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Examining the Influence of Freehand, Pilot-Guided, and Fully Guided Surgical Protocols on the Accuracy of Immediately Placed Implants—An In Vitro Study

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Featured Application: Guided surgery for immediately placed implants.

Abstract: This study aimed to evaluate the influence of the guidance level on the accuracy of immediately placed implants. Methods: Eighteen identical maxillary models (randomly split into three groups (n = 6): fully guided (FG), pilot-guided (PG), and freehand (FH)) were used to place 72 implants (n = 24). After placement, the mean global, angular, mesial–distal, buccal–palatal, and vertical deviation at the platform and apex of the placed implants, relative to the preoperatively planned positions, was calculated. Results: Significant differences in global and mesial–distal deviation were found between implants in the FG group and implants in the PG and FH groups. Significant differences were also found between the implants in the FG and FH groups as well as the implants in the PG and FH groups in terms of angular and mesial–distal apex deviation. Finally, significant differences were found between the implants in the FG and PG groups in terms of buccal–palatal platform deviation. Conclusions: The results of this in vitro study show that immediate implants placed using fully guided surgical guides have significantly less deviation, and are therefore more accurate, than implants placed freehand or using pilot guides, but this should be further validated in a clinical trial.

Keywords: dental implant; single tooth; immediate implants; accuracy; guided surgery; 3D-printed surgical guide

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1. Introduction

Immediate implant placement has been shown by multiple authors to be a predictable treatment option for single tooth replacement [1–3]. Major benefits of this treatment option are shorter treatment times and fewer surgical interventions, making it highly desirable from a patient perspective [4]. However, immediate implant placement is far more challenging from a surgical point of view, compared to placing implants in a healed ridge. Unlike in healed ridge cases, immediate implants must be placed in the frequently limited bone located on the apical and palatal aspect of the extraction socket. Immediately placed implants in this position have an increased risk of the implant's shoulder unintentionally shifting towards the buccal bone plate during site preparation [5,6]. Consequently, implants with a buccally positioned shoulder have a considerably higher chance of mucosal recession, compared to implants with a palatally positioned shoulder [7]. Furthermore, a recent systematic review has shown that immediate implants should be placed without raising a flap [8]. However, a flapless surgical approach impairs visual control of the site preparation and implant placement process.

Guided, or computer-aided, implant surgery is a popular approach to assist oral surgeons in managing these requirements for difficult procedures. With the assistance of cone beam computed tomography (CBCT) and digital intra-oral scans, an optimal three-dimensional (3D) implant position can be virtually planned within a surgical planning software package [9]. Once planned, the virtual implant position can be transferred to the mouth of the patient using guided surgery, which can be either dynamic or static. During dynamic guided surgery, the operator receives real-time feedback on the drill position and angulation during osteotomy preparation and implant placement. Static guided surgery, on the other hand, involves the use of surgical templates during osteotomy preparation and implant placement. While dynamic guided surgery has been found to be more accurate than freehand implant placement [10], static guided surgery is more practical [11] and provides similar accuracy to dynamic guided surgery [12–15].

Static guided surgery templates can be supported on bone, mucosal, or tooth levels, with surgical guides supported on the tooth level having been found to be significantly more accurate than guides supported on bone or mucosal levels [16].

The level of guidance provided by static surgical templates can be further characterized as fully guided, partially guided, or pilot-guided. Fully guided surgical guides assist during every step in the process, from initiating and preparing the osteotomy to placement of the implant using guiding sleeves placed in the guide. Partially guided surgical guides are designed to assist for the preparation of the osteotomy, after which the guide is removed, and the implant is placed freehand to retain tactile feedback of implant stability during placement [17,18]. Pilot guides only provide guidance for initiating the osteotomy using the very first (pilot) drill through an integrated metal sleeve in the guide [19]. The remainder of the osteotomy preparation and implant placement is then performed freehand using mental navigation.

