Aus der Poliklinik für Kieferorthopädie

der Heinrich-Heine-Universität Düsseldorf

Direktor: Univ.-Prof. Dr. Dr. Collin Jacobs

How accurately can the position of orthodontic mini-implants be captured using a 3D scanner and does the insertion angle affect the accuracy?

Dissertation

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Till Augustinowitz

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Dekan: Prof. Dr. med. Nikolaj Klöcker

Erstgutachterin: Univ.-Prof. Dr. med. dent. Kathrin Becker, M.Sc.

Zweitgutachterin: Univ.-Prof. Dr. phil. nat. Charlotte von Gall

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Zusammenfassung

Kieferorthopädische Mini-Implantate werden häufig zur skelettalen Verankerung verwendet und in den anterioren Gaumen inseriert. Zur Herstellung einer skelettal verankerten kieferorthopädischen Apparatur kann die Position der Mini-Implantate durch eine Silikonabformung oder einen Intraoralscan erfasst werden. Eine dritte Möglichkeit ist die voll digitale Planung, hier wird ihre Position mithilfe eines Insertionsguides direkt aus der Planung übernommen.
Ziel dieser Studie war es, die Genauigkeit dieser drei Techniken zu untersuchen und festzustellen, ob der Insertionswinkel einen Einfluss auf die Genauigkeit hat.
Je zwei Mini-Implantate wurden digital geplant und mit einem zahngetragenen Insertionsguide in den vorderen Gaumen von 11 Humanpräparaten mit unterschiedlichen Insertionswinkeln (0°, 5°, 10°, 15°, 20°, 25°, 30° zur Okklusionsebene) inseriert. Anschließend wurde die Position jedes Mini-Implantats durch eine Digitale Volumentomographie (DVT), einen Intraoralscan und eine Silikonabformung erfasst. Die Position der Mini-Implantate im DVT wurde als "reale Position" festgelegt.
Die Genauigkeitsmessungen erfolgten zwischen den DVT-Daten als Referenz und der Position der Mini-Implantate aus der digitalen Planung, dem Intraoralscan und dem Gipsmodell, das aus der Silikonabformung hergestellt wurde. Die Abweichungen wurden am Implantkopf (*Top*), am *Apex* und hinsichtlich der Angulation gemessen.
21 Mini-Implantate (n=3 pro Insertionswinkel) wurden in die Analyse einbezogen. Die statistische Analyse wurde mit einem gemischten linearen Modell durchgeführt.
Der Intraoralscanner war tendenziell genauer bei der Erfassung der Position des Implantatkopfes und des Apex, jedoch waren die Unterschiede nicht signifikant.
Die geringste anguläre Abweichung wurde bei der digitalen Planung festgestellt.
Der Insertionswinkel hatte insgesamt keinen signifikanten Einfluss auf die Genauigkeit.
Bei allen Methoden traten kleine Abweichungen auf, dennoch scheint die voll digitale Planung aufgrund des vereinfachten Workflows vorteilhaft zu sein.
Trotz Limitation einer Kadaverstudie scheinen alle Methoden für den klinischen Einsatz geeignet zu sein.

Summary

Orthodontic mini-implants (OMIs) are often used for temporary skeletal anchorage and are typically inserted in the anterior palate. For the fabrication of an orthodontic mini-implant-borne appliance, the position of the OMIs can be detected by a silicone impression or an intraoral scan (IOS). A third possibility is full digital planning; in this case, the position of the OMIs is transferred directly from the digital planning using an insertion guide.

This study aimed to investigate the accuracy of these three techniques and to evaluate whether a correlation exists between the insertion angle and the accuracy of each technique.

Two mini-implants were digitally planned and placed in the anterior palate of 11 human cadavers, each with different insertion angles (0°, 5°, 10°, 15°, 20°, 25°, 30° to the occlusal plane) using a tooth-borne insertion-guide. Subsequently, the position of each OMI was determined by cone-beam computed tomography (CBCT), an IOS and a silicone impression. The position of the OMIs in the CBCT was defined as "real position".

The measurements of the accuracy were performed between the CBCT data as a reference and the positions of the OMIs from the preoperative digital planning, the IOS and the plaster model, manufactured from the silicone impression. The deviations were measured at the *Top* (implant head), *Apex* and with regard to angulation.

Twenty-one mini-implants (n=3 per insertion angle) were included in the analysis. Statistical analysis was performed using a mixed linear model.

The IOS tended to be more accurate in detecting the position of the *Top* and the *Apex* of the OMIs, although the differences were not significant.

The smallest angular deviation was found in digital planning.

The insertion angle had no overall significant influence on the accuracy of position detection.

All methods were subject to small deviations. However, full digital planning appeared to be advantageous due to the simplified workflow.

Within the limitations of a cadaver study, all methods appear to be suitable for clinical use.

List of Abbreviations

AI	Artificial Intelligence
CAD	Computer-Aided Design
CAM	Computer-Aided Manufacturing
CBCT	Cone-Beam Computer Tomography
DICOM	Digital Imaging and Communications in Medicine
FOV	Field of view
IOS	Intraoral scan
OMI	Orthodontic mini-implant
SLM	Selective Laser Melting
STL	Standard Transformation Language

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1 Introduction

1.1. Orthodontic mini-implants

In orthodontics, “to anchor” means to hold or resist the movement of an object and “anchorage” refers to the act of gaining that hold. [1] Orthodontic anchorage is defined as the ability to resist unwanted reactive tooth movements although orthodontic forces are applied. Effective anchorage is crucial for achieving desired tooth movements, especially in complex cases involving space closure, molar distalization, or correction of skeletal discrepancies. [2]

Orthodontic anchorage is typically achieved by using a tooth or a group of teeth to move malpositioned teeth while avoiding unwanted movements of other teeth. Intraoral anchoring aids include intramaxillary transpalatal archs, lingual archs, quadhelix or intermaxillary elastic bands and forsus springs.

When using teeth as anchorage, there is a higher risk of anchorage loss. Anchorage loss is a reciprocal reaction that can impede the success of orthodontic treatment by complicating the anteroposterior correction of malocclusion. Furthermore, anchorage loss is characterized by the movement of the anchor teeth instead of the active unit. [3]

Goldmann and Gianelly introduced in 1971, in their publication *Biologic Basis of Orthodontics* [4], a foundational classification system for orthodontic anchorage. Their framework categorizes orthodontic anchorage in three primary groups:

1. Minimum anchorage: this approach permits significant movement of the anchor unit; the anchoring unit and the active unit move to the same extent.
2. Moderate anchorage: in this category, there is a balanced movement between the anchor unit and the active unit; the active unit moves more than the anchoring unit.
3. Maximum anchorage: this approach aims to minimize movement of the anchor unit, thereby allowing for the desired movement of the active unit. Here, only the active unit moves, not the anchoring unit. [4]

Since the ideal anchoring unit would be a fixed base, the idea of skeletal anchorage was introduced.

Primarily, skeletal anchorage was described by placing an additional anchorage unit in the mouth that could be loaded with a force. This force should only exert movement on the tooth to be moved and not on the anchoring unit. Endosseous osseointegrated implants were first used for this purpose, as these were established in implant and prosthetic dentistry with the first description of osseointegration by Brånemark. [3, 5-7]

For the first time, Block et al. described in an animal study the palatal bone as an insertion site for their "onplant" device, which could be connected to the teeth after integration. It was intended to demonstrate the possibility of unilateral tooth movement and its use to anchor the molars for anterior retraction. [8]

The palate as an insertion site was further explored by Wehrbein et al. who used the *Orthosystem* (Institute Straumann, Waldenburg, Switzerland), which consisted of endosseous orthodontic implants with a diameter of 3.3 mm and a length between 4 and 6 mm. The intraosseous surface was sandblasted and acid-etched (SLA), while the transmucosal part was polished smooth. Clamp-caps enabled the fixation of conventional square stainless steel orthodontic wires to the abutment components. A hollow explantation drill was used to remove the implant, leaving a bone cavity, which was then covered with an acrylic plate. [9]

Orthodontic mini-implants (OMIs) were developed in the late 1990s and were inspired by fixation screws used in maxillofacial surgery. Kanomi showed in 1997 that an OMI with a 1.2 mm diameter could resist orthodontic forces. The intraosseous surface was machined and it could be loaded with orthodontic force without requiring a long healing period. [10]

After that, OMIs gained increased popularity, especially in the United States, where many different systems were introduced. [11]

In general terms, an OMI consists of three parts: neck, head, screw (**Figure 1**). The head is the accessible part of the OMI which extends into the oral cavity. It has a special interface designed for a mini-screw driver to facilitate the insertion. This part varies significantly between manufacturers. The neck or transmucosal part passes through the mucosa. This part is very sensitive, as it represents the entry site for microorganisms and could lead to local mucosal inflammation, possibly resulting in implant loosening or loss. The screw provides mechanical retention in the bone, which serves as the basis for the stability of the OMIs. With most manufacturers, the threads have a cutting edge that facilitates insertion.

The amount of torque required for inserting an OMI and thus its primary stability, is determined by bone quality, OMI design and insertion modalities. [12-15]

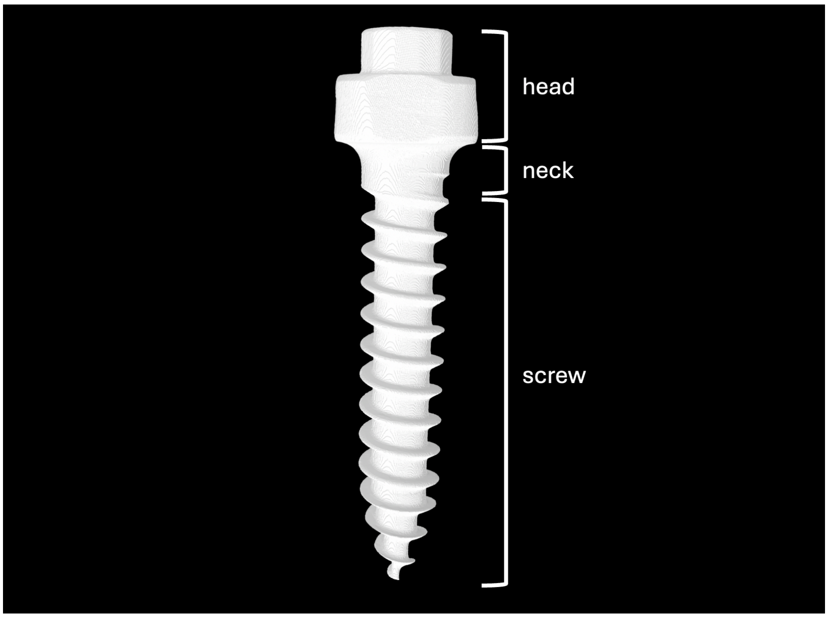

Figure 1. *Structure of an OMI* characterized by head, neck and screw.

