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Precision and Trueness of Implant Placement With and Without Static Surgical Guides: An in vitro Study

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Precision And Trueness of Implant Placement with And Without Static Surgical Guides: An In Vitro Study

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Abstract

Statement of problem

Malpositioning of implants is one of the main factors leading to hard- and soft-tissue deficiencies. Whether static computer-guided implant placement increases accuracy and prevents malpositioning is unclear.

Purpose

The purpose of this in vitro study was to determine accuracy defined by trueness and precision (according to International Organization for Standardization 5725) of computer-assisted implant surgery (fully guided and partially guided) in comparison with freehand single implant placement.

Material and methods

Implants (n=20) were placed fully guided (sleeve-bone distance of 2, 4, or 6 mm), partially guided (guide used for pilot drill), or free hand in identical replicas produced from a cone beam computed tomography (CBCT) scan of a partially edentulous patient. The achieved implant position was digitized by using a laboratory scanner and compared with the planned position. Trueness (planned versus actual position) and precision (difference among implants) were determined. The 3D-offset at the crest of the implant (root mean square between virtual preoperative planning and postoperative standard tessellation language file) was defined as the primary outcome parameter. The means, standard deviation, and 95% confidence intervals were analyzed statistically with 1-way ANOVA and the Scheffé procedure.

Results

Fully guided implant surgery achieved significantly lower 3D deviations between the planned and actual implant position with 0.22 ±0.07 mm (2-mm sleeve-bone distance) than partially guided 0.69 ±0.15 mm and freehand placement 0.80 ±0.35 mm at the crest ($P<.001$). The distance among the implants in each group was again lowest in the fully guided group and highest in the freehand group.

Conclusions

The static computer-assisted implant surgery showed high trueness and precision. The closer the sleeve to the bone, the more accurate and precise the method. Freehand implant placement was less accurate and precise than computer-assisted implant surgery (partially or fully).

Clinical Implications

Malpositioned dental implants lead to bone and soft-tissue defects, contribute to peri-implant diseases, and are challenging to restore. Computer-assisted implant surgery delivers predictable outcomes and may prevent malpositioning. Fully guided implant procedures accurately translate the planned implant position into the clinical situation.

Dental implant–supported restorations are a reliable option with good long-term results.[1] However, key factors that make implants reliable include successful osseointegration,[2] placement in a position that reduces surgical complications, such as nerve injury or cortical plate perforation,[3] and an implant position that is compatible with the prosthesis.[4] Otherwise, the functional or esthetic result might be less than optimal.[5]

The most common pathological clinical findings associated with dental implants are hard- and soft-tissue deficiencies. Hard-tissue defects at implant sites encompass intraalveolar, dehiscence, fenestration, horizontal ridge, and vertical ridge defects. Soft-tissue defects include volume and quality deficiencies with a lack of keratinized tissue. These deficiencies can cause complications, including marginal bone loss, soft-tissue inflammation, and soft-tissue recession. Among the etiologies for tissue deficiencies, incorrect positioning of an implant can be avoided by proper treatment planning and the accurate placement of the implant in the prosthetically ideal position.[6]

A correct prosthetically driven 3D positioning of the implant is essential for a successful treatment outcome.[7] In addition, correct positioning of the implant enables the definitive prosthesis to be optimally designed and makes it possible to devise and fabricate retrievable screw-retained prostheses, thereby avoiding cemented restorations.[8]

Clinical studies have reported that static computer-guided implant placement by using templates delivers accurate and predictable outcomes.[1,9, 10, 11, 12] Clinical complications of computer-assisted implant placement by using static guides are rare and comparable with those of freehand implant placement.[13]

