A Prospective Study on the Accuracy of Mucosally Supported Stereolithographic Surgical Guides in Fully Edentulous Maxillae

Jan D'haese, DDS, MSc;[*†] Tommie Van De Velde, DDS, MSc, PhD;[‡] Lucien Elaut, DDS;[§] Hugo De Bruyn, DDS, MSc, PhD[‖]

ABSTRACT

Background: Flapless implant placement using guided surgery is widespread, although clinical publications on the precision are lacking.

Purpose: The purpose of this study was to evaluate the accuracy of mucosal-supported stereolithographic guides in the edentulous maxillae.

Materials and Methods: Seventy-eight OsseoSpeed™ implants (Astra Tech AB, Mölndal, Sweden) of 3.5 to 5 mm width and 8 to 15 mm length were installed consecutively in 13 patients. Implants were functionally loaded on the day of surgery, and implant location was assessed with a computed tomography scan. Mimics 9.0 software (Materialise N.V., Leuven, Belgium) was used to fuse the images of the virtually planned and actually placed implants, and the locations, axes, and interimplant distances were compared.

Results: One implant was lost shortly after insertion because of abscess formation caused by remnants of impression material. Seventy-seven implant locations were analyzed. The deviation at the entrance point ranged between 0.29 mm and 2.45 mm (SD: 0.44 mm), with a mean of 0.91 mm. Average angle deviation was 2.60° (range 0.16–8.86°; SD: 1.61°). At the apical point, the deviation ranged between 0.32 mm and 3.01 mm, with a mean of 1.13 mm (SD: 0.52 mm). The mean deviation of the coronal and apical interimplant distance was respectively 0.18 mm (range 0.07–0.32 mm; SD: 0.15) and 0.33 mm (range 0.12–0.69 mm; SD: 0.28). These deviations are lower than the global coronal and apical deviations.

Conclusion: The present study is the first to investigate the accuracy of stereolithographic, full, mucosally supported surgical guides in the treatment of fully edentulous maxillae. Clinicians should be warned that angular and linear deviations are to be expected. Short implants show significantly lower apical deviations compared with longer ones. Reasons for implant deviations are multifactorial; however, it is unlikely that the production process of the guide has a major impact on the total accuracy of a mucosal-supported stereolithographic guide.

KEY WORDS: accuracy, dental implants, edentulous maxilla, guided surgery, stereolithography, surgical template

INTRODUCTION

Although osseointegration of dental implants is predictable,[1] thorough preoperative planning is a prerequisite for a successful treatment outcome.[2]

Anatomic limitations as well as prosthetic considerations encourage the surgeon to obtain a very precise positioning of the implants. Historically, standard radiographic imaging techniques (intraoral and panoramic) were available for investigation of potential implant sites. Throughout the years, spiral tomography and computed tomography (CT) were often used as a diagnostic tool.[3] These techniques provide a two-dimensional cross-section image of the desired implant location and enable a detailed buccolingual view of the

*Department of Periodontology and Oral Implantology, Dental School, Faculty of Medicine and Health Sciences, University of Ghent, Ghent, Belgium; †Tandkliniek Sint-Lievens-Houtem, Sint-Lievens-Houtem, Belgium; ‡Department of Periodontology and Oral Implantology, Dental School, Faculty of Medicine and Health Sciences, University of Ghent, Ghent, Belgium; §Tandkliniek Sint-Lievens-Houtem, Sint-Lievens-Houtem, Belgium; ‖Department of Periodontology and Oral Implantology, Dental School, Faculty of Medicine and Health Sciences, University of Ghent, Ghent, Belgium

Reprint requests: Mr. Jan D'haese, Tandkliniek Sint-Lievens-Houtem, Schoolstraat 2b, 9520 Sint-Lievens-Houtem, Belgium; e-mail: jdhaese@base.be

DOI 10.1111/j.1708-8208.2009.00255.x

dimensions of the jawbone. Nowadays, it is well known that three-dimensional CT scan-based pictures allow a more reliable treatment planning than when only two-dimensional data are available.[4] Transforming the CT scan images into a three-dimensional virtual image can be achieved using computer software packages,[5] allowing for a three-dimensional viewing using computer-aided design (CAD) technology. When linked with a radiopaque scanning template, based on the determined prosthetic position of the replacement teeth, a prosthetically guided surgical template can be fabricated.[6–9] The advantage is that the implants can be installed in a position that is a synthesis of both anatomic and prosthetic considerations.

