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RESEARCH ARTICLE

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Accuracy of direct insertion of TADs in the anterior palate with respect to a 3D-assisted digital insertion virtual planning

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Abstract

Background: Direct and 3D-assisted methods are an available alternative when inserting temporary anchorage devices (TADs) in the anterior palate for orthodontic anchorage. This study aimed to evaluate the differences between a planned insertion versus a direct method on digital models.

Settings and sample population: Seventy TADs were inserted by the direct insertion method in 35 patients who needed palatal TADs for orthodontic anchorage. For each patient, placement was independently planned by the superimposition of lateral cephalograms and corresponding plaster models. After mini-implant placement, impressions were taken with scanbodies. For the measurement of both linear and angle deviations, virtual planning models and postoperative oral scans were compared using 3D software for automatic surface registration and calculations.

Results: Comparing TADs positioned by the direct method and the digitally planned method, a mean linear distance was found of 2.54 ± 1.51 mm in the occlusal view and 2.41 ± 1.33 mm in the sagittal view. No significant difference has been found between TADs positioned in the right and left palatal sides. A mean distance of 7.65 ± 2.16 mm was found between the tip of the digitally planned TAD and the central incisors root apex.

Conclusions: Both direct and 3D-assisted TAD insertion methods are safe and accurate in the anterior palate. However, the use of insertion guides facilitates TAD insertion, allowing less-experienced clinicians to use palatal implants.

KEYWORDS
anchorage, miniscrew, surgical guide

1 | INTRODUCTION

Recognizing the necessary anchorage and knowing how to achieve and maintain it during treatment are among the fundamental points that lead to orthodontic success. For years, orthodontists have applied complex systems and various devices to maintain the desired anchorage, sometimes only partially succeeding. The introduction of miniscrews and temporary skeletal anchorage systems (TADs) has created a real revolution in orthodontics, modifying and simplifying the setting and management of the anchorage, which is one of the key points of orthodontic treatment.[1,2] However, after an initial enthusiasm due to the possibility of avoiding side effects related to

Newton's third law, the clinical diffusion and research on the topic focused on the limits of this method, mainly because of the failure rate and possible risks.[3-5]

Indeed, the insertion of TADs in a buccal or palatal inter-radicular site is associated with a reasonable possibility of failure. This risk is possibly related to the intrinsic characteristics of the chosen site, bone quality and inter-radicular space. All these factors can lead to a reduction in primary stability, with a consequent failure of TADs and important repercussions on the management of the anchor.[6,7] The proximity of a miniscrew to tooth structures has been reported to be a major risk factor for failure.[8] On the other hand, interference during the orthodontic movements of the TADs positioned in an inter-radicular position is no less important because it may limit or prevent the planned orthodontic movement.

To improve stability, TAD success rate and to overcome these possible limits, placement methods that minimize root contact are being developed.[9,10] Among the various sites proposed for the insertion of TAD, the anterior portion of the palate has been gaining increasing interest in recent years, presenting significant advantages such as relative safety in the paramedian area, given the absence of significant vessels or nerves (with the exception of the nose-palatine canal), absence of tooth roots, and presence of sufficient bone and cortex, with only adherent gingiva. As a consequence of these characteristics, the insertion of TAD in the anterior area of the palate shows a definitively lower failure rate than the inter-root insertion, as confirmed by several studies.[3-6 (REDUCE REF)] Even though clinical landmarks and indications have been published for TAD direct insertion in the anterior portion of the palate,[9,10] many clinicians are not immediately familiar with the placement of implants in the anterior palate and may be reluctant to use them. Hence, several authors have proposed the use of a TAD insertion guide to help clinicians overcome their uncertainty. At the same time, a guide could provide optimal TAD position, length and angulation, predetermined on the specific patient with the use of 3D software and printers.[11] This approach could optimize and improve the safety of TAD placement, leading the clinician to the correct insertion angle and depth, as well as perfect parallelism between the TADs. Furthermore, the 3D digital planning of TAD insertion could allow evaluating the distance to the roots, as the TAD is inserted into one or more cortical bones. Several studies have evaluated the accuracy of TAD insertion with the use of a 3D insertion guide.

The greatest number of studies is made in general dentistry,[12] on skulls[13] or phantoms.[14] To our knowledge, there are no studies evaluating the difference between the insertion with and without the use of an insertion guide on human subjects. Hence, the present investigation aimed to evaluate the difference between direct and 3D-assisted TAD insertion methods, in terms of position, in patients.

