The Impact of Surgical Guide Fixation and Implant Location on Accuracy of Static Computer-Assisted Implant Surgery

Running title: Guide Fixation and Implant Location on the Accuracy of sCAIS

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Conflict of Interest

The authors Roberto Pessoa, Gustavo Mendonca and Fábio Bezerra received consultant fees from S.I.N. Implant System. The remaining authors do not have any financial interests, either directly or indirectly, in the products or information listed in the paper.

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Abstract

Purpose: To evaluate the accuracy of static computer-assisted implant surgery (sCAIS) for tooth-supported free-end dental implantation with the aid/and without the aid of fixation pins to secure the surgical template through comparison between planned, 3D printed guide position and placement implant position.

Materials and Methods: Thirty-two duplicated maxillary resin models were used in the present in vitro study. Digital planning was performed and fabrication of a surgical template that allowed implant placement on the distal extension edentulous site of the model (maxillary left side). A first optical scan was performed after fitting the surgical template on the model to assess the deviation at the surgical guide level. After placing implants in the model using the surgical guide, scan bodies were attached to the implants, and a second scan was performed to record the position of placed implants. The digital representations were later superimposed to the pre-operative scan and measurements of implant deviations were performed. Global (coronal and apical), horizontal (coronal and apical), depth and angular deviations were recorded between planned implant position, guide position and placement implant position. Three-way ANOVA was used to compare implant location (#13, 14 and 15), fixation pin (with or without pin) and guide comparison (planned, guided and placement).

Results: Final implant placement based on the digital plan and based on the 3D printed guide were very similar except for depth deviation. Use of fixation pin had a statistically significant effect on the depth and angular deviation. Overall, without fixation pins and based on guide vs. placement, mean global coronal (0.88 ± 0.36 mm), horizontal coronal (0.55 ± 0.32 mm) and apical (1.44 ± 0.75 mm), and angular deviations (4.28 ± 2.01°) were similar to deviations with fixation pins: mean global coronal (0.88 ± 0.36 mm); horizontal coronal (0.67 ± 0.22 mm) and apical (1.60 ± 0.69 mm); and angular deviations (4.53 ± 2.04°). Horizontal apical without pins (1.63 ± 0.69 mm) and with fixation pins (1.72 ± 0.70 mm) was statistically significant (p=0.044). Depth deviation without pins (-0.5 ± 0.5 mm) and with fixation pins (-0.16 ± 0.62 mm) was also statistically significant (p=0.005). Further analysis demonstrated that the final sleeve position on the 3D printed guide was on average 0.5mm more coronal than the digital plan.

Conclusions: The use of surgical guides with or without fixation pins can provide clinically acceptable outcomes in terms of accuracy in implant position. There was a statistically significant difference in the accuracy of implant position when utilizing fixation pins only for horizontal apical and depth deviation. Additionally, a statistically significant difference between the planned and the 3D printed surgical guide when considering the sleeve position was detected.

KEYWORDS: digital planning, dental Implants, digital workflow, computer-aided implant surgery (CAIS), guided surgery, surgical guide

Precise implant positioning is essential to obtain favorable esthetic and prosthetic outcomes. Prosthetically driven implant surgery is recommended since it will ensure adequate prosthesis design favoring long-term stability of peri-implant hard and soft tissues.[1, 2] Surgical approaches combined with static computer-assisted implant surgery (sCAIS) can overcome likely deviations inherent to handsfree implant placement.[3-5] The last decade was marked by substantial overall improvement in the accuracy of sCAIS. Still, the variables that result in increased inaccuracies and sometimes the failure of the guided protocol are only partially known. Different factors can impact in the accuracy of the sCAIS, including but not limited to the nature of guide support, template position, fixation, fabrication process, flap approach, and implant insertion protocol (pilot-, partially- or fully-guided).[6-13] The type of guide support is considered a significant parameter in the accuracy of guided surgery. Previous studies on the topic have shown that tooth‐supported guides provided superior results than mucosa‐ or bone‐supported guides.[8, 10]

