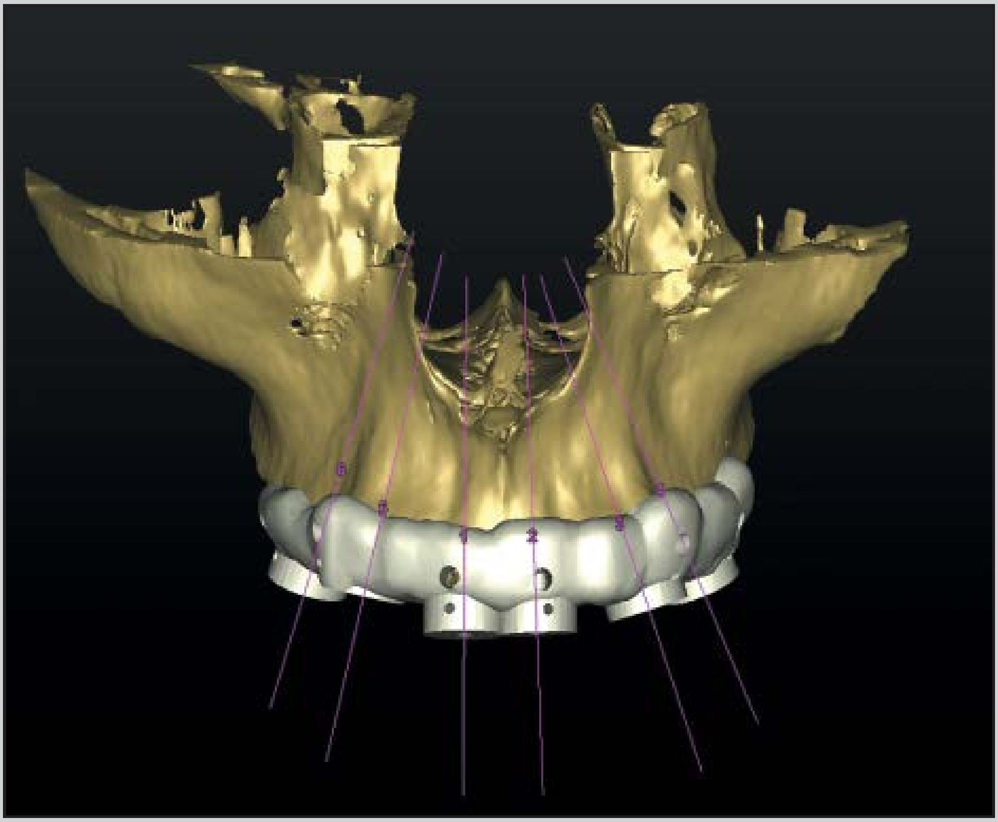

Evaluation of Accuracy and Precision of a New Guided Surgery System: A Multicenter Clinical Study

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Computer-aided design/computer-assisted manufacture (CAD/CAM) guides for surgery are becoming a widespread tool in implant dentistry. This study sought to evaluate the accuracy and precision of a new guided surgery system. Twenty-five patients were treated in eight centers, and a total of 117 implants were placed using CAD/CAM surgical guides supported by bone, mucosa, and/or teeth. A postoperative computed tomographic (CT) scan of each patient was taken and superimposed on a preoperative CT scan to evaluate any discrepancies between the planned and actual implant positions (apex and platform positions), as well as the implant tilt. Implant placement using bone- and mucosa-supported guides was found to be more precise compared to using guides supported by teeth or a combination of teeth and mucosa. However, the differences were not statistically significant. The accuracy of the guided surgery system is in line with the data found in the literature. Considering the mean positioning discrepancies between the planned and actual implant outcomes, clinicians are advised to maintain a safe distance between implants and anatomical structures of at least 2 mm. In immediate loading cases, relining a provisional prosthesis to compensate for any discrepancies between the virtual and clinical implant positions is recommended. (Int J Periodontics Restorative Dent 2014;34(suppl):s59–s69. doi: 10.11607/prd.2138)

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In the past 20 years, planning for implant dentistry has chnaged considerably from a surgical approach that strictly focused on bone availability to planning for optimal prosthetic outcomes prior to surgery and using advanced three-dimensional (3D) imaging modalities to do so. Advances in technology have made it possible to integrate restorative treatment plans with the surgical placement of implants. Computed tomography (CT), introduced into the dental profession in the late 1980s, has made it possible to fabricate surgical guides that enable clinicians to place implants with submillimeter accuracy. The use of such guides can be especially beneficial when placing multiple implants in edentulous areas, where anatomical landmarks are absent. Planning implant positions before surgery may also shorten the time required for surgical procedures.[1–8]

