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ACCURACY OF DIGITAL LIGHT PROCESSING VERSUS SELECTIVE LASER SINTERING SURGICAL-TEMPLATES FOR ALL-ON-FOUR TECHNIQUE OF COMPUTER GUIDED DENTAL IMPLANT PLACEMENT IN THE MANDIBLE: A PROSPECTIVE DOUBLE BLIND RANDOMIZED CLINICAL TRIAL

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ABSTRACT

Purpose: Success and safety of dental implants requires accurate treatment planning and precise implant placement. There should be no deviation between the virtually planned implant position and the actual implant position after the implant installation regardless the technique of construction of the surgical-guide. So this study was to evaluate and compare the accuracy of two different CAD/CAM surgical guides in placement of all-on-4 implants. ***Materials and methods:*** A prospective randomized controlled double blind clinical study was carried out, in which twenty four implants were placed in 6 edentulous patients. Patients were randomly allocated into one of the two groups: control group where surgeries were done using digital light processing (DLP) surgical-guides and study group where implants were placed using selective laser sintering (SLS) surgical-guides. Each patient received 4 implants in the anterior part of the mandible, 2 axial implants in the center and 2 tilted implants at the distal ends. CBCT were taken to the implants after the surgery and the actual implant positions were compared to the planned implant position. The deviation between the planned and actual implant positions were compared between the 2 techniques of surgical guide constructions. Results: The results of comparison between the two groups showed a statistically significant difference for all comparisons, with the SLS fabricated guides showing higher deviation from control than those fabricated by the DLP printer.

Conclusion: Although the computer manufactured surgical guides simplifies surgery and help in optimal implant placement, there is still evidence of degree of deviation from the planned implants positions in both of the surgical guides, particularly the SLS fabricated guides so a safety zone so a safety zone is recommended during planning to avoid to avoid critical anatomical structures.

KEY WORDS: All-on-four, tilted implants, implant placement, immediate loading, 3D printed surgical guide, Laser sintered surgical guide.

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INTRODUCTION

Rehabilitation of edentulous mandible could be carried out through several prosthetic treatment options: complete dentures, removable implant-retained prostheses, or fixed implant-supported prostheses. However, implant retained or fixed implant-supported prostheses provide a higher degree of patient satisfaction and better quality of life than removable prostheses. [1-3]

The problem exists when trying to place implants in patients with severely atrophic posterior jaw. These cases require extensive surgical bone augmentation with multiple surgical procedures to place the implants. These surgeries require longer treatment time with high cost. The "All-on-4 " treatment concept developed by Paulo Malo is a specific surgical and prosthetic treatment protocol that allows the rehabilitation of edentulous jaws with cost-effective, graft-less solution that provides the patient with an immediately-loaded, fixed, full-arch restoration on the day of surgery. The principle of this concept is to provide patients with full-arch restoration with only four dental implants in the anterior part of edentulous jaws. Two straight anterior implants and two posterior implants tilted up to 45°. Tilting the posterior implants enables us to avoid the mental foramen and place longer implants that provide better bone anchorage. The implants' platform in this case is placed in more posterior position which shortens the cantilever arm and improves the inter implant distance. [4-6]

In dental implants surgical placement generally and in the all-on-4 technique particularly, accuracy in treatment planning and precise implementation of this plan is vital for the functional and esthetic outcome as well as for the protection of vital structures and for predictable prosthetic results. Surgical guides play an important role in transferring the treatment plan to reality during implant placement surgery. It is well documented that dental implants placed using a surgical guide are more accurately positioned than those placed without a guide due to reduction of the possible human errors that might occur during free hand implant installation.[7-8]

Guides for completely edentulous jaws are either mucosa or bone supported. Mucosa supported guides have additional advantage as they don't require tissue reflection. The flapless surgery, using punch technique only, makes the surgical procedure easier with less postoperative pain and edema and it is faster in healing. While bone supported guides require raising a flap to place the guide on the alveolar crest. It provides a good view to implant sites so it is commonly used when edentulous sites possess thin bone.[8,9] Recently, cone beam computed tomography (CBCT) has been introduced for pre-surgical implant planning. The use of computer-aided design/computer-aided manufacturing (CAD/CAM) surgical guides serves to transfer the virtual planning to the clinical procedure. The CAD/CAM surgical guides enhances the precision of implant placement, shortens operation time and lessens the rate of complications compared to conventionally constructed guides.[10]