One should be aware of the fact that there is always a deviation between the virtual planning and the in vivo location of the implants. In a prospective clinical study, accuracy of a stereolithographic surgical guide was determined by evaluating four healthy, non-smoking patients requiring 21 implants.[10] The authors reported mean deviations between the virtual planning and the actual in vivo position at the shoulder of the implant of 1.45 mm, and at the apex of 2.99 mm. The match between the planned and achieved implant axis was within 7.25°. The deviations were presumably caused by ill fitting of some of the templates on the teeth or absence of a stable fit on the bone. In 2007, an ex vivo study reported on precision of a computer-based three-dimensional planning, using re-formatted cone beam CT (CBCT) images, for implantation in partially edentulous jaws.[11] Four cadaver jaws (one upper, three lower) were selected, and virtual implant simulation was performed using the Procera software package based on three-dimensional CBCT images (3D Accuitomo FPD, J.Morita, Kyoto, Japan). In total, 12 TiUnite self-tapping Brånemark implants (Nobel Biocare AB, Göteborg, Sweden) were installed. Postoperatively, a second CBCT scan was taken to check the positioning of the implants. Deviations ranged between 0.3 mm and 2.3 mm at the hex of the implants (mean: 1.1 mm), and between 0.3 mm and 2.4 mm (mean: 1.2 mm) at the apex.

Based on the limited research available,[12–18] accuracy of stereolithographic-guided surgery remains questionable. Transfer of the virtual three-dimensional implant planning to the surgical field is the most critical point in the procedure. Several approaches have been developed to overcome this issue. The Facilitate™ software system (Astra Tech AB, Mölndal, Sweden) used in the current study allows fabrication of a skeletal, dental, or mucosal-supported surgical guide and is based on a planning steered by the anatomy of the jawbone and the prosthetic demands. For other systems that are already being used in vivo, few publications are available regarding the precision of this implant placement procedure in vivo.

AIM

The aim of the present article is to evaluate the accuracy of dental implant placement in vivo, using a mucosal-supported stereolithographic guide in the edentulous maxilla, by measuring the divergence between the virtually planned and the in vivo placed Astra Tech OsseoSpeed™ dental implants (Astra Tech AB) in 13 consecutive patients. The treatment protocol was scrutinized and approved by both Ethical Committees of Ghent University Hospital and Onze-Lieve-Vrouwe Hospital Aalst in Belgium.

MATERIALS AND METHODS

Patient Selection

Thirteen consecutive patients requiring a fixed rehabilitation of the total edentulous maxilla were selected for this clinical trial. No specific contraindications were withheld, and smokers were not excluded. All patients underwent periodontal examination at intake. Periodontal treatment was performed when necessary. Hopeless teeth were extracted at least 3 months prior to implant surgery. As a result, initial post-extraction bone resorption took place before surgery.[19] After extraction of the last remaining teeth, a provisional, immediate removable denture was delivered to the patients. This prosthesis was made prior to the extractions, after taking a standard impression of the maxilla and mandible, using an irreversible hydrocolloid (Cavex CA37, fast set, Cavex Holland BV, Haarlem, The Netherlands) to fabricate a diagnostic cast. Second, a maxillary precision impression was made using a silicone material (Permadyne Penta H, 3M ESPE, Norristown, PA, USA). The master casts were mounted into an articulator, and a prosthetic setup was fabricated and checked for occlusion, articulation, and vertical dimension in the mouth of the patient. According to this wax-up, a prosthesis was delivered containing small radiographic glass spheres that were embedded in the resin of the base plate of

the prosthesis. These glass spheres act as radiographic markers and have the advantage of being invisible. As a result, the intermediate temporary prostheses could also be used as scanning templates. For patients already wearing an existing full maxillary prosthesis, a relining procedure was performed to adjust the prostheses in the most optimal way to the actual dimensions of the soft tissues. The radiographic glass spheres were polymerized into the resin during this procedure.

Planning Procedure

The scanning was performed using a Siemens Somatom Definition 64-slice dual-source CT scan (Siemens AG, Erlangen, Germany) according to the dual scan procedure outlined in the scanning protocol by Materialise (Materialise N.V., Leuven, Belgium). The axial plane was adjusted parallel to the plane of occlusion, with the gantry tilted at 0°. The CT scan was taken without inter-arch contact, using an occlusal index. Afterward, a second CT scan (dual scan) was taken from the prosthesis only. The resulting CT images were converted into a digital imaging and communications in medicine image and transformed into a three-dimensional virtual model using the Facilitate software system (Astra Tech AB). The clinician (J.D.) who placed the virtual implants in the resulting three-dimensional model also performed the surgeries. The potential locations for implant placement and the corresponding implant lengths and widths were planned in a prosthetically driven way. A distance of at least 3 mm from the neck of the implant to the gingival zenith, allowing the biological width to create a connective tissue contour around the abutments, was applied. Six implants and at least four fixation screws (Astra Tech AB) were planned for each patient. The images were returned to the manufacturer for surgical guide fabrication. Using a stereolithographic machine, layers of liquid polymer were laser-cured to form a guide according to the CT image data. Titanium guide tubes were inserted at the locations and axes of the planned implants.

