EVALUATION OF STEREOLITHOGRAPHIC SURGICAL GUIDE IN INDIRECT SINUS LIFTING FOR IMPLANT PLACEMENT

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ABSTRACT

INTRODUCTION: Due to the inherent characteristics of the posterior maxillary bone, oral rehabilitation with implants may present some difficulties related to poor quality and insufficient volume of bone due to sinus pneumatization. Maxillary sinus augmentation procedure is currently considered a highly predictable and safe technique that allows the insertion of implants into the atrophic posterior maxilla. The use of CAD-CAM stereolithographic surgical guide during sinus-lift procedure has been advocated for many years.

OBJECTIVES: This study was designed to evaluate the accuracy of stereolithographic surgical stent in transcrestal sinus lifting for implant placement.

MATERIALS AND METHODS: A total of fifteen implants were placed in 6 patients. They were selected to perform transcrestal sinus lifting with simultaneous implant placement using stereolithographic surgical stent.

RESULTS: Merging the preoperative plan and immediate postoperative CBCT images showed statistically significant values of the accuracy. The mean difference of angulation of the inserted implants compared to the angulation projected by the stereolithographic stent was 7.03° ± 4.53°. The mean of total coronal differences was 1.56 mm ± 1.15 mm, while the mean of total apical differences was 1.75 ± 1.14 mm.

CONCLUSIONS: For beginners, stereolithographic surgical stent is an acceptable tool for transcrestal sinus lifting with simultaneous implant placement especially for single implants.

KEYWORDS: transcrestal sinus lift, stereolithographic surgical stent, accuracy, implants.

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INTRODUCTION

Following tooth loss, the maxillary residual ridge undergoes continuous modeling and re-modeling processes. In particular, the modeling process in the posterior maxilla is the result of alveolar ridge resorption and an increased maxillary sinus pneumatization (1).

The elevation of the sinus membrane is accomplished via either a lateral or a transcrestal approach to the antrum. As an opinion of few authors, lateral approach is considered the gold standard and recommended as the treatment of choice in cases where the residual bone height is less than 5.0 mm (2-4).

However, the lateral appraoch is highly invasive technique sensitive that can lead to high risk of perforation, risk of morbidities and post-operative complications. As severe bruising, swelling and pain may be observed as a result of the inherent traumatic nature of this technique and extensive flap elevation beyond the mucogingival line (5).

The transcrestal approach is advocated as a simple, predictable and minimally invasive procedure. The advantages of this surgical approach are minimal bleeding and high patient acceptance due to its minimally invasive nature, less time-consuming intervention with a lower rate of post-operative complications, lower cost and shorter healing time with reduced time required for prosthetic rehabilitation (6).

Stereolithography, a rapid prototyping computer-aided design and computer-aided manufacturing technology (CAD/CAM), is a newer development in dentistry that allows fabrication of surgical guides from three-dimensional computer generated models for precise implant placement. Thanks to these technologies; it is now possible to predetermine the precise three-dimensional position of the planned implant before the actual implant insertion, and to transfer this position to the surgical site (7).

Nowadays computer-guided surgery using stereolithographic templates is gaining popularity among clinicians and patients. The advantages of this surgical protocol are correct implant orientation, minimize the osteotomy, reduced surgical trauma and predictable implant supported prosthesis, resulting in favorable design of prosthesis (8).

The effectiveness of the accuracy of CAD-CAM stereolithographic surgical guide technology in dental implant planning and transfer of the pre-surgical plan to the surgical site has not yet become an established fact and still needs on-going research (9).

In the light of the above information, this study was designed to evaluate the accuracy of stereolithographic surgical stent in transcrestal sinus lifting for implant placement.

MATERIALS AND METHODS

Informed Consent:

Appropriate institutional ethical clearance from the Faculty Ethical Committee and written informed consent from the patients were obtained. All patients were informed about the aim of the study.

Patients Selection and Evaluation:

In this study fifteen implants were placed in 6 patients at the posterior maxilla with deficient alveolar bone height using the stereolithographic surgical stents. Patients were selected from the Outpatient Clinic of Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Alexandria University.

The inclusion criteria of this study were: patients having residual alveolar bone height less than 8 mm at the

edentulous posterior maxillary region, adequate ridge diameter, inter-arch space and inter-occlusal space to accommodate implants, abutments and the future prosthesis, clear from any sinus pathology after sinus examination clinically and radiographically, adequate oral hygiene and patients accepting to participate in the study. The exclusion criteria were: patients suffering from acute sinusitis, long standing nasal obstruction, relevant uncontrolled systemic and/or metabolic diseases, immunosuppressive and/or autoimmune diseases, history of radiotherapy or chemotherapy in the last 6 months, heavy smokers and parafunctional habits.

