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Accuracy of Two Variants of 3D-Printed Insertion Guides for Orthodontic Mini-Implants: An Ex Vivo Study in Human Cadavers

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Abstract: Insertion guides are becoming popular for orthodontic mini-implant positioning. The aim of this study was to evaluate and compare the accuracy of two different mini-implant insertion guides, with or without pre-drilling, in a human cadaveric model. Maxillary casts of six fresh frozen specimens were digitized to create insertion guides. Sixty mini-implants were randomly inserted with full-arch or skeletonized guides, either with or without predrilling. Pre- and post-treatment CBCTs were superimposed using rigid registration. Transformation matrices of the planned and real positions were obtained, and distances at the mini-implant neck and apex, as well as the angular deviation, were calculated. The Kruskal–Wallis test was performed, followed by a post hoc test when indicated. Out of 60 inserted mini-implants, 46 could be evaluated. Of these, 10 initially assigned to no pre-drilling required this procedure due to very high bone density. Therefore, 32 implants were inserted with pre-drilling ($n = 15$ full-arch; $n = 17$ skeletonized) and 14 without ($n = 7$ full-arch; $n = 7$ skeletonized). The lowest mean deviation at the neck was 1.22 ± 0.6 mm, registered in the full-arch/pre-drilling group. The skeletonized/no pre-drilling group presented the lowest mean values at the apex, i.e., 1.72 ± 1.22 mm, as well as the lowest mean angular deviation, i.e., $8.23 \pm 4.24°$. Significant differences among groups were observed only at the neck, with higher mean deviation in the skeletonized/pre-drilling group than in the full-arch/pre-drilling one ($p = 0.014$). In conclusion, within the limitations of the study, rather high deviations between planned and real mini-implant positions were found. Further studies are needed on how to improve the accuracy within in vivo settings.

Keywords: mini-implants; insertion template; CAD-CAM; additive manufacturing; CBCT

1. Introduction

The use of temporary skeletal anchorage devices (TADs) has simplified and enhanced the efficacy of many orthodontic treatments, reducing the risk of undesired tooth movements [1]. Furthermore, they were met with a greater acceptance rate due to the reduced need for patient's compliance and their superior aesthetic appearance [2,3]. For these reasons, mini-implants are currently applied in a wide range of orthodontic treatments, such as upper molar distalization, mesialization or intrusion, rapid maxillary expansion, and extrusion of impacted teeth [4–7].

To achieve successful retention, mini-implants should be placed in the optimal insertion site, avoiding contact with dental roots and interference with the intended path of tooth movement. Moreover, they should have a diameter and length adequate to the applied forces [8]. Considering these principles, the palate seems to be the most predictable region for obtaining a successful mini-implant anchorage, with a survival rate ranging between 91.5% and 97.9% for palatal mini-implants, compared to 67.5% for the buccal ones [9,10]. In the palate, the paramedian region immediately posterior to the palatal rugae and the medial area corresponding to the palatal suture, described as the "T-Zone", constitute the most suitable regions for the insertion of palatal mini-implants [8]. This area is generally characterized by the presence of an adequate bone volume, a reduced soft tissue thickness, and the absence of anatomical structures which could be damaged, allowing, in most of cases, a predictable mini-implant insertion without performing cone beam computed tomography (CBCT) [11–13].

Another parameter strictly related to the stability of mini-implants is the insertion torque, which depends on the bone quality, on the design and size of the mini-implants, and on the predrilling procedure [14,15]. To reduce biological and mechanical complications, the ideal insertion torque should range between 5 and 10 Ncm for mini-implants with a diameter of 1.6 mm [15,16]. Although self-drilling mini-implants are associated with higher insertion torque, which provides a higher primary stability compared to the self-cutting ones [17], a tendency to fracture has been reported during the insertion of self-drilling mini-implants in thick or dense cortical bone when excessive insertion torques were applied [18]. Moreover, excessive torque in dense cortical bone may induce heat damage or vessel compression, which might lead to bone resorption and lack of secondary stability [19,20]. For these reasons, the use of pilot holes with a smaller diameter has been successfully proposed to obtain a good mini-implant primary stability by decreasing insertion torque (at least in adults) [16,21].

