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AN EVALUATION OF THE SOURCES AND EXTENT OF ERROR IN THE POSITION OF IMPLANTS PLACED USING 3D-PRINTED STEREOLITHOGRAPHIC SURGICAL GUIDES.

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Abstract:

Introduction/Background. Errors can be introduced in implant placement when using stereolithographically manufactured fully limiting surgical guides due to various factors, and at various steps, such as during designing and manufacturing of surgical guides (intrinsic error), due to built-in variations in design of mechanical components of guide systems and implant dimensions (inherent error) or due to placement error by the operator (operator error).

Aim. The aim of this study was to evaluate influence of various factors on implant position when using these guides.

Materials and Methods. Prosthetically-driven implant positions were planned with pre-operative cone beam computed tomography (CBCT) data and digital scans using a computer aided designing (CAD) software. Static guided implant surgery was performed under local anaesthesia using fully limiting mucosa-supported surgical guide. Pre-operative and post-operative CBCTs were superimposed using surgical sleeve as a reference to evaluate the placement error by operator (N=12). To evaluate intrinsic error, standard tessellation language (STL) files of the virtual design of the surgical guides and the STL file obtained after scanning the 3D printed stereolithographic surgical guides were superimposed. Inherent error was calculated using a geometric model.

Results. Intrinsic error was observed to be a major contributing factor in angular deviation of implant, linear deviation observed at implant shoulder as well as at implant apex. Operator error was observed to be a major contributing factor for mean vertical deviation observed at apex of implant.

Conclusion. This study showed that accuracy of implant placement was largely influenced by discrepancies introduced during designing and manufacturing of stereolithographic surgical guides as compared to other sources.

Key words: Stereolithographic surgical guides, error, implant placement, static guided surgery

Introduction

Static guided fully limiting surgical approach for implant placement enables clinicians to perform implant surgeries with improved accuracy, ease, significantly lesser trauma to the tissues and in shorter time duration.[1-6] The precision of such systems is of paramount importance and minor discrepancies can result in subsequent surgical as well as prosthetic complications.[7]

Errors can be introduced due to discrepancies in designing, manufacturing of guides, built-in design variations of mechanical components of guide systems and implant dimensions or due to operator related causes.[8-22] Thus, the cause of overall error in final implant position is multifactorial and would be a cumulation of errors introduced due to above-mentioned factors.[23-24]

Hence, the purpose of this study was to evaluate the influence of various factors on final implant placement when using stereolithographic fully limiting surgical guides. The null hypothesis was that no error would be introduced in implant placement due to various factors.

Materials and Methods

This study was conducted after obtaining pre-requisite approval from the institutional ethical committee. Informed consent was obtained from the patients included in this study.

The following variables were defined for the purpose of this study:

Intrinsic Errors (ItE): Error introduced during the designing and manufacturing of the stereolithographic guides.

Inherent Error (IhE): Error introduced as a result of built-in variations in the design of mechanical components of fully limiting surgical guide systems as well as variations in implant dimensions.

Placement error by Operator (OE): Error introduced while implant placement as a result of operator's skill and experience in different clinical situations.

Angular deviation of implant axis: Angle in degrees between the central axis of the implant in the digitally planned position and the central axis of the implant in the final position.

Linear deviation at implant shoulder: The distance between the central axis of the implant at the shoulder in the digitally planned position, and the central axis of implant in the final position.

Linear deviation at implant apex: The distance between the central axis of the implant at the apex in the digitally planned position, and the central axis of implant in the final position.

Vertical deviation at implant apex: The vertical distance between the apex of the digitally planned position of implant and the horizontal plane from the apex of final position.

The sample size calculation was done based on the standard deviation values obtained from a previously conducted study by Geng et al[24] using the formula $\mathbf{n=Z^2\ SD^2/d^2}$ where, n= Desired sample size, Z= Standard normal deviate (1.96), SD= Standard Deviation, d= degree of accuracy required (0.02). A minimum sample size of 5 implants was calculated to get statistically significant results.