To the best of our knowledge, no studies evaluating the accuracy of fully guided, pilot-guided, and freehand surgical approaches for immediately placed implants have been published. A clinical study comparing the accuracy of fully guided versus pilot-guided surgical approaches for immediately placed implants was published by Kraft et al. [20], while another clinical study by Chandran et al. compared the accuracy of immediate implants placed fully guided versus freehand [21].

The aim of this in vitro study was to investigate the influence of the guidance level (fully guided, pilot-guided, or freehand) on the accuracy of implants placed in simulated post-extraction sockets. The null hypothesis is that the guidance level has no influence on the accuracy of immediately placed implants.

2. Materials and Methods

This in vitro study was conducted in 18 identical maxillary models (DM-66, SEL models, Barcelona, Spain), which were randomly split into 3 groups: fully guided (FG, n = 6), freehand (FH, n = 6), and pilot-guided (PG, n = 6). Each model featured 4 extraction sockets (FDI tooth positions 12, 14, 21, 23) for immediate implant placement, allowing for 24 implants to be placed in each experimental group. A sample size calculation (with $\alpha = 0.05$ and targeted statistical power of 80%) using the global apical deviation data from Chen et al. [22] was performed in G*Power (Version 3.1) [23] and found that a sample size of 24 implants per group would be required.

Using the same implant plan for screw-retained restorations described by Pitman et al. [24], an immediate implant treatment plan to place a Ø3.75 × 14 mm bone level X implant (Straumann, Basel, Switzerland) implant in each extraction site was made in CoDiagnostix® (Version 10.8, DentalWings, Montréal, QC, Canada). All implants were planned with a sleeve height of 4 mm (H4) above the mucosal surface of the models. The virtual positions in this implant plan were henceforth considered as the ground-truth from which the deviation in the actual implant positions were calculated.

From this plan, fully guided and pilot-guided surgical guides with tooth offsets of 0.25 mm and wall thicknesses of 3 mm were designed. The fully guided surgical guides

were designed to integrate with Ø5.0 mm Polyether Ether Ketone (PEEK) self-locking T-sleeves (Reference no. 034.299V4, Straumann, Basel, Switzerland) and the pilot guides were designed for use with Ø2.2 mm stainless steel T-sleeves (Reference no. 046.712V4, Straumann, Basel, Switzerland).

Six fully guided and six pilot-guided surgical guides were then printed by the local dental lab (LaboHoet, Ghent, Belgium) using an Asiga Max 3D printer (Alexandria, Australia; resin = KeyGuide, KeyStone Industries, Gibbstown, NJ, USA; DLP technology) and assigned to models in the FG and PG groups, respectively. The PEEK and stainless-steel T-sleeves were then press-fitted into the fully guided and pilot-guided surgical guides, respectively.

Following the manufacturer's guidelines, 72 implants were placed (without creating a flap) in a randomized sequence using a random number generator (https://www.randomizer.org, accessed on 1 June 2023), according to site position and experimental group (FG, FH, and PG), by 6 experienced oral surgeons. Prior to commencing, each surgeon was calibrated by discussing the implant plan and required protocol for each type of surgery on a laptop as well as on printed copies of the implant plan. These materials were also made available for consultation during site preparation and implant placement for all test groups.

2.1. FG Group

For the implants in the FG group, site preparation was performed entirely through the surgical guide using drill handles with a 1 mm offset, starting with the Ø2.2 mm pilot drill (Reference no. 066.1701, Straumann, Basel, Switzerland) and finishing with the Ø3.5 mm drill (Reference no. 066.1704, Straumann, Basel, Switzerland). Each drill featured a mechanical stop to prevent any further drilling after the target depth was achieved. Thereafter, the implants were placed through the guide using an implant driver with laser-marked lines to indicate the depth (Reference no. 066.4403, Straumann, Basel, Switzerland).

2.2. FH Group

The implants in the FH group were placed freehand using the same drills and implant placement tool as in the FG group.