The International Organization for Standardization (ISO) standard 5725 uses the terms trueness and precision to describe accuracy. Trueness refers to the closeness of agreement between the arithmetic mean of a large number of test results and the true or accepted reference value. Precision refers to the closeness of agreement between test results.[14] The determination of accuracy in clinical trials is often limited. In trials investigating implant protocols, such as comparing freehand versus guided implant placement, the procedure cannot be repeated in the same patient with the same clinical characteristics. Authors try to bypass this limitation and refer to the standard deviation as a measure of precision.[1,11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29] The standard deviation (sigma-deviation) provides no information about the distance among the implants. Precision as the degree to which repeated measurements show the same results might be best assessed in in vitro studies with replicas of a single standardized clinical situation. Therefore, a study protocol was developed to measure not only the trueness of implant placement methods (actual versus planned position) but also to assess the precision (distance among implants) as defined in ISO 5725.

Computer-assisted guided implant surgery by using a fully guided approach (full osteotomy and implant placement by using a static surgical guide) was compared with partially guided (Guide was used for the pilot drill only.) and freehand implant placement (no guide used) in an in vitro experimental design. The null hypothesis was that no difference in trueness and precision would be found between fully guided implant placement, partially guided implant placement, and freehand implant placement.

Material and methods

The study was conducted on 100 identical mandible replicas obtained from a cone beam computed tomography (CBCT) scan of a partially edentulous patient. The CBCT scan was indicated solely for medical or dental reasons and not for research purposes. The local institutional review board (IRB) approved access to the CBCT data (IRB protocol#: HR-1807025341). The CBCT was used to acquire the 3D image data set for digital implant planning and to create a computer-aided design (CAD) file of the mandible that was transferred as a standard tessellation language (STL) file for stereolithographic printing (Gray resin version 4 using the Form 2 printer; all Formlabs Inc).

By using an implant planning software program (coDiagnostiX; Dental Wings GmbH), a single implant (Bone level tapered 4.1×10 mm; Institut Straumann AG) was virtually planned for the mandibular right first molar position according to the bone anatomy and the prosthetic design.

Surgical guides were planned for the virtual planned implant position. All guides were 3D printed with a class I biocompatible resin (Dental SG resin, 1 L RS-F2-DGOR-0; Formlabs Inc). Surgical guides for fully guided implant placement were planned with a Ø5×5-mm sleeve (T-sleeve; Institut Straumann AG) and a different sleeve for different bone distances (Fig. 1 shows an example of the surgical guide with a bone-sleeve distance of 4 mm.). The sleeve heights specified the free distances of the sleeves to bone levels of 2, 4, or 6 mm (coded as H2, H4, and H6). The sequential drilling of all osteotomies was performed according to manufacturer recommendations by 1 investigator (L.S.).

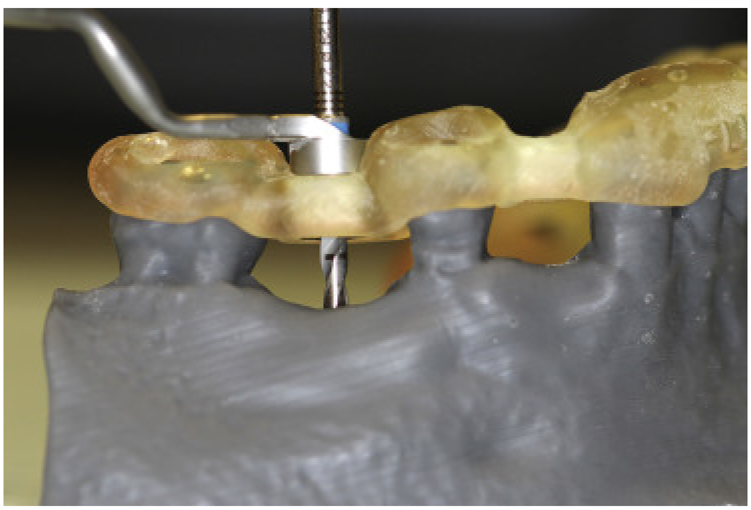

Figure 1. Surgical guide with bone-sleeve distance of 4 mm placed on 3D printed mandible with drill handle and 2.2-mm pilot drill for fully guided approach.