In 2008 Wilmes and Drescher introduced the Benefit® mini-implant system with interchangeable abutments, making the use of OMIs more convenient. A simple workflow was described. Briefly, after insertion of the OMIs, impression caps can be positioned on the head, with the OMIs subsequently being replaced on the plaster model by laboratory analogs. A variety of appliances can then be fabricated on the plaster model, eliminating the need for direct intraoral construction. This extended the range of treatment options involving skeletal anchorage. Furthermore, the insertion and removal of OMIs can be performed using only topical anesthetics and loading forces can be applied immediately after insertion. [16]
The described Benefit® OMIs were used for this dissertation.
Since then, the anterior palate has become the preferred insertion site due to high bone thickness and quality as well as relatively low rates of instability and failure. Moreover, the attached mucosa has a better prognosis compared to other areas and the risk of tooth damage is lower. [17-19]

Nevertheless, the vestibulum is also a possible site for OMI insertion, particularly due to its easy access. However, the limited space between adjacent roots poses a challenge. The main risks consist in damaging the roots, screw failure due to contact between OMI and root, screw fracture resulting from the narrower OMI dimension needed for the interradicular insertion. Considering this, interradicular OMI placement can exhibit a failure rate of up to 25%. [20, 21]

1.1.1 Anatomy of the anterior palate

The anterior palate as part of the hard palate (*palatum durum)* forms the roof of the oral cavity. Structurally, it consists of the palatal plates of the maxilla (*processus palatinus maxillae*), which are connected by a sagittal suture (*sutura palatina mediana*). The *foramen incisivum* is also located here as the joint exit of the two *canales incisivi*, which run obliquely from the nasal cavity through the palate. The mucosa of the anterior palate consists of a keratinized stratified squamous epithelium. As a regional functional morphological feature, the hard palate has three to four transverse folds (*plicae palatinae transversae*) in the anterior part, which serve as a friction surface for the tongue. The number of mucosal glands (*glandulae palatinae*) increases toward the posterior. The hard palate is innervated by the greater palatine nerve and the nasopalatine nerve. The blood supply is provided by the major palatine arteries and the nasopalatine artery. [22]

1.1.2 The anterior palate as favorable OMI insertion site

Wilmes et al. proposed five key strategies for successful OMI retention:

1. Select the optimal insertion site.
2. Avoid direct root contact with the OMI.
3. Avoid placing an OMI within the intended path of tooth movements.
4. Use tandem implants to prevent tipping and rotational tendencies due to force couples.
5. Use implants with sufficient length and diameter. [23]

Combining these strategies with further requirements - such as insertion into attached gingiva with minimal soft tissue, at least half of the OMI incorporated

by cortical bone and accessibility of the OMI head - makes the anterior palate an ideal insertion site. [24]
Taking these requirements into account, the failure rate of OMIs in the anterior palate amounts to 2.1%. [25] This is considerably lower compared to interradicularly placed OMIs. One reason for this was considered to be that two OMIs are coupled in the anterior palate and in general are connected with a rigid appliance, whereas interradicular OMIs are usually loaded alone and directly. [26]
The most important factor influencing the success of OMI insertion is the quantity of surrounding bone. The anterior palate is the most established insertion site for skeletal anchorage and a consistent bone level in this area is confirmed by several radiological studies. [24, 27-29]
More specifically, the bone level of the palate decreases laterally and posteriorly. [30] Becker et al. defined this region even more precisely noting that paramedian bone support is best lateral to the first premolar and extends to the second premolar for median insertions. [31]
Besides the surrounding bone, soft tissue thickness also plays an important role in OMI stability. Thin and keratinized soft tissue is more advantageous because the risk of inflammation is lower. [32] Furthermore, maximum OMI retention and therefore primary stability is achieved by selecting areas with thick cortical bone and thin soft tissue. [33]
Costa et al. demonstrated that soft tissue thickness in the premaxillary region increases towards the median and anterior area. They also concluded that only a small number of 6 or 8 mm OMIs achieved bicortical insertion, whereas about 40% of 10 mm OMIs did. [34] Interestingly, the midpalatal suture presents a special characteristic, as the palatal mucosa remains uniformly 1 mm thick posterior to the incisive papilla. [35]
Additionally, the risk of interference with anatomical structures like roots and the incisal canal is higher near the incisors and anterior to the third palatal ruga. [36]
As a result of these anatomical and clinical considerations, the ideal insertion site in the anterior palate is the so-called “T-Zone” which begins immediately posterior to the third palatal ruga and extends along the *sutura palatina mediana* towards the posterior. [23] **(Figure 2)**
Those guidelines were followed in this dissertation.

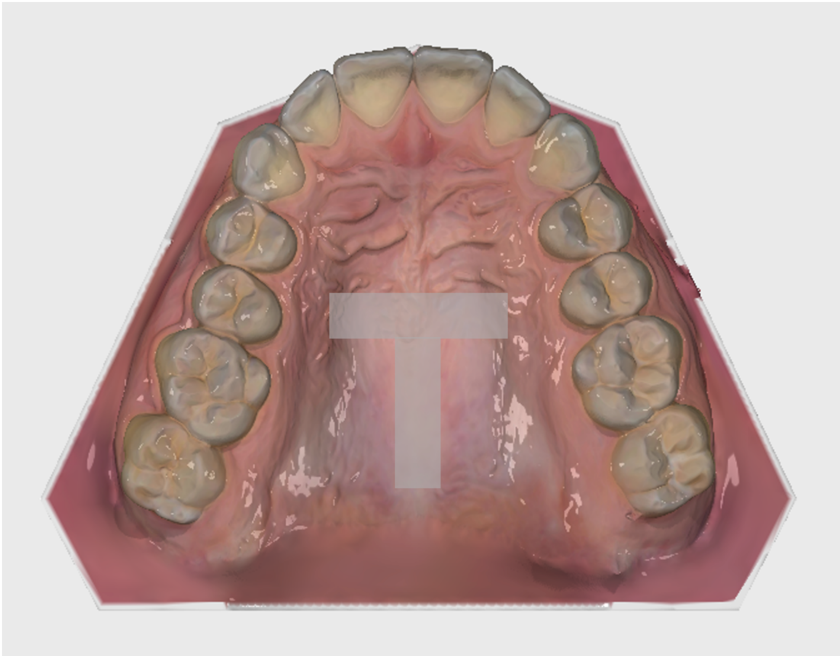

Figure 2. *Localization of the T-Zone in the anterior palate.*

1.1.3 The insertion angle of OMIs in the anterior palate

There is a wide range of recommendations regarding the ideal insertion angle for OMIs placed in the anterior palate. The main difference among these specifications is whether they refer to the curvature of the bony palate or to the occlusal plane.

It has been demonstrated that the insertion angle has a significant impact on primary stability. [37] However, the information on an ideal insertion angle is diverse and partly unspecific, as the anterior palate should be evaluated individually. [38]

Becker et al investigated the anterior palate in more detail. In addition to the previously mentioned bone support, implications for the insertion angle were also given. They revealed that the insertion angle is only clinically relevant when placing OMIs at the most posterior or anterior position of the T-Zone. For posterior insertion sites anterior tipping is advantageous (e.g. -30° to the palatal curvature), while for anterior insertion sites posterior tipping (e.g. 30° to 20° to the palatal curvature) resulted advantageous. [31]

1.1.4 Appliances for OMIs in the anterior palate

The following orthodontic appliances are some of the most commonly used palatally OMI-borne appliances.

Beneslider

The Beneslider was invented to provide distal movement of maxillary molars, particularly in patients with a Class II occlusion combined with anterior crowding or an increased overjet, while avoiding the negative side effect of anchorage loss. For this, two OMIs in the anterior palate are connected with a Beneplate or an abutment on which a stainless steel wire is laser-welded and used as a sliding mechanic as a rail. The molar bands or bonded tubes on the first molars are connected via sliding tubes to the sliding mechanic. To activate the Beneslider, NiTi coil springs are used to provide consistent and controlled forces for bodily distal tooth movement. [39, 40]

This design allows nearly bodily distal movement of molars without significant tipping. Distalization distances between 1.2 and 8.5 mm can be achieved. [41]

Recently, the Beneslider can also be produced by metal printing using selective laser melting (SLM). This procedure allows more possibilities for customization. [42]

Mesialslider

The Mesialslider is used in cases of missing teeth in the upper jaw, for example through congenital absence of lateral incisors, second premolars, teeth lost due to trauma or extremely displaced canines that cannot be orthodontically aligned. In such cases, orthodontic space closure is a considerable option, because no lifelong prosthetic restoration is needed. A predictable anchorage is crucial for this task.

To ensure this, the Mesialslider is attached to two coupled OMIs in the anterior palate and permits the mesialization of the maxillary teeth. It consists, similar to the Beneslider, in a framework, laser-welded to the coupled OMIs, an adjustable sliding lock with hook, NiTi coil spring and a sliding tube with hook for connection with the molar bands or bonded tubes. The activation of the NiTi coil spring with the sliding lock with hook works as a pull mechanic, thus, it works oppositely to the Beneslider. [43-45]

Hybrid Hyrax

The Hybrid Hyrax is required for treating skeletal crossbites, or in combination with a face mask or Mentoplate for maxillary protraction. Formerly, conventional tooth-borne appliances were used for this task. However, with tooth-borne appliances, the following side effects were observed: buccal tipping of the lateral teeth, risk of recessions and vestibular bone fenestration. To overcome these side effects, a Hybrid Hyrax is connected to paramedian placed OMIs in the anterior palate. A regular split palate screw (e.g. hyrax ® screw, Dentaurum, Ispringen, Germany) is connected by laser welding to the abutments of the two paramedian OMIs and molar bands. Because it is also connected to teeth, in most cases the first molars, it is a bone- and tooth-borne appliance. Additional indications include patients with poor anterior dental anchorage, such as missing deciduous molars or deciduous molars with resorbed roots or immature premolar roots.