A recent in vitro investigation found that the number and location of teeth providing guide support can influence implant deviations. Placement of implants in distal extension circumstances, using sCAIS, resulted in more significant deviation when compared to implants placed in posterior areas with bilateral tooth support.[14] Previous studies have also reported more inaccuracy in distal extension situations due to possible movement, tilting, and bending of the surgical guide.[15, 16] However, in previous reports the exact number of implants placed at posterior sites, the position of teeth used for guide support, and the cantilever length of the surgical guide is unclear. In posterior edentulous spaces, fixation of the guide could be a solution to enhance its' stability, helping to overcome the negative influence provided by support at one end only in such cases.[16,17] Fixation of the surgical template was considered to reduce the inaccuracy of final implant position in previous studies using mucosa-supported surgical guides in edentulous patients.[18,19] To the authors knowledge, there are no studies investigating if the use of fixation pins to secure surgical template on sCAIS, for tooth-supported free-end dental arch implantation, provide improved accuracy.

Traditionally, studies reporting on accuracy of sCAIS measures the deviations between the planned implant position and achieved implant position.[20,21] Although this is an established outcome measure in the literature, no information on the source of inaccuracy can be assessed. Comparison between digitally planned implant position and implant position obtained through a three-dimensional (3D) printed guide seated in the mouth, as well as between 3D printed guide in position with the final implant position can give insightful information on the source of produced deviations. Therefore, the aim of this study was to evaluate the accuracy of sCAIS for tooth-supported free-end dental implantation using or not fixation pins to secure the surgical template through comparison between planned, 3D guide position and placed implant position.

Material and methods

Thirty-two duplicated maxillary models of resin and simulating both cortical bone and cancellous bone and soft-tissue simulated materials (Bonemodels, Spain) were used in the present in-vitro study (Fig 1A). There were three single edentulous ridge sites (#4, 7, 11), one site simulating an extraction socket (#9), and one distal extension ridge (#13, 14, and 15). Only the distal extension sites were used in the present study. The models were scanned by an intraoral scanner (IOS) 3shape Trios 3 to generate standard tessellation language (STL) files. A CBCT scan was performed (3D Accuitomo 170, J Morita, Kyoto, Japan; setting: 5 mA, 90 kVp, 17.5 seconds, voxel size of 0.27 mm, and field of view of 140 × 100 mm) to obtain Digital Imaging and Communications in Medicine (DICOM) files.

Digital implant planning was performed in 3Shape Implant Studio (Ver 2.17.2.7, 3Shape) by a clinician with experience in prosthodontics and digital dentistry (Fig 1B, 1C). Both STL and DICOM files were imported and superimposed by matching the mutual anatomical structures of teeth using software algorithm. The accuracy of alignment was checked in the cross-sectional view. When necessary, a manual adjustment was performed to achieve the best superimposition accuracy. Implants were planned on the distal extension edentulous sites (#13, 14, 15). A virtual tooth was designed on each implant site to mimic the definitive prostheses, and the 3D position of all implants was determined considering both model simulated bone volume and virtual restoration position. Since the guide reached the entire arch, four fixation pins were designed, with two pins placed at the buccal and palatal sides of the distal extension edentulous site. Tooth-supported surgical templates were designed involving the entire arch or guide stability and fabricated by an in-office desktop 3D printer (Form 2 SLA 3D printer; Formlabs, Somerville, Massachusetts) using a liquid photopolymerized resin (Dental LT, Formlabs) (Fig 1D).

The models were randomly allocated into two groups (with fixation pins and without fixation pins) according to a computer-generated number sheet. The surgical template was tried on the models to confirm passive accurate fit. For the group without fixation pins (Fig 2A), the template was secured on the model by hand only. Subsequently, implant beds were prepared using a guided implant surgical kit (Strong SW Guided Surgery Kit, S.I.N. Implant System, Sao Paulo, Brazil) following the drill sequence recommended by the manufacturer. After simulated osteotomy, 4.5x13mm implants (Strong SW, S.I.N. Implant System, Sao Paulo, Brazil) were inserted in a fully guided approach. For the group with fixation pins (Fig 2B), four fixation pins were inserted following preparation of the pin holes, before the in vitro surgery. After, the same simulated surgical protocol previously described, was followed.