The sleeve dimensions for the surgical guide for partially guided implant placement were 2.2×6 mm (drill sleeve with funnel; steco-system-technik GmbH & Co KG), corresponding to the diameter of the pilot drill. The sleeve-to-bone distance for this guide was 2 mm. The static guide in the partially guided group was used only for the pilot drill. The remaining drilling sequence was performed free hand. No guide was used in the freehand group. The full surgical drilling sequence was performed free hand.

Twenty implants were placed by a single operator (L.S.) in the freehand group, in the partially guided group, and in 3 fully guided groups (sleeve heights of 2, 4, and 6 mm). After implant placement, scan bodies were hand tightened on the implants. The achieved implant position was digitized by using a laboratory scanner (D2000; 3Shape A/S) with an accuracy of 8 µm (claimed by the manufacturer). STL files were imported into the planning software program.

Virtually planned (reference) and postoperative implant STL files were superimposed by using a best-fit algorithm and compared with the treatment evaluation tool of the software program. The 3D deviation at the crest and apex of the implant (as root mean square between virtual preoperative planning and postoperative STL file) was defined as the primary outcome parameter. Secondary outcome parameters were the angular deviation and the mesiodistal, buccolingual, and coronoapical deviation at the crest and apex. The deviations in the buccolingual, mesiodistal, and coronoapical direction at the crest and the apex were evaluated (Fig. 2). Trueness (planned versus actual position) and precision (difference among implants) according to ISO 5725 were determined. The treatment evaluation was performed single-blinded (A.G.).

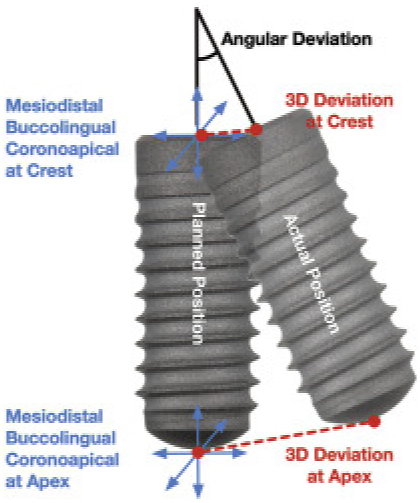

Figure 2. Assessed parameters of implant deviations from planned position.

An a priori sample size calculation determined a sample size of 20 per group (N=100) with α=.05 and an effect size of 0.42 for a targeted 80% power (G∗Power 3; free statistical software). A post hoc analysis showed that the power of the study was 91%.[30]

Means, standard deviations, and 95% confidence intervals were calculated for angulation and position discrepancies. All statistical computations were performed by using a statistical analyzing software program (IBM SPSS Statistics, v25; IBM Corp). Trueness was determined as the difference between the actual and planned (=reference) position, with each of the 20 measurements per group using the magnitude of the values. Precision was calculated as distances between each implant within a group (191 values per group). A 1-way ANOVA was conducted to assess the overall statistical significance of differences among different groups. Scheffé multiple comparison tests were used to test the differences among the groups (α=.05).

Results

The ANOVA detected significant differences among the groups, with the greatest deviation from the reference value detected when implants were placed free hand. In this group, the 3D deviation at the crest was 0.80 ±0.35 mm and at the apex 1.53 ±0.74 mm. The Scheffé multiple comparisons revealed significant differences between implant placement with a static surgical guide, either partially guided or fully guided, and freehand placement (*P*<.001). The implants placed by the partially guided protocol showed a 3D deviation at the crest of 0.69 ±0.15 mm and at the apex of 1.13 ±0.36 mm. In comparison with partially guided or freehand surgery, fully guided placement had the lowest deviation from the reference value (highest trueness) with 0.22 ±0.07 mm 3D deviation at the crest and 0.38 ±0.13 mm at the apex for the H2-group, 0.45 ±0.16 mm deviation at the crest and 0.61 ±0.18 mm at the apex for the H4-group, and 0.43 ±0.15 mm deviation at the crest and 0.69 ±0.19 mm at the apex for the H6-group (*P*<.001).