2.3. PG Group

Site preparation for the implants in the PG group was initiated using the Ø2.2 mm pilot drill through the stainless-steel T-sleeve in the pilot-guided surgical guide. Thereafter, the surgical guide was removed, and site preparation was completed freehand using the same drills as the FG and FH groups. The implants were also placed freehand using the implant driver with laser-marked lines to indicate the depth.

A graphical summary of the experimental setup is shown in Figure 1.

Once the implants had been placed, scan flags were attached to the implants (Reference no. 065.0035, Straumann, Basel, Switzerland) and the models were scanned using a lab scanner (AutoScan-DS-MIX, Shining3D Technologies, Stuttgart, Germany). The postoperative Standard Tessellation Language (STL) files from the lab scanner were imported into CoDiagnostix® and matched to the original STL and DICOM files by a single operator not involved in placing the implants (JP). The deviation in the placed implants relative to their virtual, planned positions was then performed using the 'Treatment Evaluation' tool in CoDiagnostix®. First, a 'New Study' was created, and the 'Postoperative model scan with scanbodies' study type was selected, followed by clicking on the 'Load model scan. . .' hyperlink to select the appropriate postoperative intra-oral STL scan file. After clicking on the 'Next' button, the top surface of the scanbody for each implant in the respective sites was then identified in order for CoDiagnostix to register the position of the implant. Once these positions were confirmed, the 'Next' button was clicked to calculate the results of the deviation analysis between the actual, placed implants and their virtual, planned positions.

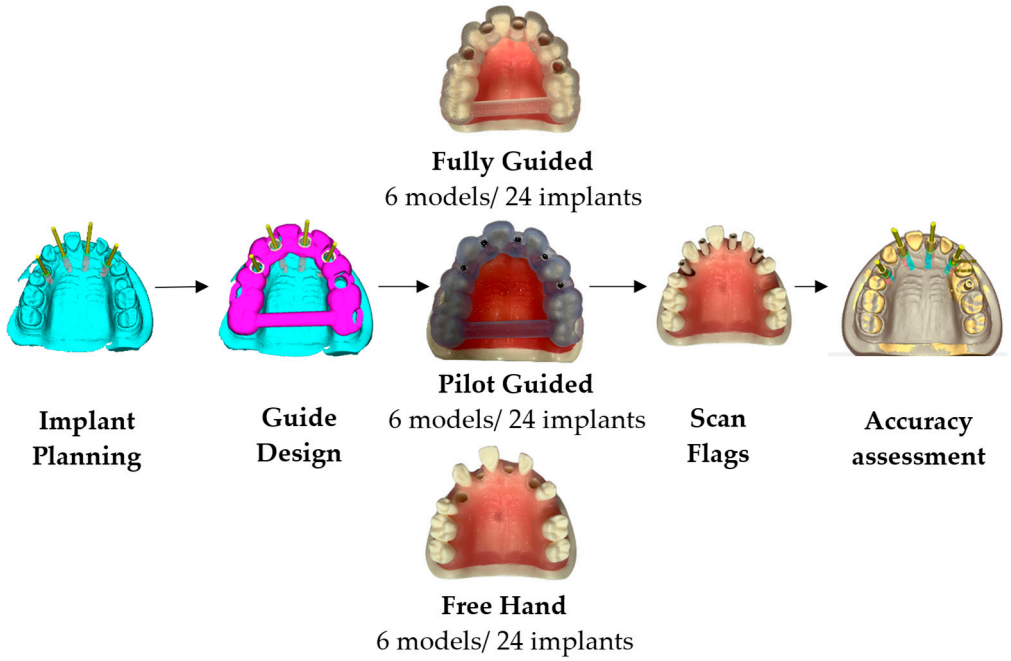


Figure 1. The experimental setup from creating the virtual implant plan and designing the master guide design and assigning the test groups according to the guidance level. Finally, scan flags were placed on the implants and the deviation in the actual, placed position of the implants are compared with the virtual, planned position.