Two optical scans were made on each model using the IOS 3shape Trios 3 to assess the deviations that occurred in different surgical steps. The first optical scan was performed after placing the surgical template on the model, capturing both the surgical guide and the model (Fig 3A). This scan was used to assess the deviation at the surgical template level. After implant placement, scan bodies were attached to the implants, and the second scan was performed to obtain the position of placed implants (Fig 3B).

A reference model of planned implant position was generated from the model scan and surgical guide 3D file. Each guide tube on the surgical guide was used as a scan body to locate the coronal and apical center of the planned implant. This reference file was imported into a dental CAD software (Exocad, Exocad GmbH, Darmstadt, Germany) for superimpositions of the post-operative scans. The post-operative scans of the template and placed implant positions were superimposed to the reference model, with a color map being used to verify the accuracy of superimposing. All the registered data were imported into BlueSky Plan software (Version 4.50, Blue Sky Bio, Illinois) along with pre-operative digital planning projects for measurements (Fig 3C, 3D). For accuracy assessment, deviations were determined as follows (Fig 3E): The global deviation was calculated as the 3D distance of coronal/apical center between the planned and actual implant positions. The angular deviation was defined as the 3D angle between the centerlines of the two positions. The depth deviation was the decomposition of the global deviation in part along the axis of the planned implant, and the lateral deviation was that in part perpendicular to it. All the above parameters were used in absolute value. Additionally, to illustrate the direction of depth deviation, the depth deviation was also recorded as positive when the actual implant is coronal to the planning or negative when apical to the planning.

All data were analyzed using a statistical software package (SPSS version 23.0). The description of data mean, and standard deviation (SD) were presented. Three-way ANOVA was used to confirm statistically significant difference for tooth position (#13, 14, and 15), fixation pin (with or without pin) and guide comparison (planned, placement and guide). The null hypothesis was that there is no deviation variance difference between the fixation pin group and without fixation pin group. Significance for statistical analyses was set at $P<.05$.

Results

Implants were placed in three areas (#13,14, and 15) to simulate the effect of the cantilevered guide on implant placement accuracy. Results are summarized in Figures 4 and 5. Discrepancies such as the fit of the surgical guide, fit of the sleeve on the printed guide, and/or from the surgical procedure itself was evaluated. In this study, three clinicians (R.S., I.S., and P.M.) performed the measurements showing excellent intra- and inter-examiner agreement, as reflected in intraclass correlations of approximately 0.9 ($p= 0.01$).

Figure 4 and 5 present data for global deviation (coronal and apical) and horizontal deviation (coronal and apical). Figure 4 shows data based on guide comparison (planned, placement and guide). Tooth position had a statistically significant effect on horizontal coronal accuracy. Tooth #15 had statistically significant differences from #13 ($p=0.009$, $F=4.797$). Comparison between digital plan and 3D printed guide had the smallest deviation with no statistically significant effect on global (coronal and apical) and horizontal (coronal and apical) accuracy ($p<0.0001$, see figure 4 for F-values). Comparison between 3D printed guide and final implant placement was statistically different from final implant placement based on the digital plan. Fixation pin had a statistically significant effect on horizontal coronal accuracy only ($p=0.002$, $F=10.035$). Figure 5 shows data comparing actual final implant position based on the 3d printed guide. It shows that horizontal coronal accuracy was affected by the fixation pin ($p=0.044$, $F=4.175$).

Depth deviation and angular deviation are presented in Figure 6 and 7. Figure 6 shows data based on guide comparison (planned, placement and guide). For depth deviation, the data was represented using absolute values (disregarding if the implant was more coronal or apical that the planning) and considering the direction. Comparison among digital plan, 3D printed guide and final implant placement also had a statistically significant effect on depth deviation (absolute values considering direction) and angular deviation ($p<0.0001$ see figure 6 for F-values). Comparison between digital plan and 3D printed guide had the smallest variation and was statistically different from final implant placement based on the digital plan and also the final implant placement based on the 3D printed guides for angular deviation ($p<0.0001$ see figure 6 for F-values). For depth deviation, there were statistically significant differences among all three comparisons. Fixation pin had a statistically significant effect on depth deviation when considering direction ($p=0.023$, $F=5.215$). The use of a fixation pin also reduced depth deviation when compared to the final implant position according to the 3D printed guide for all teeth (Figure 7). The most significant effect was noted on teeth #14 and 15 ($p=0.005$, $F=8.501$).