Pre-surgical clinical examination was performed for all patients: Patients data were collected; name, gender and age, medical and dental history were taken and the oral mucosa of the edentulous area was examined for color, texture, firmness and thickness. Also, preoperative evaluation for all patients included panoramic x-ray and cone beam computerized tomography (CBCT), to evaluate the residual ridge height and width, the anatomy of the maxillary sinus, and for virtual treatment planning, as shown in (Figure 1 and 2).

Fabrication of the CAD/CAM surgical stent by stereolithography using In2Guide™ system (manufactured by KaVo Dental GmbH on behalf of Cybermed Inc., Korea). CBCT scan (veraviewepocs 3D R100, J.morita, Japan, at 8 mA, 90 KV) for all patients and scanning of the stone models were performed. The treatment plan was performed using In2Guide™ software powered by OnDemand3D™ (version 1.0.9, Cybermed, Korea) (10).

The surgical stent was fabricated using a certified biocompatible resin, while the custom sleeves were made from titanium. It was manufactured by a dental technician under the ISO 13485 quality management system and certified by the FDA (US), CE (Europe) and KFDA (Korea) (10).

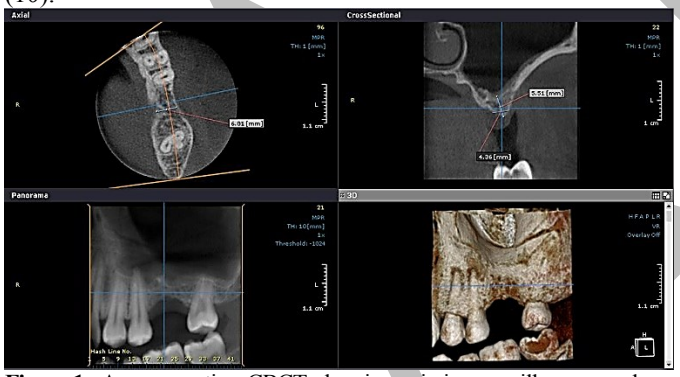

Figure 1: A preoperative CBCT showing missing maxillary second premolar and pneumatization of maxillary sinus. In the coronal cut, the vertical bone height is 5.13mm and the bone width is 4.67mm.

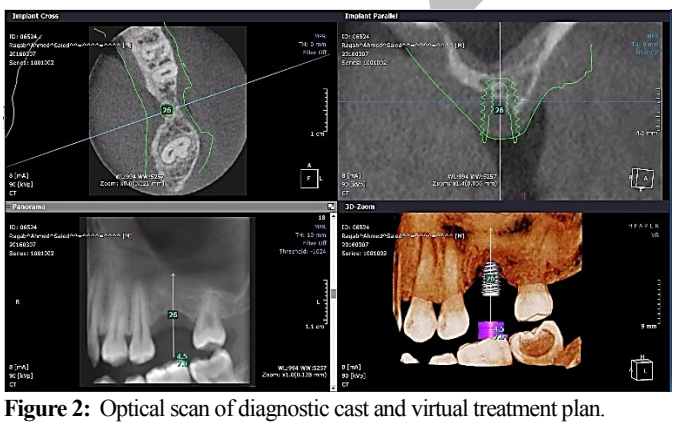

Figure 2: Optical scan of diagnostic cast and virtual treatment plan.

Surgical Procedure

All patients were treated under local anesthesia using articaine hydrochloride 4% and levonordefrin (Septanest; Septodont, France). They were instructed to rinse using Chlorhexidine gluconate mouthwash for 30 seconds (Hexitol, the Arab Drug Company, Cairo, A.R.). The stereolithographic surgical template was checked for proper seating and in edentulous or posterior end saddle cases it was secured in place by horizontal stabilization pins. A flapless approach (using tissue punch) was performed at the planned elevation site. The access to the bony sinus floor using In2Guide™ system was performed with a customized drilling sequence according to manufacture instructions to the preplanned depth 1 mm away from the Schneiderian membrane (Figure 3).

