The Influence of the Tolerance between Mechanical Components on the Accuracy of Implants Inserted with a Stereolithographic Surgical Guide: A Retrospective Clinical Study

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ABSTRACT

Background: The stereolithographic-guided surgery system involves a sequence of diagnostic and therapeutic events, and errors can arise at different stages. In these systems, one of the potentially clinically relevant errors may be the mechanical errors caused by the bur-guide gap due to the presence of a rotational allowance of the drills in the tubes.

Purpose: The purpose of this retrospective clinical study is to determine if it is possible to reduce the total error by limiting the tolerance among the mechanical components and to evaluate its clinical incidence.

Materials and Methods: Sixty-six implants were inserted using the External Hex Safe® (Materialise Dental, Leuven, Belgium) system (Group A), and 71 implants were inserted using the same system with mechanical components modified to minimize the tolerance (Group B). Regarding only the angular deviation values, the *t*-test was used to determine the influence of reduced tolerance among the mechanical components on the accuracy values.

Results: *t*-Test showed that there is a statistically significant better accuracy with the modified system (Group B).

Conclusions: Limiting the error that originates from mechanical components, total error could be statistically significantly reduced. Mechanical error is one of the most important source of error using External Hex Safe stereolithographic surgical guide.

KEY WORDS: accuracy, CAD/CAM technology, clinical study, computer-assisted, flapless implant surgery, implant, implantology, retrospective, stereo lithography

INTRODUCTION

The stereolithographic-guided surgery system involves a sequence of diagnostic and therapeutic events, and errors can arise at different stages.[1–5] In line with the literature, in this paper, the accuracy of the entire procedure is defined as the deviation between the position of the implant in the planning (or planned implant position) and the position of the implant postoperatively (or inserted implant position).[6] In this paper, we term this deviation as the "total error."

As described by D'Haese and colleagues,[7] by matching the pre and postoperative computed tomography (CT) images of the jaws, it is possible to compare the planned implants with the placed ones and determine two parameters of deviation (i.e., global, apical and coronal, and angular deviation) by using their three-dimensional coordinates at apical and coronal level. All parameters except angular deviation can be determined for both the coronal and the apical centers. The global deviation was defined as the three-dimensional distance between the coronal (or apical) center of the corresponding planned and placed implants. The angular

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deviation was calculated as the three-dimensional angle between the longitudinal axis of the planned and placed implant (Figure 1).

Complications occurring in real clinical situations have been collected and investigated in order to reduce the level of error and to improve treatment, but it has yet to be determined which of the different steps of the procedure may more frequently give rise to an error.

In the stereolithographic single-type surgical guide, dental implant positioning is "totally" guided; one guide is used for the osteotomy site preparation as well as the implant insertion.[8]

The stereolithographic-guided surgery systems permit the development of a skeletal-, dental-, or mucosal-supported surgical guide. Dental- and mucosal-supported guides could be used in a flapless surgical protocol.[9]

In these systems, one of the potentially clinically relevant errors may be the mechanical error caused by the bur-guide cylinder gap because of the presence of a rotational allowance of the drills in the tubes, which can be defined as an "intrinsic error" of the surgical guide.[10–12]

