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Three-dimensional accuracy of implant placement related to the use of guide sleeves

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THREE-DIMENSIONAL ACCURACY OF IMPLANT PLACEMENT RELATED TO THE USE OF GUIDE SLEEVES

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Introduction

Since their introduction by Per-Ingvar Brånemark[1], implant supported prostheses have provided expanded restorative options for dentists. Implants serve as the foundation for many restorative modalities including single-unit restorations, multi-unit fixed dental prostheses, hybrid dentures, and overdentures. Therefore, it is not surprising that an emphasis on improved accuracy exists. In nearly all dental implant applications, the placement of dental implants in mesio-distal, facial-lingual, and apical directions is critical to the success and long-term survivability of restorations. Surgical guides aid in accuracy of implant placement by restricting drill movement to avoid erroneous angulation. However, one must not assume that surgical guides can be used without respect to the basic principles of implant placement[2].

Advances in bone grafting and accompanying sinus procedures have made restoratively-driven implant placement a reality. Multiple factors, such as opposing arch form, plane of occlusion, and interocclusal space are considered prior to surgery, as is maintaining adequate distance away from vital structures. As documented by D'Souza *et al.*[3]*,* there are three types of surgical guide designs; nonlimiting, partially limiting, and fully limiting designs. Each of these are fabricated in a different manner according to the desired amount of tolerance or surgical restriction. The fully limiting design has the least surgical tolerance in mesio-distal and buccolingual directions during implant placement. In addition, drill stops are commonly utilized to restrict apical placement.

In recent years, computer-aided design (CAD) and computer-aided manufacturing (CAM) also has imparted a significant degree of accuracy to the fabrication of fully limiting surgical guides[4,5]. After obtaining a three-dimensional image of the proposed surgical site via cone beam computed tomography (CBCT), the surgeon or restorative dentist can virtually plan implant placement using proprietary computer software programs. This information is also used to transfer the planned implant location to the surgical guide. After the surgical guide design is completed, the information is digitally transferred to a CAM unit where the guide can be fabricated via additive or subtractive manufacturing. Material jetting, specifically PolyJet® (Stratasys Inc., Rehovot, Israel) is an example of additive manufacturing, where photo-sensitive resin is expressed in incremental layers, and subsequently polymerized using ultra-violet light. As a result of this intricate process, fully limiting implant guides allow for the least amount of error and highest degree of accuracy, as compared to conventionally produced guides[6].

Despite ongoing improvements, employing a fully limiting surgical guide will not ensure a flawless result. As emphasized in the literature[7], the accumulation and interaction of errors involved in implant surgery may add up to a significant deleterious effect. Many anatomic variables have been found to contribute to the misplacement of dental implants, such as location within the dentoalveolar complex, bony characteristics of the surgical site itself, and type of mucosa overlying the area [8–10]. Additionally, there are more potential sources of error associated with the provider, such as inaccurate analysis of the CBCT, misuse of fixation pins during surgery, type of surgical guide fabrication, metal insert and instrument attrition during the procedure, and provider experience with implant placement[4,7,11–14]. In addition to anatomic based errors and provider sourced errors, there are also allowances permitted within the manufacturing process of the surgical guide itself that impart error to the guide system. As described by Cassetta *et al.*[15], there is an “intrinsic error” introduced by the rotational allowance for the implant drill. This gap between the metal guide tube and the drill head may introduce up to 5.15 degrees of unplanned angulation error.

Lee and associates[16] described a novel way of surgical guide fabrication, in which the metal guide sleeve, was incorporated into the design and subsequently printed via stereolithography. Thus, the size of the guide tube was compensated for, and the specific thickness of each guide tube was added to each lumen of the surgical guide. While the elimination of this step may make fabrication of a surgical guide easier for the provider, it has yet to be determined if the elimination of the metal guide tube affects the accuracy of implant placement. The purpose of this study was to investigate the accuracy of a surgical guide that has compensated for the metal guide tube within the digital design, and how it compares to a traditional surgical guide that employed a metal insert. The null hypothesis was that the resultant implant placement accuracy placed with a surgical guide with three-dimensional guide sleeve compensation is not inferior to implant placement accuracy with a surgical guide that includes metal guide sleeves.

Materials and Methods

Twenty-four identical edentulous mandibles (12 per group) with distally removed rami were printed via material jetting. Two to three millimeters of crestal bone (Figure 1) was also removed crestally in the mandible to facilitate ease of implant placement, as would be performed in a clinical surgical procedure.