Final implant placement based on the digital plan (planned vs. placement) and based on the 3D printed guide (guide vs. placement) were very similar except for depth deviation (Figure 4 and 6). Further analysis demonstrated that the final sleeve position on the 3D printed guide was on average 0.5mm more coronal than the digital plan (Fig 6 and 7) ($p=0.0001$, $F=87.807$).

Discussion

The present experimental in vitro study evaluated the accuracy of implants placed in a distal extension model with and without the use of fixation pins to stabilize the surgical guide. Deviations were measured as traditionally reported between the planned and the final achieved implant position (planned vs. placement).[22-24] Additionally, differences between the planned and seated 3D surgical guide in the mouth (planned vs. guide) and the seated 3D surgical guide and final achieved position (guide vs. placement) were evaluated. Overall, deviations for the group without fixation pin in the comparison of guide vs. placement implant positions, mean global coronal (0.88 $\pm$ 0.36 mm) and apical (1.63 $\pm$ 0.69 mm), horizontal coronal (0.55 $\pm$ 0.32 mm) and apical (1.44 $\pm$ 0.75 mm), and angular deviations (4.28 $\pm$ 2.01°) obtained in this study are similar to deviations previously reported in the literature.[25, 26] A recent systematic review that evaluated the accuracy of implants placed in partially edentulous patients using fully-guided sCAIS, revealed a total mean angular deviation of 2.68° (95% CI: 2.32-3.03°), mean global coronal deviation of 1.03 mm (95% CI: 0.88-1.18 mm); mean global apical deviation of 1.33 mm (95% CI: 1.17-1.50 mm); and mean depth deviation of 0.59 mm (95% CI: 0.46-0.70 mm) [25]. In this study, when using fixation pin, mean global coronal (0.88 $\pm$ 0.36 mm) and apical (1.72 $\pm$ 0.70 mm), horizontal coronal (0.67 $\pm$ 0.22 mm) and apical (1.60 $\pm$ 0.69 mm), and angular deviations (4.53 $\pm$ 2.04°) values were slightly higher. It was the authors' understanding and operator tactile feeling that when the fixation pins were not used, the implant tried to follow the path of least resistance in the bone, often showing a bigger discrepancy to the guide orientation.

The results of this investigation demonstrate that the location of implant placement and the use of fixation pins for guide stabilization influence the accuracy of implant positions. Overall higher deviations were found for implants placed in distal extension in the present study compared to studies using similar methodology but reporting on implant location between adjacent teeth.[27, 28] Likewise, other groups reported significantly higher deviations when implants were placed in distal extension.[14, 16] Unlike the studies mentioned above, we placed three implants contiguously to estimate the effect of a greater distance between the most posterior implant location and guide support. There were statistically significant differences in accuracy between implants placed in #13, #14, and #15 positions when compared with and without fixation pins only for horizontal coronal and depth deviation. This is possibly explained by the fact that there was no difference in surgical guide fitting between the three implant locations, and careful implant site preparation and placement was performed to avoid movement of bending and tilting of the surgical guide. Implants on #14 positions showed more benefit from the fixation pin. That could be an effect attributed to the proximity of the fixation pin area and adjacent teeth.