Furthermore, a Hybrid Hyrax can be used for Miniscrew-assisted Rapid Palate Expansion (MARPE). It can be applied to expand the maxilla in adolescents and young adults without the need for Surgical-Assisted Rapid Palate Expansion (SARPE) due to its direct skeletal effect. [46-48]

When using a Hybrid Hyrax for maxillary protraction, it prevents mesial migration of the dentition by providing stable skeletal anchorage through the OMIs. [49-51]

Mousetrap / Molar intrusion device

Molar intrusion is needed in cases of overerupted upper molars due to missing lower antagonists or anterior open bite malocclusion.

Former appliances operated with miniplates or OMIs placed in the infrazygomatic area or OMIs placed interradicularly in the alveolar process. [52-54] Those regions are unfavorable due to higher failure rates, higher risk of damaging roots or anatomical structure (e.g. the sinus). [55-58]

Using OMIs placed in the anterior palate provides a safer and more stable alternative. For this purpose, the Mousetrap device was developed.

This appliance is anchored with two OMIs connected to a Beneplate in the anterior palate. Lever arms extending from the Beneplate are directed posteriorly toward the molar region. In their passive state, the distal ends of these lever arms are positioned cranially to the molar's center of resistance. When a downward force is applied to the lever arm and it is connected to the molar, a consistent intrusive force is generated. For the intrusion of a single molar, an intrusive force of approximately 100 g is considered sufficient. However, in cases of anterior open bite, where multiple teeth require intrusion, a greater magnitude of force can be necessary to achieve the desired tooth movements.

1.2 Impact of digitization in orthodontics on OMIs

Orthodontics is rapidly evolving with the advent of digital technologies. The digitization of orthodontics has revolutionized diagnosis, treatment planning, and appliance fabrication, leading to more efficient and precise therapeutic outcomes. OMIs have significantly benefited from digital technologies, especially in placement planning and integration with other digital tools. Central to these advancements are Computer-Aided Design and Computer-Aided Manufacturing (CAD/CAM) systems, IOS and their integration with OMIs. These tools enable a technological advancement of orthodontic appliances and treatment. [59]

1.2.1 The use of IOS in orthodontics

IOS has replaced traditional impressions to a large extent by providing a digital representation of the dental arch and its surrounding structures in real-time, enhancing both the accuracy and comfort of the impression process. [60]
IOS can offer significant advantages, such as reduced patient discomfort, time efficiency, simplification of clinical procedures and the benefit of capturing and storing highly accurate information. [61]
One of the primary applications of IOS in orthodontics is the creation of digital dental models for diagnostic evaluation, treatment planning and simulation. It is possible to perform precise measurements, analyze occlusal relationships and create virtual setups to visualize and plan tooth or jaw movement. Additionally, IOS data can be integrated into CAD/CAM workflows, for example to perform indirect bonding, digitally fabricated fixed orthodontic appliances or aligner planning. [62, 63]
As a result, orthodontists can create highly precise dental models for further analysis and customized appliance fabrication.

1.2.2 Guided insertion of OMIs

Conventionally, OMIs were inserted freehand, and an impression was taken with silicone. An orthodontic appliance was manufactured thereafter in the laboratory on a plaster model.

The idea of using insertion guides for OMI placement emerged in 2009 with the introduction of stents. The main advantage was seen in the accurate placement of OMIs regarding root proximity, placement in attached gingiva or alveolar mucosa and angulation. [64, 65]

With the advent of digital techniques, the use of guided insertion changed. Due to the availability of IOS and lateral cephalogram or CBCT, the digital planning of OMI positions was possible by superimposing those data. Using this procedure, it is ensured that OMIs are placed at the correct depth, parallelly and with good access for fixing an orthodontic appliance.

To transfer the digitally planned position of the OMI into the patient´s mouth, an insertion guide is commonly 3D printed in resin. Using this procedure, the orthodontist is at reduced risk of damaging anatomical structures, such as incisor roots, and patient discomfort can also be decreased. [66, 67]

Additionally, guided insertion enables a single appointment workflow. In this approach, the OMIs are digitally planned as previously described and the orthodontic appliance is fabricated in advance – either on a 3D printed resin model or via metal printing. As a consequence, the insertion guide and the orthodontic appliance are prefabricated before the insertion of the OMIs in the anterior palate. This workflow allows the insertion of both the OMIs and the orthodontic appliance in a single office visit. [68, 69]

1.2.2 The use of CAD/CAM for orthodontic appliances

CAD/CAM technologies in orthodontics were primarily used for the fabrication of occlusal splints, aligners or customized lingual brackets. [70, 71]

Graf et al. presented in 2017 a digital workflow to produce a fixed orthodontic hyrax appliance. [72] An IOS of the lower and upper jaw was performed and the hyrax was digitally designed. Conventional molar bands were replaced with 3D-printed clasps to provide a full digital procedure. A prefabricated expansion screw was inserted digitally into the appliance design.

The final digital design of the hyrax appliance was 3D-printed using selective laser-melting. After postprocessing, the expansion screw was welded into place. This procedure eliminates the need for conventional impressions and their associated disadvantages, for example gag reflex, patient discomfort or dimensional changes of impression material. Furthermore, by eliminating molar bands, the two additional appointments required for tooth separation can also be avoided. [72]

Other advantages are the freedom in design, the overcoming of limitations regarding the technician´s ability to bend wires and the possibility of excellent communication between the orthodontist and the laboratory. Moreover, the digital design is - once a certain level of experience is reached - not as time consuming as fabricating and bending appliances on a plaster model. After a specific design for an appliance is generated, it can be saved as a basic structure in a library. As a consequence, only minor adjustments for each individual appliance are necessary. Besides, there are also benefits for the patients, e.g. reduction in chair time owing to fewer appointments, comfort related to the use of IOS, less pressure due to the absence of interdental components and passive fit. [73]

CAD/CAM fabrication of appliances was also used for OMI-borne appliances.

The first digital process to custom-fabricate a metal-printed OMI-supported orthodontic appliance consisted in a two-appointment workflow. At the first appointment, the OMIs were inserted into the palate and recorded with an IOS. Subsequently, the orthodontic appliance was digitally designed and 3D metal printed via laser melting. At the second appointment, the appliance was fixed on the OMIs. [74]

Both the OMIs and the appliance can be planned digitally using eligible software (e.g. OnyxCeph, Exocad). The insertion guide can be 3D-printed in resin in the orthodontic office and the appliance can be sent to a commercial laboratory for metal printing. [75]

1.3 Ethical approval

The study was approved under IRB no: 2018-130_2 by the Ethics Committee of the University Hospital Düsseldorf.

1.4 Aims of Thesis

The present study aimed to:

1. investigate the accuracy of an IOS in comparison to a conventional silicone impression for capturing the position of OMIs placed in the anterior palate of eleven human cadavers;
2. assess the validity of a tooth-borne insertion guide to insert the OMIs and the orthodontic appliance in a single appointment;
3. evaluate whether the insertion angle of the OMIs influences the accuracy of the methods mentioned above and identify an insertion angle that yields the highest accuracy.

2 Augustinowitz, T., Schiavon, L., Mücke, K., Schwarz-Herzke, B., Drescher, D., Brunello,G., Becker, K. "Is simultaneous placement of orthodontic mini-implants and skeletally anchored appliances advisable? CBCT-based cadaver study comparing the accuracy of the digital workflow with methods requiring two visits", Journal of Orofacial Orthopedics., 2025

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ORIGINAL ARTICLE

Is simultaneous placement of orthodontic mini-implants and skeletally anchored appliances advisable?

CBCT-based cadaver study comparing the accuracy of the digital workflow with methods requiring two visits

Till Augustinowitz[1] · Lucia Schiavon[2,3] · Katharina Mücke[1,4] · Beryl Schwarz-Herzke[5] · Dieter Drescher[1] · Giulia Brunello[3,4,6] · Kathrin Becker[4]

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Abstract

Purpose For the fabrication of an orthodontic mini-implant (OMI)-borne appliance, the position of the inserted OMI can be detected by a silicone impression or an intraoral scan (IOS). In case of digital planning, it can be taken over from the planning and the appliance can be produced in advance. This study aimed to evaluate the accuracy of these three techniques and whether there is an association with the insertion angle.

Methods Two OMIs were digitally planned and placed in the anterior palate of 11 human cadavers with different insertion angles. Subsequently, the position of each OMI was detected by an IOS, a silicone impression, and a cone-beam computed tomography (CBCT) scan, whereby the CBCT scan was set as "real position". The measurements of accuracy were performed between the CBCT data as a reference and the preoperative digital planning, the IOS and the plaster model manufactured from the silicone impression.

Results The IOS was the most accurate in detecting the Top (mean deviation 0.14 mm) and the Apex (mean deviation 0.36 mm) of the OMIs. Significant linear deviations between the three modalities were registered for both Top ($p < 0.001$) and Apex ($p = 0.010$). The digital planning procedure achieved the lowest mean angular deviation of 3.7° and was significantly more accurate in this respect than the IOS ($p < 0.001$).

The authors Giulia Brunello and Kathrin Becker share the senior authorship.