2 | MATERIALS AND METHODS

This retrospective study on consecutively treated patients included thirty-five patients (14 males and 21 females; age 26.8 ± 8.9). Inclusion criteria were the need to use palatal TADs as orthodontic anchorage in the treatment plan, no systemic disease and no use of drugs affecting bone metabolism. Furthermore, pre-treatment lateral X-ray and casts had to be available. Informed consent was obtained from all patients at the acceptance of the proposed treatment plan. Any type of orthodontic treatment or appliance was accepted because it did not interfere with the aim of the study. Exclusion criteria were all patients whose treatment plan did not involve the use of palatal skeletal anchorage, or any patients refusing to have palatal TADs.

2.1 | Clinical procedure

Each patient received two TADs for a total of 70. The TAD used was OrthoEasy PAL® (Forestadent), 8 mm length, 1.7 mm diameter. A manual contra-angle (3 M Unitek) with a 10-mm blade has been used for the TAD insertion. After injecting local anaesthesia, the TADs were positioned just beyond the third palatal ruga, with an inclination of 90° degrees relative to the bone surface.[12] These two clinical landmarks have been used during TAD insertion in patients without any insertion guide or digital support.

After TAD insertion, related impression caps (Forestadent) were positioned on the TAD heads, and impressions were taken using Impregum Penta (3 M ESPE, Neuss) to optimize the accuracy, dimensional stability, reliability and precision of the anatomic details.[15] After taking the impressions, stainless steel laboratory abutments (Forestadent) were inserted into the impression caps, and all impressions were poured with super-hard plaster (Panadent). Hence, the casts obtained reproduced the position of the TADs inserted in the patients by direct method insertion. One single operator (GI) inserted all the TADs in the patients and made the impression with the impression caps.

2.2 | Experimental procedure

Pre-treatment models and models were scanned using a 3D model scanner (orthoX scan, Dentaurum) and were exported as STL files.

An expert operator (MM) performed the virtual planning of TAD insertion for each patient, using lateral cephalograms (Orthophos XG/DS 2D, Dentsply Sirona) and the initial model. The procedure included a first step where lateral cephalograms and corresponding models were matched using OnyxCeph software (TAD match, OnyxCeph, Image Instruments GmbH). Afterwards, the same miniscrews used in the clinical procedure were selected from the library and uploaded in the 3D combined model (TeleRX—maxillary model). Miniscrews were positioned with the following guidelines as position reference: adequate distance from anterior teeth roots, parallelism among the screws, insertion area in the anterior region of the palate between the second and third palatal ruga and adequate insertion depth. These guidelines were considered an 'ideal miniscrew position', and thus the best insertion possible following the indications of previous studies.[4,9,13,14]

The overlap between the cast and the lateral cephalogram allowed individualizing the TADs' 'ideal position' in terms of bone quantity and relationship to the frontal teeth roots. The process of bone evaluation on the lateral X-ray has been already compared with CBCT, reporting similar accuracy, limited to the palatal area of interest in the present study.[16,17]

Once the miniscrews were inserted, the maxillary models obtained from digital planning and direct insertion model were superimposed using 10 reference points for each model (Figure 1). Once the two models were superimposed, the difference in placement between the two screws was measurable as a distance in mm.

2.3 | Measurements

Linear distances were evaluated in mm in both sagittal and occlusal views, for the right and left miniscrews; distances were measured between the head of the virtually placed miniscrew and the head of the manually inserted miniscrew (Figure 2A,B). As a third parameter, the distance between the tip of the digitally planned TAD and the central incisor root apex was measured. The distance from the manually inserted screws and the root apex was not reported after different attempts to create an exact and reliable screw inclination on the digital model. A single operator (LP), different from the person who carried out the clinical insertion of the TADs or the virtual planning, performed the overlapping and all the measurements.

2.4 | Error analysis

Intraclass correlation coefficient (ICC) values were evaluated for sagittal and occlusal view measurements as well as for apex root distance; the value ranged between 0.87 and 0.91 (Figure 3).