All 24 mandibles were fabricated with homogenous density of material throughout; each fabricated from the same set of CBCT data to mimic realistic anatomical bony contours. Each mandible was digitally planned for the placement of 4 tapered implants being 4 millimeters in width, and 13 millimeters in length. Thus, a total of 48 tapered regular platform implants were placed of identical length and diameter. Half of the implants used in this study were of the Nobel Replace® body style (Nobel Biocare USA, LLC), while the other half of the implants were of the Biomet 3i Certain® body style (BIOMET *3i, LLC).* After a CBCT of a simulated patient's mandible was acquired, the location of each implant was planned digitally utilizing software provided by Blue Sky Bio (Blue Sky Bio, LLC) (See Figure 2). These specific implant locations were transferred digitally and integrated into the design of a fully limiting surgical guide. In order to add stability to the design, a platform surface was added to the inferior aspect of each mandible. Three fixation pins were incorporated into the guide design. In half of the fully limiting guides (equating to 48 implant sites), no metal guide sleeves were used. In these guides, the lumen of each guide sleeve hole was decreased to intimately fit the implant drill instead, thus compensating for guide sleeve size. In the remaining twelve fully limiting guides, a metal guide sleeve was inserted into each of the four holes that correspond with a specific implant location and bonded using cyanoacrylate (Fig 3).

All implants were placed according to the respective manufacturers' instructions with guided surgery kits (NobelGuide® and Biomet 3i Navigator®). The surgical guides were intimately placed over the printed mandibles and stabilized with three fixation screws (labeled A; Figure 3). Resin debris within the osteotomy sites was eliminated with bursts of compressed air at 30 PSI. All implants were placed by a single operator and tightened to the manufacturers' recommended torque values. After implant placement, a CBCT of each mandible was made to record the implants' positional information using the same settings as the pre-placement scan. After the generation of X, Y, and Z-axis coordinates and merging of like surfaces, the planned and placed implant locations were compared. The accuracy of each implant position was determined by comparing the pre-operative virtual implant position utilizing Blue Sky Bio software to the actual implant position in the second CBCT scan in GeoMagic software (3D Systems Inc., 2014). The accuracy was compared in three dimensions: angular deviation, deviation at implant entry point, and deviation at implant apex between planned and placed implants (see Fig 4). Data was analyzed using a non-inferiority test comparing guided placement with metal sleeve versus guided placement with metal sleeve dimensions integrated into digital design in angular, entry point, and apex deviation dimensions.

Data sets in Excel (Microsoft® Excel 2010) were exported into a statistical software program (SAS® 9.4; Cary, NC). For the non-inferiority analyses for angular deviation, entry point deviation, and apex deviation, p-values and confidence intervals for difference were computed using independent t-tests. The non-inferiority margins (clinically meaningful limits) were set to the mean difference in outcomes at ±1.9° for angular deviation, ±0.5mm for entry point deviation, and ±0.625mm for apex deviation. This was to test that the new treatment (without sleeves) was not worse (equivalent or better) than the control (with sleeves) within acceptable values. With the inferiority test, a P-value less than 0.05 indicated that the test rejected inferiority with the upper confidence limit well below the non-inferiority margin. Acceptable values were generated from mean error values from a previous meta-analysis[17]. In comparisons where outcomes were not normally distributed, the Wilcoxon rank sum test and Kruskal-Wallis test were used to analyze test group differences. Please see figure 5 for reference.

Results

The actual position of the implants placed was assessed relative to the digital planned implant position for guides that incorporated metal sleeves and for those that did not. The first analysis compared all implants placed with sleeves (WSB) to all implants placed without sleeves (WOB). Platform deviation for group WSB (Mean=0.584; Mdn = 0.553; IQR: 0.396 – 0.674) was significantly smaller than for group WOB (Mean=0.703; Mdn = 0.770; IQR: 0.539 – 0.847) (Z = -3.36, p = .0008). The apical deviation for group WSB (Mean=0.720; Mdn = 0.628; IQR: 0.492 – 0.925) was significantly smaller than for group WOB

(Mean=0.840; Mdn = 0.880; IQR: 0.696 – 1.001) (Z = -2.33, p = .0196). There was no significant difference for angle deviations between group WSB (Mean=1.64°; Mdn=1.535°; IQR: 0.842– 2.109°) and group WOB (Mean=1.51°; Mdn = 1.525°; IQR: 1.020 – 1.875°) (Z = 0.15, p = .88).