This study included a total of 13 implants placed using mucosa-supported stereolithographic fully limiting surgical guides (DIOnavi Digital Navigation Implant system; DIOnavi). Pre-requisite parameters for inclusion in the study were adequate bone volume as seen on CBCT, D2 or D3 quality bone, adequate mouth opening with a straightforward or advanced Surgical SAC classification.[25] Implant sites requiring bone augmentation and sinus elevation procedures were excluded.

Pre-operative CBCT data and digital scans of a completely edentulous patient who was indicated for full mouth implant placement was obtained. Prosthetically-driven implant positions were planned using a computer aided designing (CAD) software (Implant Studio; 3Shape) (Fig.1). Stereolithographic surgical guides were subsequently designed and 3D printed (Probe; DIO Inc) using a commercial printable resin (DIOnavi-SG; DIO Inc). The implant placed in maxillary right second premolar region was excluded from the study since indirect sinus elevation procedure followed by conventional implant placement was performed in this region.

Static guided implant surgery was performed under local anaesthesia. The fully limiting mucosa-supported surgical guides were placed intraorally and checked for fit. The guide was secured firmly using fixation screws. The tissue punch was followed by the bone-flattening drill. A pilot drill of 2.0-mm-diameter along with the

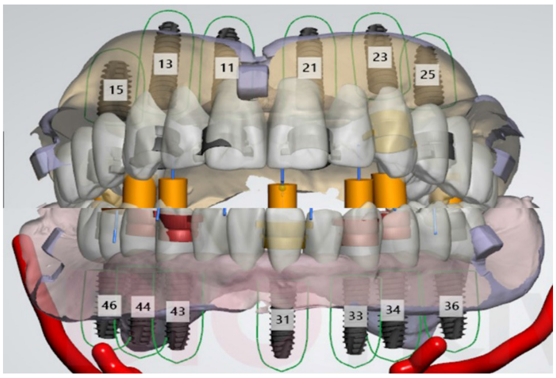

Fig. 1. Digital Planning for prosthetically-driven implant placement.

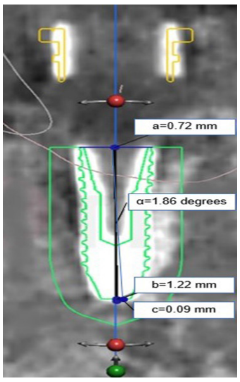

Fig. 2. Superimposition of preoperative and post-operative CBCTs using the surgical sleeve as a reference and measurement of operator error.
α=Angular deviation of implant axis, a=Linear deviation at implant shoulder, b=Linear deviation at the implant apex, c=Vertical deviation at the implant apex.

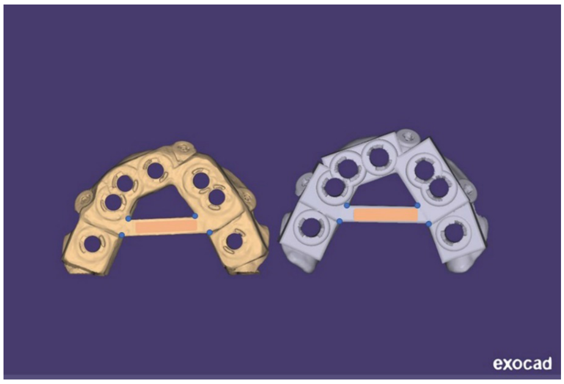

Fig. 3: STL files aligned in the same plane (STL Files 1 and 2) and Selection of 4 standard reference points to superimpose the STL files.

Fig. 4. 'Align Meshes' feature used to superimpose the STL files.