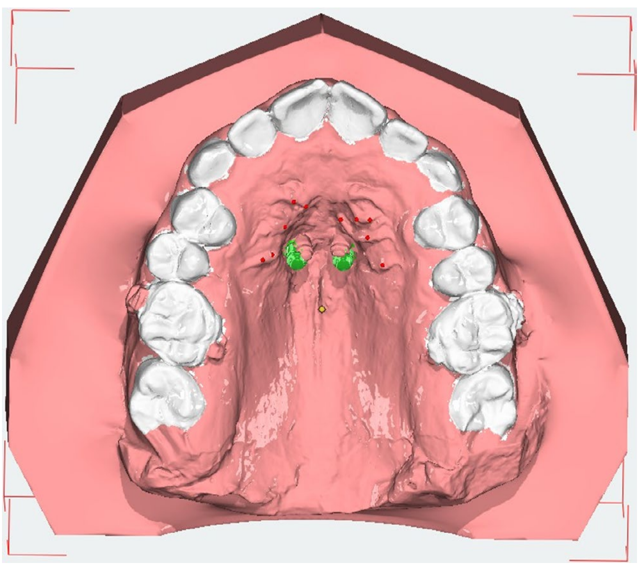

FIGURE 1 Digital planned and direct insertion model superimposition using 10 reference points

2.5 | Power of the study

The power analysis found that a sample size of 11 achieves 90% power to detect a mean of paired differences of 2.02 with a known standard deviation of differences of 1.75 and with a significance level (alpha) of 0.05. Data were acquired from a previous pilot study (unpublished data). 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 is equal to 0.[18]

2.6 | Statistical analysis

Continuous variables are given as means ±standard deviations (SD), whereas categorical variables are reported as the number or percentage of subjects.

Data were acquired and analysed in the R v3.4.4 software environment.[19]

3 | RESULTS

The sample used in the analysis included 35 patients: 14 males and 21 females. The mean age was 26.8 years. The minimum age was 10.2 years, and the maximum age was 45.3 years. The mean therapy duration was 21.5 months.

The mean linear distance for the right miniscrew was 2.49 mm (SD = 1.55) in the occlusal view and 2.33 mm (SD = 1.48) in the sagittal view. The mean linear distance for the left miniscrew was 2.59 mm (SD = 1.32) in the occlusal view and 2.49 mm (SD = 1.35) in the sagittal view (Table 1). They are represented in Figure 4

The mean distance between the tip of the digitally planned TAD and the right central incisor root apex was 7.86 mm (SD = 2.16). The mean distance between the tip of the digitally planned TAD and the left central incisor root apex was 7.44 mm (SD = 2.17, Table 1). The frequency distributions of distances from central incisors roots are represented in Figure 5.

4 | DISCUSSION

The use of TADs as part of orthodontic treatment has become increasingly common in over the last 20 years, increasing patients' compliance and expanding orthodontic limits and possibilities.[10,13,20,21] TADs were initially positioned in inter-radicular sites.[22,23] However, since Wehrbein et al introduced TADs specifically designed for orthodontic anchorage in the palate,[24] the anterior palate has become more and more common, making it a preferred insertion area for orthodontic mini-implants.[25,26] With this approach, orthodontic movements can be planned and performed without any interference with TADs because their palatal position is not in the path of moving teeth.[11,25]

In particular, the T-Zone was proposed and described as a safe and reliable insertion site for many orthodontic purposes.[15]

TADs' failure rate in the anterior palate is significantly lower than in other regions. In addition, their position is far from the dental roots with minimal possibility of root injuries. The palate has good bone quality with thin attached mucosa.[9,17] The anterior hard palate has been well studied as a region for skeletal anchorage in orthodontics. Three-dimensional computed tomography studies have evaluated the bone quantity and quality and concluded that palatal