Global deviation was defined as the linear distance of the actual implant position, relative to the planned implant position, and represents the total deviation in 3D space (shown as GD-A and GD-P). The angular deviation (shown as AD in Figure 2) was defined as the angle between the central axes of the planned and placed implant positions. The global deviation was further decomposed into directional components representing the vertical and horizontal (buccal–palatal and mesial–distal) deviations. Global deviation in the platform and apex was considered as the primary outcome. All other parameters were considered secondary outcomes. A graphical representation of all direction definitions is provided in Figure 2 [24].

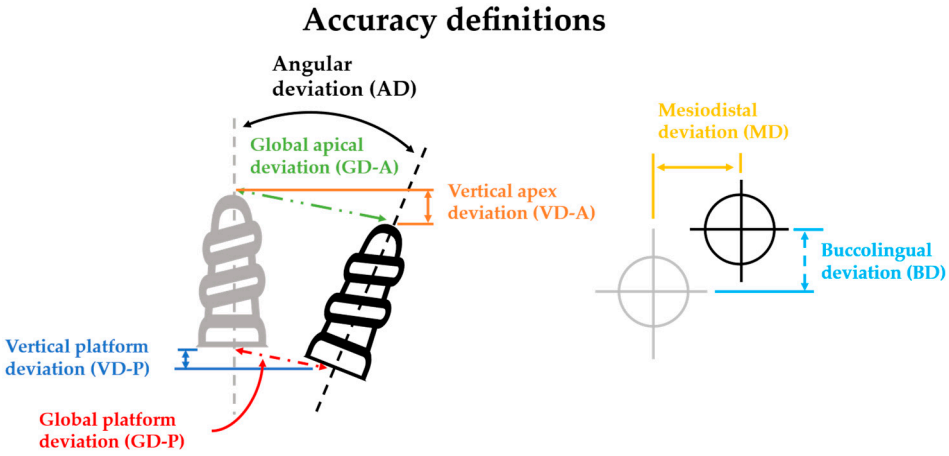


Figure 2. Definitions of the deviation parameters between the planned (indicated in grey) and placed (indicated in black) implant positions [24].

All statistical analyses were performed in IBM SPSS Statistics (Version 27; Chicago, IL, USA). Normality of the data was evaluated using the Kolgomorov–Smirnov test and

Q-Q plots and judged to be approximately normal. A linear mixed model was then applied to test for significant differences in mean deviation between the different guidance level groups, taking a possible correlation between implants placed in models by the same implant surgeon into account (using a random intercept for practitioners) and adjusting for site as a fixed effect. The estimated marginal means were computed with pairwise comparisons (using the mixed command in SPSS). The nominal type 1 error rate was controlled at 5% and Bonferroni correction was used to adjust for the 2 primary endpoints and multiple comparisons. The level of significance was therefore set at 0.0083 for the primary outcome (global deviation—apex and platform). The analysis was conducted in a stepwise manner, by first checking for significance in the primary outcomes and then for significance in the secondary outcomes.

3. Results

Adequate primary stability, with insertion torque values $\geq$ 35 Ncm, was achieved in all 72 implants. Visual representations of the distribution of the data, in the form of box and whisker plots, are provided in Figures S1 and S2. A summary of the means, minimums, maximums, and standard deviations of the primary and secondary outcomes is provided in Supplementary Table S1. Similarly, results from the linear mixed model and pairwise comparisons between groups for the primary and secondary outcomes are given in Supplementary Table S2.

Significant differences in the primary outcome (global deviation in the platform and apex) were found between implants placed using a fully guided surgical guide (FG group) and implants placed either freehand (FH group) or using a pilot guide (PG group) ($p < 0.001$). No significant differences in the primary outcome were found between implants placed freehand and implants placed using a pilot guide. These results are shown graphically in Figure 3.