In analysis two, group WSB was compared to group WOB-A (without sleeves; Nobel and 3i-adjusted). In this analysis, the 3i group without sleeves data was adjusted to compensate not only for the circumferential width of the metal sleeve, but also the vertical height of the horizontal projection at the top of the metal sleeve. With this minor adjustment, there was no significant difference for platform deviations between group WSB (Mdn = 0.553; IQR: 0.396 – 0.674) and group WOB-A (Mean=0.487;Mdn = 0.439; IQR: 0.382 – 0.590) (Z = 1.73, p = .08) and no significant difference for apical deviations between group WSB (Mdn = 0.628; IQR: 0.492 – 0.925) and group WOB-A (Mdn = 0.582; IQR: 0.469 – 0.795) (Z = 0.64, p = .52). There was also no significant difference for angle deviations between group WSB (Mdn = 1.535; IQR: 0.842 – 2.109) and group WOB-A (Mdn = 1.525; IQR: 1.020 – 1.875) (Z = 0.16, p = .88).

In analyses three and four, comparisons of implant location were made based on implant manufacturer, being Nobel Biocare and Biomet 3i respectively. In analysis three, group WSN (with sleeves; Nobel) was compared to group WON (without sleeves; Nobel). After evaluation, it was found that there was no significant difference between the two groups for platform deviation (Z = 0.98, p = .33), apical deviation (Z = 0.77, p = .44), or angular deviation (Z = 1.31, p = .19). In analysis four, significant differences between group WS3 (with sleeves; 3i) and group WO3 (without sleeves; 3i) were found in the variables of platform and apical deviation. With platform deviation, group WS3 (Mean=0.494; Mdn = 0.494; IQR: 0.392 – 0.607) was significantly smaller than for group WO3 (Mean=0.844; Mdn = 0.847; IQR: 0.778 – 0.894) (Z = -5.31, p < .0001). Similarly, group WS3 had a significantly smaller amount of apical deviation (Mean=0.646; Mdn = 0.603; IQR: 0.512 – 0.725) than group WO3 (Mean=0.968; Mdn = 0.955; IQR: 0.880 – 1.076) (Z = -4.28, p < .0001). No significant difference in angular deviation was found (Z = -1.31, p = .19).

In analysis five, the data was analyzed respective to the implant manufacturer (Biomet 3i), and group WO3-A (without sleeves; 3i) data was adjusted for more accurate sleeve dimensions, as explained previously.

When the data of the two groups, group WS3 and group WO3-A, was compared, no significant difference was found in the variables of platform (Z = 1.87, p = .06)., apical (Z = 0.42, p = .67)., or angular deviation (Z = -1.29, p = .20). See Fig. 6.

All data sets were then subjected to non-inferiority tests to test the null hypothesis (see table 1). The results confirmed that the non-significant results from the superiority hypothesis tests indicated that sleeve compensation (Nobel and 3i-adjusted) method is not inferior to the gold standard (with sleeves). For the platform and apical deviations, the group WO3 was inferior to group WS3. The group WOB was inferior to the group WSB, but it was attributed to 3i data interference. When Nobel groups WSN and WON were tested separately, the group without sleeves was not inferior to the group with sleeves (see Table 2).

Discussion

The precise and accurate placement of implants is vital to longevity and success of implant retained prostheses[18,19] . Addition of computer aided planning to implant placement and 3D-printed guides has resulted in highly accurate implant placement with minimal errors, as compared to free-hand placement [17,20,21]. Nevertheless, with the inclusion of digital technology, errors may still occur. One of the influencing factors is the accuracy of CBCT data. As discussed previously, models digitized from CBCT data failed to meet the accuracy of models printed from optical scans[22]. It should also be noted that the 3D-printing method can play a role in contributing to the cumulative error. Although PolyJet printing has been shown to be more accurate than other printing methods such as stereolithography[23], this fact should not negate the consideration that error does not occur entirely. These details should be taken into consideration when choosing to print surgical guides via additive manufacturing, based off of implant planning using CBCT technology.