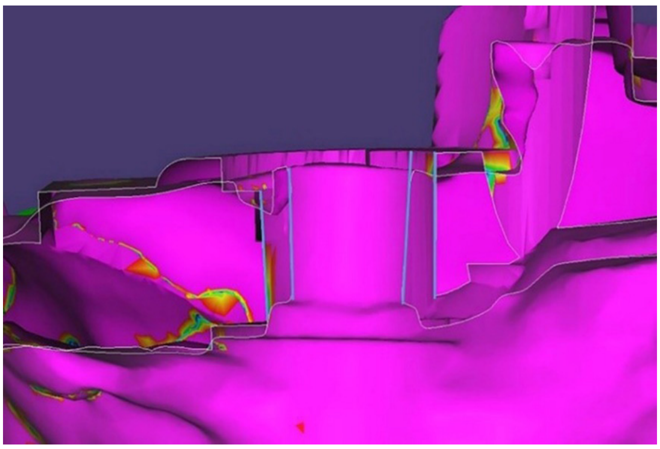

Fig. 5. Vertical Section of the sleeves.

drill key was used to prepare implant site. The implant osteotomy was then completed using a series of sequential drills as per the protocol provided (DIO Navi Guide; DIO Inc). Implants were then placed with the surgical guide secured in place (implant dimension: 13 mm X 3.8 mm in 11,13,21; 11.5 mm X 3.8 mm in 31,33,43; 11.5 mm X 4.5 mm in 44; 10 mm X 4 mm in 23; 10 mm X 4.5 mm in 34,36,46; 8.5 mm X 4 mm in 25 regions respectively). A post-operative CBCT was taken immediately after implant placement prior to removal of the surgical guide. This post-operative CBCT data was superimposed onto the pre-operative virtual implant planning data using surgical sleeves as a reference to calculate the error introduced by the operator while implant placement using a CAD software (Implant Studio; 3Shape) (Fig. 2).

TABLE 1 : Descriptive Statistics

Dependent Variable		Intrinsic Error	Inherent Error	Operator Error
Angular deviation of implant axis (in degrees)	MEAN	1.82	0.14	0.89
	SD	0.33	0	1.05
	MINIMIUM	1.1	0.14	0.02
	MAXIMUM	2.31	0.14	3.04
Linear deviation at implant shoulder (in mm)	MEAN	0.41	0.23	0.08
	SD	0.07	0	0.06
	MINIMIUM	0.25	0.23	0.01
	MAXIMUM	0.52	0.23	0.22
Linear deviation at implant apex (in mm)	MEAN	0.77	0.5	0.2
	SD	0.17	0.03	0.13
	MINIMIUM	0.41	0.44	0.03
	MAXIMUM	0.99	0.55	0.42
Vertical error at implant apex (in mm)	MEAN	0.01	0.01	0.13
	SD	0	0	0.1
	MINIMIUM	0.01	0.01	0.01
	MAXIMUM	0.02	0.01	0.35

To evaluate ItE, the standard tessellation language (STL) files of the virtual design of surgical guides and the STL file obtained after scanning the 3D printed stereolithographic surgical guides were superimposed using a computer-aided design software program (exocad; exocad GmbH). The Align Meshes feature was used to superimpose the 2 STL files using 4 points on the central bar of the surgical guide as a standard reference (Fig 3-4). The methodology followed was exactly as previously explained by Shah et al.[7] The "Measurement Tool" was used to make angular and linear measurements between the margins of the sleeves at the point of intersection of the planes and sleeve margin mesially, distally, buccally, and lingually by using the Color Map feature as a guide (Calibrated from 0 to 50 mm with 5-mm