The accuracy of implant placement using CAD/CAM surgical guides versus conventional guides was compared in an in-vitro study, where the average differences between the planned and actual entry points in the mesio-distal and bucco-lingual directions were measured. It was concluded that, accuracy of implant placement was improved using an innovative CAD/CAM surgical template.[11]

The CAD/CAM surgical guides are dependent on one of the two main technologies: either subtractive manufacturing technology or additive manufacturing technology. First, the subtractive manufacturing depends on milling technologies to manufacture the final product from a block of material. However, the additive manufacturing include various methods as stereolithography (SLA), which uses UV light or laser beam to selectively harden layers of a liquid resin bath to produce the surgical guide. The second method is the digital light processing (DLP) where a liquid polymer is exposed to light from a digital light processing projector, which hardens the polymer layer by layer until the surgical guide is built. The third method is the fused deposition modeling (FDM), where a liquefied material is extruded through a nozzle and selectively deposited onto a platform layer by layer. The fourth method is known as selective laser sintering (SLS) that uses a powder bed instead of a resin bath to manufacture the guide. A high power laser beam is directed to melt a fine layer of powder. After scanning of each cross section, the powder bed is lowered by one layer thickness and a new layer of material is applied on the top, the process is repeated until the guide is completed. Various methods of manufacturing allow the transfer of the planned surgery data with great precision; however some deviation from the virtual planning may be reported. [12-15]

The influence of surgical management on the accuracy of implants inserted using mucosa supported surgical guide was evaluated using stereolithographic template in a recent study. They found that fixation of the surgical guide improved its accuracy and resulted in better precision of implant placement.[16] A comparison of accuracy of surgical templates fabricated by milling and rapid prototyping production methods was examined in a previous study. Results showed that a vector milled surgical guide had significantly smaller deviations than did RP produced template. [17] Further investigations on the accuracy of rapid prototyping produced guides were carried out using selective laser sintering surgical guides in flapless implant placement. They reported some lateral and angular deviation from the virtual planning. In addition 41.67% of the implants had apical deviation.[18]

In another study Sommacal et al, compared the fused filament fabrication (FFF) 3D printer to the professional digital light processing (DLP) printer for the fabrication of surgical guides for dental implant surgery. They found that the accuracy of manufactured guides is strongly dependent on the printing device and method. They also added that the consumer 3D FFF printer is not suitable for the fabrication of templates for guided implant surgery.[19]

Based on the limited researches available, the accuracy of surgical guide produced by DLP & laser sintering surgical guides is still questionable. Thus, the present study was conducted to evaluate and compare accuracy of DLP and the selective laser sintering surgical guides in all on four treatment options for edentulous mandible.

MATERIALS AND METHODS

Twenty four implants were placed in six male patients, with an age range between 58 to 67 years, who required fixed prosthodontic rehabilitation of their lower edentulous ridge. Patients were selected from the outpatient clinic of Ahram Canadian University (ACU). Only cases with proper ridge width that is at least 6 mm and sufficient bone height that is at least 14 mm in the anterior mandibular segment, and adequate inter-arch distance, that is at least 22 mm, were included in the study. Patients with flappy tissues, history of recent extractions, with any pathologic conditions in the mandible, with limited mouth opening were excluded from the study. Patients who are smokers, or under radiotherapy or chemotherapy or bisphosphonate medications, or having any uncontrolled systemic disease that might affect the surgery in general or implant placement or osseo-integration in particular were also excluded. Participants were informed about the nature of the study and were asked to sign an informed consent form.