Although several computer-aided surgical programs are available that can assist in implant placement with optimal restorative results, the basic software used for the purposes of this study was

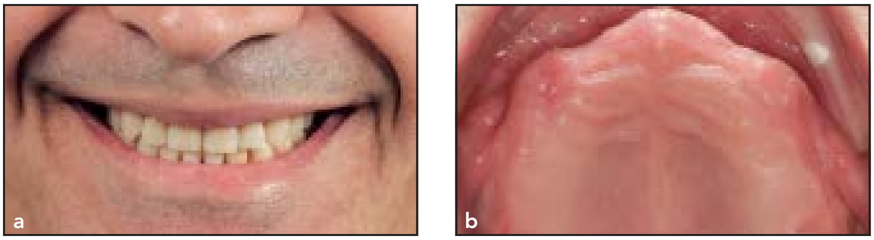

Fig. 1 (a) *A completely edentulous patient wearing a removable prosthesis in the maxilla.* (b) *Intraoral view of the edentulous maxilla.*

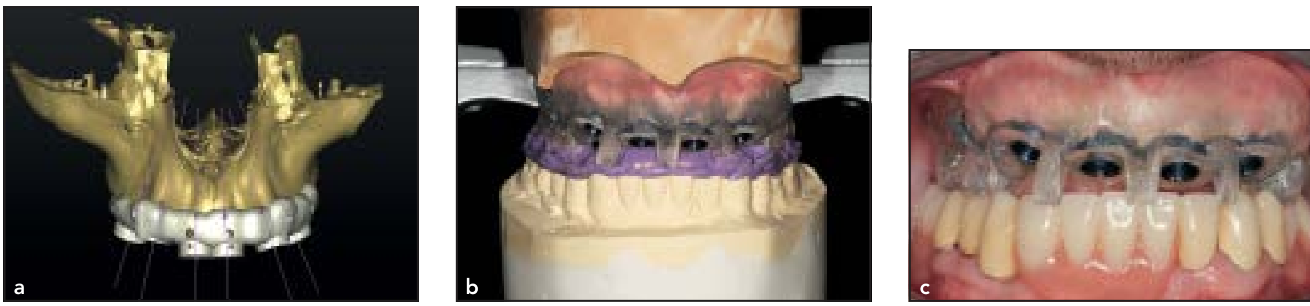

Fig 2 (a) *Virtual 3D project.* (b) *Mucosa-supported surgical stent assembled in the articulator and tested intraorally in the correct intercuspal position.* (c) *The stent has the same 3D position in the articulator and in the mouth of the patient.*

Simplant version 12.0 (Materialise Dental). Methods for fabricating surgical templates range from the industrial (eg, stereolithography) to the artisanal. Previous publications have described prosthetically directed implant placement using computer software and drilling guides made with rapid prototyping technology to ensure precise placement and predictable prosthetic outcomes.[3–5,8] The placement of implants using this technology may be partially guided, eg, using guides solely for osteotomy site preparation, or may involve the use of a single guide both for osteotomy site preparation and implant placement (eg, totally guided). The partially guided technique allows for controlled osteotomy site preparation in two planes: buccolingual and mesiodistal. Options include using multiple sequential drilling guides or drill-handle inserts into a single guide. Vertical depth during implant placement is not controlled in this approach because drilling guides are removed for countersinking (if necessary), and implant placement is performed manually into the computer-guided osteotomy sites.

In contrast, totally guided implant placement allows for either controlled osteotomy or 3D implant placement.[7,9] The SAFE SurgiGuide system (Materialise Dental) was the first to offer such total guidance. Once proof of principle was established, the technology was adapted for use in other commercial systems that facilitated the delivery of internal connection implants.[10]

Recently, a new tool for guided surgery (Navigator System, Biomet 3i) has been introduced. It uses a single guide for osteotomy and implant placement. Specific cylinders are embedded within the resin guide to accommodate drill handles or similar components that closely engage the cylinders. Site-specific drills with vertical stops to control the osteotomy site apicocoronally are then used. Hex orientation is also controlled by means of unique alignment grooves positioned within the guiding cylinder and at the top of the delivery mounts. The delivery mounts also incorporate a vertical stop for apicocoronal depth control during implant placement The drill sizes used and drill handle application depend upon the specific needs of patients and their individualized CT plans. Implants can thus be placed into a controlled buccolingual, mesiodistal, and apicocoronal depth, as predetermined by the computerized 3D plan.