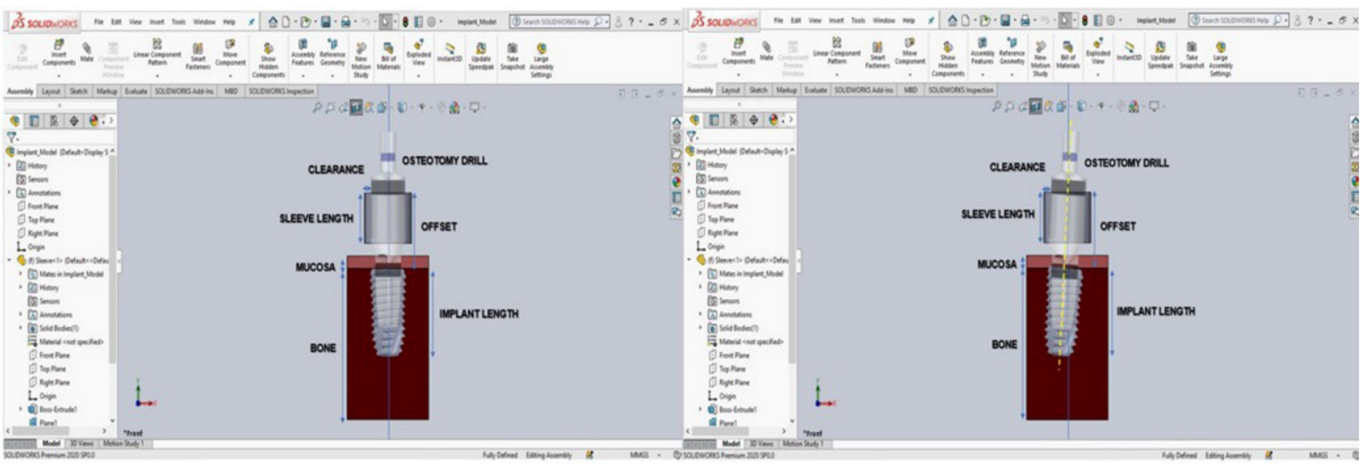

Fig. 6. 3D model simulations.

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intervals) (Fig 5).[7] Formulas provided by Shah et al[7] were used to calculate the linear deviation at the shoulder and apex of the implant as well as the vertical deviation at the apex of the implant.

To calculate the IhE, this study utilized a CAD software software (SOLIDWORKS® 2021 Software; SOLIDWORKS) and a geometric model. A 3D CAD model was designed to assess and evaluate the errors introduced during implant placement by varying the design of mechanical components of the surgical guide as well as the implant dimensions (Fig. 6). For designing this 3D CAD model, the standard tessellation language (STL) files of the metal sleeve, implant and the final drill of a commonly used static guided implant system (DIOnavi Digital Navigation Implant system; DIOnavi) were obtained via scanning of the respective components using a dental table-top scanner (MeditT300; MEDIT).

The static guided surgery was then simulated using a CAD software (SOLIDWORKS® 2021 Software; SOLIDWORKS). The "assembly" as well as the "plane and angle orient" feature was used to assemble and orient the individual STL files with respect to each other. The dimensions of the surgical guide as well as the implant were varied to evaluate their effect on final implant position. Clearance, offset, sleeve length, and implant length were identified as the 4 factors

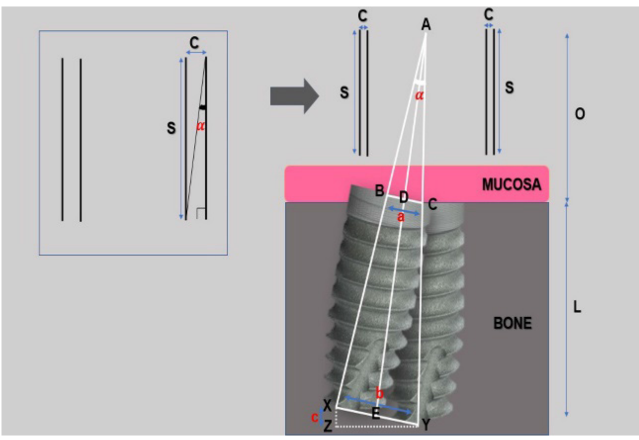

Fig. 7. Geometric model.

which affected the implant position and were considered further.

Clearance : The difference between the inner diameter of the metal sleeve and the diameter of the shaft of the drill.

