

The influence of smoking and surgical technique on the accuracy of mucosa-supported stereolithographic surgical guide in complete edentulous upper jaws

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Abstract. – BACKGROUND: The accuracy of a stereolithographic surgical guide depends on several variables that can affect at any time from the software-planning stage to the surgical field.

AIM: The purpose of this study was to evaluate the accuracy of implants inserted using a single mucosa-supported stereolithographic surgical guide determining also the influence of surgical technique (fixed and not-fixed) and smoking on the deviation parameters.

MATERIALS AND METHODS: 11 patients, totally edentate in the upper arch and needed an implant-prosthetic rehabilitation, were selected. 95 implants were planned and inserted. The pre- and post-operative CT images were compared using software.

RESULTS: Global, coronal (Mean: 1.65; Range: 3.00-0.13; SD:0.56) and apical (Mean: 2.15; Range: 4.23-0.34; SD:0.81), and angular (Mean: 4.62; Range: 15.25-0.28; SD: 2.74) deviation values were determined.

The mean values of mucosa thickness in smokers and nonsmokers patients were 4.53 mm and 3.42 mm respectively ($p < .05$). The accuracy data showed a better result for the angular deviation when the surgical template was fixed ($p = .002$) and a better global apical deviation in the nonsmokers ($p < .05$).

CONCLUSIONS: It is essential, especially in smoker patients, to respect a minimum safety distance of 3 mm from limiting anatomic structures.

Key Words:

Stereolithographic, Surgical, Guide, Accuracy, Implants, Edentulous, Template.

Introduction

From the introduction of modern implantology in the early 1980s dental implants have been placed considering only the available residual bone^{1,2}.

Several studies have clearly demonstrated that implants inserted disregarding the prosthetic demands, often leads to a compromised definitive prosthesis with a jeopardized occlusal scheme, poor esthetics, or unfavorable biomechanics³⁻⁵.

For this reason, the concept of “prosthesis-driven implantology” was introduced to combine both functional and aesthetic requirements, not only considering the presence of bone structure, but also the teeth’s positioning: the diagnostic casts and wax-up of the prosthodontic restoration guide the planning of the position and inclination of the proposed implants².

The “double-purpose templates” were used not only for the patient’s radiographic examination and evaluation, but also during surgery and placement of the implants⁶; this, however, proved to be helpful in directing the implants to a good position only during the first drilling sequence, but did not aid in the latter stages.

To overcome these limitations, Computer Tomography (CT), 3D implant planning software and computer-aided implantology (CAI) were introduced^{3,7}. The acronym CAI recognize two techniques: the image-guided templates (computer-milled templates and stereolithographic drill guides) and the computer navigation system⁸.

Mechanical positioning devices or drilling machines convert the radiographic template to a surgical template by executing a computerized transformation algorithm (computer-milled templates) while computer-aided design/computer-aided manufacturing (CAD-CAM) rapid prototyping techniques generate stereolithographic templates³. Bur tracking (computer navigation system) allows for intra-operative real-time tracking of the drill according to the planned trajectory³.

Considering only the stereolithographic surgical drill guide, while the first surgical templates,

characterized by metal tubes of increasing diameter, were used only for the preparation of the implant site⁹, today, a single guide, for both osteotomy site preparation and implant delivery, is widely used¹⁰⁻¹².

This totally guided approach may minimize the deviations found between virtually planned and *in vivo* placed implants, because of the potential influence of operator positioning error, when using more than one guide, or placing implants manually, but only a few “*in vivo*” clinical studies evaluated accuracy comparing this two methods⁹⁻¹².

Moreover, the added fixability of this more recently introduced surgical templates at the jaw to be operated on should provide for an increased implantation accuracy based on planning data⁹⁻¹⁶.

Some Authors^{4,8,13} in addition suggest that the use of a mucosa-supported surgical guide can increase the difficulty of an accurate template repositioning affecting the accuracy. This might be due to alterations in the local mucosal environment involving an increased resilience^{4,8,13}.