Although implant placement using guided systems is precise, it is not 100% accurate due to a

Fig 3 (a and b) *Patient with the definitive screw-retained prosthesis (CAD/CAM bar and composite teeth).* (c) *Postoperative orthopantomograph.*

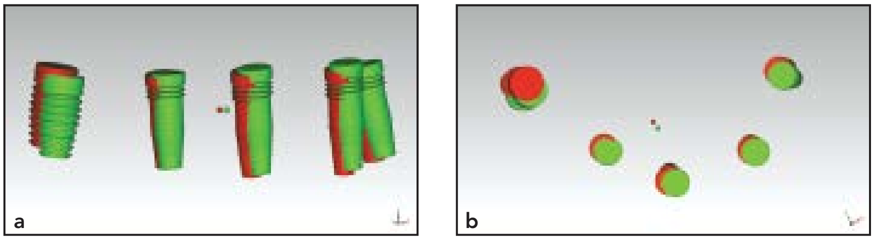

Fig 4 (a) *Frontal view of the pre-* (red) *and postoperative* (green) *superimposition of the implant 3D models extracted from CT scans. The points visible in the middle of the implants show the guide center of mass.* (b) *Occlusal view after superimposition. The center mass deviation shows that the main reason for the system deviation is due to incorrect implant guide positioning.*

number of factors. Cumulative laboratory and technical errors are inherent,[11,12] which is why a provisional prosthesis is usually relined and corrected to fit discrepancies between the virtual plan and the in vivo intraoral reality in immediate loading cases (Figs 1 and 2). In such a situation, 6 months was allowed prior to delivery of the final prostheses (Fig 3).

The aim of this study was to evaluate the accuracy and precision of the recently introduced Navigator guided surgery system.

Method and materials

At eight centers in Europe and the United States, a total of 25 patients underwent treatment using the Navigator guided surgery system. The clinicians included consecutive patients who gave their informed consent to participate in the study.

The inclusion criteria were *(1)* ability of patient to undergo surgical and restorative procedures, *(2)* patient over 18 years of age, and *(3)* possibility for each center to use the same CT machine and setup for the preoperative and postoperative examination of each patient participating in the study.

The exclusion criteria were *(1)* general contraindications to implant treatment and *(2)* irradiation to the head and neck.

Each patient was informed about the surgical and prosthetic procedures that would be performed, including possible risks, and each signed an informed consent form. The study was approved by the Ethics and Scientific Committee of the IRCCS Galeazzi Institute, Milan, Italy, and all aspects of the study were carried out in accordance with the last official version of the Helsinki Declaration on ethical standards.[13] In addition, it was essential that 3D imaging be used to maximize implant planning in concert with interactive treatment planning software that provided the link to template fabrication. The use of 3D imaging technologies is supported by recent literature and recommendations from the American Academy of Oral and Maxillofacial Radiology[14] and the International Congress of Oral Implantologists.[15]

One surgeon at each center performed the surgery. Different CT scanners were used in different centers, but the same CT scanner was used for each patient to superimpose the preoperative and postoperative CT images. After the surgical phase, an additional CT scan was taken for each patient and superimposed on the virtual plan (Fig 4). The combined scans

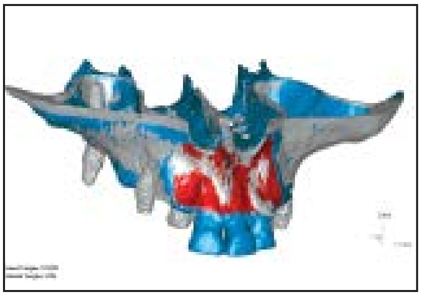

Fig 5 *Superimposition of presurgical models and quantification of the precision of the process of superimposition for each area. The selected area* (red) *is not affected by the surgery.*

were then analyzed in the following manner and the results were compared to data reported in a recent systematic review of the accuracy and clinical outcomes of various computer-guided implant planning and placement systems.[16]

Data analysis

The analysis was performed following the steps below.