In dental implant surgery, the use of computer-aided design (CAD) milled or three-dimensional (3D) printed surgical insertion guides has been widely implemented in the past years. Indeed, guided implant surgery is currently a reliable and useful method to prevent anatomical structure damage, reduce the surgical trauma, and place the dental implant in the best position for the subsequent prosthetic restoration [22,23]. More recently, the use of insertion guides has been proposed and are becoming increasingly popular for the insertion of orthodontic mini-implants. Although the "T-zone" is generally considered a safe zone for mini-implants placement, in certain conditions, such as the presence of palatally displaced teeth, cleft palate, or minor palatal bone support, the use of insertion guides can be extremely useful. Moreover, the digitally planned mini-implant position allows for the production of the orthodontic supraconstruction together with the guide, enabling its placement in the same appointment [24,25].

Different designs and techniques have been proposed for the realization of orthodontic implant insertion guides. Two recent human cadaveric studies reported on the higher accuracy in palatal mini-implants position using traditional silicone insertion guides supported by teeth, rather than soft tissue borne ones [25,26]. Recently, full-arch 3D-printed tooth-supported guides have been successfully utilized, presenting a good anchorage and stability during the mini-implant insertion [24,27]. However, this design does not allow for a visual check of the insertion depth since the entire oral mucosa, as well as the occlusal surface of the maxillary teeth, is covered. Therefore, a new skeletonized design with four occlusal supports has been introduced, giving a better insertion overview, a reduced bulk of the appliance and its good stabilization.

The aim of this study was to evaluate the accuracy of orthodontic mini-implant positioning using two different insertion guides (i.e., full-arch tooth-supported vs. skeletonized) with or without pre-drilling.

2. Materials and Methods

The study protocol was reviewed, approved, and registered with the number 5900R by the Ethics Committee of the Medical Faculty of Heinrich Heine University, Düsseldorf.

The investigations were performed on 6 human ex vivo frozen specimens from adult donors provided by the Center for Anatomy II (University Hospital Düsseldorf), presenting teeth in the premolar and molar region and intact oral tissues.

For each specimen, an initial CBCT image (Orthophos SL 3D CBCT from Dentsply Sirona Inc., York, PA, USA) was taken (T0) and, subsequently, silicone impressions (Provil novo, fast set, Kulzer GmbH, Hanau, Germany) were taken of the maxilla to obtain plaster models. These were digitized using an optical laser scanner (orthoX® scan 3D model scanner, Dentaurum GmbH and Co. KG, Ispringen, Germany) by means of a software program (orthoX® scan). For each sample, a T-shaped area (T-zone) posterior to the third pair of palatal folds was selected for inserting 10 orthodontic mini-implants (9 mm length × 2 mm diameter; BENEfit®, PSM Medical, Gunningen, Germany) with the same insertion axis using two different custom-made insertion guides (Figure 1).
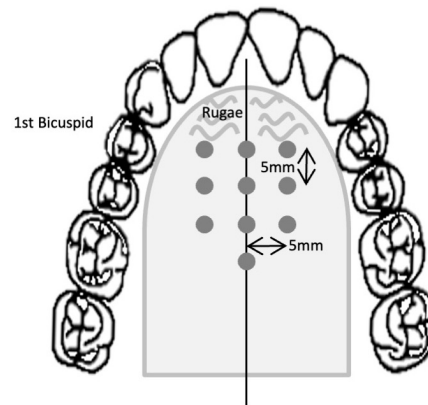

Figure 1. Insertion scheme of the 10 mini-implants in the T-zone.