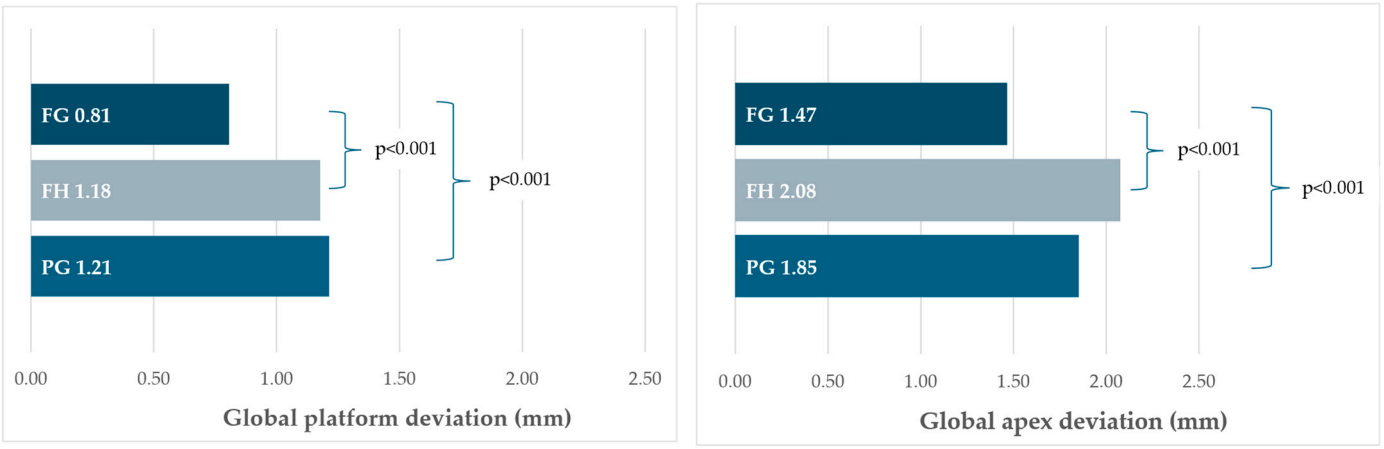


Figure 3. Results for the primary outcome (global deviation in the platform and apex): significant differences were found between implants placed using a fully guided surgical guide (FG) and implants placed freehand (FH) or using a pilot guide (PG).

In terms of the secondary variables, similar significant differences in terms of mesial–distal platform deviation were found between implants in the FG group and implants from the FH and PG groups ($p \leq 0.001$). In terms of buccal–palatal deviation, significant differences were found between implants in the FG group and implants in the PG group ($p = 0.001$). Finally, significant differences in angular deviation and mesial–distal apex deviation were found between implants in the FG and FH groups ($p < 0.001$) as well as between implants in the FH and PG groups ($p < 0.001$). These results are represented graphically in Figure 4.