- Data extraction from pre- and postoperative CT scans (bone regions and implant positions)
- Postoperative CT implant model conversion to computer-aided design (CAD) implant models
- Superimposition of the preoperative CT scan onto the postoperative CT image to set the models in the same reference system
- Comparison between the geometrical positions of the pre- and postoperative CAD implant models.

Data extraction

Bone regions
Bony areas were extracted by setting the same gray level threshold in pre- and postoperative images (Materialise Mimics 14 software).

Preoperative implant planning
The data obtained using the SimPlant software were kindly converted by the Materialise Company into a CAD project consisting of 3D models of the planned implants in stereolithography format, readable by any surface analyzing software.

Postoperative implant planning
Virtual extraction of the implants in the postoperative images was carried out using a very high threshold that included all metal parts in the dataset. The extracted implant models are affected by metal that deforms their geometry; therefore, the metals are replaced with the corresponding virtual implant models through a best-fit procedure controlled by reverse engineering software, (Geomagic Studio 12, Geomagic). This procedure inserts virtual implant models into the positions that best fit the geometry and position of the implant extracted from the postoperative CT scan. The result of this operation is the complete replacement of the metal-corrupted implant files extracted from the CT with the corresponding CAD files from the implant library.

To superimpose the virtual plan of the preoperative CT onto the postoperative CT, the best-fit overlapping of the bony areas that are not involved in the surgery is performed using the same reverse engineering tools employed in the previous step (Fig 5). After superimposition, the apical, platform, and major axis deviations were calculated.

Results

A total of 117 implants were placed in 25 patients at the 8 centers. The number of patients treated at each center ranged from 2 to 5 and the number of implants placed ranged from 7 to 23; between 1 and 11 implants were placed in each patient. At each of the 8 centers, the mean deviation between the planned and actual implant apical positions ranged from 1.16 to 1.98 mm. The mean deviation between the planned and actual platform positions ranged from 0.88 to 1.68 mm. The mean deviation between the planned and actual implant angulations ranged from 2.62 to 4.90 degrees. Table 1a summarizes these results. Table 1b shows the overall mean deviations measured in this study and comparison with those obtained in the literature.

Table 2 displays the study findings when organized according to type of surgical guide support (mucosa, bone, tooth-mucosa). Whereas guides supported by mucosa (alone) or bone showed mean deviations between the planned and actual apex points that were smaller than the data in the published literature, those supported by teeth or a combination of mucosa and teeth showed greater values. The deviation between the actual and planned implant platform positions ranged from 1.12 mm (for mucosa-supported guides) to 1.63 mm (for the dental-mucosal combination guides). The deviation between the actual and planned implant angulations ranged from 2.94 degrees (for tooth-mucosa supported) to 4.9 degrees for tooth-supported alone.

A further analysis was carried out by examining the results for implants placed in anterior versus posterior positions; in posterior implants, there was a higher discrepancy at both the implant platform (1.23 vs 1.54 mm) and the apex (1.38 vs 1.78 mm).

Table 3 combines the results of data analysis according to the position (anterior, up to the first premolar vs posterior, beyond the first premolar) and guide-supported subgroups. It is also interesting to analyze the guided surgery procedure using a central parameter that could explain possible deviations between the planned implant positions and clinical results. In other words, it would be important to understand if the deviation was due to the drill tolerance inside the guide sleeves (a "local" deviation) or to inaccurate positioning of the surgical guide within the patient's mouth (a "global" deviation). Since the guide sleeves corresponding to the planned implant positions are kept together by the guide resin, the center mass of the implants was calculated as a global group and compared to the center mass of the surgical guide. A significant difference between the center of mass of the pre- and postoperative analyses would mean that the reason for the deviation was due to surgical guide positioning in the patient's mouth rather than the precision of the guide or the manufacturing of surgical instruments. Analysis of the center of mass of the virtual and actual surgical guides showed that in 18 of 25 cases the deviations were more than 1 mm, in 8 cases the deviations were less than 1 mm, and in 1 case the centers of mass coincided perfectly.

Table 4 reports the data of the center of mass of the stents of the virtual plan compared with the centers of mass from the postoperative CT scans. Larger deviations were seen in the vertical positions.