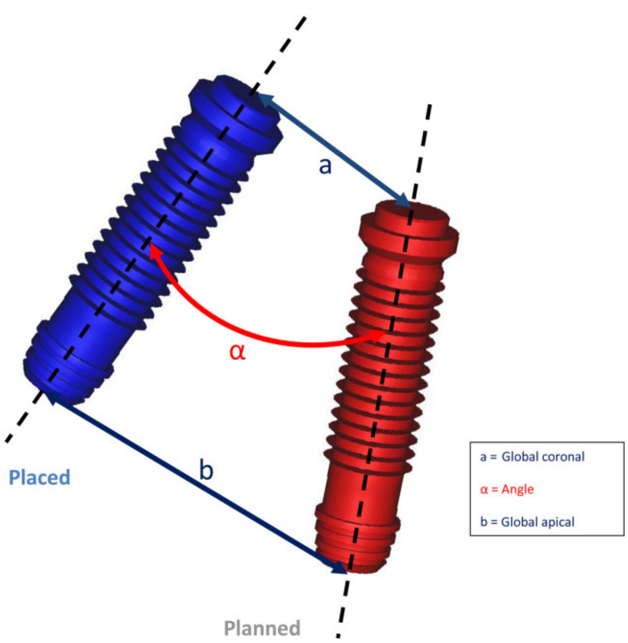


Figure 1 Three-dimensional evaluation of planned (red) and placed (blue) implant. α: the angular deviation (in degrees) between planned and placed implant axes; *A*, The global coronal deviation, the linear distance (in millimeters) between planned and placed implants at the neck. *B*, The global apical deviation, the linear distance between the apical center of the corresponding planned and placed implants.

In a "single type" stereolithographic surgical guide (External Hex Safe®, Materialise Dental, Leuven, Belgium) (Figure 2A), specific cylinders called master tubes (inner diameter of 4.2 mm and height 4 mm) are embedded within the acrylic resin guide to accommodate the implant mounting devices (Figure 2G) that intimately engage the cylinders. To accommodate the drill handles, a tube adapter called the internal tube (Figures 2B, (**)) (height 5 mm and inner diameter is 3.2 mm) is positioned within the master tube. After implant site preparation, the internal tube, which is 0.2 mm smaller than the master tube, is removed allowing close contact between the master tube and the implant mounting device.

Only two size types of single-use drills with physical stops were used: a pilot drill (diameter 2.8 mm at top, 2.0 mm at bottom) (Figure 2E) and a final drill (diameter 3.00 m at top, 3.15 mm at bottom) (Figure 2F). Implant placement was performed using specific delivery mounts (implant holder: length from 4 to 15 mm, diameter 4.00 mm) to a controlled angulation and apico-coronal depth.

When evaluating the importance of intrinsic error in determining any discrepancy between the planned and the final position of the inserted implant, only the angular deviation must be considered as in reality, the coronal deviation is affected by the distance between the bottom of the guide tube and the entry point of the drill in the alveolar ridge, whereas the apical deviation is additionally affected by the length of the implant.

If the angular error that arises from the tolerance among the different mechanical components of a "single" stereolithographic surgical guide is considered, it results in a theoretical total angular error of 5.15°.[12]

The aim of the present study was to determine if it is possible with a "single type" stereolithographic surgical guide to reduce the total error through limiting tolerance among the mechanical components (intrinsic error), and to evaluate the clinical incidence of the "intrinsic error" on the total error.

MATERIALS AND METHODS

A "single type" sterelithographic surgical guide, mucosa-supported (External Hex Safe) was used for totally edentate subjects (19 templates; 137 implants) who required