Offset: The distance between the occlusal surface of the metal sleeve and the shoulder of the implant. Offset is sleeve length plus distance between the sleeve base and implant shoulder.

Sleeve length: Total length of sleeve.

Implant length: The length of the implant from the shoulder to the apex.

The static guided implant system used in this study (DIOnavi Digital Navigation Implant system; DIOnavi) has a clearance of 100 microns, sleeve length of 4mm, offset values 9 mm, 10.5 mm and 12 mm and implant length of 7 mm, 8.5 mm, 10 mm, 11.5 mm, and 13 mm. A geometric model was prepared based on the above-mentioned contributing factors to obtain formula for calculating the error that can be introduced in implant position (Fig. 7). For obtaining the geometric formula, a perpendicular bisector was dropped from point A to point E bisecting such that ∠ADB=∠ADC=AEX=AEY=90 degrees. ABC and AXY are isosceles triangles. By applying the principles of geometry, following formulae were derived:

$$\alpha = \tan^{-1}\frac{C}{S}\,;\ a=2(O)\sin\frac{\alpha}{2}\,;\ b=2\,(O+L)\sin\frac{\alpha}{2}\,;\ c=(b)\sin\frac{\alpha}{2}$$

where C=Clearance, S=Sleeve length, O=Offset, L=Implant length, Angular deviation of implant axis, α=Linear deviation at implant shoulder, b=Linear deviation at the implant apex, c=Vertical deviation at the implant apex.

The data were entered into a spreadsheet (Excel; Microsoft Corp) and subjected to statistical analysis (One-Way ANOVA and Bonferroni-Adjusted Post Hoc Tests for intergroup comparison) using a statistical software program (SPSS Statistics v17.0; SPSS Inc).

Results

The mean, standard deviation, minimum and maximum values for angular deviation, linear deviation at shoulder and apex of implant and vertical error observed at the apex of the implant have been shown in angular deviation values are shown in Table 1. The results for One-Way ANOVA and Bonferroni-Adjusted Post Hoc Tests for intergroup comparison have been shown in table 2 and 3 respectively.

ItE was observed to be a major contributing factor to the angular deviation of the implant followed by OE. IhE contributed the least to angular deviation (*P* value <0.05).

The major contributing factor for linear deviation at shoulder of implant was found to be ItE followed by IhE. The effect of OE was found to be the least at the shoulder of the implant (*P* value <0.05).

Greater linear deviation was observed at the apex as compared to the shoulder of the implant. The major contributing factor for linear deviation at apex of implant was found to be ItE followed by IhE and OE (*P* value <0.05).

The major contributing factor for vertical error observed at the apex of the implant was found to be error introduced by the operator during implant placement. The impact of ItE and IhE on the vertical deviation of the implant at the apex was found to be negligent (*P* value <0.05).

Further, no correlation could be established between the location of implant (maxillary

TABLE 2 : One Way ANOVA

Dependent Variable	Group-wise comparison	Sum of Squares	df	Mean Square	F	p Value
Angular deviation of implant axis (in degrees)	Between Groups	16.932	2	8.466	20.717	0.00
	Within Groups	13.485	33	0.409		
	Total	30.418	35			
Linear deviation at implant shoulder (in mm)	Between Groups	0.652	2	0.326	102.339	0.00
	Within Groups	0.105	33	0.003		
	Total	0.758	35			
Linear deviation at implant apex (in mm)	Between Groups	1.987	2	0.994	63.882	0.00
	Within Groups	0.513	33	0.016		
	Total	2.5	35			
Vertical error at implant apex (in mm)	Between Groups	0.121	2	0.06	17.122	0.00
	Within Groups	0.117	33	0.004		
	Total	0.237	35			

or mandibular arch and anterior or posterior region) and proximity of implant to the fixation screws with the various types of errors.