Surgical and Prosthetic Procedure

The surgery was performed under local–regional anesthesia, with appropriate aseptic and sterile procedures. During the operation, the surgical guide was placed on the mucosa and properly fixed to the maxilla using at least four equally distributed fixation screws. An interocclusal putty index was used to confirm proper seating of the template. After fixation of the stereolithographic guide, the osteotomies were prepared at 1,500 rpm and limited to the desired depth by a vertical stop on the drills. No punching of the gingival tissues was performed prior to the preparation of the implant sites. Six OsseoSpeed implants (Astra Tech AB), with a TiO2-blasted fluoride-modified surface, were inserted into the maxilla with a maximum insertion torque of 50 Ncm. This insertion torque represents the sum of the torque applied on the implant site during preparation plus the friction because of the contact with the insertion tubes. The implants were placed to a specific depth, limited by the vertical stop on the fixture mount. During implant installation, the fixtures were guided into the prepared osteotomies. Immediately after implantation, 20° UniAbutment or angulated abutments (Astra Tech AB) were screwed onto the implants and hand torqued. The height and angulation were determined prior to surgery using the CAD/CAM software package (Facilitate, Astra Tech). After installation of the abutments, 20° UniAbutment pickup copings were mounted, and an impression was made on abutment level using a silicone material (Permadyne Penta H, ESPE) with the existing removable prosthesis used as a tray. Within 8 hours, a temporary screw-retained fiber-reinforced acrylic bridge was delivered to the patient and connected to the abutments. Occlusion and articulation were corrected whenever necessary. All suprastructures were hand torqued. No cantilevers were present in the temporary bridges to avoid excessive, occlusal non-axial forces. A typical example of the clinical procedure is summarized in Figure 1.

Postoperatively, each patient received a prescription for clindamycin (300 mg 3 times a day for 7 days), ibuprofen (600 mg maximum 3 times a day to be taken if necessary), and chlorhexidine rinse (0.12%, 2 times a day). After 48 hours, a postoperative visit was planned to check bridge screws and hand torque these when necessary, and adjust occlusion and articulation if needed. The same recall visits were planned at 2 weeks, 1 month, 3 months, 6 months, and 1 year postoperatively. At each recall visit, oral hygiene was evaluated and reinforced. Additionally, intraoral periapical radiographs were made at 3 months, 6 months, and 1 year postoperatively. The final prosthetic construction was made at least 3 months after implant installation by the referring dentist.