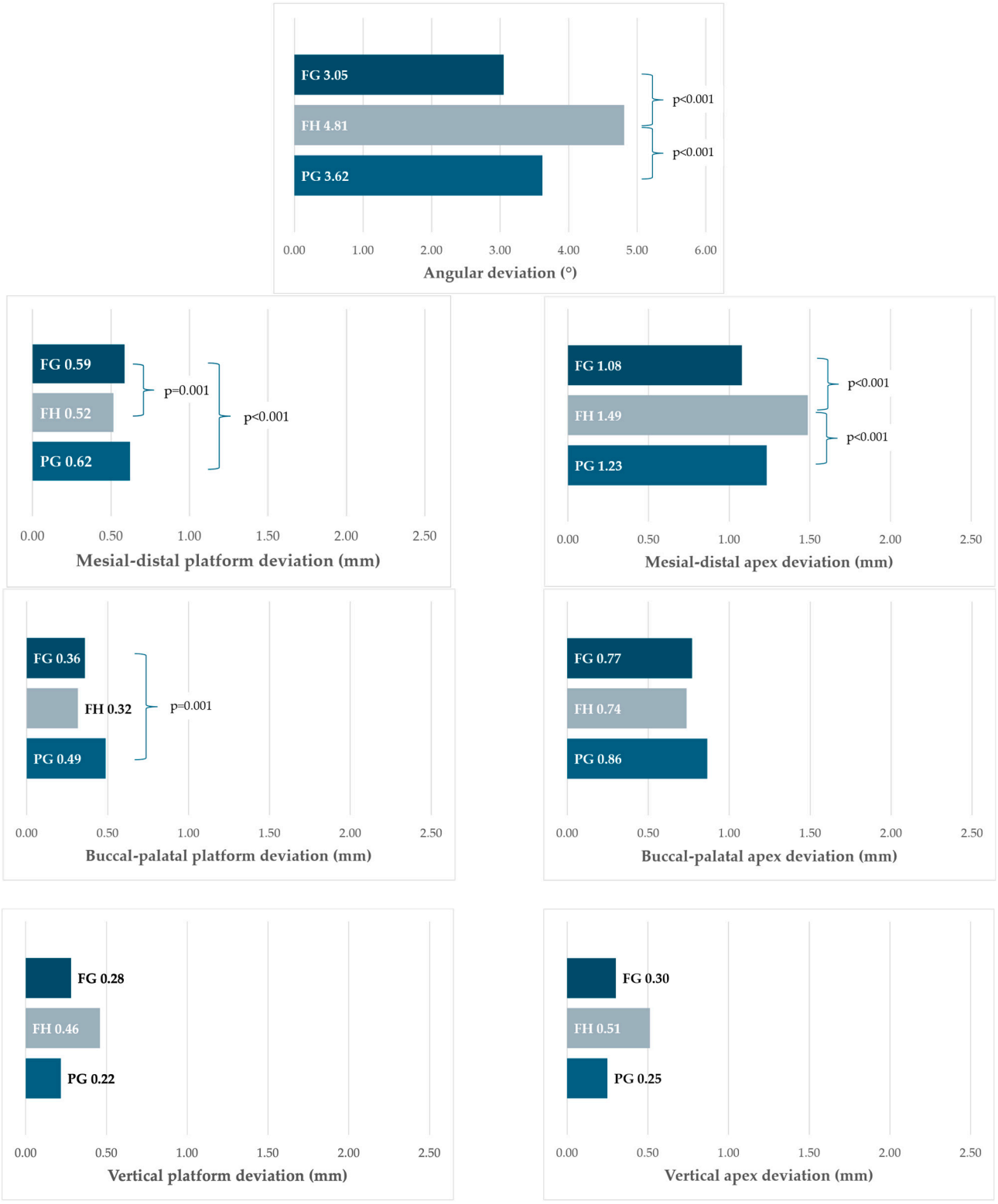


Figure 4. Secondary outcome results: significant differences between implants in the FG group and implants in the PG and FH groups ($p < 0.001$), as well as significant differences in buccal–palatal deviation between implants in the FG and PG groups ($p = 0.001$). Finally, significant differences in angular deviation and mesial–distal apex deviation were found between implants in the FG group and implants in the FH group, as well as between implants in the PG and FH groups.

In general, implants in the FG group exhibited the least global deviation at both platform and apex levels, while implants in the PG group exhibited the most global platform deviation. Implants in the FH group exhibited the most global apical deviation.

4. Discussion

Achieving the correct implant position was identified by Buser and colleagues as an important factor for achieving an optimal aesthetic outcome [5]. An incorrectly positioned implant has been reported to not only increase the risk of buccal dehiscence [25], but also the risk of peri-implantitis [26]. Static surgical guides are a means to ensure that implants can be accurately placed according to a pre-surgically planned position, thereby reducing the risk of long-term complications.

The aim of the present study was to evaluate the influence of the static surgical guidance level (fully guided, pilot-guided, or freehand) on the accuracy of implant placement in post-extraction sockets. The results presented above show that the guidance level affects the accuracy of implants placed in post-extraction sockets; therefore, the null hypothesis was rejected.