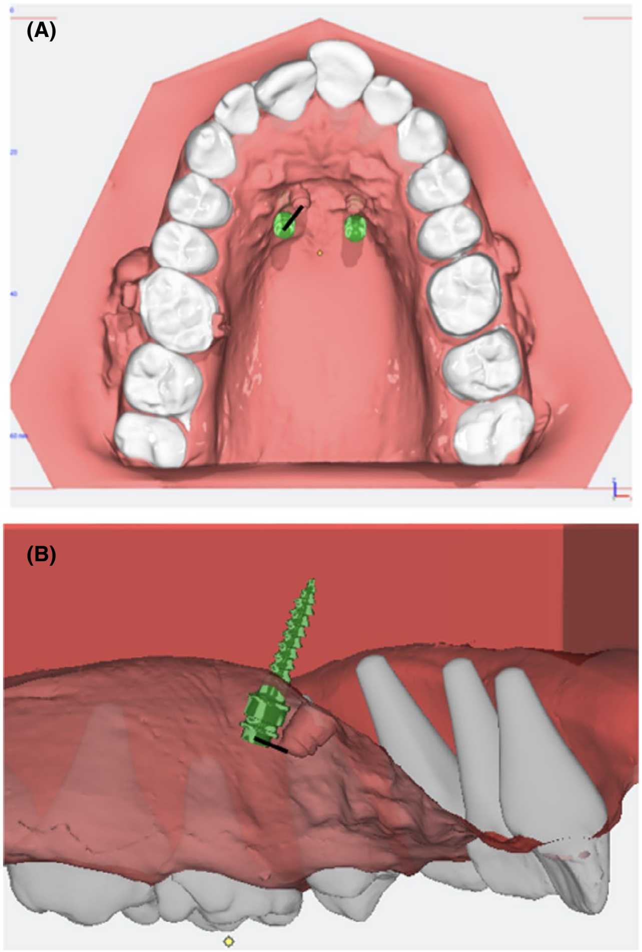

FIGURE 2 A, Linear distances evaluated in mm in occlusal view for the right and left miniscrews. B, Linear distances evaluated in mm in sagittal view for the right and left miniscrews

bone thickness is increased in the anterior hard palate at the level of the third palatal ruga.[9,27-29] The third palatal ruga is a stable and clinically identifiable landmark for the insertion of orthodontic TADs, suggesting it as the preferable insertion region for the insertion of orthodontic TADs in the upper jaw.[26]

However, many practitioners are not immediately familiar with the placement of implants in the anterior palate and may be reluctant to use them. This reluctance could be related to orthodontists' lack of familiarity with work on the palate or performing small surgical procedures.[11] The major reasons given by orthodontists for not using miniscrews in their practice were lack of training (67%) and fear of risk factors such as root damage and infection (54%). In response, several authors recently proposed the use of mini-implant insertion guides to help clinicians overcome their uncertainty by predetermining the desired TAD position, length and angulation out of the patient's mouth[11,30-33] A recent survey on the current trends in miniscrew utilization among Indian orthodontists reported that among orthodontists using TADs in their practice, 63% used a surgical guide to facilitate their placement.[34]

Several studies compared direct and guided insertion methods in dentistry[12,35] as well as in the inter-radicular position in orthodontics.[13,14,36,37] However, as far as we know, the present is the first study specifically comparing the positioning of palatal orthodontic TADs by the direct and guided methods. Möhlhenrich et al evaluated orthodontic mini-implants placed at the anterior palate. However, their study was an evaluation of the accuracy of orthodontic mini-implant placement at the anterior palate using tooth-borne or gingiva-borne guide support, without measurements, and was regarded as a direct insertion method. Furthermore, the Möhlhenrich et al study was an ex-vivo evaluation performed on cadaver heads, whereas ours was realized in vivo on real orthodontic patients.[24] Using a method similar to previous studies,[38,39] the clinical mini-implant position by intraoral scans and virtual scanbodies was determined and compared that with the virtual planned mini-implant position digitally realized by an expert operator blinded (MM) for the purposes of the study and different from the clinician who clinically inserted the TADs in the patients.

According to our results, no significant difference was found between TADs inserted in the right and left palatal sides (ie upper jaw quadrants 1 and 2). This result suggests that the clinician's position

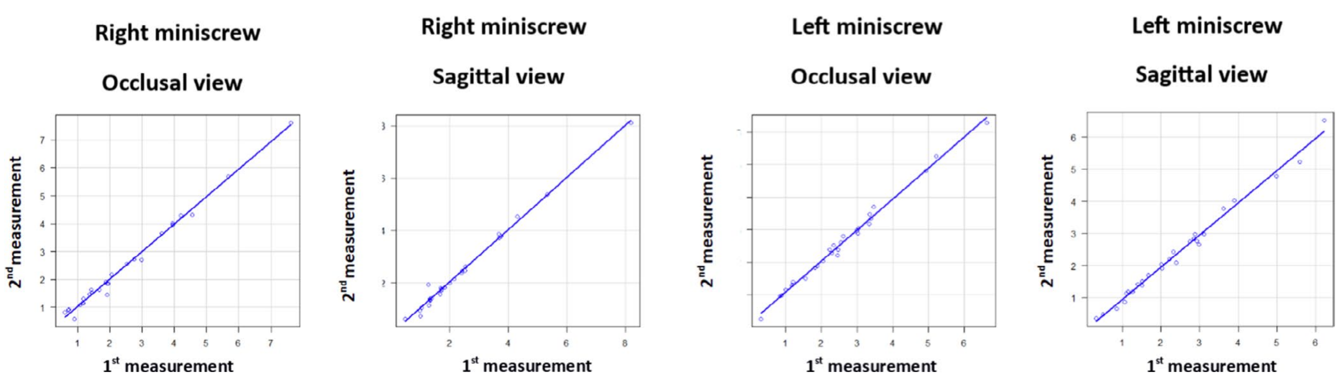

FIGURE 3 Error analysis and concordance of the repeated measurements

TABLE 1 Outcome measurements in whole population (N = 36)