Table 1a Mean ± SD deviations for each center

Center	Patients (n)	Implants (n)	Apical deviation (mm)	Platform deviation (mm)	Angular deviation (deg)
1	3	11	1.43 ± 0.84	0.94 ± 0.57	4.50 ± 3.17.
2	2	11	1.16 ± 0.34	0.88 ± 0.26	2.62 ± 1.46
3	4	22	1.51 ± 0.51	1.48 ± 0.47	3.52 ± 2.37
4	3	18	1.16 ± 0.58	1.14 ± 0.67	2.69 ± 1.16
5	3	17	1.34 ± 0.49	1.42 ± 0.69	2.71 ± 1.43
6	3	8	1.98 ± 1.13	1.68 ± 1.16	3.16 ± 1.86
7	5	23	1.74 ± 0.66	1.36 ± 0.62	4.90 ± 3.13
8	2	7	1.85 ± 1.09	1.74 ± 1.12	3.23 ± 1.48

Table 1b Overall mean deviations measured in this study and comparison with those obtained in the literature

	Patients (n)	Implants (n)	Apical deviation (mm)	Platform deviation (mm)	Angular deviation (deg)
Interoperator mean	25	117	1.52	1.32	3.26
Mean values in literature		1.63	1.07	5.26	

Table 2 Results organized according to type of surgical guide support (mean ± SD)

Type of support	Apical deviation (mm)	Implant deviation (mm)	Angular deviation (deg)
Mucosa	1.36 ± 0.64	1.12 ± 0.65	4.06 ± 2.82
Bone	1.40 ± 0.43	1.33 ± 0.47	3.19 ± 1.95
Tooth-mucosa	1.84 ± 1.00	1.63 ± 0.98	2.94 ± 1.84

Table 3 Mean results according to the position in the arch and the type of support

	Apical deviation (mm)	Platform deviation (mm)	Angular deviation (deg)
Mucosa-supported			
First premolar to first premolar	1.24	0.98	4.06
Second premolar and molars	1.66	1.48	4.06
Bone-supported			
First premolar to first premolar	1.35	1.33	3.02
Second premolar and molars	1.64	1.29	4.06
Mucosa- and tooth-supported			
First premolar to first premolar	1.73	1.52	2.55
Second premolar and molars	2.00	1.79	3.47

Table 4 Data of the center of mass of the stents

		Center of mass of surgical guides in virtual plan (mm)			Center of mass of surgical guides in postoperative CT (mm)		
Center	Arch	X	Y	Z	X	Y	Z
1	Maxilla, mucosa	87.79	69.28	–55.63	87.57	69.02	–55.89
	Maxilla, bone	85.69	59.89	–60.78	85.72	59.83	–60.59
2	Maxilla, mucosa and tooth	60.58	54.64	20.00	60.11	54.04	19.46
	Maxilla, bone	65.74	30.08	–51.22	65.66	30.07	–50.6
3	Maxilla, bone	60.46	42.79	–559.98	59.81	41.50	–560.28
	Mandible, mucosa and tooth	84.59	68.74	49.82	85.13	67.56	50.41
	Maxilla, bone	69.86	49.47	–600.2	68.13	49.61	–601.63
	Mandible, bone	69.28	45.83	–647.47	68.66	45.42	–645.72
	Mandible, bone	36.78	48.89	–550.53	37.22	48.10	–549.74
4	Maxilla, mucosa	76.35	42.59	20.42	77.99	42.72	20.75
	Maxilla, mucosa	57.79	30.1	20.39	58.35	31.56	20.90
	Mandible, mucosa	60.5	39.31	22.89	60.10	39.74	23.95
5	Maxilla, mucosa	42.59	22.33	25.88	42.44	22.42	25.03
	Maxilla, mucosa	45.84	28.95	16.74	45.46	28.31	15.48
	Mandible, bone	44.7	24	23.62	44.67	24.01	23.62
6	Maxilla, mucosa and tooth	87.25	68.47	8.45	87.13	68.17	7.92
	Maxilla, mucosa and tooth	82.16	76.94	12.74	81.85	75.31	9.72
7	Mandible, mucosa	74.95	63.24	–24.53	74.75	64.22	–24.63
	Mandible, mucosa	70.33	39.47	–18.42	70.00	39.14	–18.20
	Maxilla, mucosa and tooth	68.52	67.62	–3.39	68.56	66.85	–4.45
	Maxilla, mucosa and tooth	74.92	39.61	–62.03	75.06	39.40	–63.74
	Mandible, mucosa and tooth	66.75	34.96	–86.17	66.83	33.64	–84.07
	Mandible, bone	80.77	65.31	6.85	81.06	65.49	7.85
8	Mandible, mucosa and tooth	85.34	58.5	26.88	85.91	59.06	29.43
	Maxilla, mucosa and tooth	60.43	34.6	17.03	60.37	34.54	18.10

Table 5 Differences between surgical guides using unpaired *t* test

Type of support	Apex	Platform	Angle
Mucosa vs bone	.73	.09	.09
Mucosa vs tooth-mucosa	.01*	.01*	.10
Bone vs tooth-mucosa	.01*	.09	.81

*Statistically significant difference.