The data are presented in Figures 3, 4 as box-plot diagrams. The reference value in these diagrams is set as zero. The closer the actual values to the zero line, the higher the trueness of the respective method. The H2 group showed the lowest deviation from the planned position and therefore had the highest trueness.

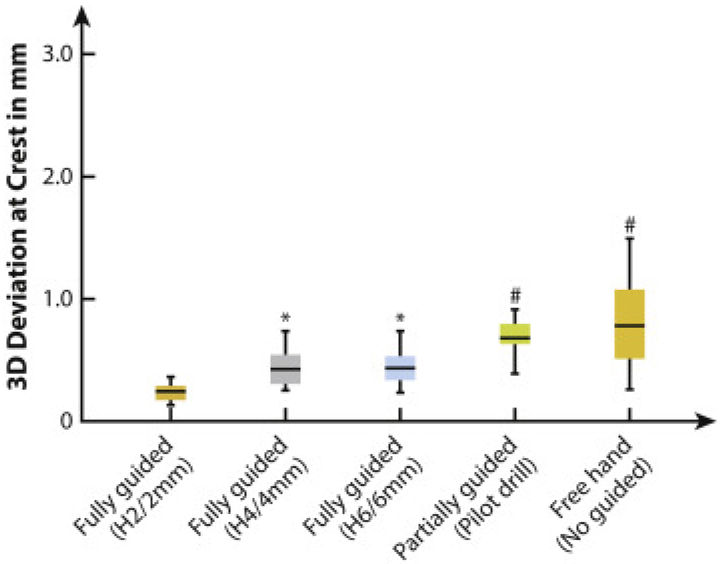

Figure 3. Three dimensional deviation at crest of each n=20 implants. Lowest deviation found in fully guided group with 2-mm bone-sleeve distance (∗*P*<.05, significantly different from H4 and H6). Partially guided and freehand implant placement significantly higher 3D deviations than all fully guided groups (#*P*<.05).

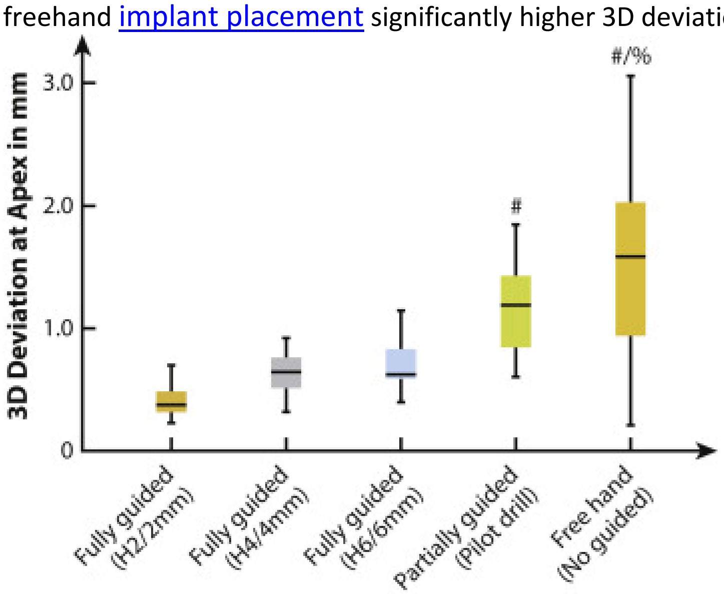

Figure 4. Three dimensional deviation at apex of each n=20 implants. Partial and freehand placement showed significantly higher 3D deviation than fully guided placement (#*P*<.05). Freehand placement resulted in higher deviation than partially guided placement (%*P*<.05).