	Right		Left	
	Occlusal	Sagittal	Occlusal	Sagittal
Distance from planned position (mm)	2.49 ± 1.55	2.33 ± 1.48	2.59 ± 1.32	2.49 ± 1.35
Min	0.61	0.49	0.31	0.33
Max	7.62	8.20	6.64	6.22
Distance from central incisor root (mm)	7.86 ± 2.16		7.44 ± 2.17	
Min	4.36		4.47	
Max	11.85		12.02	

Results are expressed as mean ± standard deviation.

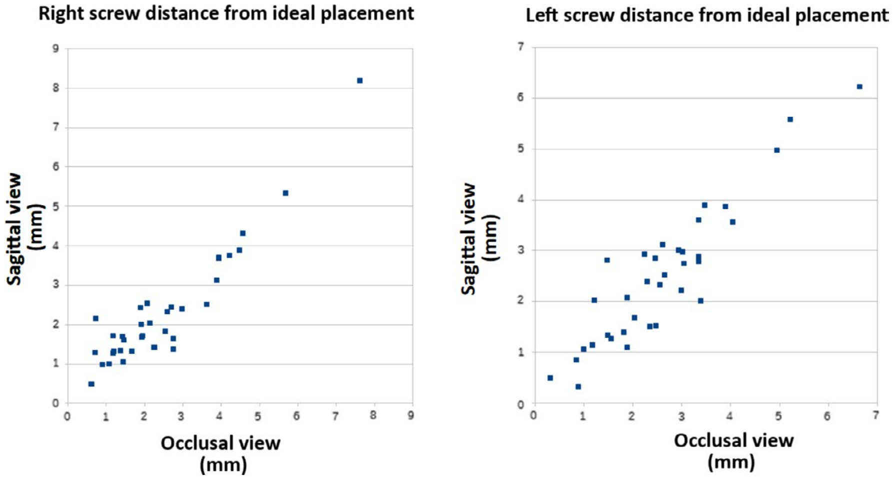

FIGURE 4 Dispersion graph of linear measurements in the occlusal and sagittal view for the right and left miniscrews. The origin of the graph represents the ideal insertion point

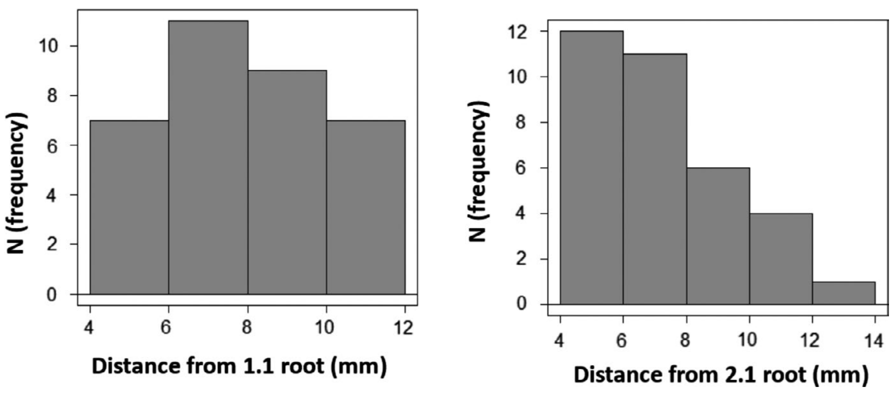

FIGURE 5 Frequency distributions of the measured distances between the tip of the digitally planned TAD and central incisor root apex

at the chair cannot be considered as a factor that influences TAD positioning. However, we must note that a right-handed operator inserted all the TADs in our sample; no information can be given for left-handed clinicians. Furthermore, it has to be underlined that direct miniscrew insertion was performed by an experienced operator, and thus, the results of this study should consider this limit.