Thirty mini-implants were placed using full-arch guides (from Easy Driver, Uniontech, Parma, Italy) (Figure 2a), and thirty using skeletonized templates fabricated in-house using Blender software (Blender Foundation, Amsterdam, The Netherlands) and an SLA-printer (Form 3, Formlabs Inc., Berlin, Germany) (Figure 2b).

(**a**)　　　　　　　　　　　　　　　　(**b**)

Figure 2. (**a**) Full-arch insertion template in which the entire oral mucosa as well as the occlusal surface of the maxillary teeth is covered; (**b**) skeletonized insertion guide, supported by selected teeth in premolar and molar region and leaving the oral palatal mucosa visible.

The groups were randomized according to the different regions of the palates, and half of the mini-implants were inserted using a pre-drilling procedure, while the other half were inserted without. For each maxilla, the implants were randomized using a true random number generator (random.org, Dublin, Ireland) as follows: (1) randomization

of the palatal side on which the mini-implants were inserted with pre-drilling or without pre-drilling (split-mouth design); (2) randomization of the four median mini-implants in pre-drilling group and non-pre-drilling group; (3) randomization of the 60 mini-implant in the two different insertion guides group (i.e., full-arch or skeletonized). The Surgic Pro + motor was used both for pre-drilling and mini-implant insertion, with the following settings: 40 rpm speed and 30 Ncm insertion torque. In the pre-drilling group, a 1.4 mm pre-drill was used. Further details on the allocation process are provided in Figure 3.
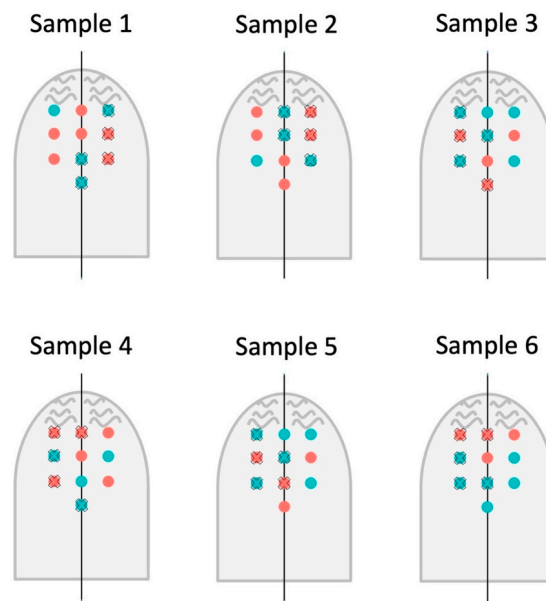

Figure 3. Graphical representation of the randomization process. In orange: full-arch insertion template; in green: skeletonized insertion template; x: pre-drilling.

After mini-implant insertion, another CBCT of the sample was taken using the Orthophos SL 3D CBCT (Dentsply Sirona Inc.) (T1) and then superimposed to the initial one using Amira (Amira R 6.4.0 Thermo Fisher Scientific, Waltham, MA, USA). The CBCTs were acquired using the high-definition mode. Further details on the acquisition parameters are provided in Table 1.

Table 1. Overview of the modes and settings used for CBCT scans.

Parameter	Pre-Operative Setting	Post-Operative Setting
Mode	High Definition (HD)	High Definition Plus (HD+)
Tube current (mA)	6	7
Voltage (kV)	85	85
Exposure time (s)	14.4	14.4
DAP (mGyXcm^2)	1515	1771
FOV (cm)	11×10	11×10

DAP: dose area product; FOV: field of view.

Maxillary bone segmentation was performed in Amira (Amira R 6.4.0, Thermo Fisher Scientific) using the following threshold settings: 240 (preoperative and postoperative CBCTs); while for mini-implant segmentation, the threshold was set to 1500. The postoperative scans and the original plannings contained in the pre-operative scans were superimposed using rigid registration.