The means, standard deviations, and 95% confidence intervals for the angular deviations from the actual position, as well as the linear deviations in the mesiodistal, buccolingual, and coronoapical direction at the crest and apex and the *F* and *P* values for the ANOVA test, are presented in Table 1. The higher the *F* value, the higher the difference between the groups.

Table 1. Trueness of implant position as discrepancy between planned and actual position

Trueness (Planned vs Placed)		**Fully Guided (2 mm)**	**Fully Guided (4 mm)**	**Fully Guided (6 mm)**	**Partially Guided**	**Free Hand (No Guide)**	**ANOVA**	
		Mean (SD) [95% CI]	**Mean (SD) [95% CI]**	**Mean (SD) [95% CI]**	**Mean (SD) [95% CI]**	**Mean (SD) [95% CI]**	***F* Value**	***P***
Angle (degrees)		1.35 (0.52) [1.10-1.60]	1.47 (0.62) [1.17-1.76]	1.79 (0.57) [1.51-2.00]	2.85[c] (1.47) [2.16-3.53]	4.86[c,d] (2.10) [3.89-5.82]	28.37	<.001
Crest (mm)	Distal	0.11 (0.09) [0.07-0.15]	0.15 (0.09) [0.11-0.19]	0.19[a] (0.13) [0.13-0.26]	0.14[c] (0.11) [0.09-0.20]	0.67[c,d] (0.27) [0.48-0.87]	24.87	<.001
	Buccal	0.08 (0.07) [0.05-0.11]	0.13[a] (0.09) [0.09-0.17]	0.25[a] (0.11) [0.19-0.29]	0.62[c] (0.15) [0.55-0.69]	0.27[c,d] (0.12) [0.18-0.36]	53.01	<.001
	Apical	0.10 (0.13) [0.04-0.16]	0.37[a] (0.17) [0.29-0.45]	0.23[a,b] (0.17) [0.15-0.32]	0.20[b] (0.14) [0.13-0.26]	0.16 (0.12) [0.10-0.21]	9.18	<.001
Apex (mm)	Distal	0.20 (0.14) [0.14-0.27]	0.33 (0.17) [0.17-0.37]	0.38[a] (0.24) [0.27-0.51]	0.37[a,b] (0.35) [0.21-0.52]	1.30[c,d] (0.90) [0.88-1.72]	18.95	<.001
	Buccal	0.26 (0.11) [0.20-0.31]	0.27 (0.21) [0.17-0.37]	0.45[a,b] (0.21) [0.34-0.53]	1.00[c] (0.34) [0.84-1.16]	0.48[c,d] (0.40) [0.29-0.66]	23.84	<.001
	Apical	0.12 (0.11) [0.07-0.17]	0.37[a,b] (0.17) [0.29-0.45]	0.23[a,b] (0.17) [0.15-0.31]	0.19[b] (0.13) [0.13-0.25]	0.14 (0.11) [0.09-0.19]	9.77	<.001

Means, standard deviation (SD), and 95% confidence intervals [95% CI] of discrepancies between reference and actual position for n=20 implants per group.

a*P*<.05 significantly different from H2 group.

b*P*<.05 significantly different fromly H4 group.

c*P*<.05 significant different from fully guided.

d*P*<.05 significantly different from partially guided.

Table 2. Precision as discrepancies of implants among one another. Means, standard deviation (SD), and 95% confidence intervals [95%-CI] of discrepancies among implants presented for n-20 implants per group

Precision (Implants Among One Another)		**Fully Guided (2 mm)**	**Fully Guided (4 mm)**	**Fully Guided (6 mm)**	**Partially Guided**	**Free Hand (No Guide)**	**ANOVA**	
		Mean (SD) [95% CI]	**Mean (SD) [95% CI]**	**Mean (SD) [95% CI]**	**Mean (SD) [95% CI]**	**Mean (SD) [95% CI]**	***F* Value**	***P* Value**
Angle (degrees)		0.61 (0.46) [0.54-0.67]	0.81 (0.57) [0.73-0.89]	0.74 (0.60) [0.65-0.82]	1.75[c] (1.27) [1.57-1.93]	2.40[c,d] (1.74) [2.16-2.65]	104.81	<.001