Preoperative preparations: Patients were submitted to Cone Beam Computer Tomography scans (CBCT) where a scanning appliance was created for each patient to use during the CBCT scan. All patients were planned for mucosa supported surgical guides, so they were summited to dual scan protocol. CBCT images were acquired using a Next Generation i-CAT scanner (Imaging Sciences International, Inc., Hatfield, USA). A scout view was obtained and adjustments were made to ensure that patient was correctly aligned in the scanner according to adjustment light beam before acquisition. The machine is supplied with Amorphous Silicon Flat Panel Sensor with Cesium Iodide (CsI) scintillator, 0.5mm focal spot size, 14 Bit gray scale resolution, and operating at the following protocol for all the scans of the study: Tube voltage was 120 kVp, Milliampere was 37.07 mAs, Voxel size was 0.250 mm, Scanning time was 26.9 seconds, Exposure time was 7 seconds, and finally the Field of view was 6 cm Height * 16 cm Diameter. Patients' CBCT and scan appliance data were merged at the planning software (NemoScan, Nemotec, Spain). Afterwards the virtual implant planning was made using the CMI IS implants (NeoBiotech Co, Seoul, Korea) with 2 axial implants in the center and 2 tilted implants at the distal ends (fig. 1). The distal implants were planned to be place at 30° angle to the crest of the ridge to accept SCRP multi abutment (NeoBiotech Co, Seoul, Korea). The design of surgical guide was then finalized and the STL file was exported for 3D printing (fig. 2). Patients were randomly allocated into one of the two groups: study group in which implants were placed using selective laser sintering (SLS) surgical-guides constructed through Laser sintering 3D printer (EOS-FORMIGA 1000, Germany) and control group in which surgeries were done using digital light processing (DLP) surgical-guides printed by DLP 3D printer (Form 2, FORMLABS, USA). After acquiring the surgical guides from printers, finishing and installation of the metal sleeves was carried out. The sample randomization was achieved by the aid of a computer generated randomization table. All work was conducted in accordance with the Declaration of Helsinki 1975, as revised in 2000.

Surgical phase: One hour before the surgery patients were given 2 g oral amoxicillin (Amoxil, Kahira Pharm. and Chem. Ind. Co., Egypt). Before the surgery patients were also asked to rinse the mouth for one minute using chlorohexidine mouth wash (Hexitol, The Arab Drug Company ADCO, Cairo, Egypt). All surgeries were performed by the same operator under complete aseptic conditions. All patients were locally anesthetized where bilateral inferior alveolar and lingual nerve blocks anesthesia were used. The surgical guide was inserted inside the patient's mouth (fig.3); the punch was used, through the preplanned holes in the guide, to cut gingiva on the crest of the ridge expose the planned osteotomy sites. Then the surgical guide was removed and the gingival discs were separated by mucoperiosteal elevator. The surgical guide was placed back and fixed in position by fixation screws (fig.4). The osteotomy sites were prepared, through the planned locations and angulations of the surgical guides, using drills of the 3DDX universal

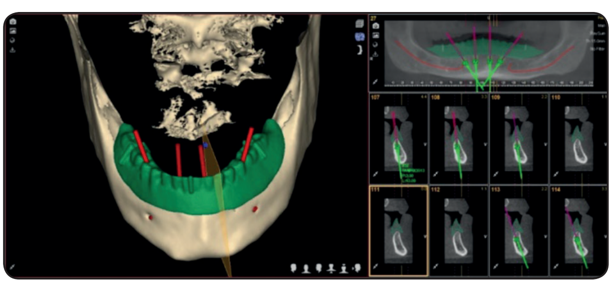

Fig. (1) Restoration driven virtual implant planning.

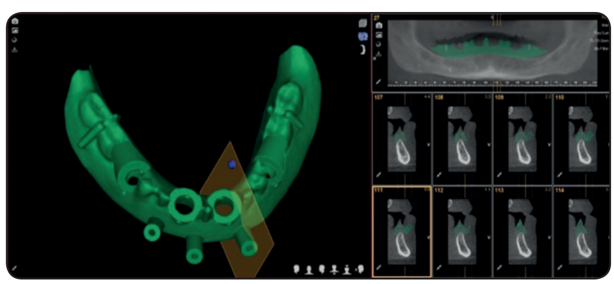

Fig. (2) STL of CAD surgical guide ready for exporting to 3D printing.