To the best of our knowledge, this is the first in vitro study to estimate the influence of fixation pins on the distal extension of tooth-supported surgical guides. Stabilization of the surgical guide can offer an advantage in limiting guide movement during surgery. However, it adds an extra step to the procedure that is not free of potential errors. If the surgical template is not fully seated, the deviations generated by the surgical guide will accumulate and contribute to the final achieved position. Moreover, the use of fixation pins in a location distant to the edentulous surgical site can increase invasiveness of surgery by requiring anesthesia of an extra area, drilling through alveolar mucosa and potential risk of close relationship of roots and/or other important anatomical structures. Seating of the surgical guide was tested through IOS, and no statistically significant differences were noted when fixation pins were used or not. Intriguingly, deviations obtained from guide fitting were not fully incorporated during placement, meaning that deviation from the planned and actual position is not exactly the sum of deviations between planned and guided positions, plus deviation between guide and final position.

Concerning the accuracy of implant position in the apical-coronal direction it was noted in the present study that surgical guides were often approximately 0.5 mm more coronal than planned position (planned vs. guide). This specific finding suggests that the seating of the 3D-printed guide presented an error that would lead to the placement of the implant 0.5mm coronal to the planned position. Information on implant depth control is essential in guided surgery, since it is critical to avoid damaging vital anatomical structures.[29] In this study, implant depth deviation was analyzed in two ways. Positive values were considered for implants placed coronal to the planned position while negative values depicted an implant placed apical to the planning. When guide vs. placement implant positions were compared, implants were placed 0.25mm apical (negative values) to the position established by the surgical guide. When observing the comparison between planned vs. placement implant positions, the implants were placed 0.25mm coronal (positive values) than position depicted by the surgical guide. This variation came from the previously mentioned discrepancy between the planned guide and the 3D printed guide positions. Interestingly, implants in the group without fixation pin were approximately 0.5mm more apical whereas when the fixation pin was used the average depth deviation was only 0.2mm more apical than planned implant position. This finding can be explained by the result of pressure exerted by the stop of insertion driver in the apical direction that was not fully controlled by the operator. Without using the fixation pin when a drill stop or the implant carrier pressed over the surgical guide the soft tissue would compress and allow for the implant to be placed deeper. While a minimum of 0.5 mm as a vertical safety distance was recommended in 2012 at the third European Academy of Osseointegration (EAO) consensus conference, others have suggested a 1mm safety distance in the vertical direction.[6, 30] It is also important to mention that an absolute number can show an overall variation of implant vertical position, but this number cannot tell where exactly an implant is placed according to its' planning.

A comparison between digital planned implant position and implant position obtained from the 3D printed guide seated in the mouth showed small deviations. Previous published in vitro and clinical study have demonstrated that inadequate fitting of the surgical guide is an important source of inaccuracy in sCAIS.[31, 32] Deviations verified between final implant position compared to the digital plan, and also deviations between final implant position compared to the guide, were statistically greater than deviations between guide position compared to the planned position. This may lead to the observation that the major source of inaccuracy for guided surgery comes from the surgical procedure rather than the treatment plan. Previous reports have shown that movement of the surgical guide, limitations of patient mouth opening, and operator experience, significantly influence on the accuracy of outcomes.[33, 34] A simulated flapless surgical approach was used in the present study. Although opening or not a flap is recognized as risk factor for implant deviation, the literature remains controversial on the magnitude of this influence. Li and colleagues demonstrated in a cadaver study that open-flap group shows better depth control when manually inserting the implant (semi-guided sCAIS).[7] On the other hand, a clinical study by Dersken and coworkers, utilizing fully-guided surgery, exhibited no significant differences between flapless and open flap methods.[22]

Limitations of this study include but are not limited to the nature of the in-vitro study design, where a bone model simulating a patient jaw was used, and bone density together with anatomy is only partially represented. Also, the use of one surgical guide for multiple implant placement, limitation of the measurement methods used, including scanning procedure, alignment of the implant, scan body, and 3D printed surgical guide, can be source of deviations. The use of four fixation pins versus two fixations pins (restricted only to the surgical area) could not be assessed. Thus, conclusions regarding the clinical performance of surgical templates stabilized with fixation pins in distal extension cases must be cautiously drawn, and controlled clinical trials should be conducted to elucidate the influence of guide stabilization and implant position on accuracy of sCAIS.