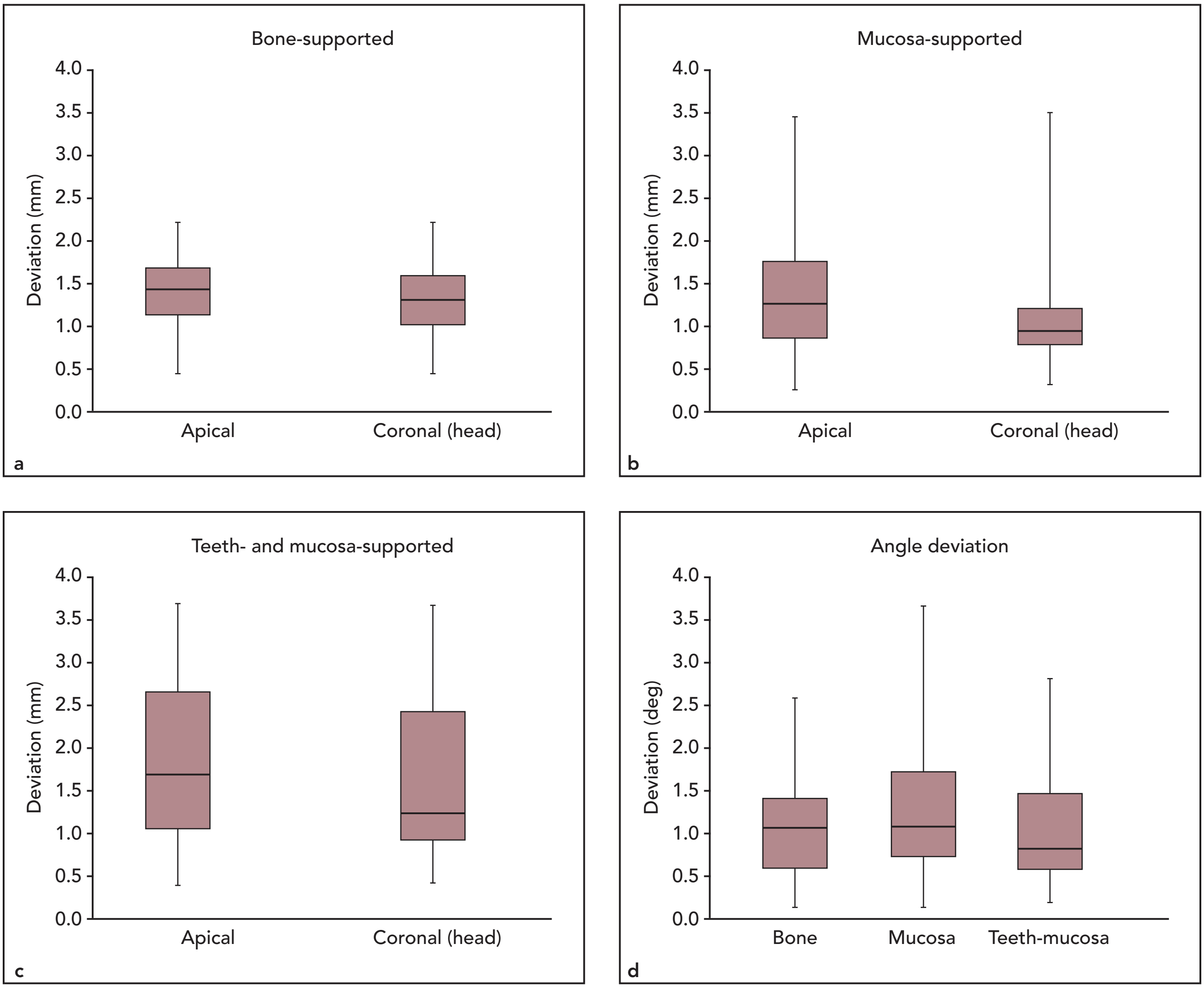

Fig 6 (a) *Bone-supported guide.* (b) *Mucosa-supported guide.* (c) *Teeth- and mucosa-supported guide.* (d) *Angle deviation measured with the three examined supports.*

Table 5 reports the significance of the differences between types of surgical guide by unpaired *t* test. The overall data collected in the study for the different supports are summarized in Fig 6.