Till Augustinowitz
till.augustinowitz@hhu.de

Lucia Schiavon
lucia.schiavon@zzm.uzh.ch

Katharina Mücke
katharina.muecke@med.uni-duesseldorf.de

Beryl Schwarz-Herzke
beryl.schwarz-herzke@med.uni-duesseldorf.de

Dieter Drescher
d.drescher@uni-duesseldorf.de

Giulia Brunello
giulia.brunello@med.uni-duesseldorf.de

✉ Prof. Dr. Kathrin Becker
kathrin.becker@charite.de

1 Department of Orthodontics, University Hospital Düsseldorf, Moorenstraße 5, 40225 Düsseldorf, Germany

2 Clinic of Reconstructive Dentistry, Center for Dental Medicine, University Zurich, Plattenstrasse 11, 8032 Zurich, Switzerland

3 Department of Neurosciences, Dentistry Section, University of Padua, Via Giustiniani 2, 35128 Padua, Italy

4 Department of Orthodontics and Dentofacial Orthopedics, Charité – Universitätsmedizin Berlin, corporate member of Freie Universität Berlin and Humboldt-Universität zu Berlin, Aßmannshauser Straße 4–6, 14197 Berlin, Germany

5 Institute of Anatomy II, Medical Faculty, Heinrich Heine University, Universitätsstraße 1, 40225 Düsseldorf, Germany

6 Department of Oral Surgery, University Hospital Düsseldorf, Moorenstraße 5, 40225 Düsseldorf, Germany

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Conclusion All methods were subject to small, but clinically irrelevant deviations. Within the limitations of a cadaver study, all methods appear to be suitable for clinical use. However, the digital workflow could be advantageous, requiring only a single visit for OMI placement and simultaneous appliance fitting.

Keywords Orthodontic anchorage procedures · Digital workflow · Ex vivo study · Optical impression · Cone-beam computed tomography

Ist die gleichzeitige Platzierung von kieferorthopädischen Mini-Implantaten und skelettal verankerten Apparaturen ratsam?

DVT-Kadaverstudie zur Genauigkeit des digitalen Workflows im Vergleich mit zweizeitigen Methoden

Zusammenfassung

Zielsetzung Zur Herstellung einer auf Mini-Implantaten befestigten kieferorthopädischen Apparatur kann die Position der Mini-Implantate durch einen Silikonabdruck oder einen Intraoralscan erfasst werden. Bei einer digitalen Planung kann sie aus der Planung übernommen und die Apparatur anhand dieser Planung hergestellt werden. Ziel dieser Studie war es, die Genauigkeit dieser 3 Techniken zu vergleichen und festzustellen, ob es einen Zusammenhang mit dem Insertionswinkel gibt.

Methoden Zwei Mini-Implantate wurden digital geplant und in den vorderen Gaumen von 11 Humanpräparaten mit unterschiedlichen Insertionswinkeln eingesetzt. Anschließend wurde die Position jedes Mini-Implantats durch einen Intraoralscan, einen Silikonabdruck und eine DVT(digitale Volumentomographie)-Aufnahme ermittelt. Die Position in der DVT wurde als „reale Position" festgelegt. Die Genauigkeitsmessungen wurden zwischen den DVT-Daten als Referenz und der digitalen Planung, dem Intraoralscan und dem aus dem Silikonabdruck hergestellten Gipsmodell durchgeführt.

Ergebnisse Der Intraoralscan erwies sich als am genauesten bei der Erkennung des Kopfes (mittlere Abweichung: 0,14 mm) und des Apex (mittlere Abweichung: 0,36 mm) der Mini-Implantate. Signifikante lineare Abweichungen zwischen den 3 Techniken wurden sowohl für den Kopf ($p < 0{,}001$) als auch für den Apex ($p = 0{,}010$) festgestellt. Die digitale Planung erzielte die geringste mittlere Angulationsabweichung von 3,7° und war diesbezüglich signifikant genauer als der Intraoralscan ($p < 0{,}001$).

Schlussfolgerungen Bei allen Methoden traten kleine, aber klinisch irrelevante Abweichungen auf. Mit den Einschränkungen einer Kadaverstudie scheinen alle Methoden für den klinischen Einsatz geeignet zu sein. Die komplett digitale Planung könnte jedoch vorteilhaft sein, da nur ein einziger Termin für das Inserieren der Mini-Implantate und das Einsetzen der Apparatur notwendig ist.

Schlüsselwörter Kieferorthopädische Verankerungsverfahren · Digitaler Workflow · Ex-vivo-Studie · Optischer Abdruck · Digitale Volumentomographie

Introduction

Orthodontic mini-implants (OMIs) have gained increasing popularity as a tool for skeletal anchorage of orthodontic appliances due to their ease of use, minimally invasive insertion, and the reduced need for patient compliance. Furthermore, they allow the insertion of a variety of appliances with good control of three-dimensional (3D) tooth movements [1, 2].

One of the most utilized sites for OMI insertion is the anterior palate, especially in the T-zone located immediately posterior to the palatal rugae. Indeed, this zone is characterized by good bone thickness and a limited risk of interference with teeth and other relevant structures [3].

OMI-supported appliances are conventionally manufactured on a plaster model obtained from a silicone impression [4]. More recently, digital technologies have revolutionized the fabrication of these appliances. The position of the OMIs can be obtained with an intraoral scanner (IOS) and the appliances can be digitally designed and produced using additive manufacturing, such as laser melting printing. Afterwards, the orthodontic appliance is placed in a second appointment [5].

In addition, the OMI position can be digitally planned for guided insertion based on a 3D model of the upper jaw, as an alternative to freehand insertion, and it is possible to design the orthodontic appliance directly at the same time. This approach permits appliance placement immediately after OMI insertion in a single appointment [6, 7]. However, the fitting of this appliance largely depends on the accuracy of OMI placement.

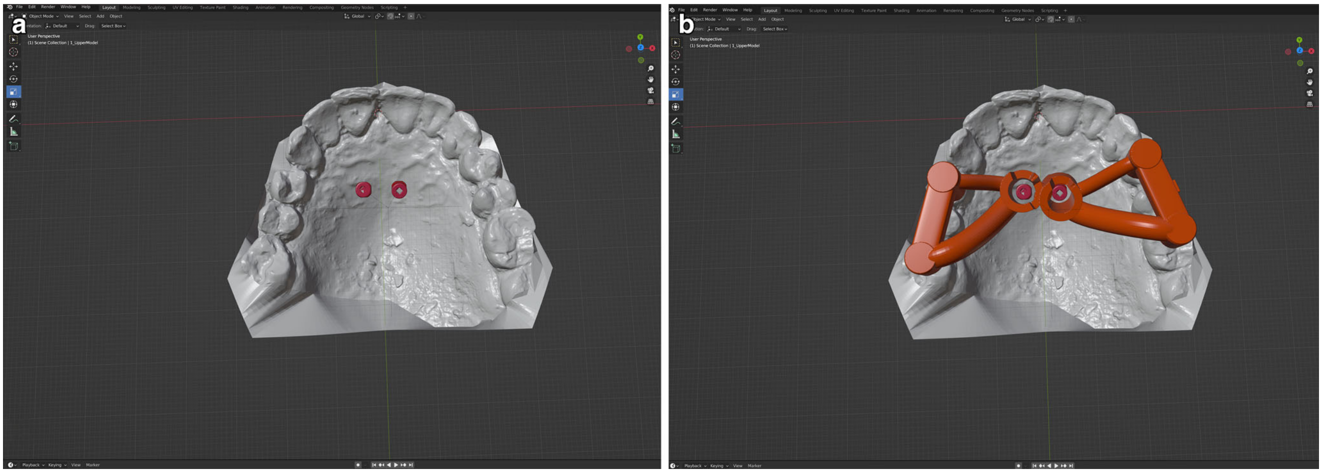

Fig. 1 Digital planning: **a** the orthodontic mini-implants (*OMIs*) were planned with insertion angles between 0 and 30° to the occlusal plane; **b** design of an OMI insertion guide

Abb. 1 Digitale Planung: **a** Die kieferorthopädischen Mini-Implantate wurden mit Insertionswinkeln zwischen 0 und 30° zur Okklusionsebene geplant; **b** Design eines Insertions-Guides für kieferorthopädische Mini-Implantate

Therefore, the primary aim of this study on human frozen maxillae was to investigate the accuracy of OMIs placed paramedian in the anterior palate using digitally planned tooth-borne guides and to compare it with the accuracy of OMI detection by means of a subsequent IOS or conventional silicone impression.

The secondary aim was to examine whether the insertion angle of the OMIs had an influence on the accuracy of the three methods mentioned above (i.e., IOS, silicone impression, and digital planning) since in implant dentistry the implant angle does not seem to affect the accuracy when IOS is utilized [8].

Materials and methods

Preparation of the human cadaver

Eleven frozen heads of human cadavers were utilized. To improve the working field at the anterior palate, the mandible, the tongue, and the calvaria up to the orbits were removed.

In cases of insufficient residual dentition, the maxillary dentition in the premolar and molar region was restored using a resin-based restoration fixed to the maxilla with lateral fixation pins (Art. No. 010.6124, Institut Straumann AG, Basel, Switzerland) to provide sufficient support for a tooth-borne OMI insertion guide. To this aim, a cone-beam computed tomography (CBCT) scan (Orthophos SL 3D, Dentsply Sirona, York, PA, USA) and an IOS (TRIOS 3, 3Shape, Copenhagen, Denmark) were taken. The resin base of the restoration was designed with coDiagnostiX® (DentalWings, Institut Straumann AG) and then 3D-printed. Subsequently, the dental arch was set up on the base using resin teeth. Representative images of a resin-based restoration are provided in Suppl. Fig. 1.

Digital planning of the OMI position and production of the insertion guides

For each sample, two OMIs (2 × 9 mm, BENEfit® System, PSM Medical GmbH, Gunningen, Germany) were digitally planned on a maxillary IOS (TRIOS 3, 3Shape). In the samples that had received a resin-based restoration, a new IOS was taken after fixation of the prosthesis for OMI planning.

The OMIs were planned at insertion angles between 0 and 30° to the occlusal plane in the paramedian area of the anterior palate in the anterior part of the T-zone using the software Blender (Blender Foundation, Amsterdam, The Netherlands; Fig. 1).

An insertion guide was designed and 3D printed in resin (Surgical Guide Resin, Formlabs Inc., Sommerville, MA, USA) using an SLA printer (Form 3, Formlabs Inc.). A total of 22 OMIs were planned, of which 21 were used for measurements, i.e., 3 OMIs for each insertion angle (0, 5, 10, 15, 20, 25, and 30°). Details of the procedures are provided in Suppl. Table 1. The distribution of the insertion angles was chosen so that two OMIs with the same insertion angle were not inserted in the same sample.