Crest (mm)	Δ3D	0.08 (0.07) [0.07-0.09]	0.21[a] (0.15) [0.18-0.23]	0.20[a] (0.15) [0.18-0.22]	0.18[a] (0.15) [0.15-0.20]	0.42[c,d] (0.28) [0.38-0.46]	95.63	<.001
	Distal	0.14 (0.10) [0.00-0.53]	0.16 (0.13) [0.11-0.19]	0.20[a,b] (0.15) [0.17-0.21]	0.19[a,b] (0.14) [0.17-0.21]	0.53[c,d] (0.35) [0.47-0.58]	124.57	<.001
	Buccal	0.12 (0.08) [0.11-0.13]	0.18[a] (0.12) [0.16-0.20]	0.18[a] (0.12) [0.16-0.20]	0.18[a] (0.14) [0.16-0.20]	0.38[c,d] (0.27) [0.34-0.42]	69.42	<.001
	Apical	0.13 (0.10) [0.12-0.15]	0.21[a] (0.16) [0.18-0.23]	0.21[a] (0.15) [0.17-0.23]	0.24[a] (0.16) [0.21-0.26]	0.22[a] (0.16) [0.20-0.24]	14.37	<.001
Apex (mm)	Δ3D	0.15 (0.12) [0.14-0.17]	0.25 (0.20) [0.22-0.28]	0.38[a,b] (0.38) [0.32-0.43]	0.43[a,b] (0.32) [0.39-0.48]	0.87[c,d] (0.59) [0.79-0.96]	110.24	<.001
	Distal	0.22 (0.17) [0.20-0.24]	0.34[a] (0.25) [0.30-0.37]	0.37[a] (0.28) [0.33-0.41]	0.49[c] (0.37) [0.44-0.55]	1.13[c,d] (0.78) [1.02-1.24]	135.08	<.001
	Buccal	0.32 (0.24) [0.28-0.35]	0.35 (0.25) [0.31-0.38]	0.35 (0.29) [0.30-0.39]	0.41[c] (0.31) [0.36-0.45]	0.64[c,d] (0.45) [0.58-0.71]	33.69	<.001
	Apical	0.13 (0.10) [0.12-0.15]	0.21[a] (0.16) [0.18-0.23]	0.21[a] (0.15) [0.19-0.23]	0.24[a] (0.17) [0.22-0.27]	0.21[a] (0.15) [0.19-0.23]	15.02	<.001

Means, standard deviation (SD), and 95% confidence intervals [95% CI] of discrepancies among implants presented for n=20 implants per group.

a*P*<.05 significantly different from H2 group.

b*P*<.05 significantly different from H4 group.

c*P*<.05 significantly different from fully guided.

d*P*<.05 significantly different from partially guided.

Precision describes the degree of distribution of the actual values, with a higher degree of precision when actual values are close to each other. Table 2 shows the results for precision. The highest precision was achieved by the computer-assisted implant surgery with the fully guided approach with a 2-mm sleeve-to-bone distance. This group showed the lowest distances among the implants, significantly lower than those observed in all other groups ($P<.001$).

Among the other 3 groups, the use of a surgical stent (fully guided with 4- and 6-mm sleeve distance and partially guided group) produced no statistically significant differences regarding the precision of the procedures. Freehand implant placement demonstrated the highest distances among the implants and therefore the lowest precision when compared with all other groups ($P<.001$) (Fig. 5).