To measure the deviation between the planned and the actually achieved position of the mini-implants, the respective transformation matrices were obtained. The coordinates of the implant neck and apex were copied, and using MATLAB software (MathWorks, Portola Valley, CA, USA), the distances at the respective positions were calculated.

Statistical Analysis

Statistical analysis was performed using the software R [28]. A normal distribution of the values for the deviations of the measuring points neck, apex, and angle from the planned position was observed by the normal QQ plots. Boxplots were created for descriptive purposes for each selected variable (i.e., neck, apex, and angle). To assess differences in each considered variable between mini-implants with planned pre-drilling and unplanned pre-drilling (originally randomized as no pre-drilling), the Wilcoxon test was performed. For each variable, the Kruskal–Wallis test was used to assess differences among the four insertion groups (i.e., full-arch/no pre-drilling, full-arch/pre-drilling, skeletonized/no pre-drilling, skeletonized/pre-drilling). In case of significance, the Wilcoxon post hoc test with p-value correction using the Holm method was performed. The results were found to be significant at $p < 0.05$.

3. Results

Four mini-implants were excluded from the evaluation for the following reasons: one implant fracture occurred during the insertion process; two implants collided; and one implant was found not to be placed into bone at the CBCT evaluation. Moreover, one sample was excluded due to not reliable measurements. Thus, a total of 46 mini-implants were analyzed.

Out of these 46 included in the final evaluation, due to hard bone, 10 were inserted using pre-drilling despite being planned to be inserted without. Therefore, 32 implants ($n = 15$ full-arch; $n = 17$ skeletonized) were inserted with a pre-drilling procedure and 14 implants ($n = 7$ full-arch; $n = 7$ skeletonized) without.

Mini-implants with planned pre-drilling and unplanned pre-drilling presented no significant differences for all the investigated variables, i.e., neck ($p = 0.795$), apex ($p = 0.610$), and angle ($p = 0.388$).

The distance between the planned and the real position of the mini-implant neck is reported in Figure 4. The highest mean deviation at the implant neck was 2.09 ± 0.92 mm, recorded in the skeletonized/pre-drilling group. The Kruskal–Wallis test revealed a statistically significant difference between the four groups ($p = 0.012$). Therefore, a post hoc test was conducted, and corrected p values are reported in Table 2. Deviations at the neck were statistically higher in the skeletonized guides with pre-drilling as compared to full-arch guides with pre-drilling. No other significant differences were observed among the groups.
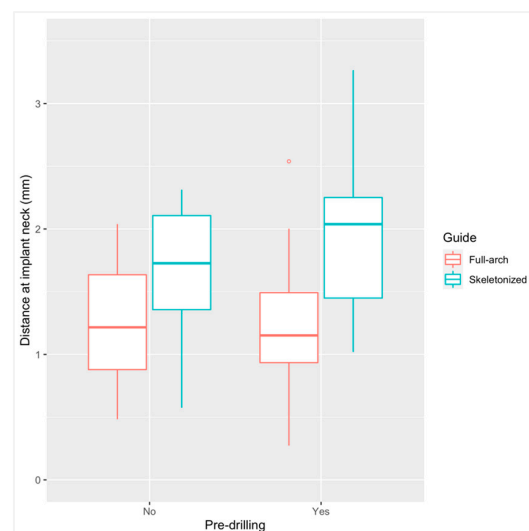

Figure 4. Boxplot reporting the deviations (in mm) from the planned and the real mini-implant neck position in the four groups.

Table 2. The Wilcoxon post hoc test with *p*-value correction using the Holm method was performed to compare deviations in implant neck position in the four groups.

	Full-Arch/ No Pre-Drilling	Full-Arch/ Pre-Drilling	Skeletonized/ No Pre-Drilling
Full-arch/pre-drilling	0.910	_	_
Skeletonized/no pre-drilling	0.626	0.492	_
Skeletonized/pre-drilling	0.141	0.014 *	0.910

Corrected *p* values are reported in the above table. Significant values are labeled as follows: * *p* < 0.05, ** *p* < 0.01, *** *p* < 0.001.