The remaining subantral bone of 1 mm was compacted and pushed up using blunt ended Microdent sinus compactors of the appropriate size. The grafting material (easy graft™ CRYSTAL) of 0.25 ml was introduced and pressed into each implant site (Figure 4). The selected implant was carried out using the corresponding connector pin and placed into the osteotomy site, and then it was threaded using the handpiece connector. A titanium cover screw supplied with the implant was inserted on the implant with the use of implant screwdriver then the stent was removed.

All patients were advised to; apply cold packs extra orally intermittently (10 mins on and 10 mins off for one hour) and avoid hot food on the first day, apply hot packs on the second day and avoid eating hard food at the surgical site. Chlorhexidine mouth wash (Hexitol, the Arab Drug Company, Cairo, A.R.) was started on the 2nd post-operative day 3 times daily for 2 weeks. Also patients were instructed to avoid sneezing, nose blowing or other actions that might create high intranasal and intrasinusoidal pressure or vacuum, to avoid drinking with straws for a week and not to wear any prosthesis over the surgical site for at least one week after surgery.

Post-operative medication in the form of a broad spectrum antibiotic Amoxicillin 875 mg + Clavulanic acid 125 mg tablets (Augmentin 1 gm Smithline Beecham Pharmaceutical Co., Bentford, England) every 12 hours for 5 days to avoid post-operative infection. Non-steroidal anti-inflammatory analgesic diclofenac potassium 50 mg tablets (Cataflam 50 mg tablets, Novartis Pharma AG, Basle, Switzerland) every 8 hours for 3 days to avoid the possibility of pain. Anti-edematous Chymotrypsin and Trypsin 300 EAU tablets (Alphintern 0.24 gm, Amoun pharmaceutical Co. SAE. El-Obour City, Cairo, Egypt) every 8 hours for 5 days. Nasal Decongestant as Ephidrine nasal drops (Otrivin spray/nasal Drops 10 ml, Novartis Pharma AG, Basle, Switzerland) 3-5 times daily for 5 days.

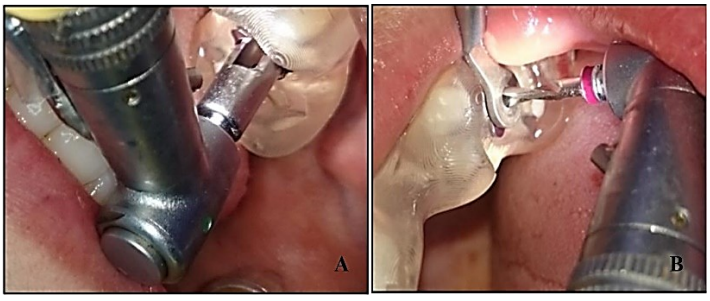

Figure 3: A photograph showing (A) tissue punch inserted through the surgical stent and (B) implant site drilling.

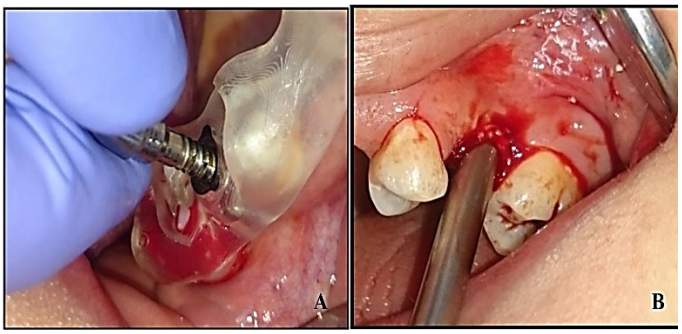

Figure 4: A photograph showing (A) the sinus floor was carefully separated from the schneiderian membrane using blunt ended expander and (B) easy graft™ CRYSTAL application.

Postoperative evaluation

All patients were examined the day after surgery then weekly for the first month postoperatively, then on intervals of 1, 4 and 6 months postoperatively. The clinical parameter of importance for determination of implant success included implant mobility. Pain and discomfort were examined using visual analogue scale (VAS) (11). Edema was evaluated by its ability to pit according to visual descriptor scale (12).

Immediate Postoperative CBCT scan was conducted with the same apparatus and settings as the preoperative scans to evaluate the accuracy of the implants placed using the stent, as shown in (figure 5). The preoperative and postoperative scans were then overlapped using a dedicated algorithm, which allowed the comparison of the virtually planned and the actual implant positions. Three deviation parameters between each planned and placed implant were measured. Angular deviation (measured in degrees), coronal differences (error at the entry point, measured at the center of the implant head in mm) and apical differences (error at the apex, measured at the center of the implant apex in mm). CBCT was obtained 6 months postoperatively for all patients, as shown in figure 6.