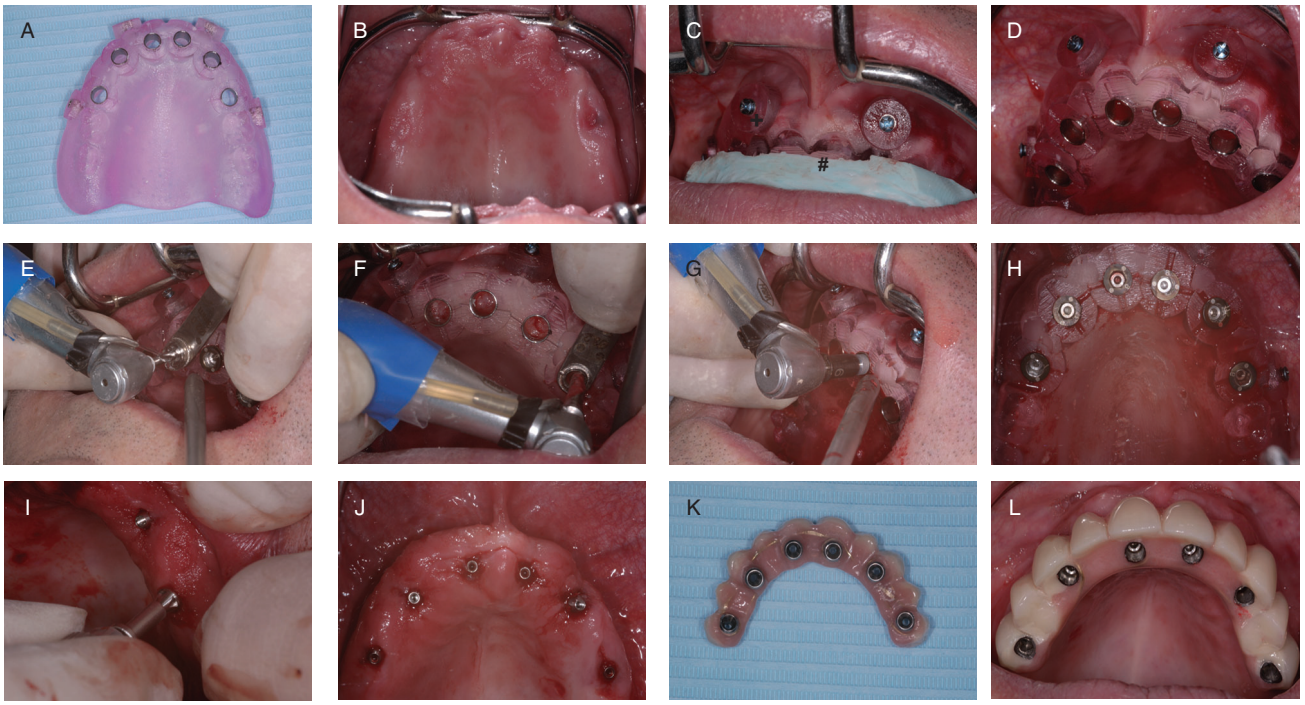

Figure 1 Clinical example illustrating the treatment protocol: *A*, Stereolithographic guide with equally distributed fixation screws. *B*, Maxilla before implant insertion. *C*, Fixation of the guide using an intermaxillary putty index (#) and fixation screws (+). *D*, Guide in situ. *E*, Preparation of the osteotomies using sufficient irrigation. *F*, Evacuation of the debris through the guiding cylinder. *G*, Guided implant installation. *H*, All implants installed. *I*, UniAbutment screwed on top of the fixtures. *J*, All abutments in place. *K*, Fiber-reinforced acrylic screw-retained bridge. *L*, Bridge in situ.

Accuracy Analysis

Within 4 to 8 weeks after surgery, a new CT scan was taken. Software (Mimics 9.0, Materialise N.V.) was used to fuse the images of the virtually planned and actually placed implants, and the locations and axes were compared (Figure 2). In order to evaluate the deviations between the planned and the placed implants, an object registration was performed to pair-wise align the preoperative three-dimensional representations of the jaws with their counterparts in the postoperative images. In this case, an iterative closest point algorithm was used to match the jaws. The thereby established coordinate transformation operations were also applied to the three-dimensional representations of the planned implants, allowing for relative comparisons with respect to the postoperative implant positions. All operations were performed in the Mimics® 9.0 software. Four deviation parameters (i.e., global, angular, depth, and lateral deviation) were defined and calculated between the planned and the placed implants, using the coordinates of their respective apical and coronal points[20] (Figure 3). All parameters except the angular deviation were determined for both the coronal and the apical centers. The global deviation was defined as the three-dimensional distance between the coronal (or apical) centers of the corresponding planned and placed implants. Next, the angular deviation was calculated as the three-dimensional angle between the longitudinal axes of the planned and placed implant. To establish the lateral deviation, a plane, perpendicular to the longitudinal axis of the planned implant and through its coronal (or apical) center, is defined and is referred to as reference plane. The lateral deviation was calculated as the distance between the coronal (or apical) center of the planned implant and the intersection point of the longitudinal axis of the placed implant with the reference plane. The depth deviation was calculated as the distance between the coronal (or apical) center of the planned implant and the intersection point of the longitudinal axis of the planned implant with a plane parallel to the reference plane and through the coronal (or apical) center of the placed implant.

Furthermore, the interimplant distances between planned and placed implants were evaluated. Therefore, the mean interimplant deviation was defined as the difference between the virtual and the real interimplant

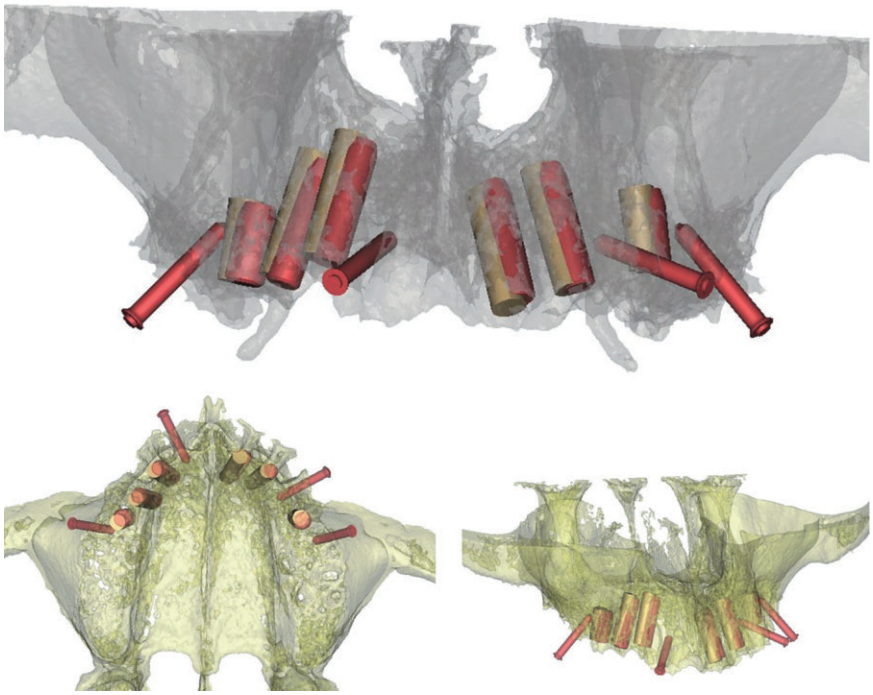

Figure 2 Fusion of the preoperatively planned implants (*red*) with the postoperative scanning data (*yellow*).

distance (Figure 4). The coronal interimplant distance (D_c) was defined as the distance between the coronal centers of two neighboring implants. This distance was also measured in the preoperative computer planning and is defined as the virtual, coronal interimplant distance (D_c'), for example, D_c'6-5. Same measurements were performed for the apical interimplant distance (D_a/D_a'). The mean coronal interimplant distance deviation between virtual planning and real implant position was defined as $(D_{c6\text{-}5} - D_{c'6\text{-}5}) + (D_{c5\text{-}4} - D_{c'5\text{-}4}) - \ldots +$ $(D_{c2\text{-}1} - D_{c'2\text{-}1})$ / n, where n represents the number of implants placed. The same measurements were performed for the apical deviations.