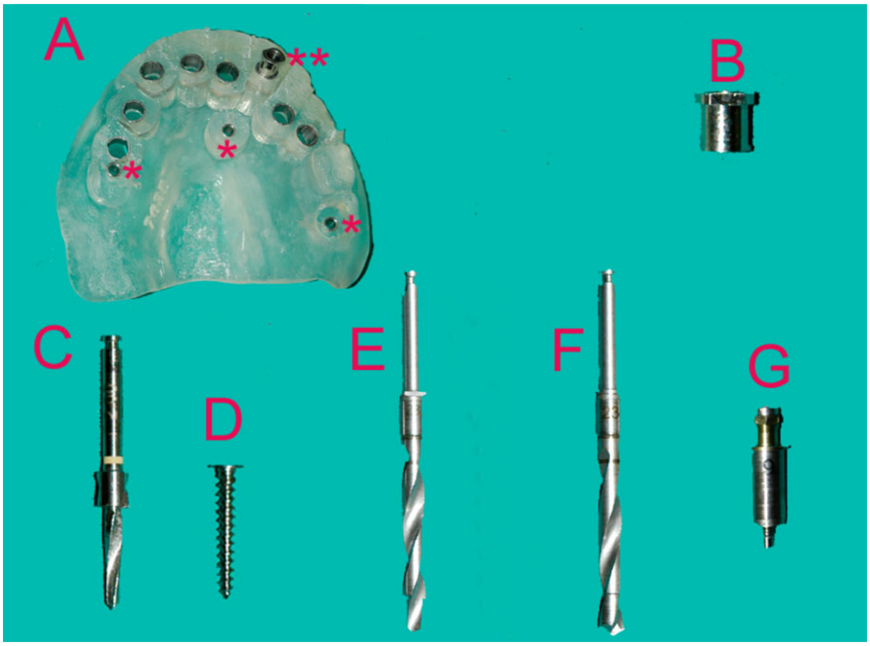


Figure 2 Surgical components and instruments used in a single stereolithographic-guided surgery system (External Hex Safe): *A*, Stereolithographic surgical guide with eight specific cylinders, called master tubes, embedded within the acrylic resin guide; *B*, internal tube; *C*, fixation screw drill; *D*, fixation screw; *E* and *F*, diameter and depth calibrated drills for guided osteotomy; *G*, implant holder for guided implant insertion; (*) guide sleeve for fixation screw installation; (**) internal tube inserted in the guide sleeves to guide drilling procedure.

an implant-prosthetic rehabilitation. All patients consecutively treated with computer-aided implantology between February 2004 and June 2012 were included in this retrospective study.

The surgical interventions were performed by the same operator (MC), expert in computer-aided-implantology, who also made the virtual surgical planning using an implant planning software (SimPlant®, Materialise Dental).

Sixty-six implants (40 in the upper arch and 26 in the lower arch) were inserted using nine External Hex Safe stereolithographic surgical guides (five in the upper arch, four in the lower arch) (Group A), and 71 implants (48 in the upper arch and 23 in the lower arch) were inserted using the same system but with modified mechanical components (10 stereolithographic surgical guides: seven in the upper arch, three in the lower arch) which minimized the tolerance (Group B).

To reduce the total number of External Hex Safe system mechanical components, the guide tubes were connected directly to the head of the surgical handpiece (Figure 3). Guide tubes were constructed of decreasing length in order to advance the surgical osteotomy with maximum control (Figure 4).

During osteotomy, decreasingly longer guide tubes were inserted into the master tube and they progressed inside the master tube with only a vertical movement of entry and exiting (Figures 5 and 6).

The tolerance to be considered between the mechanical components of this modified system is the

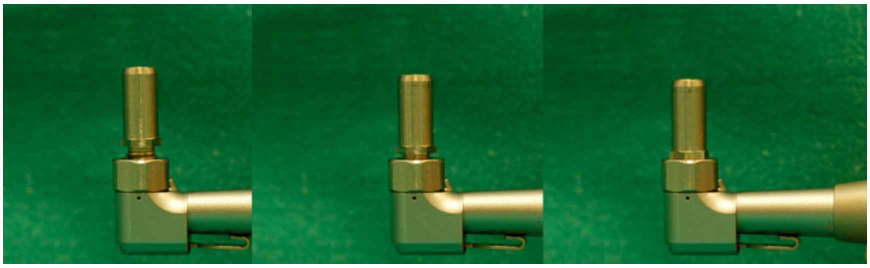


Figure 3 A guide tube directly screwed to the head of the surgical handpiece.

Figure 4 Guide tubes of decreasing length used to advance the surgical osteotomy screwed to the head of the surgical handpiece.

one between the master tube and the guide tube of the surgical handpiece that is 0.05 smaller than the master tube.

This tolerance leads to a maximum theoretical angular error of 0.71°, as demonstrated by the following calculation: $\alpha = \text{arctg } 0.05/4 = 0.71°$.

The protocol employed in this clinical study consisted of an integrated treatment sequence that involved the following steps:

1 Development of a radiopaque diagnostic template (scanno-guide) consisting in an exact replica of the removable, partial, or total prosthesis that answered to the aesthetic and functional requirements of the subject.
2 CT scan of the subject's arch performed with a spiral CT device (Asteion Multi-Toshiba Medical System, Rome, Italy). The scans included the scanno-guide.