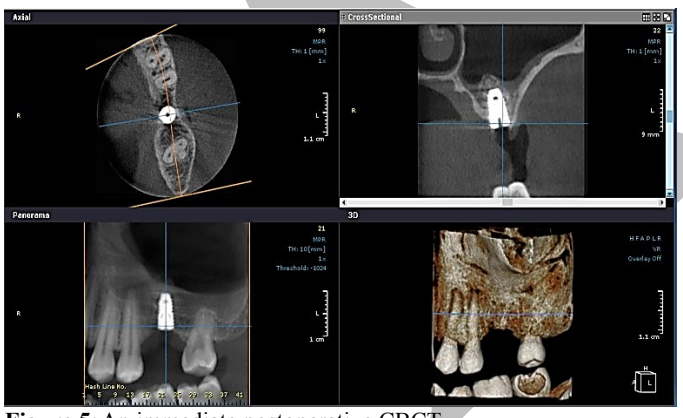

Figure 5: An immediate postoperative CBCT.

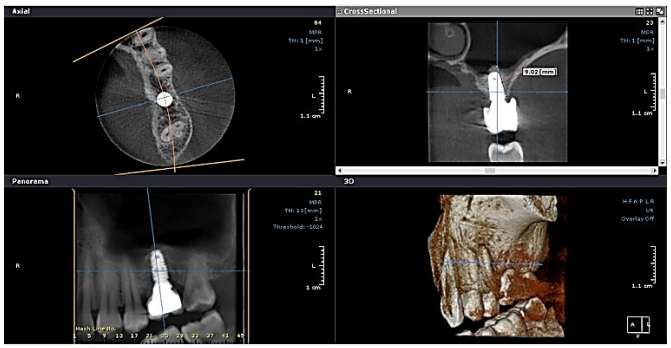

Figure 6: A 6 month postoperative CBCT.

STATISTICAL ANALYSIS OF THE DATA[13]

Data were fed to the computer and analyzed using IBM SPSS software (Package version 20.0. IBM Corporation, 1 New Orchard Road, Armonk, New York, United States).

Quantitative data were described using range (minimum and maximum), mean, standard deviation and median. The distributions of quantitative variables were tested for normality using Kolmogorov-Smirnov test, Shapiro-Wilk test and D'Agstino test. If it reveals normal data distribution, parametric tests were applied. If the data were abnormally distributed, non-parametric tests were used. For abnormally distributed data, comparison between two independent populations was done using Mann Whitney. Significance of the obtained results was judged at the 5% level.

RESULTS

In this study, fifteen sinus floor augmentations were performed on six patients. The selected patients were 2 males and 4 females, and their age ranged from 33-52 years with a mean age of 42.5 years. The mean height of the alveolar ridge from the marginal crest to floor of the maxillary sinus was 6.68 ± 1.01 mm (Range: 4.67 – 8.15 mm).

I. Clinical evaluation

1. Pain

Pain was evaluated at the second day, after 1 week and after 4 months through visual analogue scale (VAS) from 0 to 10 ("0" is pain free and "10" is extremely severe pain). After surgery, three patient experienced mild pain (VAS=1) and four patients experienced moderate pain (VAS=2) at surgical site for 1-3 days' duration.

2. Edema

Five patients suffered from trace oedema, which subsided totally by the 2nd post-operative day, while two patients suffered from mild edema which lasted for 4 days.

3. Post-operative complications

No post-operative complications were recorded regarding infection or maxillary sinus involvement in the early follow up period. One failed implant has been recorded in this study. This failed implant was due the loss of buccal bone that occurred during preparation of osteotomy site due to patient accidental movement and short drilling sleeve. The implant failed while uncovering the implant after 4 months with no signs of infection nor oroantral communication.

II. Radiographic evaluation

Accuracy of implant placement was evaluated by comparing the preoperative plan and the immediate postoperative CBCT images for all fifteen implants. Angular deviation, coronal deviation and apical deviation were determined. Data collected were tabulated. (Table 1). The mean of angular difference in implants with stereolithographic stent was 7.03˚ ± 4.53˚ with minimum value of 1.0˚ and maximum value of 17.9˚.