3D-printed surgical guides are subject to cumulative errors. In various studies[24,25], an assumed tolerance within the guide sleeve inserts that allows a small amount of movement of the implant osteotomy drill from the planned pathway has been demonstrated. This can lead to deviation in implant placement if the surgical drill is not kept parallel to the guide sleeve after the surgical guide is fully seated and stabilized. Even a minor deviation from the planned pathway can result in binding of the surgical drill, inaccurate implant placement, and a resultant incomplete seating of the implant mount (see Figure 7). Specifically in this study, it was observed that the Nobel Biocare guide sleeves were prone to becoming debonded from the lumen of the surgical guide, as well as being prone to apical displacement. This was not found to be true of the guide sleeves fabricated by Biomet 3i, due to the top metal edge of the guide sleeve design that prevented vertical displacement (see Figure 8). However, it should be noted that the thickness of the top metal edge should be accounted for when fabricating 3D-printed guides that compensate for the dimensions of the guide sleeves. This was not initially done in this study for the Biomet 3i surgical guides that did not utilize a metal guide sleeve, but was later mathematically accounted for in the data analysis. This represents a potential decrease in the internal validity of the study. All of the factors listed can also be exacerbated by lack of operator experience, which can also contribute to a significantly larger amount of error, as compared to expert operators[26].

Other patient-based factors that can contribute to implant placement accuracy not mentioned due to the edentulous in vitro design of this study are density of bone, number of teeth to support the surgical guide, and implants placed in extraction sockets versus healed ridges[27]. In this in vitro design, the mandible was printed of homogenous material that had physical properties dissimilar human bone. This created drilling protocol issues for both surgical systems. Future research could account for this through development of a more accurate in vitro model closely mimicking the various densities of cortical and cancellous bone.

In this study, the inclusion of the verticality of the horizontal projection at the top of the Biomet 3i guide sleeve proved to be significant. When all implant positions were analyzed and the Biomet 3i data was calibrated to reflect accurate guide sleeve dimensions, there was no significant difference between the implants placed with a surgical guide that contained metal guide sleeves and the implants placed with a surgical guide that compensated for the dimensions of the guide sleeve.

When the data was separated into groups, the findings were similar. With the Nobel guides, there was no significant difference between the implants placed through a guide with metal guide sleeves, or a guide that did not contain metal guide sleeves. Interestingly, the group WSN had a much higher angular deviation than that of group WON, which may be explained by the frequent dislodgement of the guide sleeves within the lumen of the surgical guide. It should be noted that although this difference was larger, it was not statistically significant. With the Biomet 3i guides, when the group containing metal guide sleeves (WS3) was compared to the group without metal guide sleeves (WO3), there was a significant difference in implant placement in platform and apical deviation. However, when the Biomet 3i data was adjusted to include the top horizontal projection of the guide sleeve, there was no significant difference in the three variables investigated.

The inferiority testing was done in this study to discern whether one treatment was inferior to another in regards to inclusion or compensation for the metal guide tube. In this analysis, statistically significant differences were found between the WSB and WOB comparison, and also the WS3 and WO3 comparison. In the assessment of these data pairings, the group that included guide sleeve dimensions in the surgical guide design, thus not requiring the guide sleeves, was found to be an inferior treatment as compared to groups WSB and WS3, which included the metal guide sleeve. However, when the data was adjusted to include the vertical projection of the Biomet 3i guide sleeve, it was found the surgical guides not requiring guide sleeves resulted in implant placement that was not statistically inferior to the implant placement with surgical guides that included metal guide sleeves.

Caution should be exercised when extrapolating the in vitro study conclusions of this study to clinical practice. More in vivo studies are needed to include patient-based variables that were not able to be replicated in this investigation, such as tissue thickness, implant angulation, anatomical variations, and bone density variation.

Conclusion

Within the limitations of this study, it can be concluded that the capability to print surgical guides that compensate for the complete dimensions of the guide sleeve resulted in implant placement accuracy that was not inferior to the implant placement accuracy resultant from printed surgical guides that include luted metal guide sleeves into the design.

Disclosure

The opinions or assertions contained herein are the private ones of the author(s) and are not to be construed as official or reflecting the views of the DoD or USUHS.

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Tables:

Table 1. Mean Deviation of Implants from Planned Position

Mean Deviation			
Group	Platform (mm)	Apical (mm)	Angulation (deg)
WSB	0.5842432	0.7200103	1.640333
WOB	0.7034729	0.8405496	1.510854
WOB-A	0.4874161	0.6621078	1.511688
WSN	0.6748425	0.7939738	1.998167
WON	0.5626495	0.7134430	1.547125
WS3	0.4936438	0.6460468	1.282500
WO3	0.84430	0.9676563	1.474583
WO3-A	0.4121827	0.6107726	1.476250

Table 2. Summary of Non-inferiority test results.