In our sample, a mean linear distance of 2.54 ± 1.51 mm was found in the occlusal view and 2.41 ± 1.33 mm in the sagittal view when comparing TADs positioned by the direct method and the digitally planned one. These differences could be considered clinically acceptable, especially considering the accuracy data reported by previous studies on guided insertion method.[40] In a systematic review of the accuracy of computer-guided implant dentistry, Schneider et al found a mean deviation at the entry point of 1.07 mm and the apex of 1.63 mm. In an orthodontic application, Möhlhenrich et al found lateral deviations up to 1.65 ± 1.03 mm, and Cassetta et al reported coronal and apical deviations of 1.38 ± 0.65 mm and 1.73 ± 1.03 mm, respectively. However, it is important to note that a direct comparison with this current literature is difficult because of different methods of measurement and because no previous study compared specifically direct and 3D-assisted insertion methods. Nevertheless, from our data and these previous studies, it seems that the desired insertion position was reached with both the direct and guided insertion methods, and the differences are not clinically significant.

In our sample, we found a mean distance of 7.65 ± 2.16 mm between the tip of the digitally planned TAD and the central incisor root apex (Table 1). These results are in agreement with Hourfar et al who reported an average distance between the third ruga and the central incisor root of 8.9 mm, before treatment, and 7.6 mm after treatment.[14] These data confirm that an 8 mm long mini-implant can be safely inserted at the third ruga in an oblique direction with both the direct and the guided insertion methods.

Furthermore, the frequency distribution of the measured distances between the tip of the digitally planned TAD and the root apex of the central incisor reveals that most cases present a distance of 6-10 mm and 4-8 mm, respectively, for the right and left incisors. We found no case with a distance lower than 4.36 mm, confirming the safety of the procedure. Half of the digitally planned screws were more distally positioned than the manually inserted, 4 were positioned in the same position, and the others, that were placed manually, were more distally placed.

This result is a very important difference from previous studies evaluating the use of a TAD insertion guide in the inter-radicular position. Qiu et al reported no root damage in the stent group, whereas four of 10 miniscrews contacted roots in the freehand group. Similarly, Bae et al found 84% of the miniscrews were placed without contacting adjacent anatomic structures, whereas in the control group, 50% of the miniscrews were placed between the roots.[15,26] These data led the authors to conclude that TADs were placed more accurately and safely when surgical guides were used than when a direct method was used. Conversely, considering the difference in the zone of insertion method (ie anterior palatal vs inter-radicular), our data do not sustain this difference, confirming that both approaches appear to be safe as for use in orthodontic clinical practice.

However, a significant limitation of our study was that a single expert operator (GI) inserted all TADs. Hence, we did not evaluate the difference in accuracy and safety according to the operator skill level, as was done by previous authors,[15] nor the difference in accuracy due to the operator skills in performing the digital planning. Moreover, the 3D-assisted digital procedure allowed to take into consideration additional insertion guidelines, such as mutual parallelism and insertion depth of miniscrews. Nevertheless, we suppose that a TAD insertion guide can potentially assist clinicians to overcome their uncertainty, especially during the first steps on the procedure learning curve, providing assurance and guiding their hands towards the right position, length and angulation.[19]

Furthermore, the use of an insertion guide can be promising and helpful when using pre-welded orthodontic appliances as well as for delivering the orthodontic appliance during the same appointment as the TAD insertion.[19] Moreover, the use of TAD insertion guides could be particularly helpful in clinical cases presenting impacted teeth or mixed dentition. These represent specific clinical cases where TAD direct insertion in the anterior palate could be more dangerous and riskier. An accurate pre-evaluation using cone beam computed tomography (CBCT) and a 3D insertion guide could help the clinician to address these specific and more difficult orthodontic scenarios.

When considering when to use the 3D-assisted method of TAD insertion, the clinician also must consider the associated costs for manufacturing the insertion guide.

5 | CONCLUSION

Both direct and 3D-assisted TAD insertion methods are safe and accurate in the anterior palate. However, the use of insertion guides could facilitate TAD insertion, providing the opportunity to use palatal implants to the less-experienced clinicians. Furthermore, the use of insertion guides allows orthodontists to insert the TADs and fit a prefabricated appliance in a single appointment. In addition, orthodontists can address more complex clinical situations, such as cases with impacted teeth or mixed dentition.

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Not applicable.

COMPETING INTERESTS

The authors declare that they have no competing interests.

CONSENT FOR PUBLICATION

Not applicable.

AUTHORS' CONTRIBUTIONS

GI provided study models and designed the study. RN designed the study and reviewed the text. SD analysed data and performed statistics. LR and GT involved in data acquisition. ASB interpreted the data. MM involved in study project, reviewed, designed the study, and supervised the data analysis.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Not applicable, study on digital models.

DATA AVAILABILITY STATEMENT

The data sets used and/or analysed during the current study are available from the corresponding author on reasonable request.

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