The mean of total coronal differences in stereolithographic guided implants was (1.56 mm ± 1.15 mm) with minimum value of 0.52 mm and maximum value of 5.56 mm. The mean of total apical differences in stereolithographic guided implants was (1.75 ± 1.14 mm) with minimum value of 0.45 mm and maximum value of 5.57 mm.

Table 1: Statistical analysis of the studied cases according to total accuracy (n=15)

All accuracy	Min. – Max.	Mean ± SD.	Median
Degree Diff	1.0 – 17.9	7.03 ± 4.53	7.41
Coronal Diff Sum	0.52 – 5.56	1.56 ± 1.15	1.20
Coronal Diff Dx	0.05 – 1.83	0.66 ± 0.50	0.62
Coronal Diff DY	0.02 – 2.21	0.51 ± 0.69	0.20
Coronal Diff DZ	0.07 – 5.08	0.94 ± 1.16	0.68
Apical Diff Sum	0.45 – 5.57	1.75 ± 1.14	1.58
Apical Diff Dx	0.07 – 2.04	0.82 ± 0.50	0.66
Apical Diff DY	0.01 – 2.02	0.83 ± 0.70	0.61
Apical Diff DZ	0.09 – 5.13	0.89 ± 1.15	0.57

DISCUSSION

Standard implant placement in the posterior maxilla is often limited by the lack of vertical bone height due to the pneumatisation of the sinus cavity. Several techniques have been developed to enter this cavity and elevate the membrane to enable implant placement. These methods may involve the use of bone grafts, membranes and implant placement (14).

Regarding the initial bone height, from the alveolar crest till the maxillary sinus floor, it was designed to be more than 5 mm but less than 8 mm. This is supported by a study conducted by Rios et al (14) in 2009, who recommended a minimal of 5 mm of residual bone height so as not to jeopardize the initial implant stability for a single-stage procedure and a higher implant survival predictability.

All surgical guides fitted perfectly on the ridge without the need for adjustments. All guides were well stabilized, except for one edentulous patient where the stent rested mainly on the soft tissue structure and two anchor pins rather than three. This lead to movement of the stent during osteotomy site preparation. This was also recorded in the studies of Widmann et al (15) in 2010, Pozzi et al (16) in 2014 and Reyes et al (17) in 2015. They stated that correct seating of the guides is of utmost importance in any system, since a minor error can be amplified during drilling of the osteotomy. The stent should be secured by 3 anchor pins to prevent rotation of the stent along an axis and rocking during the drilling procedure. Also, Vasak et al (18, 19) stated that accuracy is significantly higher when the template is tooth-born compared to the ones supported by a mucosal bearing area.

In this study, three patients needed single implants, which was simple along with a short operating time and favourable outcomes. While, one patient needed two implants bilaterally and another patient needed three implants bilaterally, which was time consuming and caused slight discomfort for the patients during the operation. This coincided with the systematic review of Schneider et al (20) in 2009, where they stated that the surgical stent for 3 implants or less was preferable with predictable outcomes.

Throughout the evaluation period, there was one failed implant. The failed implant was due to positional error while uncovering the implant after 4 months with no signs of infection nor oroantral communication. The cause was loss of buccal bone that occurred during preparation of the osteotomy site due to patient's accidental movement. This is in accordance with a study performed by Stumpel (21) in 2012, who stated that slight movement of the stent, during drilling, may produce a significant risk and provide undesirable outcomes. In the literature review by D'haese et al[(22)] in 2012, they stated that patient's stability, during the procedure, is a valuable factor for a desirable outcome.

In this study, the implants length varied from 8.0 to 13 mm and the mean original bone height was 6.7 ± 1.01 mm pre-operatively. Six months after sinus floor augmentation, the mean alveolar bone gain was 10.02 ± 1.14 mm with mean bone difference 3.51 ± 1.2 mm. Thus, the final bone gain was in the range of 3-4 mm. At 6th months the increase in vertical bone height was found to be statistically significant (p-value < 0.001).

This technique represents a minimally invasive transcrestal procedure that avoids a large flap elevation or the removal of the lateral wall of the maxillary sinus. The main advantages of this technique includes less bone resorption as there is no flap elevation, thus maintaining blood supply to the alveolar ridge, maintenance of vascularization to the graft material, minimal bleeding, minimal postoperative discomfort, and better patient acceptance for this surgical procedure (23).