Discussion

The current study calculated the influence of various factors (ItE, IhE and OE) on the final implant placement when using stereolithographically manufactured fully limiting surgical guides. Based on the findings of this study, the null hypothesis that no error would be introduced in implant placement due to ItE, IhE and OE, was rejected.

Intrinsic error can be introduced by variety of factors such as errors introduced during data acquisition, software handling, including data loss during conversion from the Digital Imaging and Communications in Medicine (DICOM)

TABLE 3 : Bonferroni-Adjusted Post Hoc Tests : Intergroup comparison

Dependent Variable	Group-wise comparison		Mean Difference	Standard Error	p Value	95% Confidence interval	
						Lower Bound	Upper Bound
Angular deviation of implant axis (in degrees)	Intrinsic Error	Inherent Error	1.67667	0.26098	0.00	1.0184	2.3349
		Operator Error	.92833	0.26098	0.003	0.2701	1.5866
	Inherent Error	Intrinsic Error	-1.67667	0.26098	0.00	-2.3349	-1.0184
		Operator Error	-.74833	0.26098	0.021	-1.4066	-0.0901
	Operator Error	Intrinsic Error	-.92833	0.26098	0.003	-1.5866	-0.2701
		Inherent Error	.74833	0.26098	0.021	0.0901	1.4066
Linear deviation at implant shoulder (in mm)	Intrinsic Error	Inherent Error	.18167	0.02305	0.00	0.1235	0.2398
		Operator Error	.32917	0.02305	0.00	0.271	0.3873
	Inherent Error	Intrinsic Error	-.18167	0.02305	0.00	-0.2398	-0.1235
		Operator Error	.14750	0.02305	0.00	0.0894	0.2056
	Operator Error	Intrinsic Error	-.32917	0.02305	0.00	-0.3873	-0.271
		Inherent Error	-.14750	0.02305	0.00	-0.2056	-0.0894
Linear deviation at implant apex (in mm)	Intrinsic Error	Inherent Error	.26667	0.05091	0.00	0.1382	0.3951
		Operator Error	.57500	0.05091	0.00	0.4466	0.7034
	Inherent Error	Intrinsic Error	-.26667	0.05091	0.00	-0.3951	-0.1382
		Operator Error	.30833	0.05091	0.00	0.1799	0.4368
	Operator Error	Intrinsic Error	-.57500	0.05091	0.00	-0.7034	-0.4466
		Inherent Error	-.30833	0.05091	0.00	-0.4368	-0.1799
Vertical error at implant apex (in mm)	Intrinsic Error	Inherent Error	0.0025	0.02426	1.00	-0.0587	0.0637
		Operator Error	-.12167	0.02426	0.00	-0.1829	-0.0605
	Inherent Error	Intrinsic Error	-0.0025	0.02426	1.00	-0.0637	0.0587
		Operator Error	-.12417	0.02426	0.00	-0.1854	-0.063
	Operator Error	Intrinsic Error	.12167	0.02426	0.00	0.0605	0.1829
		Inherent Error	.12417	0.02426	0.00	0.063	0.1854

format to STL, during the 3D printing of the guide, and from polymerization shrinkage of the resin material.[7,11-14] Weitz et al[11] evaluated evaluate the accuracy of a surgical template-aided implant placement produced by rapid prototyping using a DICOM dataset and reported deviations between 2.0 and 3.5 mm. Stumpel[12] and Chen et al[13] evaluated the errors in the manufacturing of surgical guides by comparing production processes of different manufacturing systems when using the same DICOM file. They reported that production processes of the different manufacturers do influence the accuracy of the produced surgical guides. Gjelvold et al[14] evaluated the deviation in final implant position using surgical guides fabricated from 2 different desktop printers in a digital workflow and reported accuracy levels varied with different printers. The above-mentioned studies have evaluated individual factors influencing intrinsic error, but the overall contribution of these factors on implant placement still remains indeterminate. In the present study, ItE was evaluated by superimposing the STL files of the virtual design and the STL files obtained by scanning the stereolithographic surgical guides followed by using a geometric derivation to calculate the influence of this error on implant placement. This study reported a mean angular deviation of 1.82 degrees (Range : 1.1-2.4 degrees) of the guide sleeve which could lead to a 0.41mm linear deviation at shoulder of implant and 0.77mm at apex, and 0.01mm vertical error at apex of implant.