kit (3 DDX, Boston, USA) running with 1300 rpm speed using Surgical motor (Implantmed drive unit, W&H Dentalwerk, Bürmoos Salzburg, Austria) and 20:1 surgical contra angle hand-piece (W&H Dentalwerk, Bürmoos Salzburg, Austria) under copious irrigation. After the last drill, 4 implants (NeoBiotech Co., Seoul, Korea) were screwed down the osteotomy sites through the surgical guide using the Neobiotech surgical kit. Two anterior axial implants were tightened manually to 35N/cm and two posterior tilted implants were tightened at 30 N/cm. Finally cover screws were tightened (10 N/cm) to the implants and the surgical guides were removed. Patients were given postoperative instructions and medications as follows, amoxicillin 500 mg Capsules, diclofenac Potassium 50 mg tab (Cataflam, Novartis Pharma S.A.E. Cairo, Egypt) , each of them every 8 hours for 5 days and Chlorohexidine mouth wash twice daily for 7 days.

After the surgery, patients were submitted to CBCT scan using the same parameter as the preoperative scan. And the data of the postoperative scan was superimposed over the preoperative plan to assess the accuracy of the implant placement using the software (figs.5 and 6). Assessors in this study were blinded regarding the type of guide used in each case. Finally measurements were recorded and tabulated for statistical analysis.

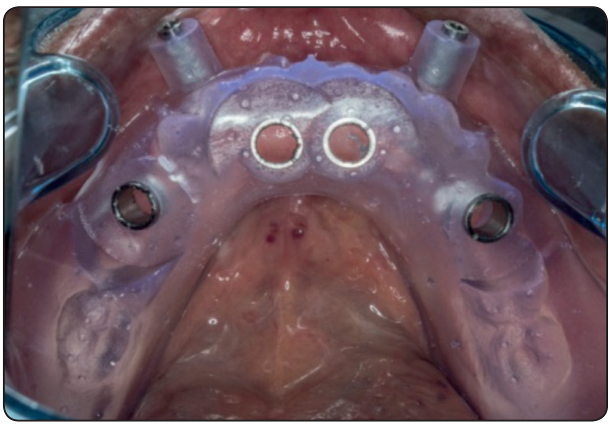

Fig. (3) A case from the control group, DLP surgical guide in place before soft tissue removal by the punch.

Fig. (4) A case from the study group, SLS surgical guide fixed in place by the screws.

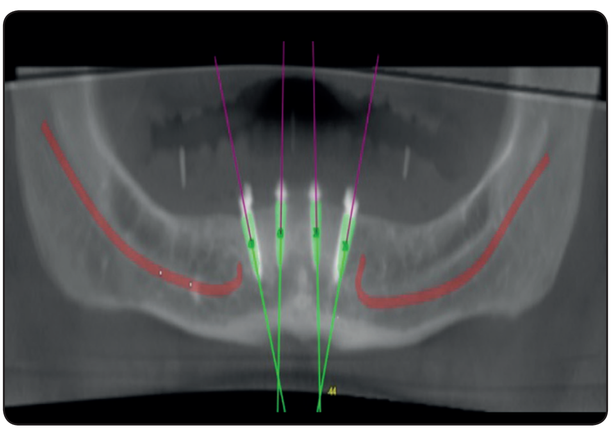

Fig. (5) Superimposition of postoperative Scan over preoperative planning for accuracy assessment.

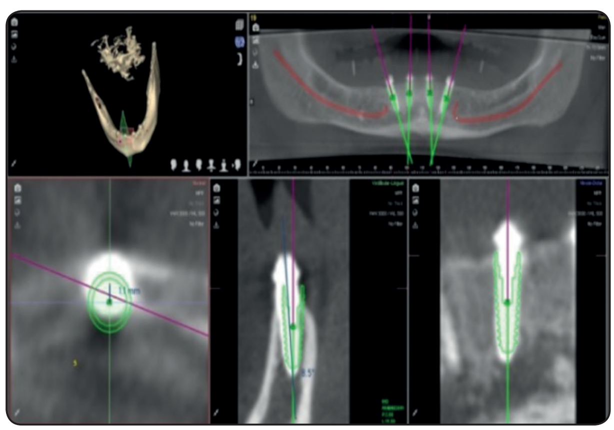

Fig. (6) Assessment of difference between virtual plan and real implant positions in multiple views.