Ex vivo insertion and postoperative capturing

Predrilling was performed with a pilot drill and the OMIs were inserted using a torque-limited handpiece (iSD900, NSK, Tochigi, Japan). The correct insertion depth was guaranteed by a vertical stop on the pilot drill and the insertion

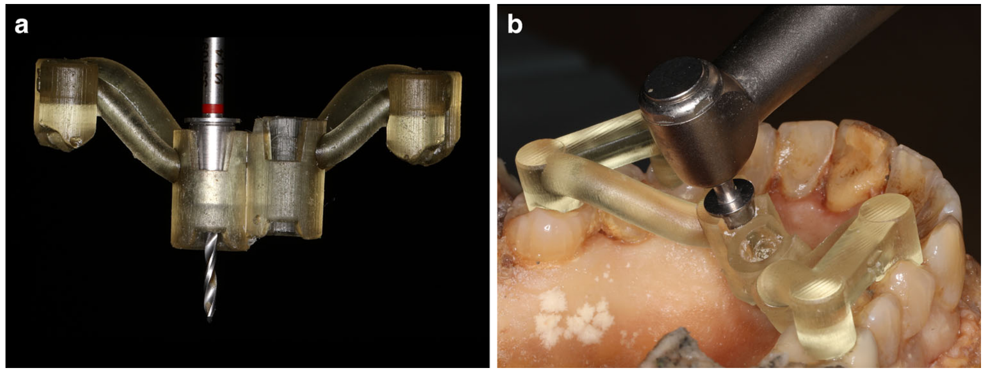

Fig. 2 The pilot drill (**a**) and the insertion tool (**b**) were provided with a vertical stop, allowing the insertion of the orthodontic mini-implant at the desired depth
Abb. 2 Vorbohrer (**a**) und Insertionsinstrument (**b**) wurden mit einem vertikalen Anschlag versehen, der das Inserieren der kieferorthopädischen Mini-Implantate in der gewünschten Tiefe ermöglicht

tool (Fig. 2). A postoperative CBCT was taken using the following acquisition parameters: 85 kV, 12 mA, exposure time 14.4 s, 8 × 8 cm FOV, voxel size 160 µm. The OMI position was recorded three times with an IOS (TRIOS3, 3Shape) without scan bodies. Afterwards, a biphasic silicone impression was taken (Express STD-Putty + Express 2 Light BodyFlow, 3M, St. Paul, MN, USA) with impression caps (BENEfit® System, PSM Medical GmbH). Hard plaster casts were obtained and digitized with a laboratory scanner (E4, 3Shape). A flowchart summarizing the study design is presented in Suppl. Fig. 2.

Accuracy of OMI position detection with IOS and silicone impression

For each sample, the .dicom file from postoperative CBCT and .stl files of the three postoperative IOSs and of the digitized plaster model were imported into OnyxCeph (Image Instruments, Chemnitz, Germany). All measurements were performed by the same operator (T.A.) using a 23.8 inch, Full HD (1920 × 1080), 75 Hz monitor (Acer Vero RL242Y).

Each .stl file (IOSs and digitized plaster model) was aligned to the occlusal plane and matched to the CBCT to evaluate the accuracy of the IOS and silicone impression, as compared to the CBCT scan that was used as a reference to represent the real OMI position. For superimposition, the radiopaque structures of the jaw and the fixation pins of the resin-based restorations were used as reference points without considering the position of the OMIs.

For each CBCT/IOS and CBCT/digitized plaster model evaluation, an .stl file of the OMI provided by the manufacturer was matched to the OMIs and used for measurements. A cone was designed with Blender on the top of each OMI, with its axis corresponding to the vertical axis of the OMI. The vertex of the cone was identified as *Top*. Then, the most apical point of each OMI, along its vertical axis, was determined and referred to as *Apex*. These two points were used for measurements and allowed a line passing through the vertical axis of the OMI to be drawn (Fig. 3).

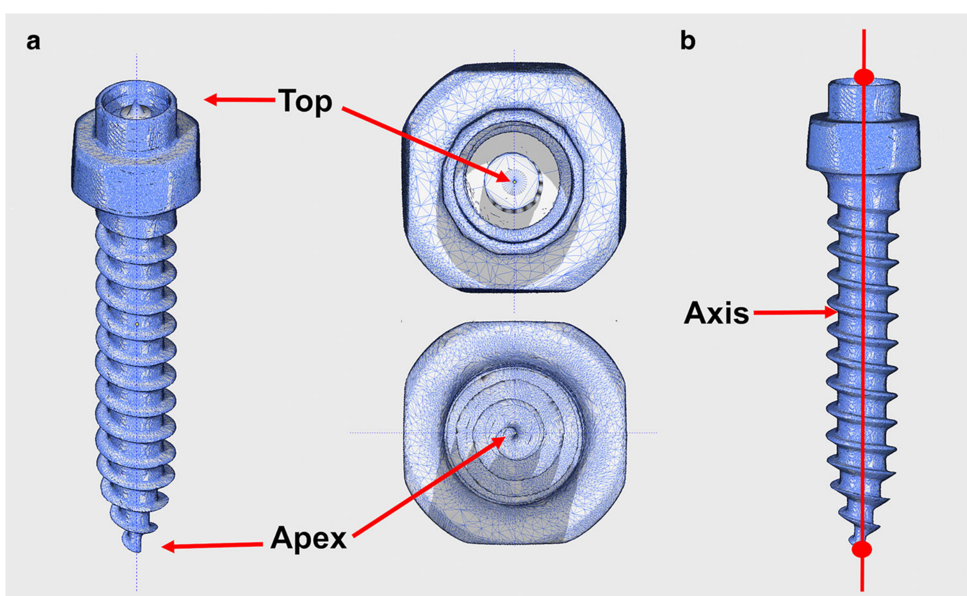

Fig. 3 **a** Identification of the points *Top* and *Apex*. **b** Vertical axis of the orthodontic mini-implant passing through the points *Top* and *Apex*
Abb. 3 **a** Definition der Punkte *Top* und *Apex*. **b** Vertikale Achse der kieferorthopädischen Mini-Implantate, die durch die Punkte *Top* und *Apex* verläuft

For each sample, all three IOSs and the silicone impression were measured separately. The right and left OMIs were also evaluated individually.

The respective distances at the *Top* and *Apex* were measured in mm, representing the discrepancies between the techniques. In addition, the position of the points *Top* and *Apex* was exported as a vector to assess the deviation in a coordinate reference system, allowing the identification of the direction of the deviation in the three axes (i.e., X: transversal; Y: vertical/insertion depth; Z: sagittal).

Furthermore, the deviation of the angulation of the OMI as compared to the CBCT was determined in degrees based on the vertical axis of the OMI defined by *Top* and *Apex*.

Accuracy of digital planning

The maxillary scans including the planned OMIs (see section "Digital planning of the OMI position and production of the insertion guides") were exported from Blender, imported into OnyxCeph (Image Instruments), aligned to the occlusal plane, and matched with the postoperative CBCT. As previously described in the section "Accuracy of OMI position detection with IOS and silicone impression", for both the planning and the CBCT an .stl of the OMI was aligned to the position of each OMI. The deviation between the planned position and that detected at the postoperative CBCT was computed for each OMI at the *Top* and at the *Apex* and in terms of angular deviation (Fig. 4).

Statistical analysis

Statistical analysis was performed using R [9]. For intraexaminer calibration for each analyzed OMI, one randomly selected measurement on IOS data was repeated after at least 15 days using the icc-function from the irr-package (model = "two-way", type = "consistency"). Boxplots were created to summarize the absolute values of the measured data, considering the pooled data from the repeated IOSs. Linear mixed effect models were used to analyze the effect of the three techniques (i.e., digital planning, silicone impression, or an IOS) and of the planned OMI angulation (0 to 30°) on linear (*Top* and *Apex*) and angular deviations. Additionally, the impact on linear deviations was assessed per x-, y-, and z-direction. The absolute amount of the measured values was considered. Regarding linear deviation, data were pooled per axis (x-, y-, z-) and/or measurement position (*Apex*/*Top*) when needed. The technique and the OMI angulation were considered as fixed effects, whereas intercepts for the cadavers were defined as random effects representing the variability resulting from each donor. *P*-values were obtained by likelihood ratio tests (analysis of variance, ANOVA) of the full model with the effects in question, i.e., of the interaction between technique and angulation, as well as of technique separately. In case of significance, the Tukey post hoc test was carried out. Visual inspection of residual and Q–Q plots revealed no obvious de-

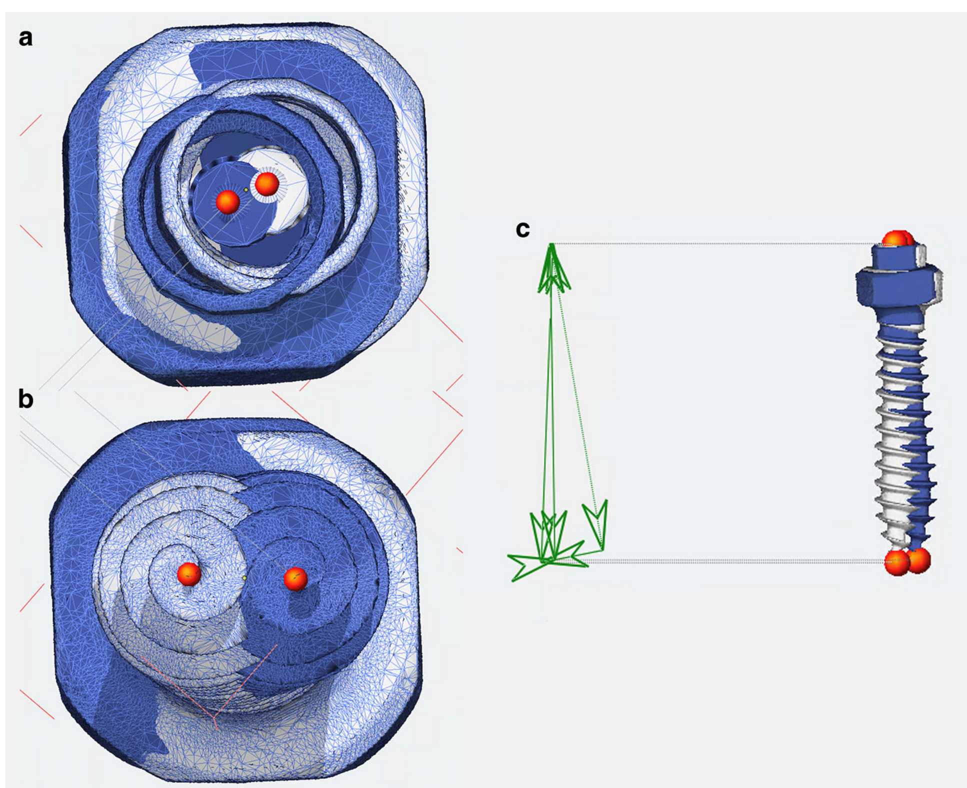

Fig. 4 **a** Measurement of the deviation at the *Top*. **b** Measurement of the deviation at the *Apex*. **c** Measurement of the angular deviation