Whatever method is being used, everyone must be aware of the fact that there is a variable deviation between the virtual planning and the *in vivo* position of the implants inserted using CAI.

The transfer of the virtual three-dimensional implant planning to the surgical field without deviations is unrealistic and it is essential to know the level of accuracy of the method used and the conditions which may influence the degree of accuracy.

Most of the stereolithographic surgical guide systems allow the fabrication of bone-, dental-, or mucosa-supported template: the degree of accuracy of this surgical guides may vary depending on the type of support used, but the data given by the literature about accuracy rarely distinguish the results on the basis of the support used⁹⁻¹².

The aims of the present study was to evaluate:

1. The accuracy of the Safe System[®], a totally guided implant system, allowing the control of the osteotomy site preparation and implant placement in three dimensions using in completely edentulous upper jaws a single mucosa-supported stereolithographic surgical guide (External Hex Safe[®], Materialise Dental, Leuven, Belgium);
2. The difference of the mucosa thickness between smokers and nonsmokers upper jaw completely edentulous patients;
3. The influence of surgical templates fixation (using at least three osteosynthesis screws with tripod arrangement) and smoking on accuracy;

4. The surgeon-specific learning effect to determine the reliability and security of this procedure during the early phases of learning.

Materials and Methods

11 patients were selected from the Department of Oral and Maxillofacial Sciences of “Sapienza” University of Rome. These were totally edentate in the upper arch and needed an implant-prosthetic rehabilitation.

Patients with unhealthy systemic health status, parafunctional habits, poor oral hygiene, severe alveolar bone deficiencies, uncontrolled diabetes mellitus, current irradiation to the head or neck, psychological disorders and alcohol or drug abuse were excluded.

The current smokers (more than 10 cigarettes/day) were not excluded allowing to divide the study population in a smoking and nonsmoking subgroup.

In each selected patients the extraction of any remaining dental elements were executed at least three months before the implant-prosthetic rehabilitation and a complete denture was developed, satisfying both the aesthetic and functional requirements.

All patients included in this retrospective study were consecutively treated with CAI between February 2007 and June 2011 and informed of the study protocol signing an informed consent form.

The study protocol was scrutinized and approved by Ethical Committee of “Umberto I” University Hospital, Rome, Italy.

The surgical interventions were performed by the same operator (MC) that performed the virtual surgical planning and surgical procedures. The treating clinician was an expert in implant dentistry, but not in CAI.

A radiopaque diagnostic template, the so-called “Scanno-Guide”, which represents an exact replica of the complete denture, was initially created. The CT scan of the patient’s arch, was performed with spiral CT devices, using an Asteion Multi (Toshiba Medical Systems, Rome, Italy).

The scans, that included the Scanno-Guide to integrate the anatomic data with the functional and esthetic requirements, were taken without inter-arch contact, using an occlusal index to prevent overlapping between the images of the opponent teeth arch and the scanno-guide. The potential lo-

cations for implant placement and the corresponding implant length and width were planned using SimPlant® (Materialise Dental, Leuven, Belgium). The computer program employed in the present study used the original CT data, in DICOM (Digital Imaging and Communications in Medicine) format, to produce axial, 3d, panoramic, and cross-sectional images, all of which are visible at the same time in four interactive windows on a computer monitor. Using this software, the implants were virtually placed according to bone anatomy and prosthetic designs and a CAD (Computed-aided design) design of surgical template was developed. The surgical template (Safe®, Materialise Dental), to transfer the digital planning to the surgical environment, was created using the stereolithography. The surgical guides were employed in each patient to accommodate two specified drills of increasing diameters used for osteotomy preparation and did not require flap reflection, but a flapless/transmucosal approach. The punching of the gingival tissues was performed before the preparation of the implant site. 95 PIH cylindrical implants (Plan 1 Health, Amaro, Udine, Italy), with an external hexagon (diameter 3.75 mm and lengths ranging from 10 mm to 15 mm) were inserted in 11 completely edentulous upper arches.