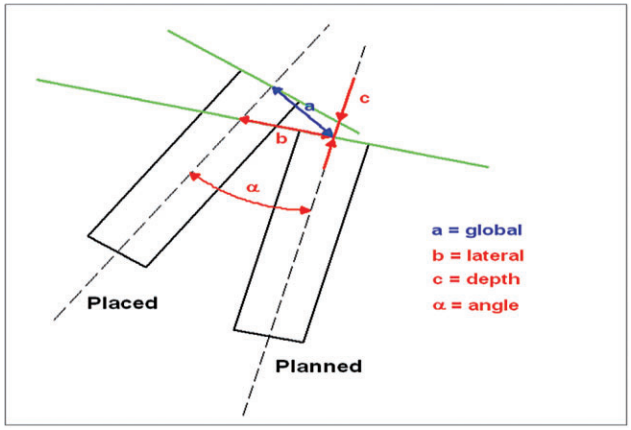

Figure 3 Three-dimensional evaluation of the virtually planned and the in vivo placed implants.

Statistical Analysis

Statistical analysis was performed with SPSS for Windows (16.0) computer software (SPSS Inc., Chicago, IL, USA). Descriptive statistics for all parameters were based on all implants, for each different implant length group, and for incisor, premolar, and molar sites separately. As not all data were equally distributed, a nonparametric analysis was performed (Kruskal-Wallis test followed by Mann-Whitney U test). Differences were considered statistically significant if $p < .05$.

RESULTS

Surgical and Prosthetic Procedure

Thirteen edentulous adults were included in this clinical trial. The population consisted of 11 males and 2 females. Mean age was 53.3 years (range 36–72). Out of the 13 patients, 5 were current smokers (more than 10 cigarettes/d). The total number of implants inserted with computer-aided mucosal-supported stereolithographic guides was 78. Implant characteristics are summarized in Table 1. One implant was lost shortly after insertion because of abscess formation caused by

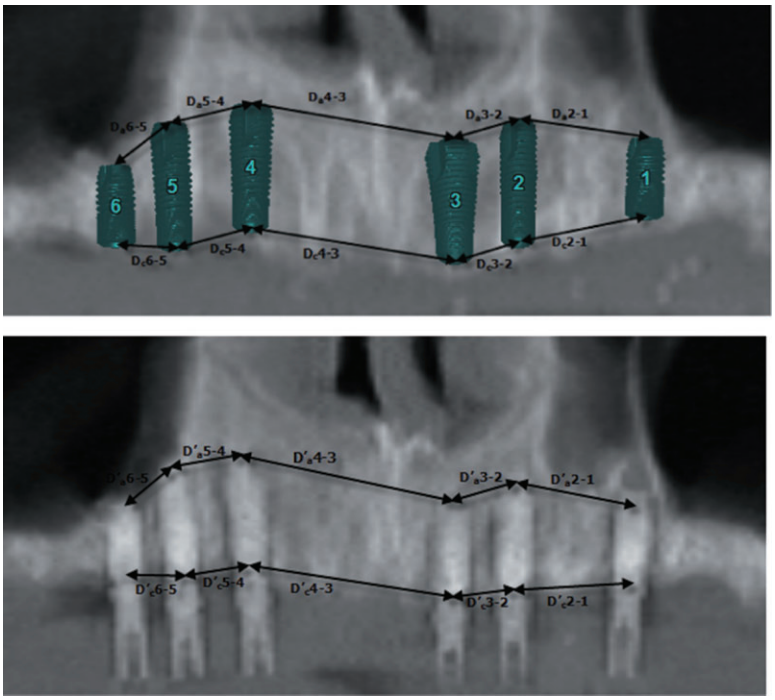

Figure 4 Evaluation of the interimplant distances in the preoperative planning (*upper*) compared with the postoperative position (*lower*).

remnants of impression material. The preoperatively determined choice of implant length and width was respected during the surgical procedure. There were no complications such as cracking or breaking of the surgical template, and metal tubes did not detach during the drilling procedure. No major complaints such as hemorrhages, sinus pathology, or severe postoperative pain were noted after the surgical procedure.