Abb. 4 **a** Messung der Abweichung am Punkt *Top*. **b** Messung der Abweichung am *Apex*. **c** Messung der Abweichung vom Insertionswinkel viations from homoscedasticity or normality. Results were considered significant at $p < 0.05$.

Results

In 5 cases (samples no. 1, 2, 3, 4, and 5 of Suppl. Table 1), the manufacturing of resin-based restorations was required. All OMIs presented no mobility after insertion, including one OMI inserted accidentally in the nasopalatine canal, as revealed by the postoperative CBCT.

Linear deviation—*Top* and *Apex*

Repeated linear measurements resulted in a very good intraclass correlation (icc = 0.886, $p < 0.001$), revealing high reliability. A summary of the linear deviations is provided in Suppl. Table 2.

Taking into consideration the overall linear deviation, pooling the data of deviations at the *Top* and *Apex*, IOS was found to be the most accurate method, followed by silicone impression and digital planning, with a mean linear deviation from the real position (postoperative CBCT) of 0.25, 0.38, and 0.52 mm, respectively.

The detection of the *Top* was most accurate using IOS, which presented a mean deviation from the real position of 0.14 mm, followed by silicone impression (0.20 mm) and digital planning (0.48 mm; Fig. 5). Statistical analysis confirmed significant differences between the modalities ($p < 0.001$).

The best results were also registered with IOS at the *Apex* with a mean total deviation of 0.36 mm (Fig. 6). Similar mean values at the *Apex* were recorded for digital planning (0.57 mm) and silicone impression (0.56 mm). A significant deviation at the *Apex* between the digital planning, IOS, and silicone impression was registered ($p = 0.010$).

The adjusted *p*-values for both the *Top* and *Apex* measurements are reported in Suppl. Table 3.

Regarding the direction of the deviation, at the *Top,* significant differences were found between the three techniques for all the tested axes ($p \leq 0.001$; Suppl. Table 4), with digital planning exhibiting lower accuracy in all directions as compared to both IOS and silicone impression.

At the *Apex,* the differences between the groups were not so pronounced, with only one significant difference registered in the y-direction between IOS and digital planning ($p = 0.008$). Despite the likelihood ratio test having also revealed significant differences in the x-direction, these were not confirmed after performing the post hoc test.

Angular deviation

As regards angular deviation (Suppl. Table 5), the lowest mean deviation was achieved using digital planning (3.71°). IOS reached a mean deviation of 4.51° and the silicone impression of 5.48° (Fig. 7). The latter also presented the highest maximum deviation value equal to 16.40°. Statistical analysis revealed a significant difference between the three entities ($p < 0.001$). The results of the post hoc tests are given in Suppl. Table 6.

Influence of the insertion angle on linear and angular deviations

The interaction of the insertion angle and the use of different techniques (i.e., digital planning, IOS, silicone impression) had a significant impact on the overall linear accuracy ($p < 0.001$), as well as at the *Top* ($p < 0.001$), and *Apex* ($p = 0.010$), separately. Similarly, a significant difference was detected for angular deviation ($p < 0.001$). Post hoc tests confirmed significant differences only for an insertion angle of 15° for both linear and angular measurements (Suppl. Table 7), with lower deviations found in the IOS group for all parameters.

Discussion

The primary aim of this study was to investigate the accuracy of OMI positioning using digitally planned tooth-borne insertion guides as well as the accuracy of IOS in comparison to a conventional silicone impression for detecting OMIs placed paramedian in the anterior palate. For producing an OMI-borne appliance, the detection of the *Top*, which provides the most relevant information, was most accurate using IOS, followed by silicone impression. However, digital planning also achieved a mean deviation of 0.48 mm at the *Top*, which can still be considered clinically acceptable based on clinical experience. However, it must be noted that evidence is lacking to what extent discrepancies between the planned and achieved positions can be tolerated.

The secondary aim was to examine whether the insertion angle of the OMIs has an influence on the accuracy. It could be shown that only the use of an insertion angle of 15° had a significant influence on the accuracy and that also, among the 15° measurements, IOS was the most accurate technique.

Inaccuracy of computer-guided implant surgery using tooth-supported drill guides based on preoperative IOS and CBCT scans has been reported in implant dentistry [10]. In order to transfer this knowledge to orthodontics, different aspects must be considered, such as the design and the

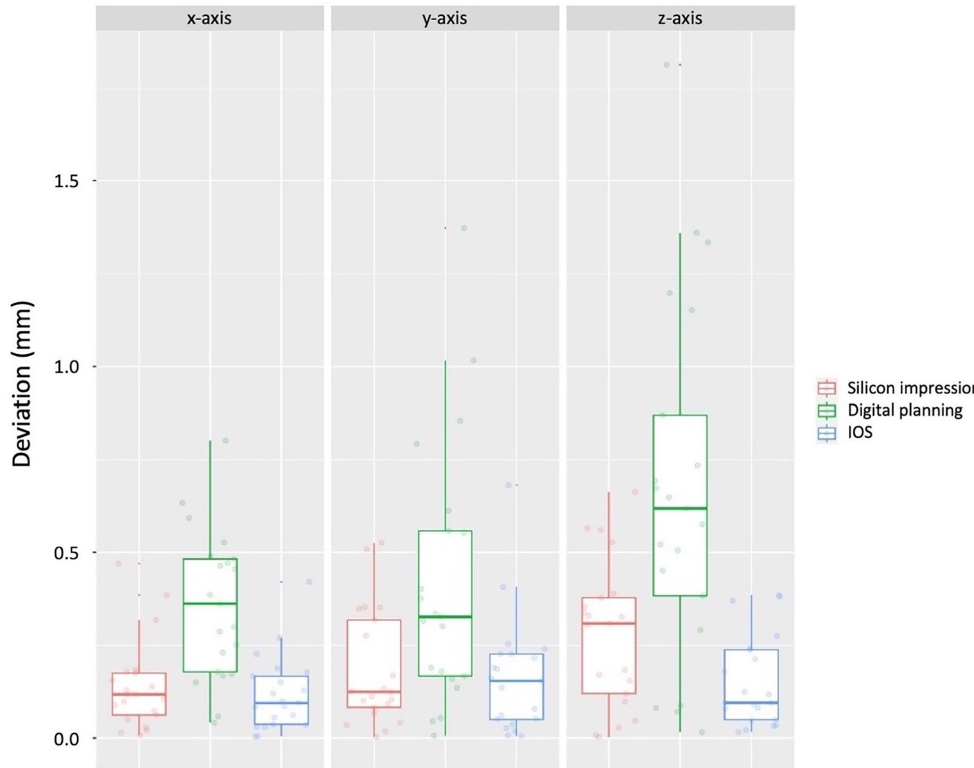

Fig. 5 Measured deviation at the *Top* using digital planning, intraoral scan (*IOS*), and silicone impression
Abb. 5 Gemessene Abweichung am Punkt *Top* bei Verwendung der digitalen Planung, des Intraoralscans (*IOS*) und der Silikonabformung

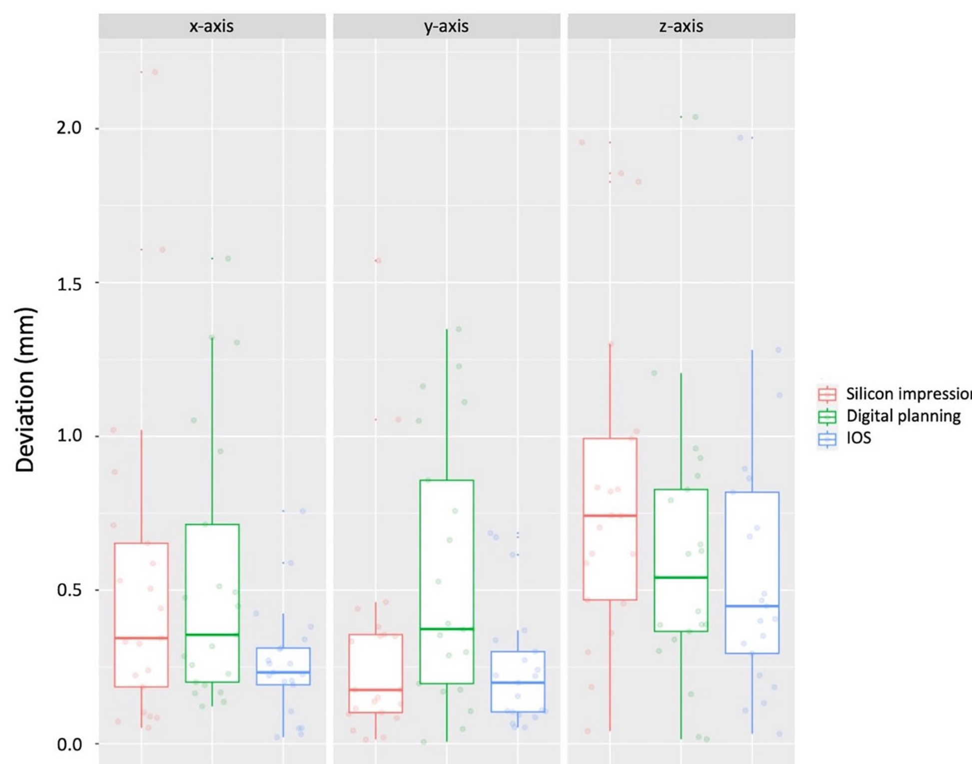

Fig. 6 Measured deviation at the *Apex* using digital planning, intraoral scan (*IOS*), and silicone impression
Abb. 6 Gemessene Abweichung am *Apex* bei Verwendung der digitalen Planung, des Intraoralscans (*IOS*) und der Silikonabformung

material of the insertion guides. Möhlhenrich et al. found that the accuracy of the insertion guide can be increased by extension of the guide involving more teeth [11]. Furthermore, Mang de La Rosa et al. confirmed the suitability of 3D-printed insertion guides using the same resin utilized in the present study for direct placement of the orthodontic appliance after OMI insertion [12]. Basing the selection of our guide material and the tooth-borne design on the successful application in the above-mentioned studies, the low deviations at the *Top* obtained in all groups further support the potential immediate placement of the orthodontic appliance on the OMIs in a single appointment [13].