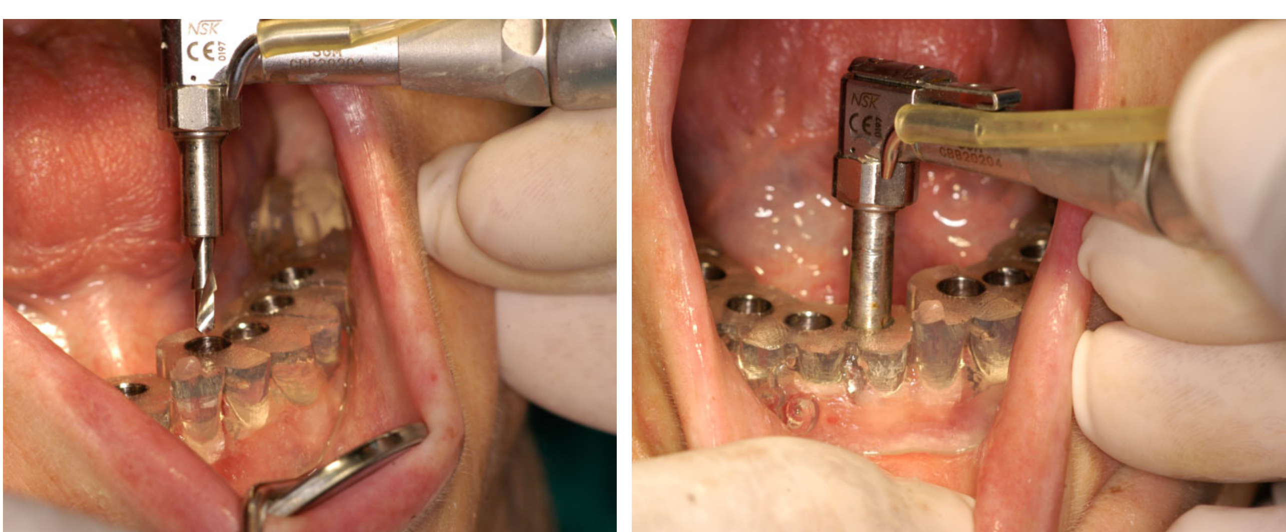
The CT parameters used were: 0° gantry tilt, high resolution bone Kernel, 0.5 mm nominal slice thickness, 0.5 mm interval, and 0.5 mm pitch.

3 Digital three-dimensional CT-based surgical planning. The computer program employed in the present study (SimPlant) uses the original CT data in Digital Imaging and Communication in Medicine (DICOM) format to produce axial, three-dimensional, panoramic, and cross-sectional images, all of which are visible at the same time in four interactive windows on a computer monitor. With this software, implants are virtually placed according to bone anatomy and prosthetic design.

The Hounsfield Units (HU) threshold used was the Simplant's predefined one for bone (250–3071 HU).

4 Computer-aided design (CAD) of the stereolithographic surgical guide; the clinician, in the CAD environment, designs the drilling template.
5 Computer-aided manufacturing of the stereolithographic surgical guide to transfer the digital planning to the surgical environment.

All the templates were firmly fixed to the jaw using at least three fixation screws (Figure 2).



Figures 5, 6 One of the decreasing guide tubes screwed to the head of the surgical handpiece inserted into the master tube.

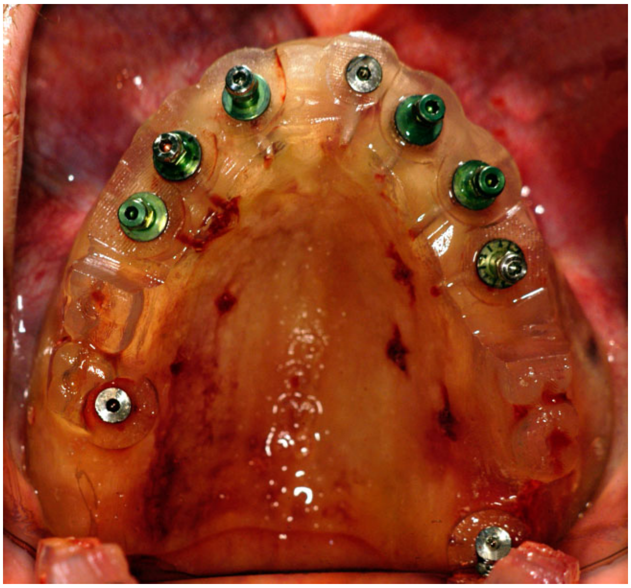


Figure 7 The insertion of six implants in the upper arch using a fixed External Hex Safe surgical guide and the guide tubes of decreasing length screwed to the head of the surgical handpiece. The mounting devices are visible in green.