Accuracy Analysis

Seventy-seven out of the 78 implants were analyzed postoperatively by matching the preoperative planning with the in vivo position of the implants (see Figure 2), and the results are summarized in Table 2. No significant differences were found when comparing the global coronal deviation for the different implant length groups. Statistically significant differences ($p < .05$) were found when comparing the global apical deviation for the different implant length groups (Figures 5 and 6). A slight tendency to have larger apical deviations for implants placed in the posterior region was noticed, although no statistically significant differences in global apical deviation could be observed between implants placed in the posterior (premolars and molars) versus the anterior (incisors and canines) maxilla (Figure 7). Evaluating the cumulative percentage of implants and their corresponding global apical deviation, it was observed that 55% of all implants showed an apical

TABLE 1 Overview of the Inserted Implants Related to the Position and Length (mm)

Implant Length	Incisor	Canine	Premolar	Molar	Total
8	0	0	8	0	8
9	0	0	9	0	9
11	21	8	8	2	39
13	10	3	2	0	15
15	3	2	2	0	7
Total	34	13	29	2	78

TABLE 2 Mean Values, Minimum, Maximum, and Standard Deviation (in mm) of Global Coronal, Global Apical, and Angular Deviation

	Mean	Standard Deviation	Minimum	Maximum
Global coronal deviation (mm)	0.91	0.44	0.29	2.45
Global apical deviation (mm)	1.13	0.52	0.32	3.01
Angular deviation	2.60°	1.61°	0.16°	8.86°

deviation higher than 1 mm. Looking at the 2 mm cutoff point, only 10% of all implants showed a higher apical deviation (Figure 8).

Table 3 represents the differences in coronal and apical interimplant position, comparing the virtual distance with the in vivo interimplant distance after surgery on patient level as shown in Figure 3. Applying these interimplant distances to measure the accuracy of the guide leads to a mean coronal deviation of 0.18 mm and a mean apical deviation of 0.33 mm. These deviations are substantially lower than the global coronal and apical deviation.

DISCUSSION

Although limited data are available regarding the accuracy of mucosal-supported stereolithographic surgical guides, the deviations described in the present study are somewhat lower than previously published.[10,11,21–23] This could be explained by the fact that only full, mucosal-supported guides were used. These cover a maximum of soft tissues to increase the fit and were additionally properly fixed onto the supporting soft tissues using sufficient fixation screws. A greater global deviation between the planned and the actual positions was found at the implant apex than at the implant head. This is absolutely logical and has a pure mathematical explanation, based on the initial angular deviation. It can be explained by the fact that implant guidance is most optimal in the coronal part of the prepared osteotomies because of the limited effect of the angular deviation on the global deviation, which increases at a larger distance, that is, further into the bone. As a result, statistically significant differences were found when comparing the global apical deviation of short versus long implants.

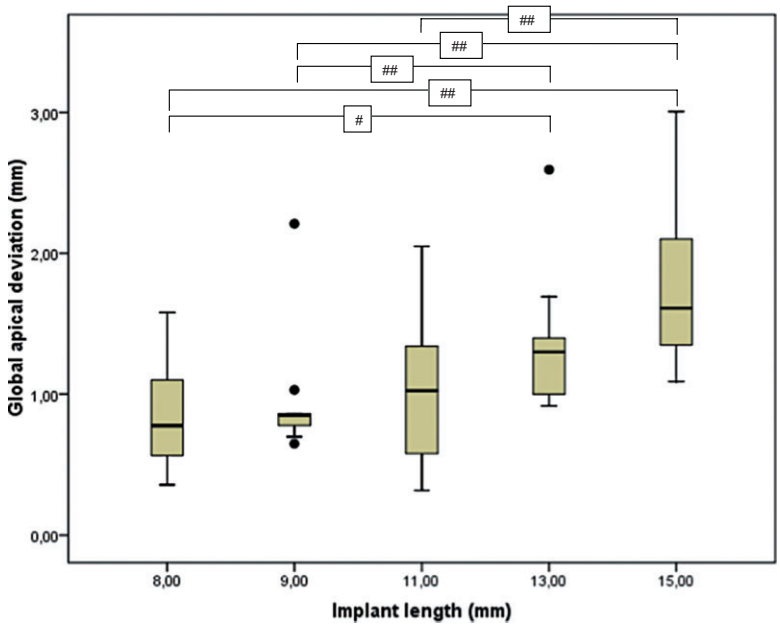

Figure 5 Box plot showing median, quartile, range, and outliers of global apical deviations (in mm) of 77 implants. The extreme outliers represent initially unstable implants. Bars represent statistically significant differences (Mann-Whitney *U* test; #$p < .05$; ##$p < .01$).