Additional inaccuracy may occur during guided insertion when too much pressure forces the insertion tool to have a false angle [14].

Another reason for an improper fit of a digitally planned orthodontic appliance is an excessive time interval between the preoperative IOS and the appointment of the fitting. The appliance and the insertion guide can deviate because of possible patients' growth or variations in the position of the teeth [15].

An additional IOS or silicone impression would be necessary when digital planning has not been performed or in case of replacement of the orthodontic appliance utilizing the same OMIs as anchorage in the sense of multipurpose use [16].

In recent years, 3D technologies have gained popularity in orthodontics due to related improvements in patient care,

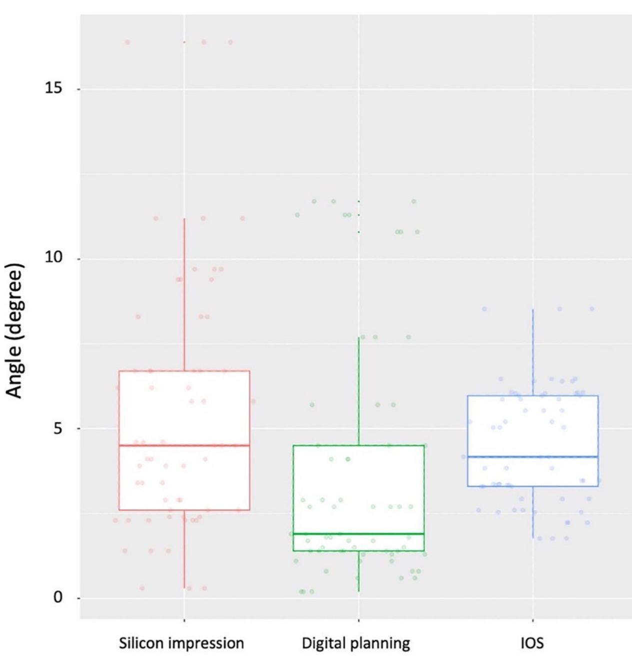

Fig. 7 Measured angular deviation using digital planning, intraoral scan (*IOS*), and silicone impression
Abb. 7 Gemessene Winkelabweichung bei Verwendung der digitalen Planung, des Intraoralscans (*IOS*) und der Silikonabformung

the reduced planning time and the optimized workflow [17]. Performing an IOS results in a quicker workflow and brings advantages in terms of costs and time. It is probable that the IOS will become the option of choice for clinicians over traditional methods in the near future [18].

Therefore, this study aimed to investigate whether a conventional silicone impression could be replaced by an IOS. The present findings showed even a slightly higher accuracy with IOS at the OMI *Top* compared to the silicone impression. It must be taken into consideration that the performance of ex vivo scanning is easier for the operator than in clinical settings.

In addition, no scan bodies were used when performing the IOS in the present study. Clinical practice has shown that these can be dispensed with [19].

In general, if there is a minor discrepancy in the fit between the OMIs and the connector of the appliance, small chairside adjustments of the appliance connector are possible. These can be minimally widened by using a milling cutter and the rigid printed parts can be bent slightly [15].

Age correlates positively with a higher mucosa thickness and should not significantly influence the bone level in the selected paramedian region [20]. Nevertheless, the retention of the OMI might be reduced in situations with a thicker mucosa upon loading [21].

Indeed, one OMI was placed in the incisal canal, as revealed by the postoperative CBCT. The malpositioning of this OMI can be explained by the study design, which did not consider the ideal insertion angle [14].

The use of a lateral cephalogram combined with an IOS for planning the position of the OMIs in the anterior palate could be useful for the assessment of the vertical bone height [22, 23]. Since the anatomy of the anterior palate was found to exhibit a typical pattern, no CBCT is needed for digital OMI planning within the T-zone in the majority of cases [14, 24]. In the present study, neither a lateral cephalogram nor a CBCT were used for planning the OMI positions. The postoperative CBCTs confirmed the efficiency of the procedure, since no damage to roots was observed, and OMIs were surrounded by a sufficient amount of bone tissue. A CBCT, however, might be indicated when OMIs are planned in palatal areas rather than in the T-zone, in the presence of palatally displaced or retained teeth, or in the suspicion of inadequate vertical palatal bone height based on the routine cephalogram [22, 25]. In this respect, the development of low-dose CBCT protocols might allow more frequent use of 3D imaging to reducing the risk of injury to sensitive anatomical structures in the future [26].

A limitation of this study is represented by the age of the donors. Most of the human cadavers presented prosthetically reconstructed extended edentulous spaces or abraded teeth, which could not guarantee the same insertion guide stability as the teeth of common young orthodontic patients.

Additionally, it has to be noted that the cadavers had been freshly frozen prior to the study and were defrosted to room temperature for the experiments. As the hardening of the silicone is temperature-dependent, the defrosting process might constitute a limitation. To mitigate the effect of the temperature, impressions were kept longer in the oral cavities than in clinical settings. Finally, a slight deviation may have derived from the superimposition of the IOS with the postoperative CBCT, as well as from the superimposition of the inserted OMIs with the .stl file of the OMI. Minimal metal artifacts were detected by the examiner deriving from a combination of partial volume effect, beam hardening, and Compton scatter. Nevertheless, they should have only negligibly contributed to deviations affecting the reliability of the CBCTs as references to validate the placement of the mini-implants.

Conclusion

Within the limitations of this ex vivo study, all three applied methods appeared to be suitable for clinical use. Deviations, especially at the orthodontic mini-implant's (OMI) *Top* which is the most important region for the fitting of an orthodontic appliance, were acceptably low with all methods. Despite the fact that the use of intraoral scan (IOS) after OMI insertion seemed to be the most accurate among the three investigated methods, the use of the other two approaches can also be recommended based on the current evidence. In daily practice, digital workflow could be advantageous over the other methods, since it would enable OMI placement and appliance fitting in a single appointment. Further investigations could evaluate the potential benefit of using scan bodies for IOS. Additionally, since the insertion angle had a significant influence only at 15°, no universally valid advice can be given in this regard.

Supplementary Information The online version of this article (https://doi.org/10.1007/s00056-025-00578-x) contains supplementary material, which is available to authorized users.

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Author Contribution T. Augustinowitz: software, formal analysis, investigation, data curation, writing—original draft preparation, writing—review and editing, visualization; L. Schiavon: investigation, writing—review and editing; K. Mücke: formal analysis, writing—review and editing; B. Schwarz-Herzke: resources, writing—review and editing; D. Drescher: resources, writing—review and editing; G. Brunello: methodology, formal analysis, investigation, data curation, writing—original draft preparation, writing—review and editing, supervision; K. Becker: conceptualization, methodology, software, formal analysis, resources, data curation, writing—original draft preparation, writing—review and editing, supervision, project administration

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Data Availability Statement Data will be provided upon reasonable request.

Declarations

Conflict of interest D. Drescher is shareholder of the Tadman GmbH company (Gunningen, Germany). T. Augustinowitz, L. Schiavon, K. Mücke, B. Schwarz-Herzke, G. Brunello and K. Becker declare that they have no competing interests.

Ethical standards Ethics approval was obtained from the Ethics Committee of the Medical Faculty of Heinrich Heine University, Düsseldorf (protocol number: 2018-130_2). Eleven frozen heads of human cadavers were provided by the Institute of Anatomy of the Heinrich Heine University. Informed Consent Statement: Not applicable.

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3 Discussion and Conclusion

Conventionally, a silicone impression with impression caps positioned on the OMIs was necessary to transfer the position of OMIs after their placement in the anterior palate. [16] However, with the increasing use of IOS in orthodontic practice, it has also been applied for this purpose. It is known from implant dentistry that silicone impressions can be replaced by an IOS with similar and clinically acceptable results. [76, 77] One aim of this work was to examine whether the same is also valid for OMIs in orthodontics.

Originally, special scan bodies, analogous to the impression caps, were used for this procedure, as they are also commonly used in implantology. A previous cadaver study concluded in 2021 that further research was needed to assess whether the clinical application of scan bodies and IOS was sufficiently accurate for clinical use. [78] Graf et al. already showed in 2018 that scan bodies can be eliminated in clinical orthodontic practice. [74] The feasibility of directly scanning OMIs depends on the accuracy of the IOS device which is used. Nevertheless, scan bodies may still be beneficial in cases with extreme undercuts on the OMIs. [74, 79]

Due to these findings and in order to present clinically relevant results, scan bodies were not used in the present study.