Discussion

Several authors have demonstrated that stereolithographic surgical drilling guides enable more precise and accurate osteotomy preparation compared with a conventional nonguided approach.[6,17–20] A totally guided approach may allow for the achievement of even greater accuracy because it eliminates the potential influence of operator positioning error when using more than one guide or placing implants manually. Totally guided placement also offers the opportunity for minimally invasive surgery with the obvious clinical benefits of reduced pain and swelling.[21] Surgical goals can be achieved precisely and a dental prosthesis can be fabricated prior to surgery, enabling the delivery of teeth on the day of surgery. However, a totally guided approach demands the highest attention to detail in all phases of treatment.

Important elements influencing the ability to achieve desired treatment outcomes include:

- Quality of CT imaging, including panoramic, cross-sectional, and axial two-dimensional views
- Reliability of the 3D reconstruction created by the radiology technician using computer software
- Quality of the rapid prototype model
- Challenge of determining the accurate position of thin crestal bone, which often competes with other radiodense structures (eg, teeth, scanning appliances)
- Regional anatomy characteristics
- Dimensional stability of the stone model optically imaged for tooth-supported cases
- Accurate placement and stability of the scanning appliance at the time of imaging
- Extent of any radiation artifacts
- Movement and fit of the guide during surgery
- Knowledge and experience in CT analysis and interpretation.[22]

One of the most important factors in CT-guided implant dentistry is the ability to precisely transfer the implant plan to the operating field. If the system is not precise and the actual positions of the implants do not reproduce the virtual plan, intraoperative surgical complications (such as bone dehiscences or implant malposition) may happen. Most studies that investigated the accuracy of guided surgical implant placement have shown deviations from the planned implant entry point of approximately 1 mm and deviations from the planned angulation of around 5 degrees. Van Assche et al[17] and Ruppin et al[23] compared virtual and actual implant placement in cadavers and noticed mean angular deviations of 2 and 7.9 degrees, respectively. The difference between the two studies may have been due to the fact that in the first, tooth-supported guides were used to rehabilitate partially edentulous sections, whereas in the second, bone-supported guides were used. The two-dimensional deviation in virtual and actual platform positioning was 1.1 mm and 1.5 mm, respectively.

Similar values were found in two other human studies, one involving a living subject and the other a cadaver. Ersoy et al[24] reported an angle deviation of 4.9 degrees and a 1.2-mm linear distance in the implant platform. Ozan et al[25] found a deviation of 4.1 degrees and a linear distance of 1.11 mm. All these data agree with a recent systematic review of the literature carried out by Schneider et al.[16]

The mean values found in the present study are in line with the known data in the literature,[16] but the implant angulations were more accurate for all types of guide support compared with the means reported in the literature, A recent clinical study[9] in 116 implants using multiple sandblasted, large-grit, acid-etched templates found that the mean global deviations between planned and actual implant positions at the coronal and apical ends were 1.47 mm and 1.83 mm, respectively; the mean angular deviation was 5.09 degrees. There were significant linear correlations at the implant level between coronal and angular deviations and between coronal and apical deviations. The discrepancies in results may be due to the fact that this study used one template to compare multiple guides for each patient. Even though it is quite difficult and misleading to compare different guided surgery systems that use different technology, the data could be valid within each study.

Closer analysis of the deviations recorded in each center showed that, at two of the centers, the accuracy of apical and platform positioning, as well as the accuracy of the angulation, was greater than that reported in the literature. Three centers displayed greater than reported accuracy for apical positioning and angulation, and three centers displayed greater than reported accuracy only for the angulation. Analysis of the center of mass of the guides indicated that even when guides were in the planned position, inaccurate implant positioning sometimes occurred. This may be explained by the fact that even when the center of mass of the planned guide placement coincided with the actual placement, the guide may have been incorrectly rotated, resulting in an implant platform placement that was too lateral.