Prosthetic phase: The patients were recalled after one week and primary alginate impressions were made for the lower arch. Study models were poured for construction of lower custom tray with a window cut over the implants. The covering screws were removed and the octa-abutments were attached to the implant fixtures, then the impression transfer copings were screwed to the octa abutments using long fixation screws. Acrylic resin rods was premade on the study casts to splint the impression copings together. They were fixed in place in the patient s mouth using duralay self-care acrylic resin (Reliance, IL, USA). Impression was registered in polyether material using an open tray splinted technique. Master casts were fabricated using extra hard stone type IV and the implant analogues were fixed in their specific position inside the casts. Wax patterns were fabricated on the master casts to be casted into metal frameworks. Each metal framework was tried in the patients' mouth to assure passive fit. (fig. 7).

A wax rim was built over the metal framework and the vertical dimension and bite registration were taken. The models were then mounted on semi-adjustable articulator and the teeth set up was done, following the lingualized occlusal concept ensuring there is no interference with jaw movements into eccentric position, then tried in the patient's mouth. The final restoration was made with acrylic teeth and screwed in to the implants' abutments (fig. 8).

Fig. (7) Metal Framework during trial in patient's Mouth

Fig. (8) Final prosthesis in place.

RESULTS

In this study twenty four implants were placed in six patients without any complications. Twelve implants in three patients were placed through the SLS-3D CAD/CAM surgical guide and the other 12 implants were placed in three patients through DLP-3D CAD/CAM surgical guide. All patients were males, ranging in age between 58 and 67 years with mean age 62. All patients completed the follow up and the prosthetic phase till end of the study with no attrition of the sample.

After the surgery, patients were submitted to CBCT scan and the data of the postoperative scan was superimposed over the preoperative plan to assess the accuracy of the implant placement. Accuracy of the implant placement was assessed by measuring global distance between the virtual implant and real implant. crestal platform, global distance between virtual implant and real implant apex, and angular deviation between the virtual implant and real implant at mesio-distal and bucco-lingual aspects

First, there was a substantial intra-observer agreement of results for both the DLP and SLS surgical guides' results, with higher matching for SLS results (Table 1).

TABLE (1) Intra-observer agreement values for SLS and DLP results

	Measurement of agreement	Asymp. Std. Error	No of valid implants
SLS	0.726*	0.081	12
DLP	0.659*	0.088	12

(< 0) Poor agreement, (0.0 – 0.20) Slight agreement, (0.21 – 0.40) Fair agreement, (0.41 – 0.60) Moderate agreement, (0.61 – 0.80) Substantial agreement, (0.81 – 1.00) Almost perfect agreement

Regarding the Horizontal deviation: **first at the crestal level** the results of comparison between the control, SLS and DLP showed a significant difference between the groups with a higher deviation values for the SLS than DLP (F= 29.871, P <0.001) (**Table 2**).

The results of pairwise comparison for the control and test groups using Tukey's HSD pairwise comparison of means* also showed a statistically significant difference for all comparison with the SLS showing higher deviation from control than DLP (**Table 3**).

Second, at the apical level, again, there was a statistically significant difference between the groups with a higher deviation values for the SLS than DLP (F= 43.890, P <0.001) (**Table 4**).

TABLE (2) Mean values of crestal deviation for SLS and DLP

	Mean	SD	SEM	Minimum	Maximum	Range
Control	0	0	0	0	0	0
SLS	1.6	0.562	0.102	0.4	3.05	2.65
DLP	1.28	0.326	0.059	0.42	1.9	1.48

Where SD=standard deviation, SEM=standard error of mean

TABLE (3) Pairwise comparison of control, SLS and DLP for crestal deviation

Comparison	Diff. of Means	q	P
DLP vs. Control	1.28	7.037	<0.001*
SLS vs. DLP	0.319	2.69	0.01*
SLS vs. Control	1.6	10.731	<0.001*

: significant at P<0.05; P>0.05 (non-significant), P<0.05(significant), and P<0.01 (highly significant).