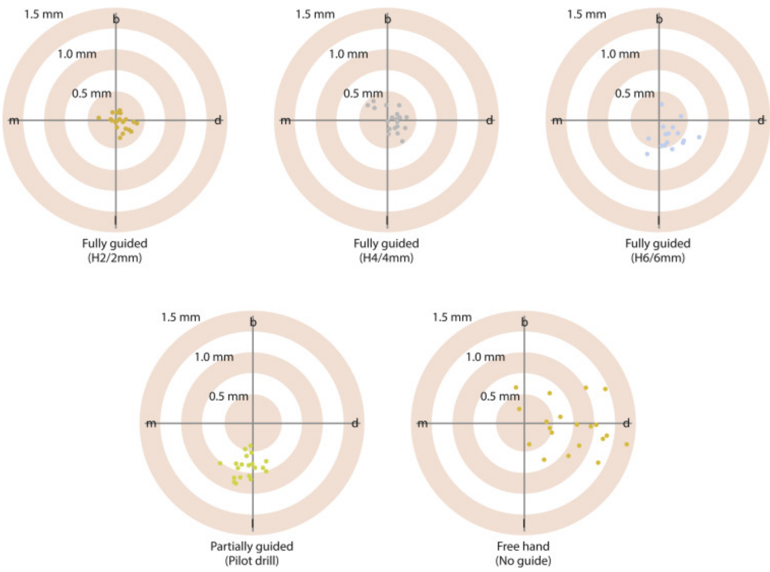

Figure 5. Actual implant positions in mesiodistal (m, d) and buccolingual (b, l) direction. Fully guided implant placement by using static surgical guides resulted in true and precise (=accurate) outcomes, while freehand implant placement was less reliable with low precision and low trueness. Partially guided placement showed higher precision than trueness.

Discussion

This study investigated the accuracy in terms of trueness and precision of different implant placement protocols. Implant placement with static surgical guides delivered predictable (high trueness) and reproducible (high precision) outcomes, while placement without a surgical guide was less predictable and less reproducible. Therefore, the null hypothesis that static guides have no influence on the accuracy of implant placement was rejected.

The parameters that affected the accuracy of the implant placements most were the angular deviations and the discrepancies in comparison with the reference position in the mesiodistal followed by the buccolingual direction. The coronoapical deviation appeared not to have a major impact on the 3D deviation. The deviations were higher at the apex than at the crest.

A correct prosthetically driven 3D positioning of the implant fixture is believed to play a crucial role in the long-term successful treatment outcome of implant-supported prostheses. In addition, a recent study on risk assessment for peri-implantitis showed that nearly half of the patients with peri-implantitis had been associated with implant malpositioning.[7]

Static computer-assisted implant surgeries (sCAIS) by using a virtual treatment planning software program give the ability to visualize, manipulate, and refine implant positions presurgically, thereby avoiding inaccurate implant placement.[24]

The results of this study demonstrated that in the fully guided groups, all sleeve heights with distances of 2, 4, and 6 mm from the sleeve to the bone (H2, H4, H6) delivered predictable results. The differences (as 3D deviations) between the planned and actual implant position (trueness) for the sleeve heights of H4 and H6 were statistically different from those of H2 ($P<.001$). This has clinical significance and demonstrates that the closer the sleeve to the bone, the higher the accuracy. The results of the present study are consistent with those of El Kholy et al,[24] who also reported that the higher the drilling distance, the greater the angular deviation. Based on engineering principles, more lateral vibration and chattering occurs if drilling length is increased.[24] The presented results are also consistent with those of Schneider et al,[25] who reported that lateral movement of the drills can be significantly minimized by the use of 3D printing with reduced drill distance from the apical portion of the sleeve to the crest of the bone. Park et al[26] also reported that the closer the sleeve to the bone, the more accurate the implant position. Guided placement reproduced the target position more accurately than freehand insertion.