A known limitation of IOS regarding direct scanning of OMIs and their attached appliances is light reflection, particularly from metallic surfaces. One solution is the use of opacifying scan spray. [80] More recently, most manufacturers of IOS are implementing artificial intelligence (AI) in their software. [81] With this additional tool light reflection represents a minor issue. Our investigation supports this assumption, because the Trios scanner (Trios3, 3Shape, Copenhagen, Denmark), which was also used in this study, is equipped with technology that compensates for reflective surfaces, and direct scanning of the OMIs was feasible in almost all cases without any problems. [82]

Nevertheless, in the present study, AI also led to a problem in one sample by removing the scanned OMIs recognized as part of the soft tissues of the palate. By specifically turning off the AI tool for this sample for the scanning of the anterior palate, the OMIs could still be sufficiently recorded by the IOS.

For a good clinical fit of the digitally designed appliance or if the OMIs are not exactly represented in the IOS, the scanned OMI can also be replaced by a virtual one from the manufacturer for the fabrication of the appliance. [83] The virtual replacement of the scanned OMIs was also used in this study to measure accuracy.

Ultimately, the use of IOS without scan bodies was found in the present study to be the most accurate method in terms of linear deviations and was classified as acceptable for clinical use. Accordingly, the question arises as to whether scan bodies are necessary. Especially in the light of ever-improving scan quality and software performance, which suggests that they may become obsolete.

On the other hand, the full digital planning was more accurate in terms of angular deviations with the lowest mean deviation. One explanation for this could be that the insertion tool is guided axially through the drill sleeves by the insertion guide throughout the entire insertion process.

However, it is possible that the additional use of scan bodies could improve angular precision of capturing the position of OMIs with an IOS.

It can therefore be speculated that a potential clinical indication for scan bodies could be the insertion of multiple OMIs in the palate, for example when a Quad-expander is used, as the OMIs can often not be inserted parallelly and more undercuts occur in the IOS.

To further improve the conventional workflow, the elimination of both the silicone impression and even an IOS is possible in the case of a fully digital workflow, which allows a one-visit protocol, using a tooth-borne insertion guide. In this procedure, the OMIs and the orthodontic appliance are inserted during the same appointment. Digital planning of OMIs in combination with an orthodontic appliance requires only an IOS of the upper jaw and a lateral cephalogram or eventually a CBCT. [67]

In addition to the advantages for the patient, such as fewer treatment sessions and no need for orthodontic band adjustment, orthodontists also benefit from this approach. The insertion of the OMIs is safer and allows for placement in the optimal position, with appropriate length and correct angulation. Furthermore, the position of the OMIs can be precisely adapted to the requirements of the appliance. [68]

The success of this procedure mainly depends on the accurate transfer of the position of the OMIs from the digital planning into the patient´s anterior palate. The insertion guide and its design, therefore, play a decisive role.

There has been debate on whether the insertion guide should be tooth- or gingiva-borne.

However, the results of a previous cadaver study showed that the extension of the insertion guide involving the patient's teeth significantly increased its transfer accuracy. [84]

In the present study, the insertion guide design was a tooth-borne skeletonized insertion guide that consisted of four posts supported mainly by first molars and first premolars.

The exact fit of the guides may have been impaired in the present study, as the teeth of the human cadavers were more abraded due to their older age. In contrast, the teeth of the typical orthodontic patients show very pronounced fissures and pits due to their younger age. As a result, a more accurate fit may be assumed in clinical reality than in the present study. Additionally, in some cases the cadaver had to have missing teeth replaced with skeletally anchored prostheses to provide a sufficient anchorage for the insertion guides.

It is likely that a greater accuracy could be achieved by modifying the insertion guide. For example, the guide could be designed like a splint which would not only be supported by four teeth but also extend to more teeth and embrace them circumferentially, to improve stability. Another option would be the creation of a continuous bar extending over the entire posterior teeth instead of using four individual posts. This would capture more teeth and could make it easier for the clinician to stabilize the insertion guide during OMI placement. [85]

Skeletonized guides are successfully applied in clinical practice for adolescent patients, but the modifications mentioned above could be relevant for older patients with more abraded teeth or in patients with few abutment teeth.

Furthermore, no lateral cephalogram was used in the study in addition to the IOS of the maxilla for digital planning. A lateral cephalogram can be useful for digital planning, as on the one hand the distance to the roots of the incisors can be maintained and on the other hand the support of the bone is ensured. CBCT studies have shown that the bone contour visible in the lateral cephalogram corresponds to the palatal bone contours located approximately 5 mm to the right and left of the midline (corresponding to the *sutura palatina mediana*). Therefore, the bone contour visible in the lateral cephalogram is well suited for digitally planned OMIs in the anterior T-zone to ensure optimal bone support. [67, 86]

In the postoperative CBCT, no injury to the root of the incisors was detected. Only one OMI was placed in the incisive canal. Penetration of the nasal floor was not observed in the present study. Neither placement in the incisive canal nor penetration of the nasal floor could be definitively prevented with a lateral cephalogram. [87]

Only injury to the roots of the incisors can be potentially avoided using a lateral cephalogram. Nevertheless, such injuries are rarely observed when placing OMIs in the anterior palate and general rules of paramedian insertion are followed. Still, a lateral cephalogram can serve as an additional safety measure during digital planning in everyday clinical practice, as it is routinely performed as part of pre-therapeutic diagnostics and does not expose the patient to additional radiation.

In addition to the superimposing of the IOS with a lateral cephalogram, it is also possible to use a CBCT for digital planning. However, it is recommended to only perform a CBCT in specific cases – such as in case of presence of displaced or impacted teeth, unerupted upper incisors, cleft patients, extremely narrow maxillae or when planning OMIs in regions beyond the anterior palate. [67]

If a CBCT is performed for digital planning, the radiation dose should be reduced as much as possible, considering the typically young patient population. This can be achieved by limiting the field of view (FOV) to Ø 5 × 8 cm or Ø 5 × 5 cm and using a low dose protocol. [88]

Since the implementation of a one-visit protocol involves not only the guided insertion of OMIs in the anterior palate but also the direct placement of a bone-borne appliance, there are technically two methods for fabricating such appliances.

Initially, when the one-visit protocol was first described by Gabriele et al., the appliances were fabricated by conventional laboratory techniques on 3D-printed resin models containing the digitally positioned OMIs. [69]

Graf et al. later demonstrated that bone-borne appliances can be also digitally planned and 3D-printed using SLM metal printing. [74] This approach is now considered as a fully digital workflow. Whereas the fabrication on 3D-printed resin models is regarded a hybrid workflow since the appliance is manually bent on the model.

The development of a digital workflow leads to certain advantages and disadvantages, along with specific indications and contraindications.

Advantages of the digital workflow include the elimination of tooth separation and the inconvenient step of band seating. Furthermore, Wilmes et al. concluded that the digital workflow eliminates potential sources of errors, such as band transfer from impression to a plaster model or incorrect transfer of OMI positions to the dental laboratory. [89]

The last consideration is also consistent with the results of the present study. The conventional workflow using impression caps and a silicone impression was the least accurate of the methods investigated.

Moreover, 3D-metal-printing yields very rigid appliances, which can be particularly beneficial for applications such as forced palatal expansion. In addition, a highly individualized appliance design is allowed, as 3D-printing overcomes the limitations of manual wire bending.

One of the disadvantages associated with digital planning of OMIs is that the mucosa depth cannot be routinely integrated into the digital workflow. As previously noted, the soft tissue thickness plays an important role for OMI stability. When inserting OMIs freehand, the mucosa depth can be measured clinically using a dental probe fitted with a rubber stop. [90] This option does not exist with routine digital planning, since the soft tissue thickness can only be estimated using CBCT.

Additionally, fabricating orthodontic appliances in a full digital workflow can lead to increased costs and time requirements, particularly due to the need for specialized design software and training.

The rigidity of metal-printed appliances may also present a disadvantage, as they cannot be adjusted or bent post-fabrication. Furthermore, a higher failure rate of CAD/CAM-produced shells compared to conventional bands, which are retained also in the undercut area of the molars, has been reported. [89]

This disadvantage could be eliminated by using the hybrid workflow mentioned above, as this allows for a manually bent appliance to be inserted together with OMIs in a single session.
Furthermore, current studies on metal 3D-printing in orthodontics are mostly case reports with a lack of evaluation regarding long-term corrosion resistance in the oral environment, biocompatibility, surface morphology and reproducibility of printed components. [68, 79, 91]
Therefore, the gap between technical potential and clinical validation highlights the need for interdisciplinary research that combines material science and material testing under *in vitro* and *in vivo* settings. It would be an important step to develop standardized and validated protocols in order to implement metal 3D -printing safely and efficiently in orthodontics.

Beside the fundamental principles that influence the insertion angle such as primary stability, sufficient bone support and safe distance to anatomically relevant structures, it could also be assumed that the insertion angle affects the accuracy of performing a silicone impression or an IOS, as well as the use of a tooth-borne insertion guide for full digital planning. [31, 92]
However, the present investigation showed no overall significant influence of the insertion angle on the detected accuracy. Only an insertion angle of 15° demonstrated a significant influence on the accuracy, with IOS proving to be the most accurate technique at this angle.
One of the major limitations of this present study is the *ex vivo* performance. The limitation of missing teeth due to increased age of the cadavers was addressed by replacing them with skeletally anchored prostheses. Nevertheless, the abrasion of the teeth was a limitation with regard to the exact fit of the insertion guides. Since orthodontic patients are typically younger and exhibit deeper fissures and pits on their teeth, the direct transferability of these findings to clinical practice is limited.
On the other hand, fresh frozen cadavers offer a realistic comparison to clinical conditions, particularly regarding insertion modalities. Unlike fixed cadavers, fresh frozen cadavers show insertion torque values similar to those seen in living patients. [93]

In conclusion, IOS proved to be the most accurate method for detecting OMIs placed in the anterior palate and could thus replace conventional silicone impressions. Despite this, a full digital workflow with guided insertion also yielded clinically suitable results and resulted to be the most accurate in terms of angular deviations.

The clinician can therefore choose the most suitable method based on individual clinical requirements. The same applies to the associated workflow for the production of the appliance, whether it should be rigidly SLM-printed or conventionally bent on a model.

With regard to the insertion angle, the study supports that maintaining a safe distance from anatomically relevant structures and ensuring adequate bone support should take priority, as no specific insertion angle was found to offer an advantage for OMI position detection.

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