TABLE (4) Mean values of apical deviation for SLS and DLP

	Mean	SD	SEM	Minimum	Maximum	Range
Control	0	0	0	0	0	0
SLS	1.93	0.684	0.124	0.39	3.64	3.25
DLP	1.63	0.502	0.0917	0.52	2.75	2.23

Where SD=standard deviation, SEM=standard error of mean

* Tukey's HSD (honestly significant difference) test, is a single-step multiple comparison procedure used in conjunction with an ANOVA to find means that are significantly different from each other

The results of pairwise comparison for the control and test groups using Tukey's HSD pairwise comparison of means showed a statistically significant difference for all comparison groups except DLP versus SLS (P= 0.085), with the SLS showing higher deviation from control than DLP **(Table 5)**.

Now regarding the Angle deviation, it was measured at sagittal plan and at coronal plan. First for the Angle Deviation A (Sagittal plane),there was a statistically significant difference between the groups with a higher deviation values for the SLS than DLP (F= 57.071, P <0.001) **(Table 6)**.

The results of pairwise comparison for the control and test groups using Tukey's HSD pairwise comparison of means showed a statistically significant difference for comparison except SLS versus FDM (P= 0.055). SLS is showing higher deviation from control than DLP **(Table 7)**.

Then for the Angle Deviation B (Coronal Plane), there was a statistically significant difference between the groups with a higher deviation values for the SLS than DLP (F= 77.692, P <0.001) **(Table 8)**.

The results of pairwise comparison for the control and test groups using Tukey's HSD pairwise comparison of means showed a statistically significant difference for all comparison with the SLS showing higher deviation from control than DLP **(Table 9)**.

TABLE (5) Pairwise comparison of control, SLS and DLP for apical deviation

Comparison	Diff of Means	q	P
DLP vs. Control	1.63	7.716	<0.001*
SLS vs. DLP	0.3	1.786	0.085*
SLS vs. Control	1.93	15.46	<0.001*

: significant at P<0.05; P>0.05(non-significant), P<0.05(significant), and P<0.01 (highly significant).

TABLE (6) Mean values of angle deviation A for SLS and DLP

	Mean	SD	SEM	Minimum	Maximum	Range
Control	0	0	0	0	0	0
SLS	4.976	2.529	0.461	1.04	11.6	10.56
DLP	3.857	2.333	0.426	0.8	9.44	8.64

Where SD=standard deviation, SEM=standard error of mean

TABLE (7) Pairwise comparison of control, SLS and DLP for angle deviation A

Comparison	Diff of Means	q	P
DLP vs. Control	3.857	9.052	<0.001*
SLS vs. DLP	1.11	2	0.055
SLS vs. Control	4.976	10.77	<0.001*

: significant at P<0.05; P>0.05(non-significant), P<0.05(significant), and P<0.01 (highly significant).

TABLE (8) Mean values of angle deviation B for SLS and DLP

	Mean	SD	SEM	Minimum	Maximum	Range
Control	0	0	0	0	0	0
SLS	4.67	2.07	0.379	0.65	9.1	8.45
DLP	2.99	1.55	0.283	0.55	6.44	5.89

Where SD=standard deviation, SEM=standard error of mean

TABLE (9) Pairwise comparison of control, SLS and DLP for angle deviation B

Comparison	Diff of Means	q	P
DLP vs. Control	2.99	10.58	<0.001*
SLS vs. DLP	1.67	3.31	0.002
SLS vs. Control	4.67	12.321	<0.001*

: significant at P<0.05; P>0.05(non-significant), P<0.05(significant), and P<0.01 (highly significant).

Within group comparison for deviation from control

SLS and DLP showed a statistically significant difference between the measured deviation at the crest and angle deviation B (F= 29.871, P <0.001 F= 77.692, P <0.001for SLS and DLP respectively).