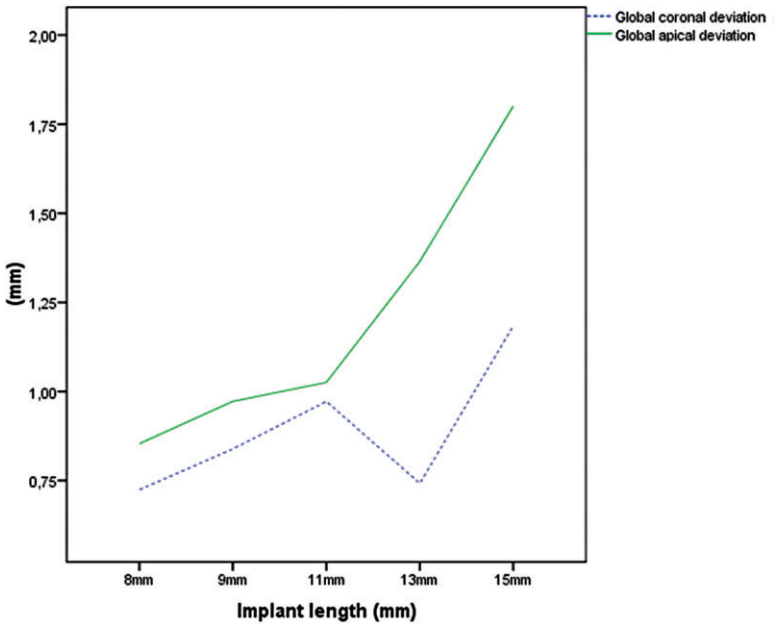

Figure 6 Mean global coronal and mean global apical deviation related to the different implant lengths used.

This could have clinical consequences when large implants are installed in anatomically compromised regions. An important technical aspect affecting the outcome is the support and stability of the guide on the mucosa. Mucosal-supported guides should cover a maximal surface. This offers the surgeon a more reproducible way to position the guide on the soft mucosa, leading to less positioning errors. The degrees of freedom in an edentulous patient is higher than in a non-edentulous patient, leading to problems in accurate positioning of the template. Therefore, control of the proper fit of the surgical guide is of major importance during the scanning procedure as well as during implant surgery. We used an interocclusal silicone index to stabilize both the scanning template and the surgical guide. After fixation of the guide, the resilience of the mucosa could be responsible for slight rotations of the guide in situ while performing the osteotomies. Therefore, optimal positioning of the fixation screws is a critical issue. Fixation screws should be optimally spread over

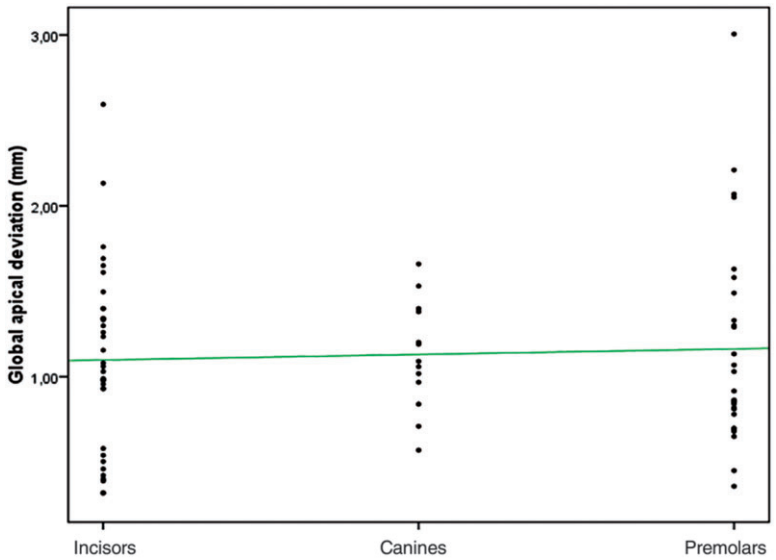

Figure 7 Range of global apical deviations related to implant position.

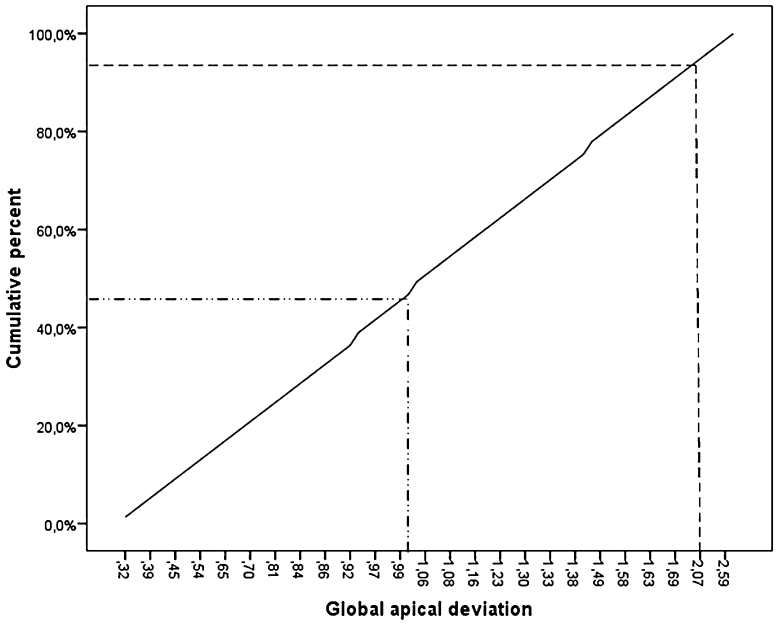

Figure 8 Graphic showing the cumulative percentage of global apical deviation. Fifty-five percent of all implants show a higher apical deviation at the arbitrarily chosen 1 mm cutoff point. This is reduced to 10% at the 2 mm cutoff point.