The virtual implant placement using a 3D CAD model helped identify clearance, offset, sleeve length, and implant length as the potential sources of inherent errors while using fully limiting static guide systems. A 3D geometric CAD model software-based study format was chosen over an in-vivo study design to evaluate the contribution of these factors in implant placement and to eliminate operator error. As shown in the geometric derivations, angular deviation was found to be dependent on the sleeve length and clearance. An increase in sleeve length would decrease angular deviation whereas an increase in clearance would increase the angular deviation and vice versa. The linear deviation at shoulder of the implant was dependent on the offset and clearance values. An increase in offset would amplify the effect of angular deviation on the linear deviation at shoulder of implant. The linear deviation at the apex of the implant was found to be influenced by the offset, implant length and angular deviation values. The vertical error at apex depended mainly on the linear deviation at the apex of the implant and the angular deviation values. The results of this geometric model are in accordance with the results of Koop et al,[15] Choi et al,[16] Cassetta et al,[17-18] Van Assche et al,[19] Lee et al,[20] and Schneider D et al. Koop et al[15] evaluated the degree of deviation that can occur during the drilling procedure, and reported that variations in the sleeve height, offset and clearance of the surgical guide influenced total error in implant placement. Choi M et al[16] also varied the clearance, offset and channel length, and found that channel length was the primary controlling factor in minimizing deviated angulations. Cassetta M et al,[17-18] Van Assche et al,[19] Lee DH et al,[20] and Schneider D et al[21] evaluated the error that originated from the clearance in the surgical guides and reported that this factor significantly influenced implant placement. The results of the aforementioned studies are a cumulation of operator and inherent error. Thus, the role of inherent error still remained unclear.

The OE was calculated by superimposing the pre-operative and post-operative CBCT by utilising the metal sleeve of the surgical guide as a reference following which the linear and angular measurements were made. This was done intentionally to nullify the impact of incorrect positioning of the surgical guide while placing the implants. This helped identify the influence of the operator on the final implant position. A paucity of data was observed with respect to evaluation of the role of operator in introducing error during implant placement.

Various authors have conducted systematic reviews to assess the overall error in implant placement when using static guide systems. Schneider et al[9] conducted a systematic review of 10 articles and their meta-regression analysis revealed a total mean deviation of 1.07 mm at the entry point and 1.63 mm at the apex. Van Assche et al[23] in their review reported a mean error of 0.99 mm (ranging from 0 to 6.5 mm) at the entry point and 1.24 mm (ranging from 0 to 6.9 mm) at the apex. The mean angular deviation reported was 3.81 degrees (ranging from 0 to 24.9 degrees). In the current study the cumulative error values of ItE, IhE and OE are less than the error values in the aforementioned studies. A reason for this disparity could be that this study has evaluated 3 different sources of error.

This study utilised a mucosa supported surgical guide. Varied results might be observed with tooth supported guides since tooth supported guides have a reportedly better accuracy due to their superior fit and stability.[24] Also, this study used only one static guided system. The results may vary with different systems. Hence, similar studies should be further conducted on different systems to fully evaluate the sources and extent of various errors.

Conclusions

1. Errors introduced during the designing and manufacturing of the stereolithographic guides was observed to be a major contributing factor towards the total error in angular deviation of the implant, linear deviation observed at the implant shoulder and in linear deviation observed at the implant apex.

2. The error introduced as a result of operator's skill and experience in different clinical situations (operator error) was observed to be a major contributing factor for mean vertical deviation observed at the apex of the implant.

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