Group Comparison	Outcome	Noninferiority Margin	P for rejecting inferiority
WSB vs. WOB	Platform Deviation	0.5	1.00
	Apical Deviation	0.6	1.00
	Angle Deviation	1.9	<.0001
WSB vs. WOB-A	Platform Deviation	0.5	<.0001
	Apical Deviation	0.6	<.0001
	Angle Deviation	1.9	<.0001
WSN vs. WON	Platform Deviation	0.5	<.0001
	Apical Deviation	0.6	<.0001
	Angle Deviation	1.9	<.0001
WS3 vs. WO3	Platform Deviation	0.5	.9995
	Apical Deviation	0.6	1.00
	Angle Deviation	1.9	<.0001
WS3 vs. WO3-A	Platform Deviation	0.5	<.0001
	Apical Deviation	0.6	<.0001
	Angle Deviation	1.9	<.0001

Table 2. P-value < 0.05 indicates the test rejects inferiority.

Figures

Figure 1.

Figure 2.

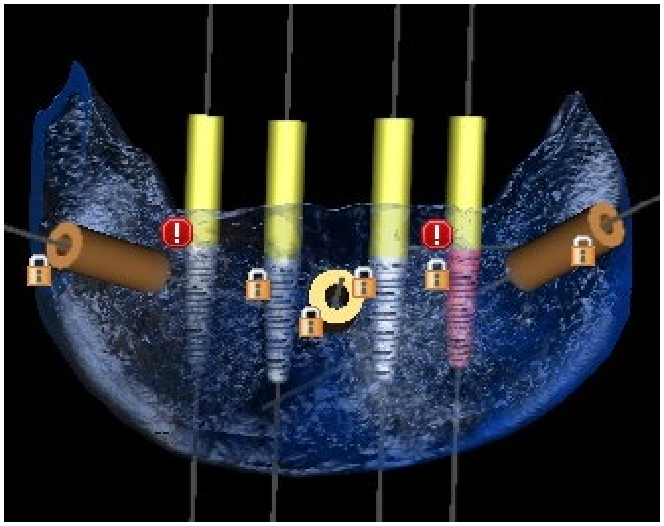

Figure 3.

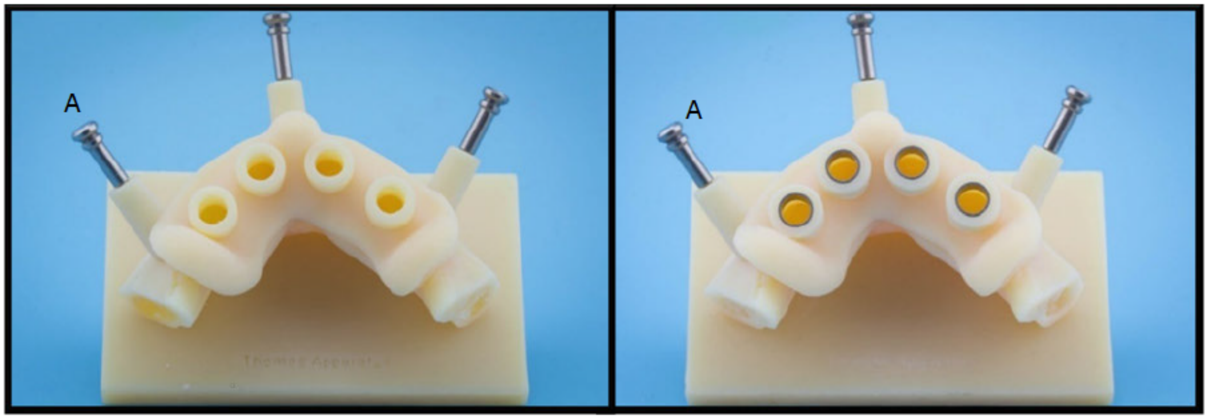

Figure 3: Design with guide tube compensation vs. design with guide tubes included (fixation pins labeled A). Note the resin platform added for stability.

Figure 4.