Conclusion

There was a statistically significant difference in the accuracy of implant position when utilizing fixation pins to stabilize surgical guides only for horizontal apical and depth deviation (when considering direction). We also noted a difference between the planned and the 3D printed surgical guide when considering the sleeve position and that was considered the major reason for the depth deviation. Both ways of using surgical guides can provide clinically acceptable outcomes in terms of accuracy in implant position. Additionally, measuring the fit of the surgical guide seated in position before surgery provides noteworthy data on the source of deviation.

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Figure legends

Figure 1 (A) Model used in the present study, (B) and (C) Digital planning of implant sites and fixation pins, (D) 3D-printed surgical guide.

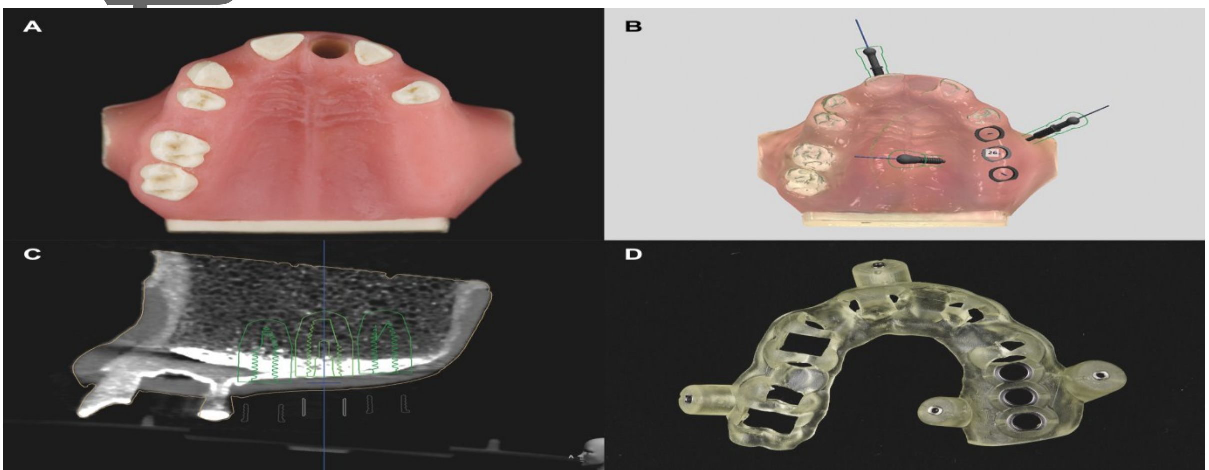

Figure 2 Implant osteotomy preparation (A) Group without fixation pins, (B) Group with fixation pins.

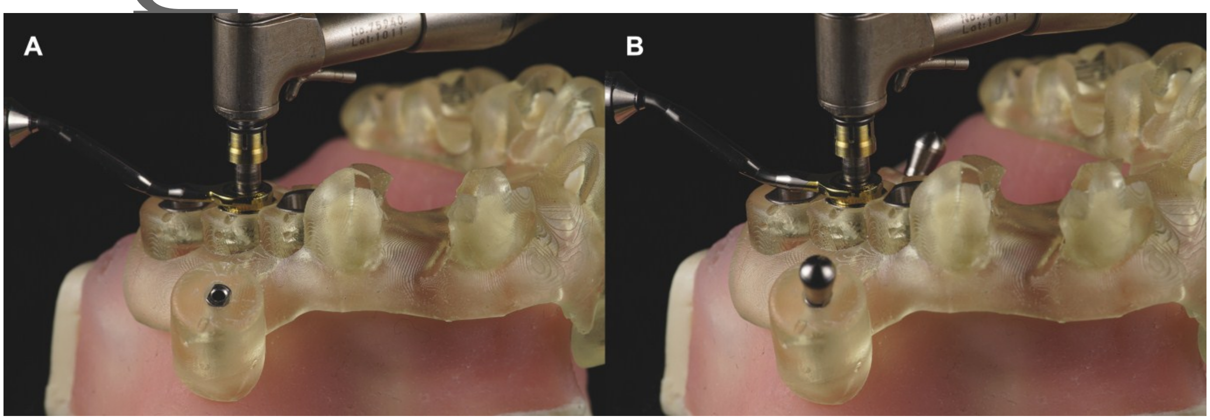

Figure 3 (A) Scan of surgical template with model, (B) Scan of implants position with model, (C) Comparison between guide position and planning position, (D) Comparison between placed implant position and planning position (E) Implant accuracy measurements.