The deviation between the planned and the real position of the mini-implants was analyzed also at their apex, with median values above 1 mm in all groups (Figure 5). At the apex, the highest deviation was of 3.04 ± 1.44 mm and was registered in the full-arch/no pre-drilling group, while the lower mean deviation of 1.72 ± 1.22 mm was observed in the skeletonized/no pre-drilling one. No statistically significant difference was found between the four groups, as revealed by the Kruskal–Wallis test ($p = 0.131$).
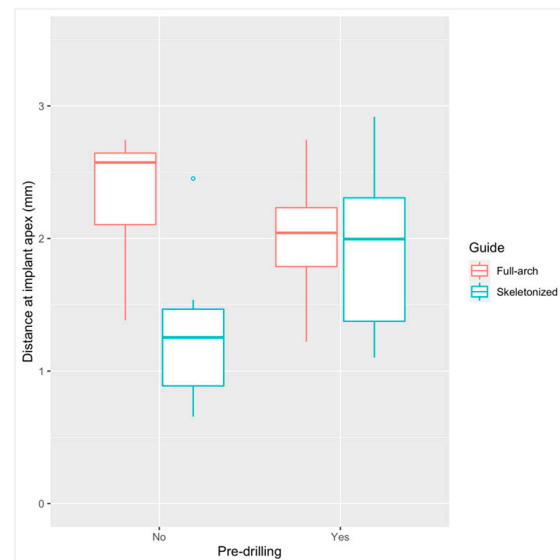

Figure 5. Boxplot reporting the deviations (in mm) from the planned and the real mini-implant apex position in the four groups.

Finally, the angle between the planned and the real position of each mini-implant was measured (Figure 6). The lower mean angular deviation was of $8.23 \pm 4.24°$ and was registered in mini-implants inserted using a skeletonized guide without a pre-drilling procedure, while in all the other groups, the mean angular deviation was higher than $11°$. Even for this variable, it was not possible to find a statistically significant difference between the four groups ($p = 0.511$). Further details on descriptive statistical analysis are provided in Table 3.
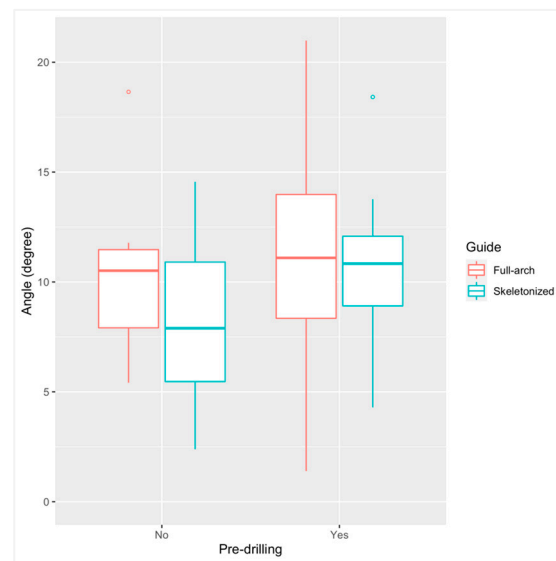
Figure 6. Boxplot reporting the angle between the planned and real mini-implant position in the four groups.

Table 3. Descriptive statistic data on the deviation of the mini-implants neck, apex, and angle. Values are reported in mm.