The cumulative treatment time is reduced due to the combined approach of the grafting procedure with immediate implant placement (the same healing period for both procedures). Reducing the total treatment time minimizes the number of surgical procedures, the pain medications required post-surgically and recovery time, resulting in reducing the total cost of treatment for the patient. The main indication of this procedure is the minimally invasive implant treatment single missing tooth in the posterior area of the maxilla with inadequate alveolar bone height, where the conventional lateral approach to augment the sinus with its postoperative morbidity, discomfort, and increased treatment costs would not be required for these patients (23).

Evaluation of the accuracy of placement was done by measuring the overall deviations between virtually planned and surgically placed dental implants. The mean of total angular difference in implant with stereolithographic stent were 7.03 ± 4.43°. These differences were close to angular differences reported by Di Giacomo et al (24) in 2005 (7.25 ± 2.67°) and Valente (25) in 2009 (7.9°).

The Mean of total coronal differences in stereolithographic guided implant were 1.56 mm ± 1.15 mm. These differences were close to coronal differences reported by Di Giacomo (24) (1.45 ± 1.42 mm) and Farley (26) in 2013 (1.43 ± 0.67 mm).

The mean of total apical differences in stereolithographic guided implant were 1.75 ± 1.14 mm. These differences were close to apical differences reported by Valente (25) (1.6 mm), Farley (26) (1.72 ± 0.61 mm), Schneider (20) in 2009 (1.96 mm) and D'haese (22) in 2012 (1.64 mm).

Measurements and statistical comparison revealed higher deviations at the apical position compared with coronal position, which was according to expectation, due to the free movement of the apical region of the implant in maxillary sinus. In summary, the accuracy of the CAD/CAM guides used for the current study was well within the range of results reported by previous authors.

The final results of accuracy shown in our study are the sum of the deviations that occurred during each step of the whole treatment procedure. This is similar to deviations of studies reported by Yu et al (27) in 2012, Cassetta et al (28) and Bruno et al (29) in 2013.

The mentioned deviations may be due to acquisition of tomographic image, inaccurate planning, inaccurate positioning of the guide resulting in displacement during perforation, improper guide fixation, incorrect angulation of the drills causing lateral deviation, mechanical errors caused by angulation of the drills during perforation that may cause lateral deviations, reduced mouth opening bone density, the length of the implants and human errors, such as not following the implant installation protocol, all influence accuracy (28).

An error might also occur during the manufacturing of the surgical template for example in the simulation software, the precision of the stereolithographic machine, production and quality control, rigidity and physical properties of the material used, the precision of the guide cylinders and metal tubes, and verification of the guide (16).

Many sources of error may affect the results when using stereolithographic surgical templates, but the most important source of error is the intrinsic or inherent error that origins from the mechanical component tolerance in the surgical guides (28).

It is difficult to pinpoint a certain factor that is particularly significant to the final outcome. Stumpel (30) in 2008 highlighted that the errors in the fabrication process of the surgical guide may lead to unfavourable clinical outcomes.

Limited studies in the literature consider potential errors that could arise from the inherent limitations of stereolithographic surgical guides (the intrinsic error). Despite the lack of data in the literature, it remains important to examine the mechanical factors that may influence the accurate placement of an implant when a stereolithographic surgical guide is used, in order to fabricate a surgical guide that limits the deviation of the drills being used (31).

Theoretically, all errors could have a cumulative effect even if, in most instances, they compensate each other. Therefore, it is important when using a system, to be aware of the largest deviation reported. It is possible to minimise some of the errors if the surgeon considers these sources of variation and carefully follow the instructions of the protocol. For example, patient movements during CBCT scan, and fitting and placement of the surgical template are considered to be clinical factors that influence the final implant positions. The surgeon should remember that even the patient selection, the first step in the treatment, will affect the accuracy of implant placement (17).

This technique has certain drawbacks. Special training for familiarity with the entire system and special equipment is necessary. In addition, a considerable number of technique-related complications were observed (32).

Although the guided surgery in implantology exhibits some limitations, Ewers et al (33), with clinical experience during 7 and 12 years with virtual planning, described that this technology is essential for evolution of clinical safety and treatment success with implants.

CONCLUSIONS

For beginners, using a stereolithographic stent for transcrestal sinus lifting along with implant placement is more preferable in single implant than multiple implants. For multiple implants, stent stability is of utmost importance for accurate placement and perfect prosthetic results. The guided surgery represents an excellent treatment alternative for patients with satisfactory bone quantity for implant insertion and can be indicated for complete and partially edentulous arches in the maxilla.

CONFLICT OF INTEREST

The authors declare that they have no conflicts of interest.

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