6 Computer-aided surgery. One hundred thirty-seven implants cylindrical, with an external hexagon (diameter ranging from 3.75 to 4.00 mm and length ranging from 10 to 18 mm), were inserted in completely edentulous subjects using stereolithographic templates (Figure 7).

In Group A, the External Hex Safe system was used; in Group B, the same system was used; however, the mechanical components were modified in order to reduce tolerance and minimize the intrinsic error.

7 As described by D'Haese and colleagues,[7] a postoperative CT was undergone by all subjects using the same preoperative CT parameters.

The pre and postoperative images were compared. In order to evaluate the deviations between the planned (virtual) and the placed (actual) implants, a registration was performed to pairwise align the preoperative three-dimensional representations of the jaws with their counterparts in the postoperative images. Typically, an iterative closest point algorithm was used to match the jaws (the software runs until it finds the best overlap between the images of pre and postoperative jaws) (Mimics® software, Materialise Dental) (Figure 8). The established coordinate transformation operations were then applied to the three-dimensional representations of the planned implants, allowing for relative comparisons with respect to the postoperative implant positions (Figure 9).

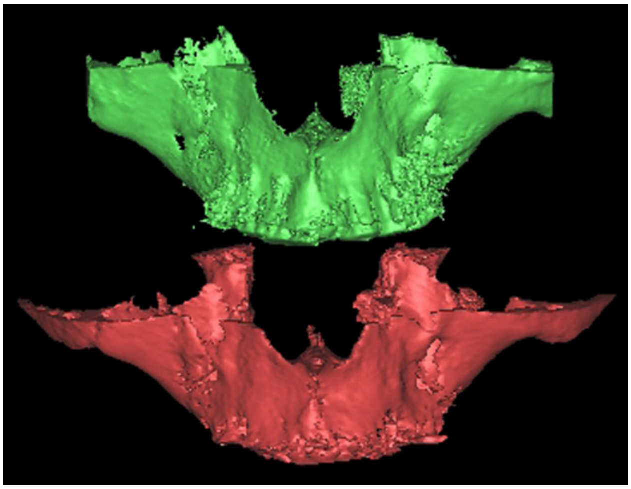


Figure 8 The matching of preoperative three-dimensional computed tomography representations of maxilla with the postoperative using Mimics software.

The angular deviation of planned and placed implants was determined and calculated by using their three-dimensional coordinates at apical and coronal level[3] (Figure 1).

Statistical Analysis

Data was evaluated using SPSS® software (Statistical Package for Social Science, IBM Corporation, NY, USA).

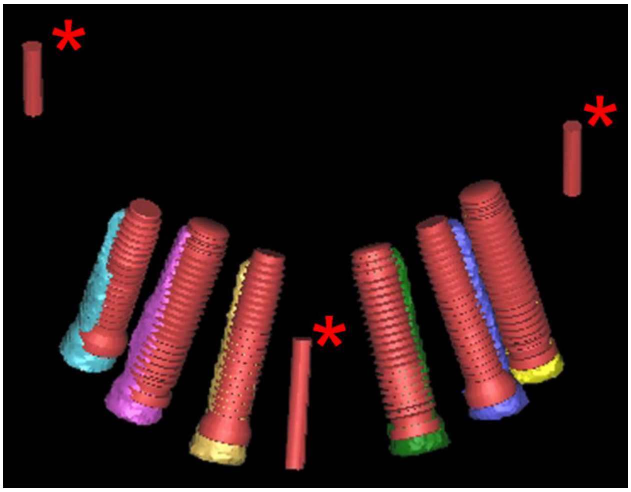


Figure 9 The total error between the planned (red) and the placed implants, performed by aligning the preoperative three-dimensional representations of the jaws with their counterparts in the postoperative three-dimensional images. (*) The planned osteosynthesis fixation screws.