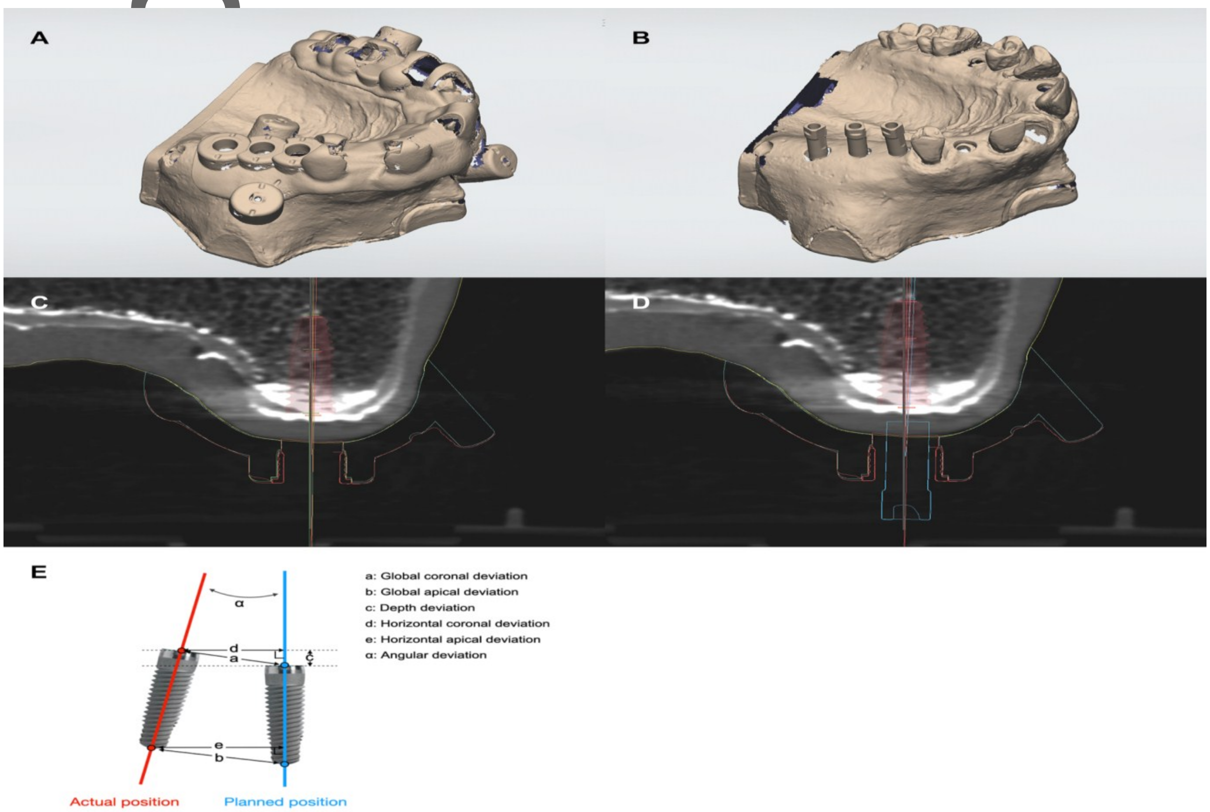

Figure 4. Box plots for implant deviations (A) Global coronal deviations of implant position without and with fixation pins (planned vs placement; guide vs. placement; planned vs. guide), (B) Global apical deviations of implant position without and with fixation pins (planned vs placement; guide vs. placement; planned vs. guide), (C) Horizontal coronal deviations of implant position without and with fixation pins (planned vs placement; guide vs. placement; planned vs. guide), (D) Horizontal apical deviations of implant position without and with fixation pins (planned vs placement; guide vs. placement; planned vs. guide).