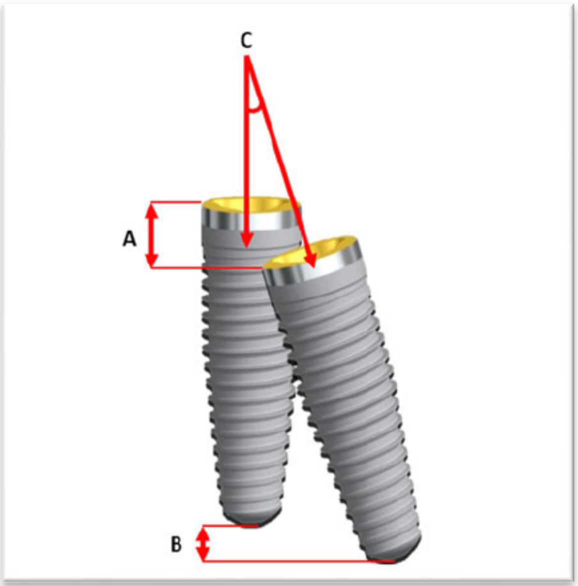

Fig. 4: Variables tested were: A) platform deviation; B) apical deviation; and C) angular deviation.

Figure 5.

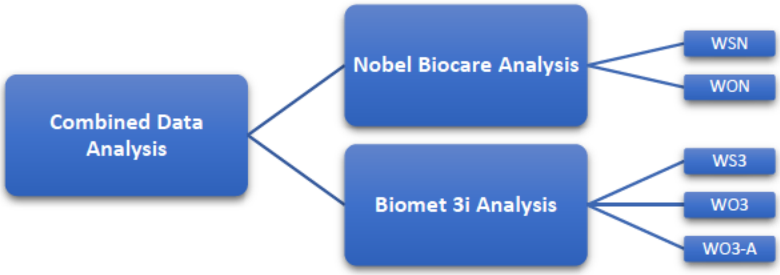

Fig 5. Analyses were performed separately for each implant manufacturer, and also combined.

Figure 6.

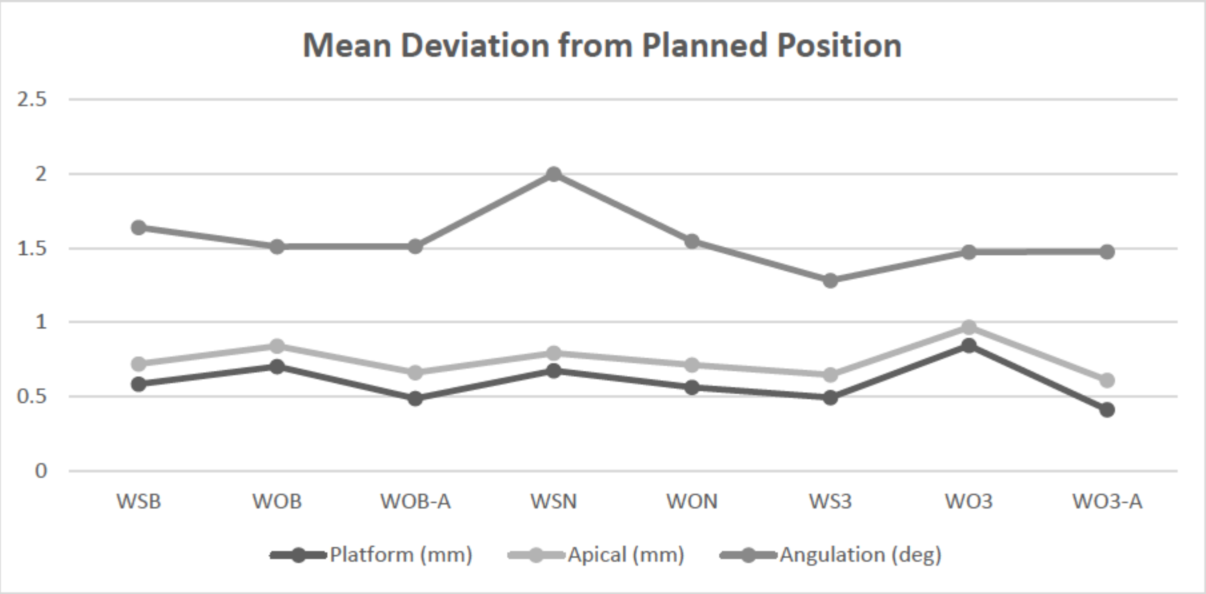

Figure 7.