Location	Group	Mean	SD	Median	Min	1st Quart	3rd Quart	Max
Mini-implant neck	Full-arch/ no pre-drilling	1.25	0.56	1.22	0.48	0.88	1.64	2.04
	Skeletonized/ no pre-drilling	1.65	0.62	1.73	0.57	1.36	2.11	2.31
	Full-arch/ pre-drilling	1.22	0.60	1.15	0.27	0.93	1.49	2.54
	Skeletonized/ pre-drilling	2.09	0.92	2.09	1.02	1.52	2.28	4.65
Mini-implant apex	Full-arch/ no pre-drilling	3.04	1.44	2.64	1.38	2.34	3.41	5.73
	Skeletonized/ no pre-drilling	1.72	1.22	1.26	0.66	1.01	1.99	4.13
	Full-arch/ pre-drilling	2.69	1.40	2.10	1.22	1.92	3.13	6.46
	Skeletonized/ pre-drilling	2.76	1.55	2.30	1.10	1.93	3.61	6.67
Implant angle	Full-arch/ no pre-drilling	12.75	6.96	10.54	5.41	8.77	15.22	25.33
	Skeletonized/ no pre-drilling	8.23	4.24	7.89	2.39	5.47	10.90	14.55
	Full-arch/ pre-drilling	12.47	7.23	11.21	1.39	8.92	14.43	31.30
	Skeletonized/ pre-drilling	11.78	6.04	10.90	4.30	8.94	12.18	31.52

4. Discussion

The accuracy of digitally planned mini-implant positions is a clinically relevant topic since it represents a prerequisite for the immediate placement of the pre-operatively CAD-CAM fabricated orthodontic appliance. This allows for a reduction in the number of the appointments and, therefore, the overall duration of the orthodontic treatment [25]. Moreover, depending on the location of implant insertion, high accuracy can be crucial to

avoiding iatrogenic damage to the surrounding structures, including the nerves and roots of the adjacent teeth [29,30].

The present cadaver study aimed to assess the accuracy of digitally planned mini-implants inserted using four different procedures. When assessing the distance between the planned and the real positions of the mini-implants, the lowest discrepancies were found at the neck, where the full-arch guides exhibited better results compared to the skeletonized ones; while for full-arch guides, the deviation from the planning was comparable between pre-drilling and no pre-drilling procedures; the mini-implants inserted with the skeletonized guides without pre-drilling tended to perform better than self-drilling ones.

When the distance between the real and the planned positions was measured at the apex of the mini-implants, like values were obtained with pre-drilling, independently of the insertion guide. By trend, despite their insignificance, more pronounced differences were observed between the two self-drilling groups, with the biggest deviation from the plan in the full-arch group.

As regards the angular deviation between the planned and the real positions, comparable values were observed between the four investigated groups. In some of the analyzed samples, high angular deviation was observed, with maximum values above 30° in the pre-drilling groups.

A recent in vitro study in resin models analyzed the accuracy of mini-implants inserted with two traditionally manufactured and three different 3D-printed rigid tooth-borne templates [31]. Despite an acceptable accuracy being achieved with all templates, better outcomes were obtained with the conventional ones. In this study, the median deviation between the planned and the true position of the mini-implants at the neck ranged between +0.73 mm and −0.76 mm, between +0.57 mm and −0.66 mm at the apex, while the angular deviation ranged between 0.70° and 6.03° [31]. In our study, higher median deviation values were found for all the considered measurements. However, the lower accuracy observed in our study might be related to the use of a cadaveric model. Contrary to resin models, which present a homogeneous structure, the density and thickness of human bone differed between the included samples and the different palatal insertion regions. In another cadaveric study, comparing the accuracy between the real and the planned position of mini-implants inserted using gingival-borne or tooth-born guides, a statistically higher accuracy was found using the latter [25]. The authors reported a mean sagittal angular deviation of 3.67° and 6.46° ($p = 0.043$) and a mean transverse angular deviation of 3.60° and 4.06° ($p = 0.62$) in the tooth-borne and gingival-borne guide group, respectively [25]. Another factor that might have affected our results was the absence of a stop during the insertion, which could be responsible for an incorrect vertical placement. This problem could partially be solved with the use of skeletonized guides which do not cover the whole palate, thus allowing for a visual check of the insertion depth.