TABLE 1 Frequency Distribution and Angular Deviation Values of Two Groups

	Angle Deviation				
	Max	Min	Mean	Standard Deviation	*n*. Implants
Group A	14.34	0.28	4.30	2.45	66
Group B	3.48	0.30	1.80	0.89	71

TABLE 3 *t*-Test to Determine the Influence of a Limited Tolerance among the Mechanical Components on Angular Deviation Values Significance Was Set at $p \leq .05$

Group A vs Group B	Sig. (p)	Difference between Means	Standard Error
Angle deviation	.000(*)	2.49749	0.31064

*Statistically significant.

Quantitative data of the two groups was described with frequency distribution, mean values, and standard deviations.

Regarding the angular deviation value only, the *t*-test was used to determine the influence of limited tolerance among the mechanical components (i.e., reduced intrinsic error) on accuracy (Group A vs Group B). The significance threshold value was set at $p \leq .05$.

The *t*-test was also used to evaluate if, when reducing the tolerance among the mechanical components, the arch of support involved also resulted in a statistically significant difference (Group A1, External Hex Safe system, upper arch vs Group B1, modified External Hex Safe system, upper arch; Group A2, External Hex Safe system, lower arch vs Group B2, modified External Hex Safe system, lower arch). The significance threshold value was set at $p \leq .05$.

RESULTS

Tables 1 and 2 illustrate the mean values, the range, and the standard deviation of the sample divided into Group A (External Hex Safe system) and Group B (modified External Hex Safe system), Group A1 (External Hex Safe system, upper arch) and Group B1 (modified External Hex Safe system, upper arch), Group A2 (External Hex Safe system, lower arch) and Group B2 (modified External Hex Safe system, lower arch).

t-Test showed that there is a statistically significant improved accuracy when the modified system was used (Group B) (Table 3).

Statistically significant better results of Groups B1 and B2 also resulted when the two groups (Group A and Group B) were analyzed according to the arch of support (Group A1, upper arch; Group A2, lower arch; Group B1, upper arch; Group B2, lower arch) (Tables 4 and 5).

DISCUSSION

The use of a stereolithographic surgical guide has several benefits, but at each step of the process, individual errors can accumulate making high precision challenging to reach.

Van Assche and colleagues[6] estimated error only at the level of guiding tools using an experimental model.

These authors[6] measured the angular deviation between the ideal implant position and the deviated implant position which arises from the tolerance among the mechanical components of two stereolithographic surgical guide systems. A mean angular deviation of 5.4° (SD: 0.4, range 4.8–6°) for Nobelguide® (Nobel Biocare, Göteborg, Sweden) and a mean angular deviation of 3.9° (SD: 0.3, range 3.5–4.3°) for Facilitate® (Astra Tech AB, Mölndal, Sweden) were determined.[6] The same authors

TABLE 2 Frequency Distribution and Angular Deviation Values of Two Groups Considering Separately the Two Arches of Support

			Angle Deviation				
			Max	Min	Mean	Standard Deviation	*n* Implants
Arch	Upper	Group A1	14.34	0.28	3.96	2.68	40
		Group B1	3.38	0.41	1.71	0.81	48
	Lower	Group A2	9.81	1.28	4.81	1.99	26
		Group B2	3.48	0.30	1.98	1.04	23

TABLE 4 *t*-Test to Determine the Influence of Limited Tolerance among the Mechanical Components on Angular Deviation Values in the Upper Arch. Significance Was Set at $p \leq .05$

Upper Arch Group A vs Group B	Significance (two tails)	Difference between Means	Standard Error
Angle deviation	.000(*)	2.25132	0.40682

*Statistically significant.

stated that neither the implant length nor the distance of the sleeve to the bone had any influence on the angular deviation.

Van Assche and colleagues[6] also showed that apical and coronal deviations increased in line with an increasing distance of the sleeve from the bone. What is more, even when keeping the same distance between the bottom of the guide tube and the bone, increased deviation for a longer implant was noted.[6]

These results coincide with those of a recent study conducted by Cassetta and colleagues.[12]

These authors[12] assessed the error that originates from the tolerance among the mechanical components of a single stereolithographic surgical guide (the intrinsic error), mathematically determining a theoretical error of 5.15°.