The Safe® allowed us to control the implant site's preparation and the guided implants insertion, using osteotomy site-specific drills that have vertical stops to control the depth of the implant site preparation and specific delivery mounts (implant holder, diameter 4.00 mm, length from 4 mm to 15 mm). In some cases, after reviewing the precise seat of the template and checked the occlusal relationships with the opposing dentition or the antagonist prosthesis using a bite registration, the surgical guide was bony fixed with at least three osteosynthesis screws.

During surgery, no complications were recorded.

All patients after surgery underwent a post-operative CT and the pre- and post-operative images were compared. In order to evaluate the deviations between the planned (virtual) and the placed (actual) implants, an object registration was performed to align the pre-operative 3d representations of the jaws with their counterparts in the post-operative images. Typically, an iterative closest point (ICP) algorithm was used to match the jaws.

The established coordinate transformation operations were also applied to the 3D representations of the planned implants, allowing for rela-

tive comparisons with respect to the post-operative implant positions (Mimics® Software Materialise, Leuven, Belgium). Three deviation parameters (i.e. global coronal, global apical, angular deviation) were defined and calculated between the planned and the placed implants, using the coordinates of their respective apical and coronal points.

The global deviation was defined as the 3D distance between the coronal (or apical) centre of the corresponding planned and placed implants; the angular deviation was calculated as the 3d angle between the longitudinal axis of the planned and placed implant⁸.

The overlap of the jaws and the measuring was automatically performed by the Mimics® Software and did not require any intervention of the examiner, excluding any possible measurement error.

To determine the possible influence of mucosal thickness on accuracy, using the SimPlant® software (Materialise Dental, Leuven, Belgium), additional measurements of mucosa thickness were taken.

The reference points were defined within each patient. The reference points regarding the upper arch were located at the first right molar, the right canine, the right central incisor, the left canine, the left first molar, the midpalatal suture at the first premolar level, and the midpalatal suture at first molar level. The mucosa thickness was defined as the distance between the surface of the alveolar crest and the base of the scanning template, after drawing a line parallel to the long axis of the tooth from the base of the template at the center of the alveolar ridge. To record the mucosa thickness at the midpalatal suture level a line from the contact point between the second right premolar and the first right molar to the contact point between the second left premolar and the first left molar was drawn; a second line, perpendicular to the first one and passing through the midpalatal suture was drawn and the distance between the base of the scanning template and the midpalatal suture was measured. Likewise a measurement was taken with the same method based on a line passing through the contact point of the right canine and the first right premolar and the left canine and the left first premolar.

Statistical Analysis

Quantitative data was described using mean values, minimum and maximum values (range of deviation), standard deviation values.

The deviation data were also described by dividing the sample in the following groups: fixed and not-fixed surgical guides, smokers and non-smokers.

t-test was used to determine if there is a statistically significant difference between the mucosa thickness of smokers and nonsmokers patients. Significance was set to $p \leq .05$.

t-test was also used to determine the influence of determined variables. The following influencing variables were defined as categorical factors: smoking habit (smokers/nonsmokers) and surgical technique (with/without stabilization screws). Significance was also set to $p \leq .05$.

The deviation parameters were analyzed at implant level.

Scatter plots were used to evaluate intra-operator variability of accuracy and to determine whether a learning curve was present. After dividing the sample on the basis of the surgical technique used (fixed and not-fixed), the deviation values were regressed vs time (number of computer guided surgery performed). Once again, significance threshold values were set to $p \leq .05$.

Data was analyzed using SPSS® for Windows software (Statistical Package for Social Science Inc., Chicago, IL, USA).

Results

Accuracy

11 adults were included in this study, totaling 95 planned and inserted implants. There was no anesthesia, paresthesia, abnormal hemorrhages, sinus pathologies or complication related to the anatomy or to an inaccurate placement of the implants.