The results from this study confirm that a fully guided approach provides significantly less global deviation for immediately placed implants (and is therefore more accurate), compared to pilot-guided and freehand approaches. This result contrasts with Kraft et al., who reported no significant difference in accuracy between the fully guided and pilot-guided groups [20]. In terms of global platform deviation, Kraft et al. reported greater mean deviations in the FG and PG groups (1.26 $\pm$ 0.57 and 1.34 $\pm$ 0.99, respectively), compared to the FG and PG groups in the present study (0.81 $\pm$ 0.21 mm and 1.21 $\pm$ 0.41 mm, respectively; see Table S1). Similarly, greater global apical deviation was reported by Kraft et al. in the FG and PG groups (2.50 $\pm$ 1.67 mm and 1.97 $\pm$ 1.04 mm), compared to the corresponding groups in the present study (1.47 $\pm$ 0.31 mm and 1.85 $\pm$ 0.33 mm; see Table S1). Possible reasons for smaller global deviations being found in the present study compared to the randomized controlled trial (RCT) of Kraft et al. include patient-related factors such as varying quality or quantity of available bone, as well as a lack of support for the implant on the facial aspect of the socket during placement. A common consequence of this lack of support is that the implant tends to drift facially during placement, especially when placed in a socket with softer bone. The greater global apical deviation in the FG group compared to the PG group reported by Kraft et al. [20] suggests that this may have been the case, since 16 mm long implants were used and implant placement through a fully guided surgery impairs visual control.

On the other hand, the significant difference in accuracy between the fully guided and freehand groups from the present study agrees with the results from the RCT by Chandran et al. [21]. While global platform and apical deviation results were not reported by Chandran et al., the mesial–distal deviation results at platform and apex levels for the FG group (0.40 $\pm$ 0.28 mm and 0.95 $\pm$ 0.52 mm, respectively) were in roughly the same range as the corresponding secondary outcomes from the FG group in the present study (0.52 $\pm$ 0.16 mm and 1.08 $\pm$ 0.35 mm, respectively; see Table S1). Similarly, the buccal–palatal deviation results at the platform and apex level for the FG group reported by Chandran et al. (0.42 $\pm$ 0.24 mm and 0.90 $\pm$ 0.65 mm, respectively) were roughly in the same range as the corresponding secondary outcomes in the FG group in the present study (0.32 $\pm$ 0.23 mm and 0.74 $\pm$ 0.41 mm, respectively; see Table S1). However, the angular deviation results in the FG group from Chandran et al. (0.94 $\pm$ 0.59°) were considerably smaller than the angular deviation results in the FG group in the present study (3.05 $\pm$ 0.97°; see Table S1). This discrepancy is perplexing as the angular deviation results from the FG and PG groups in the present study (3.05 $\pm$ 0.97° and 3.62 $\pm$ 1.01°, respectively; see Table S1) are in the same range as those reported by Kraft et al. (5.36 $\pm$ 4.53° and 3.60 $\pm$ 2.84°) [20].

The mesial–distal deviation results at platform and apex levels in the present study (0.59 $\pm$ 1.49 mm and 1.49 $\pm$ 0.59 mm, respectively; see Table S2) were considerably smaller than those reported by Chandran et al. [21] for the corresponding variables in the FH

group (1.30 ± 0.83 mm and 5.38 ± 1.78 mm, respectively). The same trend was also seen in the buccal–palatal deviation results from the present study at platform and apex levels (0.36 ± 0.28 mm and 0.77 ± 0.59 mm, respectively; see Table S2), compared to the results reported by Chandran et al. (1.06 ± 0.91 mm and 4.36 ± 1.84 mm, respectively). These differences could be explained by the lack of real-life clinical elements such as a patient's tongue or limited occlusal space in the present study's experimental setup.