Only the angular deviation values were evaluated; indeed, if other deviation values such as coronal and apical global deviations are considered, the influence of mucosa thickness and implant length must be evaluated: the mucosa thickness affects coronal and apical deviations, whereas the implant length only affects the apical deviation.[12]

Van Assche and and colleagues additionally suggested that another way to minimize the inaccuracy is to increase the height of the drill key that is the drill tube.[6]

TABLE 5 *t*-Test to Determine the Influence of Limited Tolerance among the Mechanical Components on Angular Deviation Values in the Lower Arch. Significance Was Set at $p \leq .05$

Lower Arch Group A vs Group B	Sig. (*p*)	Difference between Means	Standard Error
Angle deviation	.000(*)	2.82782	0.46220

*Statistically significant.

The apical deviation decreased from 1.1 to 0.6 mm when a drill key of 8 mm instead of 5 mm was used, the degree decreased from 3.5 to 2°.[6]

These data coincide with the data mathematically determined by Cassetta and colleagues:[12] the length of the guide tube is in fact one of the parameters that can affect the level of accuracy of a stereolithographic surgical guide.[12]

In another recent experimental study, Koop and colleagues[13] assessed the impact of employing different types of sleeve inserts, of sleeve insert height, of sleeve insert diameter, and, finally, of the sleeve height on accuracy.

These authors[13] determined that the apical and coronal deviation increased for different sleeve inserts if the distance of the sleeve from the bone was increased.

The same authors also found that hand hold sleeve inserts gave less deviation than drill hold sleeve inserts.[13]

Koop and colleagues[13] moreover determined that lower apical and coronal deviations as well as angulations were observed if the sleeve insert was longer.

Regarding the sleeve insert diameter, an increase of 0.1 mm in sleeve insert diameter gave only slightly higher apical and coronal deviations, as well as minimal changes in angular deviation, but a tighter fit led to a smaller deviation.[13] Koop and colleagues[13] also assessed decreasing apical and coronal deviations as well as angular deviation with increasing sleeve heights.

A discrepancy between the drill and the sleeve insert is necessary to prevent overheating and the wearing down of metal, but unfortunately, it creates a certain tolerance.[6]

Koop and colleagues[13] concluded with a hope that a device can be created that guides the drills, and whose wear, because of the cutting of the metal of the sleeve insert by the drill, and overheating can be reduced.

The modified system used in the present study, by sliding in two opposing tubes, guides the drill, preventing any contact between the drill and the guide tube. This system reduces the tolerance without generating friction and prevents the overheating and the cutting of the metal guide tube by the drill and, as a consequence, the widening of this insert.

The surgical bur rotates inside the surgical handpiece guide tube without creating any friction, without overheating the implant site, but offering better control over the osteotomy. The contact occurs only between the internal tube and the guide tube of the handpiece, but it does not generate any type of friction during its progression in depth because there is no rotation between these components.

The modified design described eliminates the drill allowance between the master tube and the drill, but the total number of the mechanical components is not reduced.

If two drill sizes are needed and six guide tubes are used for each drill size, it is necessary to change the guide tube more times to complete one osteotomy site.

No difficulties were recorded in putting the modified handpiece into such a close fit tubing system (0.2 mm vs 0.05 mm).

Koops and colleagues[13] finally highlighted that sleeves of 7 and 9 mm gave less deviation compared with shorter sleeves, although currently short sleeves up to 5 mm are commonly used and this implies a large mouth opening, which is not easy feasible for all patients. Using the system described in this study however, it is not necessary to modify the length of the guide tubes because the tolerance is very low and a longer guide tube does not substantially modify the results.

The accuracy of a stereolithographic surgical guide arises from the hardware used and the technical procedure applied.[14,15]

As stated by D'Haese and colleagues,[3] error in positioning of a surgical template is categorized as procedure related, whereas the accuracy or stiffness of a surgical template is considered product related. The results of the present study confirm that accuracy is influenced by the surgical guide's intrinsic error showing that by limiting the error that originates from the mechanical components, the total error could be statistically significantly reduced.

Hence, computer-aided implant surgery should still be considered as being in the developmental stage and still need to be improved to reduce inaccuracies and complications.

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