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Original Article

Comparative Assessment of Clinical and Predicted Treatment Outcomes of Clear Aligner Treatment: An in Vivo Study

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ABSTRACT

Objective: The objective of this clinical study was to assess the predicted software models and clinical models and to compare the stage models of both the groups so as to evaluate the efficacy of tooth movement with clear aligner.

Methods: The sample size included 10 cases with mild anterior crowding treated with aligner therapy. The predicted software models were superimposed on the clinical stereolithography (STL) models at various stages by using the MeshLab software. The predicted software models showing orthodontic tooth movement were compared with the actual movement achieved clinically.

Results: The results of the present study have shown that when a comparison was made on the basis of irregularity scores in both the groups, it was seen that the irregularity score was higher at 2.55 at T4, 1.65 at T6, and 1.0 at T8 in the clinical STL group at each stage, whereas it was 2.0 at T4, 0.90 at T6, and 0.25 at T8 in the software model group. In addition, in comparing the mean accuracy of these three stages, the analysis of data showed that the mean accuracy is 62.5% at T4, 68.8% at T6, and 78.1% at T8.

Conclusion: The predicted software models do not accurately reflect the patient's tooth position. There is an overestimation by predicted software as compared with actual clinically achieved tooth position. There is a need of overcorrection to be built in the treatment planning stage itself and execution of the anticipated end result.

Keywords: Clear aligners, clinical outcome, predicted outcome, comparison, accuracy

INTRODUCTION

Movement of teeth without the use of bands, brackets, or wires was described as early as 1945 by Dr H.D. Kesling (1). He reported the use of a flexible tooth positioning appliance. Later, Nahoum et al. (2) wrote about various types of overlay appliances, such as invisible retainers.

Minor tooth movements have also been achieved with a technique developed by Raintree Essix (New Orleans, LA, USA). This technique used clear aligners formed on plaster models of the teeth. This type of appliance was effective in correcting mild discrepancies in the alignment of the teeth (3-5). However, movements are limited to 2–3 mm, (4) and beyond this range, another impression and a new appliance were advocated.

Currently, in this modern world of orthodontics, various new techniques have been developed to make the treatment more comfortable and aesthetic for the patient. The patient has a plethora of options to choose from based on different factors, such as cost, treatment time, aesthetics, and comfort, and so on. Owing to these factors, increasing numbers of adult patients have sought orthodontic treatment, and the demand for aesthetic appliances has increased in recent years (6).

With further advancement in orthodontic technology, Align Technology introduced Invisalign™ in 1998, a series of removable polyurethane aligners, as an aesthetic alternative to fixed labial appliances. Usually scanned

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images are converted to physical models by using different stereolithography (STL) techniques to fabricate a series of aligners that sequentially reposition the teeth (7, 8). Stereolithographic models are constructed at every stage (9). Each aligner is programmed to move a tooth or a small group of teeth 0.25-0.33 mm every 14 days (10).

Since there can be many variables that could affect tooth movement, (6) these variables can be biological factors, such as periodontal ligament, age and sex of the patient, root length, bone levels, bone density, and medications, and certain systemic conditions can have inhibitory, synergistic, or additive effects on orthodontic tooth movement (OTM) (11). Variability among patients can affect OTM. Hence, it is necessary to evaluate the difference between the predicted and actual teeth movement achieved. Consistently performing these analyses during treatments will provide a useful database that could be used to study treatment progress and variables affecting tooth movement over time.

There is a lack of literature that determines the deviation of the clinical outcome of clear aligners with their predicted outcome. No in vivo study has compared the predicted and stage clinical treatment outcome. In addition, no study has been conducted at different stages of aligner therapy to measure the disparity in predicted and achieved outcome. In the fast growing aligner market, it is essential to know the efficacy of the appliance being used. Hence, there is a need to evaluate and compare the clinical and predicted treatment outcome of clear aligners.

The aim of the present study was to compare the clinical treatment outcome and the predicted treatment outcome of clear aligner.

The objectives of the present study were as follows:

1. To evaluate the predicted treatment outcome of clear aligners,
2. To evaluate the clinical treatment outcome,
3. To compare the predicted and clinical treatment outcome.

Methodology

- Source of the patients: Patients visiting the department who were indicated for comprehensive orthodontic treatment.
- Study subjects: 10 orthodontic patients with mild to moderate crowding in the lower incisors were scheduled for regular evaluation using Little's Irregularity Index (12).

Sample Size Calculation

The sample size was calculated using the nMaster 2.0 software. The power of the study was 80% with 95% confidence interval (CI).

Inclusion Criteria

- Adult patients.
- Healthy, compliant, and motivated patients who can visit the department regularly.
- Mild to moderate lower anterior crowding according to Little's Irregularity Index.
- Non-extraction treatment plan in the lower arch.
- The tray should not be altered with scissors or thermopliers for treatment.

Exclusion Criteria

- Severe crowding.
- Large restorations in the lower anterior teeth.
- Prosthetic replacements in the lower anterior teeth.
- Gross gingival/periodontal problems in the lower anterior teeth.
- Recent extraction and tooth trauma.

Study Design

Steps in the study protocol were

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Ten patients with lower anterior crowding were selected.

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All patients were treated with clear aligners.

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The average time for the treatment was 6 months–1 year.

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The predicted outcome simulated by computer-aided software was evaluated in STL format at different stages 4, 6, and 8.

↓

The clinical outcome using clear aligners was converted and evaluated in STL format at different stages.

↓

The predicted and clinical treatment models were superimposed.

On the basis of Little's Irregularity Index, a sample size of 10 patients including males and females with mild to moderate crowding was selected.