Patient and treatment characteristics are summarized in Table I.

The mean values of mucosa thickness in smokers and nonsmokers patients were 4.53 mm and 3.42 mm respectively; *t*-test showed a statistically significant difference in mucosa thickness between smokers and not smokers at patient level ($p = .000$).

The global coronal (mean: 1.65; range: 3.00-0.13; SD:0.56), global apical (mean: 2.15; range: 4.23-0.34; SD:0.81) and angular (mean: 4.62; range: 15.25-0.28; SD:2.74) deviations were determined via the image registration technique.

The mean values, the range and the standard deviation, dividing the sample in fixed and not-fixed and smokers and non smokers are illustrated in the Tables II and III.

Results of the *t*-test with regard to the influence of the surgical technique on the angular deviation parameter, appear to show that this variable exerted a significant effect on the accuracy ($p = .019$).

A statistically significant difference, at the implant level, was found when comparing the global coronal deviations between the smokers and nonsmokers; otherwise no significant differences were found for angular and global apical deviations of these two groups (Table IV).

Both in the fixed and not-fixed surgical techniques, correlating the angular, apical and coronal deviation values with time variable, indicating the number of computer-guided surgeries performed by surgeon, the intra-operator variability analysis did not indicate a clear learning curve. As such, the time variable was evaluated as having a minor impact on the accuracy data of the implants inserted using a fixed or not-fixed, mucosa-supported stereolithographic surgical template.

Table I. Patients and treatment characteristics.

	Mean	Total	Number of guides	Number of implants
Age	56			
Number of implant		95		
Number of subjects		11	11	95
Gender				
Male		10	10	85
Female		1	1	10
Type of safe guide				
Fixed			8	66
Not fixed			3	29
Smoke				
Smokers			6	54
Nonsmokers			5	41

Table II. Deviation of planned and inserted implants, dividing the sample on the basis of the surgical technique used (fixation of surgical template). (N = 95)

	Surgical technique							
	Fixed				Not fixed			
	Mean	Max	Min	Standard deviation	Mean	Max	Min	Standard deviation
Apical deviation (mm)	2.11	3.67	.46	.75	2.22	4.23	.34	.91
Coronal deviation (mm)	1.66	3.00	.13	.57	1.64	2.79	.66	.56
Angle deviation (degrees)	4.10	14.34	.28	2.43	5.44	15.25	.30	3.02

Discussion

The accuracy of a stereolithographic surgical guide is defined as the deviation in location or angle of implants planned compared to the inserted and includes all possible single errors, cumulative and interactive, from the image acquisition to the surgical implant positioning^{3,9-12}.

The risk of deviation using stereolithographic surgical guides for the placement of dental implants is substantial and the clinicians should be warned that three-dimensional implant deviations are to be expected.

Many methods have been used to measure deviations, both analog and digital, complicating the comparison between the results obtained by various authors^{2,16}.

Considering only the deviation data obtained from those clinical studies that used an image-processing software to match pre-operative planning with post-operative images, the results are poor¹².

Comparable accuracy data with the present study were reported by Arisan et al¹⁷. Considering only the mucosa-supported single-type guides, the Authors recorded, using 11 mucosa-supported guides firmly fixed by osteosynthesis screws¹⁷, a mean angular deviation of 2.9° (range 0.8-3.5; SD: ± 0.39), a mean global coronal deviation

of 0.7 mm (range 0.2-0.83; SD: ± 0.13), and, finally, a mean global apical deviation of 0.76 mm (range 0.4-0.99; SD ± 0.15).

According to the Authors¹⁷, the lower deviation values recorded were a results of the lack of interference or slight guide movements in fully edentulous cases. The use of a single guide throughout an osteotomy of a specific drill kit and the integration of a depth-control mechanism, has been recommended to reduce deviations and to ensure a safe osteotomy and the accurate positioning of the implants¹⁷.