the entire maxillary arch to obtain a stable fit. Ideally, two fixation points should be located in the front, and two in the posterior region, distal of the most posterior implant site. This should overcome the issue of bending of the template in the distal areas of the surgical field as described previously.[11]

The global accuracy of mucosal-supported stereolithographic flapless surgery is not only determined by correct positioning of the surgical template intraoperatively. One should be aware of the fact that the stereolithographic surgical guide manufacturing process consists of three major steps: the CT scan for acquisition of the anatomic data, the image segmentation using a specified software package, and the building of the surgical guide itself using rapid prototype technology. Each of these steps has its own source for geometric errors and distortions. However, errors occurring during one of these steps may also compensate each other. For the overall manufacturing process, it was described that deviations up to 0.7 mm could occur.[24] Regarding the CT scan, the scan protocol is a more important issue than the type of scanner used. From the accuracy viewpoint, a high spatial resolution protocol is mandatory to obtain the best results. The factor found to have the biggest impact was, however, data segmentation. It was described that segmentations of the same data set by different persons showed high accuracy variations. As the dual scan protocol was used, the manual segmentation did not influence the accuracy of the surgical guide. Most of the rapid prototype technology systems were found to produce deviations less than 0.25 mm.[24]

When comparing the interimplant distance between the virtual planning and the postoperative scanning data, mean coronal and apical deviations are substantially lower. These accuracy measurements bypass the positioning error of the surgical template. The interimplant distance gives a more detailed view on the accuracy of mucosal-supported stereolithographic

TABLE 3 Mean, Minimum, and Maximum Interimplant Deviation at Coronal and Apical Point Based on 64 Interimplant Distances Measured between 77 Implants

	Mean	Minimum	Maximum	Standard Deviation
Coronal	0.18	0.00	0.61	0.15
Apical	0.33	0.00	1.13	0.28

surgical guide sensu stricto. Only production errors and errors occurring during the surgical procedure contribute to the interimplant deviations. Our data indicated that a mean deviation of 1.13 mm was found apically compared with a mean apical interimplant deviation of 0.33 mm. These data differ substantially from each other, leading to the conclusion that production errors and deviations because of surgical manipulation itself are not a major factor regarding accuracy. The total accuracy of a stereolithographic, full, mucosal-supported surgical guide is mainly determined by the positioning error of the surgical template. However, when implants are initially unstable (because of bone conditions), it is likely that the accuracy is also deteriorated. Moreover, connecting an abutment immediately after implant installation may cause an additional deviation in less-stable implants because of the torque applied during abutment fixation. In the current report, this was observed in three cases, each time with one implant. Two implants were located in the posterior region (second premolar position) and one in the incisor area. This explains why angular deviations up to 8.8° were observed. Doing the CT analysis immediately after surgery prior to abutment installation should overcome this possible error; however, this is clinically unrealistic. A difference was observed in mean apical deviations that was related to implant length, with longer implants (>11 mm) showing significantly higher apical deviations compared with shorter ones. This can be explained by the fact that drilling deeper into the bone with a similar angle of insertion results in a higher apical deviation for a longer than for a shorter implant. No significant differences were found when evaluating inaccuracy according to the implant position, although there is a tendency to have more deviation in the posterior area of the maxilla (see Figure 5). Probably, bone quality is also an important issue regarding implant deviations, as soft bone, as often encountered in the posterior maxilla, contributes to higher deviation values. More research is needed, however, to confirm these findings. In general, it could be difficult to reach the desired implant depth at installation. This can be explained by the fact that the implant is not guided during the first moments of placement because of the length of the implant and implant carrier in relation to the height of the guiding cylinder. This could lead to a slight divergence in angulation during the first millimeters of insertion, which has to be corrected when the implant container reaches contact with the guiding cylinder, leading to some stress in the bone surrounding the implant. Additionally, a slight friction between the implant carrier and the guide tube within the stereolithographic guiding template requires a slightly higher insertion torque. To our knowledge, under preparation of the implant bed to reach more primary stability is out of question.[25] Only 3 of the 78 placed implants did not reach sufficient primary stability following the drilling protocol as presented by the manufacturer.

CONCLUSION

The present study is the first to investigate the accuracy of stereolithographic, full, mucosally supported surgical guides in the treatment of fully edentulous maxillae. Clinicians should be warned that angular and linear deviations are to be expected. Short implants show significantly lower apical deviations compared with longer ones. Reasons for implant deviations are multifactorial; however, it is unlikely that the production process of the guide has a major impact on the total accuracy of a mucosal-supported stereolithographic guide.

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