 2 tip	−0.25 ± 0.92	−0.27 ± 0.42	−0.44 ± 0.83
Screw 2 top	−0.19 ± 0.47	−0.49 ± 0.44	−0.10 ± 0.34

Note. Values (in millimeters) are intended in the 3 directions of the reference system (Cartesian axes X, Y, and Z). Positive values indicate that a more lateral (along X), deeper (along Y), or mesial (along Z) displacement has been observed in the cited setting with respect to the other one. Results are expressed as mean ± standard deviation or median (IQR).

analysis showed significant differences among the 3 groups evaluating the mutual position of the miniscrews; the greatest differences (median, 6.22°) were found between the achieved positions and the planned ones. Because no inconveniences were noticed during the appliance fixation phase, those differences cannot be considered clinically significant.

Differences were observed between the planned and model positions and between the model and the achieved positions. These results indicate a certain amount of error in this workflow. The inaccuracies can be related to the incongruences between the mouth dimension, 3D printed phase, and intraoral scan precision errors.

Considering linear values, some discrepancies were observed in the 3 axes among the 3 groups. These differences are minimal and reflect the adequate and good performance of the workflow. Some vertical displacement was noticed: in particular, the inserted miniscrews were not as deep as planned (values ranged from 0.76-1.16 mm). This could result in less intrabone miniscrew portion as well as some imprecision in device position (ie, molar band fitting) and could mainly be ascribable to the fact that the intraoral scan with the scan body may not reflect the exact position of the miniscrew position in the vertical and lateral direction if compression between the scan body base and palatal mucosa exists during the intraoral scan.

Limits of this study include the use of only a stereolithographic insertion guide. It would be reasonable to include the use of a 3D printed guide as another control group in the analysis, which is another viable alternative to those studied in the present research. Furthermore, comparing more operators could be useful to validate the procedure from a clinical point of view because the clinician that performed the planning and the insertion of the miniscrews had significant experience in the procedure.

CONCLUSIONS

This study led to the following conclusions:

- The median parallelism loss of 2 screws between the planned position and the achieved one was 6.22° (IQR: 4.35°, 9.08°). Part of this parallelism was already lost in the 3D printed model.
- The median parallelism loss between the 3D printed model and the achieved result was 4.57°.

AUTHOR CREDIT STATEMENT

Marco Migliorati contributed to conceptualization and methodology, Sara Drago contributed to formal analysis, Lucia Pozzan contributed to software, and Luca Contardo contributed to manuscript review and editing.

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