D’Haese et al¹⁸ in a prospective clinical study on the accuracy of a “single” mucosa-supported stereolithographic surgical guide, used in fully edentulous maxillae, described the deviation values measured between seventy-seven planned and placed implants. The authors, as in the current study, used a software (Mimics® – Materialise, Leuven, Belgium) to fuse the images of the virtually-planned and actually-placed implants. The global coronal deviation ranged between 0.29 mm and 2.45 mm (SD: 0.44 mm), with a mean of 0.91 mm; the mean angle deviation was 2.60° (range 0.16-8.86°; SD:1.61°); the mean apical deviation was 1.13 mm (range 0.32-3.01 mm; SD: 0.52 mm). The Authors^{18,19} asserted that the deviation values of the study were somewhat lower than previously published because only

Table III. Deviation of planned and inserted implants, dividing the sample on the basis of smoking habit. (N=95)

	Smoking habit							
	Smokers				Nonsmokers			
	Mean	Max	Min	Standard deviation	Mean	Max	Min	Standard deviation
Apical deviation (mm)	2.28	4.23	.34	.84	2.04	3.99	.46	.79
Coronal deviation (mm)	1.80	3.00	.59	.51	1.52	2.79	.13	.58
Angle deviation (degrees)	4.41	15.25	.43	3.00	4.79	12.48	.28	2.52

Table IV. *t*-test regarding the influence of smoke habit on deviation value ($p < 0.05$). (N=95)

	Sig.	Difference between means	Standard Error
Smokers vs nonsmokers			
Coronal deviation	.014*	.28135	.11234
Angle deviation	.512	-.37278	.56626
Apical deviation	.159	.23676	.16687

*Statistically significant.

full, mucosa-supported guides were used. These guides, in fact, covering a maximum of soft tissues, increased the fit and were in addition properly fixed onto the supporting soft tissues using sufficient fixation screws. In a recent study on accuracy of template-guided implantation system NobelGuide™, conducted by Vasak et al¹³, a newly developed fusion method was used to superimpose post-operative CT data with the pre-operative CT data and the planning data for the virtual implant positions and to determine the deviation between planned and post-operatively achieved implant positions.

Although the method used by these Authors for the overlapping of pre-and post-operative images is different from the one used in the current study, a maximum linear deviation of 2.02 mm and a maximum angular deviation of 8.1° were registered. The same Authors¹³ have also highlighted significantly smaller deviations for implants inserted in the anterior tooth region than for those inserted in the posterior region and significantly smaller deviations in implants inserted the mandible vs. the maxilla, in exclusively mesio-distal direction.

As stated by Widmann et al³ it is essential to carefully distinguish between the accuracy achieved at the base of the implant and the accuracy achieved at the tip. Accuracy at the tip is more important, as the tip is situated in the vicinity of vital anatomic structures³. Naturally, the accuracy at the base is always better because of the lack of angular deviation which is added by drilling further into the bone³. The evidence of higher apical deviation values compared to the coronal value is also confirmed by the results of the present study. Considering, however, the deviation values, it should be highlighted the need to consider the maximum deviation values rather than the mean values in order to minimize the risk of damaging the limiting anatomical structures. In fact, as confirmed by the present data, even if the mean deviation values can be tolerated clinically, the risk for deviation remains sub-

stantial and the presence of maximum error should be considered. Moreover, the respect of a 3 mm minimum safety distance should be recommended especially when a stereolithographic surgical guide is used or without fixation screws.

The influence of smoking habits in accuracy of stereolithographic surgical template was infrequently investigated.

In a recent study conducted by D'Haese et al⁸, a statistically significant difference was found for global coronal and apical accuracy of implants placement when comparing smokers with nonsmokers. Considering only the global apical deviation the same Authors⁸ observed that, at the arbitrarily chosen 1mm cutoff point, the 65% of the implants showed an apical deviation higher than 1mm in the smokers group compared with 45% in the nonsmokers group, while at the 2 mm cutoff point, still, 10% of the implants in the smokers group had a higher apical deviation compared with almost 0% in the nonsmokers. The Authors concluded that the flapless implant placement using mucosa-supported surgical guides should be carefully implemented in a smoking population, but considering the limited number of 13 drill guides, a further research is suggested.