Precision is defined as the degree to which repeated measurements in unchanged conditions show the same results. In the present study, implants with a sleeve height of 2 mm (H2) were placed more precisely than the implants with a surgical guide and sleeve heights of 4 mm (H4) or 6 mm (H6). These results are comparable with those of Sarment et al,[21] who reported that in an in vitro study of 3D printed guides delivered more reproducible results than standard conventional guides (enlarged axis holes), especially when multiple parallel implants were placed. An assessment of clinical reliability showed that the use of 3D planned templates as drill guides during surgery was reliable for implant placement.[20]

One-degree angle deviation translates during implant placement to a 0.34-mm deviation in length in the apical area when an implant fixture with 10-mm length is used. A 5-degree angle deviation translates to a 1.7-mm deviation in length. If the space between the implant and tooth root was set at 1.5 mm during implant planning, a 5-degree angle error will impact the adjacent tooth root. Thus, the angle deviation should not exceed 3 degrees if the implant is to be installed safely without any damage to the adjacent tooth root.[27] In the present study, the angular deviation for free hand was 4.86 ±2.10 degrees, for partially guided 2.85 ±1.47 degrees, and for fully guided 1.35 ±0.52 degrees, indicating that the angular deviation was more than the suggested 3-degree threshold for the freehand and partially guided groups.

Limitations of the present study included its in vitro design, which allowed an assessment of both trueness and precision under standardized conditions. A recent meta-analysis calculated the accuracy (trueness) of guided implant placement to be 1.1 mm at the crest level and 1.4 mm at the apex of the implant. The average angular deviation was reported to be 3.9 degrees.[10] A higher deviation at the apex was also observed in the present in vitro study. However, in a clinical scenario, the deviation from the planned position might be higher than that in a laboratory test. Furthermore, the model used identical mandibles with a partially edentulous dentition and a single implant. Nevertheless, it is suggested that computer-assisted implant surgery offers a high degree of accuracy even in the presence of different configurations of the residual dentitions.[22] The implant positions were compared by using a digital workflow. Tang et al[11] recently reported that this method has an accuracy similar to that of a postoperative CBCT. Finally, the implants were placed by a single operator. Operator experience may affect the accuracy (trueness) of implant placement, especially when partially guided approaches are used.[28] Therefore, future studies should evaluate the influence of the operator experience on the trueness and precision of fully guided implant placement.

Vercruyssen et al[23] discussed the accuracy and efficacy of guided surgery. They defined accuracy as matching the position of the planned implant in the software program with the actual position of the implant in the mouth of the patient and the efficacy of guided implant placement by comparing the implant survival and success rate after guided placement with those after conventional implant placement. Guided implant placement resulted in more predictable results with respect to the osseous implant position but also with respect to the achieved implant-prosthetic result than freehand placement, which corresponds with the present findings.

In a recently published clinical trial, the accuracy of freehanded, pilot-drill guided, and fully guided implant surgery were compared.[12] Fully guided surgery was most accurate followed by partially guided surgery. Freehand surgery resulted in a large deviation from the ideal position. This was confirmed by Smitkarn et al[16] in a randomized clinical trial comparing freehand implant placement with computer-assisted implant surgery. Considering the increased risk of adjacent root damage, cement-retention peri-implantitis, and suboptimal emergence profiles, Younes et al[12] suggested that fully guided implant surgery should be considered the standard approach for accurate implant placement, especially since in-office 3D printed surgical guides provide a convenient and cost-effective means of assuring proper implant placement.[29]

Conclusions

Based on the findings of this in vitro study, the following conclusions were drawn:

1. The introduced model allowed an assessment of the accuracy of the methods in determining trueness and precision.
2. Static computer-assisted implant surgery (fully guided approach) showed significantly higher trueness and precision than partially guided or freehand single implant placement.
3. When a fully guided approach is used, sleeve heights of 2 mm or 4 mm should be preferred over a 6-mm sleeve height.
4. The closer the sleeve to the bone, the higher the trueness and precision of the implant placement.
5. Partially guided implant surgery was significantly more accurate than freehand placement.
6. Free hand showed lower trueness and precision than partially guided and fully guided implant surgery.

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