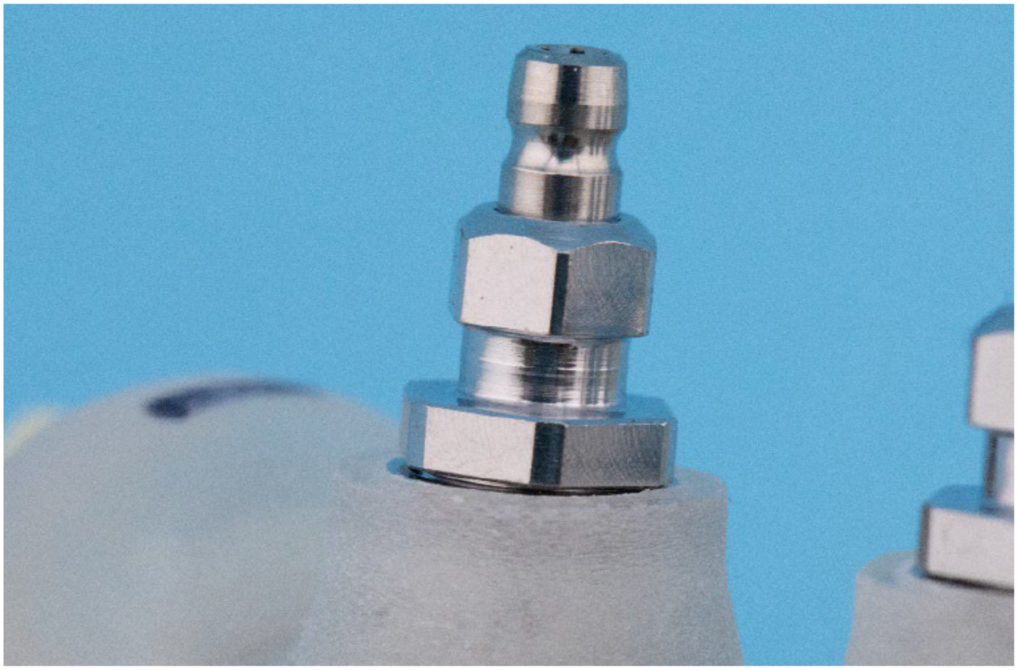

Fig. 7: Deviation from the planned drill pathway is evidenced by incomplete seating of the implant mount.

Figure 8.

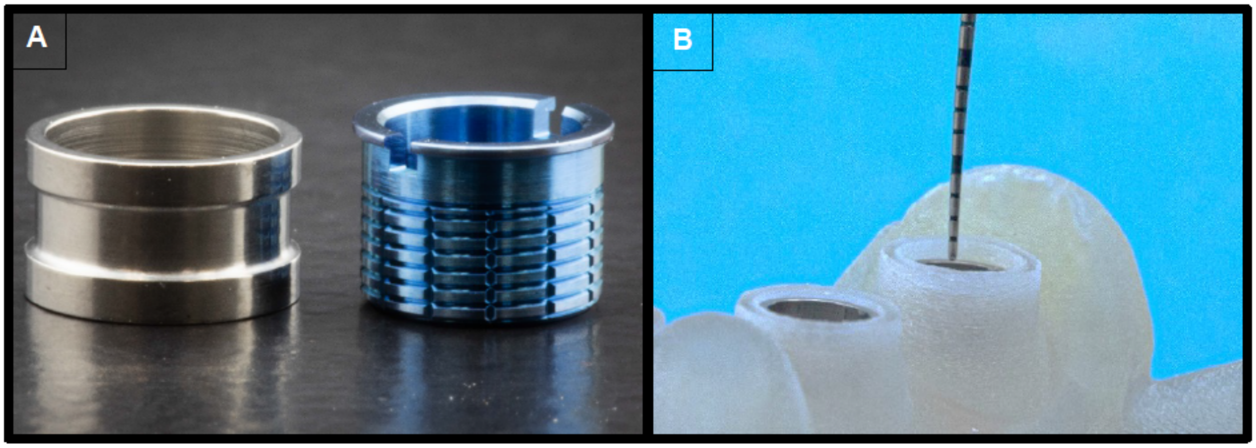

Fig. 8: Horizontal metal projections at the top of the guide sleeve (A; right guide sleeve) can prevent dislodgement and vertical displacement of the guide sleeve, as seen in with surgical guide (B).