Pre-drilling is deemed to be a useful procedure by which to reduce the insertion torque and, consequently, the risk of mini-implant fracture during the insertion or removal [15,32]. Interestingly, in this study, the median distance between the real and planned position, when measured at the mini-implant neck, was lower with the full-arch guides than with the skeletonized ones. By contrast, at the apex, the highest median values were observed in the full-arch groups, particularly without pre-drilling (2.64 mm). This finding might be the result of a slight deviation of the pre-drilling path, leading to an incorrect angulation of the mini-implant, and this would be in line with angular measurements. Even though no significant differences were found in any of the investigated variables between planned and unplanned pre-drilling, the need to insert, via a pre-drilling procedure, six mini-implants that were initially assigned to the no pre-drilling group may have had a major impact on the apical deviation in the full-arch/no pre-drilling group. Freshly frozen specimens/cadavers were unfrozen and utilized to mimic the clinical situation as much as possible. Nonetheless, and specifically owing to the advanced age of the donors, the bone might have been harder than in younger individuals, who are the most commonly treated patients in orthodontic

practice. Additionally, it has to be noticed that pre-drilling is recommended in adult patients, and the present investigation further underlines the necessity of this recommendation.

Full-arch 3D-printed tooth-supported guides have been described as successful and useful devices, and they are supposed to provide good anchorage and stability during mini-implant insertion [27] insertion. However, if braces are in place, the insertion of rigid full-arch guides can be challenging [25]. Therefore, skeletonized insertion guides can be a valid alternative in these cases. Moreover, they provide the advantage of a visual check of the palate during the insertion procedure. However, the insertion kit utilized in this study has been improved in the meantime with the introduction of vertical stops. A problem faced during the study was the reduced stability of skeletonized insertion guides where occlusal planes were flat or abraded. This might be due to the age of the donors, while it is unlikely to occur in young patients that represent the main target of this treatment. However, the exact age of the donors was not provided due to anonymization; therefore, this information could not be retrieved. Cuspidal coverage might be considered in some cases to improve the retention of the guide and the reproducibility of its insertion.

Although ex vivo cadaver models have their own limitations, fresh frozen specimens highly mimic the human clinical situation. Another limitation of the present study consisted of the insertion of several mini-implants in each palate, as well as in uncommon clinical positions and in areas with reduced bone thickness. This strategy was chosen to reduce the number of donors needed, despite the fact that it may not accurately represent typical clinical scenarios and limit the generalizability of the results. For the same reason, the mini-implants were placed very close to each other compared to the common clinical conditions. These two factors might have been responsible for the introduction of errors at this stage since a marked deviation in the insertion of one implant could have compromised the correct placement in neighboring sites. For instance, implant tipping leading to the undesired contact of two mini-implants was observed in the paramedian region, which is frequently characterized by a reduced thickness of the bone.

To reduce the error related to CBCT metal artefacts, STL datasets from the original mini-implant STLs were superimposed; thus, minor matching errors might have been generated at this stage. Indeed, the computer-based workflow was very extensive, since all datasets had to be registered, including the original implant without artefacts.

5. Conclusions

In conclusion, a high deviation between the planned and real positions of the mini-implants was found. This might partially be explained by the high number and proximity of implants per cadaver, as well as the high amounts of tooth abrasions. Therefore, it is likely that lower deviations would be found in clinical practice, especially after the introduction of vertical stops.

Future studies are needed in order to improve skeletonized guides for patients with high degrees of tooth abrasion. Indeed, the stability issues encountered with the skeletonized insertion guides in cases with flat or abraded occlusal planes highlight the importance of a correct patient evaluation and of optimized design of the guides. Furthermore, well-designed clinical studies are needed in order to assess the accuracy of different guided insertion protocols within in vivo settings. However, in order to avoid overexposing the patients to radiation, and if the reliability of the latter can be verified, CBCTs might be replaced by intraoral scans.

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