In flight dynamics, the parameters of yaw, pitch, and roll are three critical axes to which spatial positioning of an aircraft in flight can be oriented. Similar navigation coordinates of X, Y, Z axes were compared in this study using the center of mass as the principal axis of planned and actual implant positions. In the current context of CT-guided implant dentistry using CAD/CAM surgical guides, it may simply be impossible to have absolute precision on a consistent basis between planned and actual implant outcomes due to inherent discrepancies within the system. The slightest rotational and/or translational movements (which may not be humanly detectable) of the guide can occur at any point during the surgery, introducing error. At present, there is no current method of verifying and validating positional accuracy of the guide or implant placement other than to compare before-and-after implant outcomes using pre- and postoperative CT data as was done in this study.

To obtain absolute precision between the plan and the outcome, and to avoid additional radiation to the patient, a likely solution would need to incorporate positional navigation systems in the future that would allow for coordination of axes positioning between the planned center of mass and the actual center of mass before beginning osteotomy site preparation. Coordinating the center of mass of a surgical guide at the time of surgery would allow for verification and validation of positional accuracy between the plan and the actual guide position to ensure precision. The same information would be needed after implant placement to ensure coordination of axes between implant plan and outcome, thereby confirming what has been transferred to the patient was indeed what was intended from the surgical plan. Unless such a level of repeatable verification and validation can be accomplished, inherent inaccuracy of the system will be inevitable in this field. At the present time, such solutions exist in neurosurgery, spine/craniofacial/otolaryngological, and orthopedic surgery, but such applications are likely to be cost prohibitive for use in everyday dental private practices.

Other factors may also influence the precision and accuracy of the actual implant platform positions, including the guide material used and other aspects of surgery. The detailed analysis of implant location confirms that the precision of the system is influenced by the possibility of performing a correct drilling phase without applying any micromovement to the surgical guides by the handpiece. Placement could be less accurate in posterior areas because access to those areas is often more difficult and the guide may shift from its original position if the clinician is tilting and/or forcing the handpiece into the sleeves of the template during the drilling phase or implant placement.

Planning guided surgery for patients with limited intraoral access presents a challenge because the constricted space can significantly impede the use of rotating instruments and corresponding adaptors or prevent the clinician from operating the handpiece without applying force. The position of the apex may also be influenced by the extent to which the burs are worn, which causes an increase in tolerance and may result in the flagging of the burs and malpositioning of the implant. The worst results were seen in the cases of guides supported by teeth or a tooth-mucosa combination; the statistical significance of the difference between the guide types is shown in Table 5.

The difference may be due to the fact that restorative and/or prosthetic reconstructions often render imprecise radiologic images, and that imprecision may then affect the surgical guide fabrication. The better precision of the bone-supported guides may be due to the extensive flap elevation carried out that leads to a better overall fit of the guides. However, extensive flap elevation is more invasive and generally associated with more postoperative discomfort. Use of a flapless technique (with mucosa-supported guides) certainly offers more advantages both to the patient and clinician. It reduces the duration of the operation, along with postoperative discomfort, bleeding, and swelling—all of which may be particularly important for patients with systemic conditions or phobias. Published reports have demonstrated that implants placed with a flapless surgery have success rates comparable to those placed using standard techniques but show less bone resorption and less postoperative discomfort.[26]

Conclusions

Computerized planning and guided surgery of dental implants have become important diagnostic and clinical aids. The results reported in this study show that implants placed using the studied guided system have an accuracy comparable to that previously reported in other systems. When considering immediate restoration supported by implants in the context of CAD/CAM-driven CT-guided implant surgery, it is highly recommended that such approaches be used to ensure accuracy, reduce operator and patient anxiety, reduce surgical treatment time, and in most cases reduce patient morbidity.

However, due to the mean discrepancies between the virtual plan and the actual implant positioning, it is advised to keep a safety margin of at least 2 mm between implants and other anatomical structures. In cases of immediate loading, it is recommended to deliver a relined provisional prosthesis that can compensate for any discrepancies between the virtual plan and actual implant placement. The definitive prosthesis can be delivered several months after implant placement, allowing for appropriate soft tissue maturation, during which time the patient will never be without teeth. Future directions to improve CT-guided implant dentistry will need methods of pre- and postsurgical verification and validation of positional accuracy using both local and global concepts and may require surgical navigation modalities to achieve such precision on a repeatable basis.

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