The same Authors observed that smokers had a significantly thicker mucosal biotype compared with nonsmokers and this condition could explain the fact that implant placement was significantly more accurate in nonsmokers compared with smokers when using stereolithographic-guided surgery.

D'Haese et al⁸ highlighted also that the stereolithographic surgical guide in totally edentulous patients should cover a maximum of supporting mucosal structures in order to position the guide properly. The smoking patient showed differences in mucosal thickness compared to nonsmoking patient with a lower accuracy due to an higher degrees of freedom when positioning a scanning prosthesis or a surgical guide. This different out-

come regarding accuracy of stereolithographic surgical template appear to be correlated, as stated by D'Haese et al⁸, to the variations in thickness of mucosal structures between smokers and non-smokers that could lead to a different resilience.

Regarding the influence of mucosa thickness on accuracy data Vasak et al¹³ also showed a significant correlation between mucosa thickness at the implantation site and the degree of deviation that affected the reproducibility of purely mucosa-supported template position as well as the seat of the template regardless of anchoring elements.

According to the literature, the data of the present study indicates the presence of a thicker mucosa in smokers with related higher deviation values.

Regarding the learning curve, in the sample of the present study, the deviation values were not influenced by the operator's experience. In the stereolithographic surgical template technique, as stated by Widmann et al³, a prefabricated template is used, which makes the procedure less dependent on the surgeon's expertise.

In contrast to the bur tracking, however, the use of stereolithographic templates lacks of interactive control. While using this technique in fact it is necessary to make a meticulous and exact pre-operative planning because it is not possible to make modification during the operative procedure, however this allows to obtain excellent results immediately. This of course does not mean that an inexperienced operator can achieve good results, but may mean that an expert operator can simplify a complex treatment obtaining better and predictable results eliminating possible manual placement errors and systematizing reproducible treatment success.

Unlike determined in the present study, Vasak et al¹³ observed a learning effect using the template-guided implantation system Nobel Guide™ (Nobel Biocare, Gothenburg, Sweden) over the time period of performance of the surgical procedures.

Otherwise Valente et al²⁰ reported the absence of a clear learning curve, assuming the hypothesis that human factors can play a limited role in computer-guided, template-assisted surgery. However, these data refer to the accuracy values detected by the use of "multiple" surgical guides²¹.

Conclusions

The results of the present study points out an high accuracy of fixed mucosa-supported stereolithographic surgical template used in the upper

arch; the reason is due, probably, to the fact that the use of fixation screws or a greater surface support increase the accuracy of the surgical guide's placing and reduce their possible movements in each moment of the surgery.

When a stereolithographic mucosa-supported surgical template is fixed in the upper arch the accuracy of the system is higher, with a statistically significant differences in the angular deviation value.

The use of stereolithographic surgical guides in experienced hands can simplify the treatment of complex clinical cases but the risk of deviation however is substantial.

The linear and angular deviations of the system used must be well known by the operator for determining the variation of the system used and will also be used to assess the needed safety distances.

When evaluating the safety distances, the average deviations values must not be considered; especially with templates for flapless surgery the maximum deviation of the system should be considered.

The mucosa thickness, in fact, influences the accuracy and there is a statistically significant correlation between mucosa thickness and the degree of global, coronal and apical, deviation data that do not arise from errors in positioning of the surgical guide.

The influence on accuracy of the mucosa thickness becomes more important when the flapless technique is used in smoking patients presenting a statistically significant increased thickness of the mucosa compared to nonsmoking patients.

Based on the results of this and other studies of the literature about the accuracy of the use of stereolithographic surgical guides, a further evaluation of the accuracy is required to refine the procedure and the system, but is essential in any case to respect a minimum safety distance of 3 mm from limiting anatomic structures.

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