While implants placed fully guided may have deviated the least from their planned positions, the maximum global deviation was still almost 2 mm; therefore, a safety margin of 2 mm around important anatomical structures is still recommended.

An unexpected result from the present study was the lack of a significant difference in global platform and apical deviation between implants placed freehand and those placed using a pilot guide. This result is contrary to a recent study by Chen et al., in which a significant difference in global platform and apical deviation was found between immediate implants placed using partially guided surgical guides and implants placed freehand. However, the osteotomies in the partially guided group were fully prepared through the surgical guide, after which the guide was removed for implant placement [22]. The non-significant result from the present study could therefore be explained by the lack of guide support during osteotomy preparation after the pilot drill.

The benefit of guided surgery for healed sites is well established, with multiple RCTs reporting significant differences in accuracy between implants placed with a guide (full, partial, or pilot) and implants placed freehand [19,27–29]. On the other hand, there is a lack of RCT studies comparing full, partial, and pilot-guided approaches versus freehand in post-extraction sockets. The global deviation results from the present study would suggest that pilot guides have limited value for placing implants in post-extraction sockets compared to a freehand approach. However, immediate implant placement is a technically challenging procedure for any surgeon. When considering the angular deviation, there is a significant difference between implants placed using a pilot guide and implants placed freehand (see Supplementary Table S2).

The 'Treatment Evaluation' tool in CoDiagnostix® has been used by multiple authors to calculate postoperative implant deviation [20,28,30] and was a logical choice in the present study as it is fully integrated within the software package. All postoperative scan files were added to the original implant plan using the standard tool for importing intra-oral scans, thereby preserving the original coordinate system and clinical directions. This contrasts with other evaluation tools in similar accuracy studies [19,21,22,27], where the process of matching of the pre- and postoperative scan or CBCT files and calculating the deviation was more manual and the original coordinate system and clinical directions from the implant plan were lost.

Finally, the results of the present study should be interpreted with caution. Important real-life clinical elements (such as patient movement or limited occlusal distance) could further influence the deviation in implants placed in post-extraction sockets, which was not possible to reflect in the present study. The mechanical properties of the resin in the surgical teaching models were also not entirely representative of human bone, which could be seen as a limitation of the present study. Human bone is highly anisotropic and varies widely in terms of both quantity and quality and comprises important factors in immediate implant placement. However, the focus of the present study was on the influence of the guidance level on the accuracy of implants placed in simulated extraction sockets. The use of surgical teaching models herein provided a level of consistency that is impossible to replicate in a clinical setting. In this context, the present in vitro study has certain value.

Additionally, a simplified power calculation was performed, which may not have fully reflected the complexity of the study: six surgeons using three different surgical approaches to place implants in four different sites. However, the fact that small, yet significant, differences were found between groups for six of the nine study outcomes (despite the use of a conservative Bonferroni correction) suggests that the study was not

entirely underpowered. Nonetheless, it is possible that the study was underpowered for some of the study outcomes.

5. Conclusions

The results of this in vitro study show that immediate implants placed using fully guided surgical guides have significantly less deviation, and are therefore more accurate, than implants placed freehand or using pilot guides. Furthermore, no significant difference in accuracy could be found between implants placed using a pilot guide and freehand. These results should be further validated in a randomized clinical trial.

Supplementary Materials: The following supporting information can be downloaded at: https://www.mdpi.com/article/10.3390/app14209253/s1, Table S1. Descriptive statistics of the primary and secondary variable for the surgical guidance level groups. Table S2. Results of the pairwise comparisons between the guidance level groups. Table S3. Minimal dataset. Figure S1. Distribution of the primary outcome data. Figure S2. Distribution of the secondary outcome data.

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Conflicts of Interest: Jan Cosyn has a collaboration agreement with Nobel Biocare (Göteborg, Sweden) and Straumann (Basel, Switzerland). The collaboration partners had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript; or in the decision to publish the results. The remaining authors declare no conflicts of interest.

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