TABLE (10) Mean values of measured deviations for SLS and DLP

	SLS		DLP	
	Mean	SD	Mean	SD
Horizontal Crestal Deviation	1.6	0.562	1.28	0.326
Horizontal Apical Deviation	1.93	0.684	1.63	0.502
Angle Deviation A	4.976	2.529	3.857	2.333
Angle Deviation B	4.67	2.07	2.99	1.55

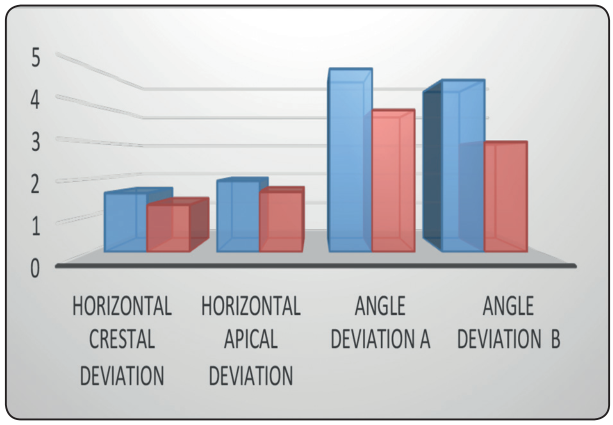

Fig. (8) Bar chart showing mean values of measured deviations for SLS (blue) and DLP (red).

DISCUSSION

Ideal implant placement enhances the establishment of favorable forces on the implants and the prosthetic component. In this sense, CAD/CAM surgical guides were utilized in this study to achieve better prosthetic results.[20,21]

In this study, twenty four implants were installed in six patients without any complications, using mucosa supported DLP and SLS surgical guides. All surgical guides were placed and fixed in position by fixation screws to improve its accuracy and allow for better precision of implant placement.

The results of this study reported some deviations from the virtual planning in the two studied groups with statistically significant difference (as P<0.05). Many authors have reported deviations in their clinical in-vivo studies between the postoperative position and the preoperative plan.[16,22,23] Some of them attributed this finding to the variation in the thickness of mucosa at the implant insertion site. They observed a significant correlation between mucosa thickness and the degree of deviation as it affects the accurate positioning as well as the stability of the guide.[22] In addition precision of muco-supported surgical guides with and without fixation screws in the edentulous ridges was evaluated by Cassetta et al,2014 and they showed that the fixed guides resulted in better precision of implant placement, which was statistically significant for angular deviation.[16] Other authors referred this deviation to the bone structure itself. They reported a more pronounced deviations in the dental implants position, when the jaw bone had lower resistance to torque (mostly medullary as that of maxilla), compared to compact bone.[16,23]

Regarding the horizontal deviation, the mean apical deviation values for the two studied groups were higher than that at the crestal region (it was 1.63 and 1.93 for DLP and SLS respectively at the apical region, while it was 1.28 and 1.6 at the crestal region). This finding was in accordance with D'haese *et al, 2012 and* Vieira et al, 2013, who reported greater deviation at the apex of the implants. They have argued that apical deviations are dependent on mucosal thickness and morphological type of bone structure [22,23]

However, the mean of angular deviation values for the two studied groups in this study (3.85 and 4.97 for DLP and SLS respectively at the sagittal plane, while it was 2.99 and 4.67 for DLP and SLS respectively at the coronal plane) were higher than that reported by Pettersson *et al who reported* an angular deviations of 1.93° that represent greater accuracy of implant placement. [24] On the other hand, angular deviation less than 5° was recorded by Ersoy et al, 2008, which is similar to the deviation reported in our study.

The results of comparison between the two groups showed a statistically significant difference for all comparison with the SLS showing higher deviation from control than DLP. This finding was supported by another clinical study that made to evaluate the accuracy using selective laser sintering surgical guides for flapless dental implant placement and immediate definitive prosthesis installation. They reported a mean angular coronal and apical deviations of 6.53°, 1.35 mm and 1.79 mm, respectively. Thus they concluded that the computer-aided dental implant surgery still requires improvement and should be considered to be in the developmental stage.[18] Therefore; we recommend a safety zone of at least 2 mm is necessary to avoid critical anatomical structures.

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