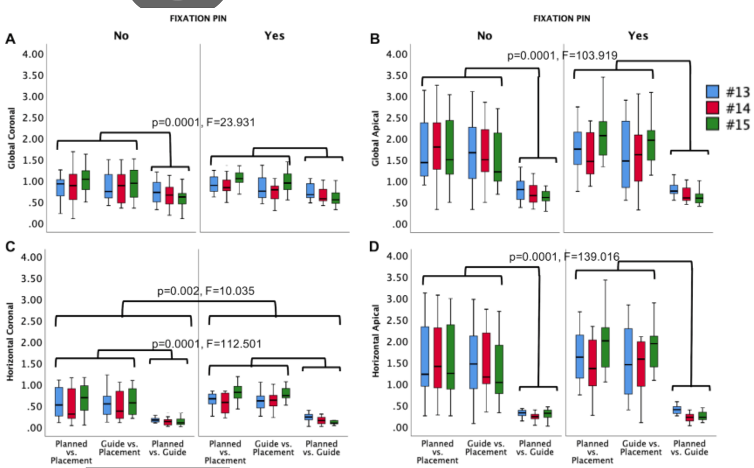

Figure 5. Box plots for implant deviations (A) Global coronal; (B) Global apical; (C) Horizontal coronal; and, (D) Horizontal apical deviations of final implant position without and with fixation pins based on the 3d printed guide (guide vs. placement).

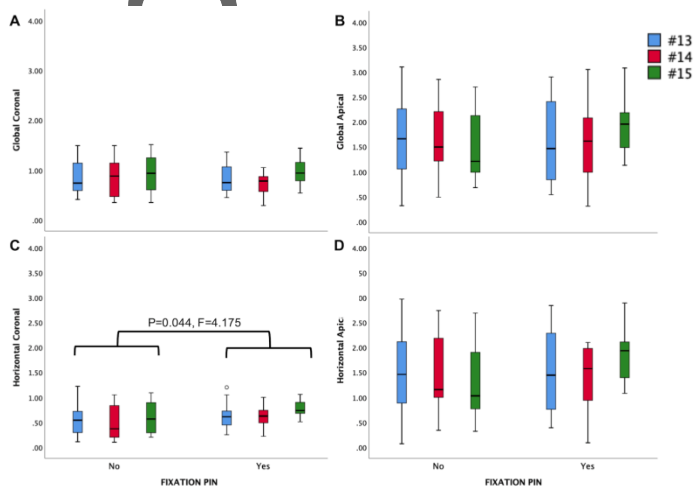

Figure 6. Box plots for implant deviations. (A) Depth deviation of implant position without and with fixation pins (positive values describes coronal direction and negative values refers to apical direction compared to planned position) (planned vs placement; guide vs. placement; planned vs. guide), (B) Depth deviation of implant position without and with fixation pins (considering absolute values) (planned vs placement; guide vs. placement; planned vs. guide), (C) Angular deviations of implant position without and with fixation pins (planned vs placement; guide vs. placement; planned vs. guide.

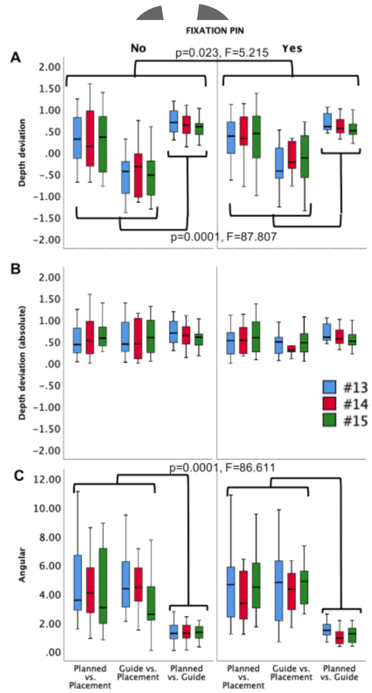

Figure 7. Box plots for implant deviations. (A) Depth deviation; (B) Depth deviation (absolute values); and, (C) Angular deviations of final implant position without and with fixation pins based on the 3d printed guide (guide vs. placement).