Impressions were taken repeatedly with polyvinyl siloxane at different stages and sent to the laboratory for 3D scan of dentition to make a virtual model of the cast. After completing the initial series of aligners, polyvinyl siloxane impressions were taken at various stages starting from stages T4, T6, and T8; and mailed to the aligner company whose aligners were used (13, 14).

T0 is zero aligner, T4 is the stage after aligner no. 4, T6 is the stage after aligner no. 6, and T8 is the stage after aligner no. 8. The stage impressions were scanned using the extra oral dental scanner Maestro 3D MDS400 (Figure 1) and converted to an STL format. A clinical STL file was created for each set of models for maxillary and mandibular arch separately. The company, whose aligners were used, shared the files in STL format for software models as well.

The MeshLab software (Figure 2) with the support of the 3D-coform project program was used in the study to superimpose the stage clinical STL files and the software STL files. The MeshLab software is software for processing 3D scans, which consist of a fully automated voxel-based registration method. In each of the comparisons, the STL superimpositions used the reference points. To maintain uniformity, the same operator performed the point based gluing. The clinical STL and software STL files were superimposed with the points of a first mesh (clinical STL) onto the corresponding points of a second mesh (software STL), within the same reference space with an accuracy of 8 µm. T

Figure 1. Maestro 3D MDS400

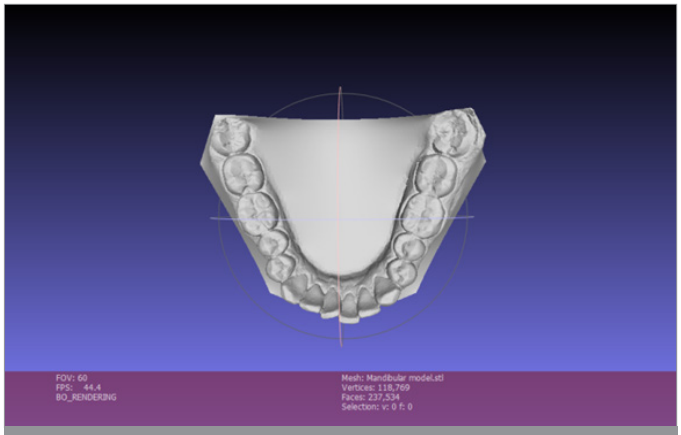

Figure 2. MeshLab software

The software also includes a measuring tool, allowing for linear measurements between points to measure the irregularity scores on both the clinical STL models and software STL models and compare the achieved teeth position at different stages, namely, T4, T6, and T8. With the aid of a measuring tool, it measured the resolution of crowding, rotation, and alignment of each anterior tooth (Figure 3). The difference between the scores of the clinical model and the software model is calculated for total score and/or discrepancy.

The clinical and software STL models of zero aligner at T0 stage, aligner at T4 stage, aligner at T6 stage, and aligner at T8 stage were taken, and superimpositions were done (Figure 4-7). Once two models are superimposed, the software will perform an efficacy analysis report that will show quantitative measurements for predicted and achieved movements. The percentage of accurate tooth movement will be determined by the following equation:

Percentage of accuracy=100%–[(|predicted–achieved|/|predicted|)×100%].

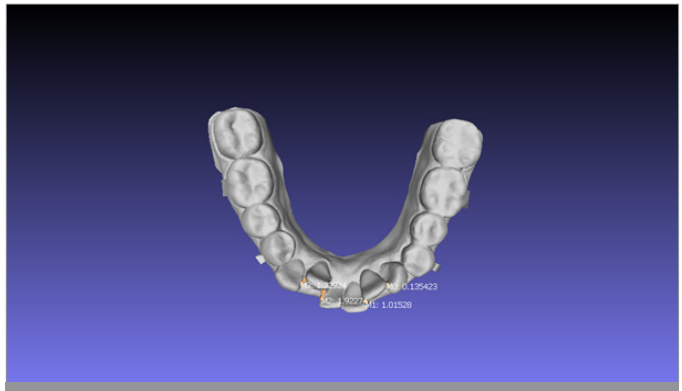

Figure 3. Measuring tool software in MeshLab

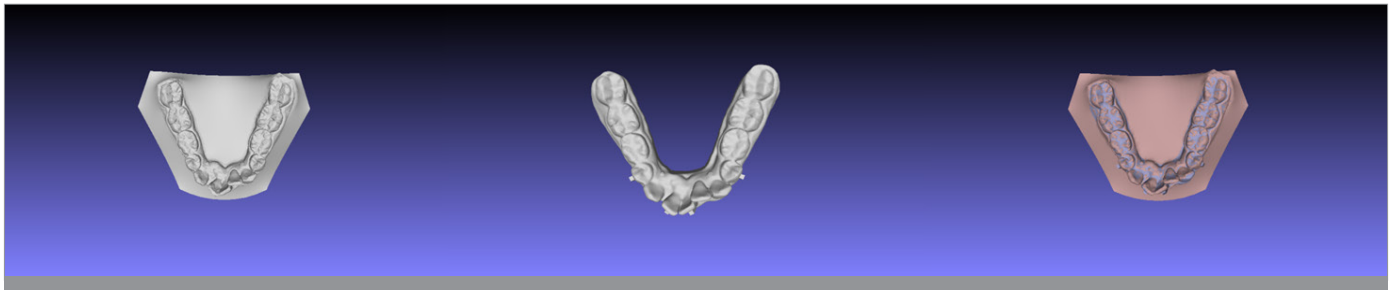

Figure 4. Clinical models, software models, and their superimposition at T0

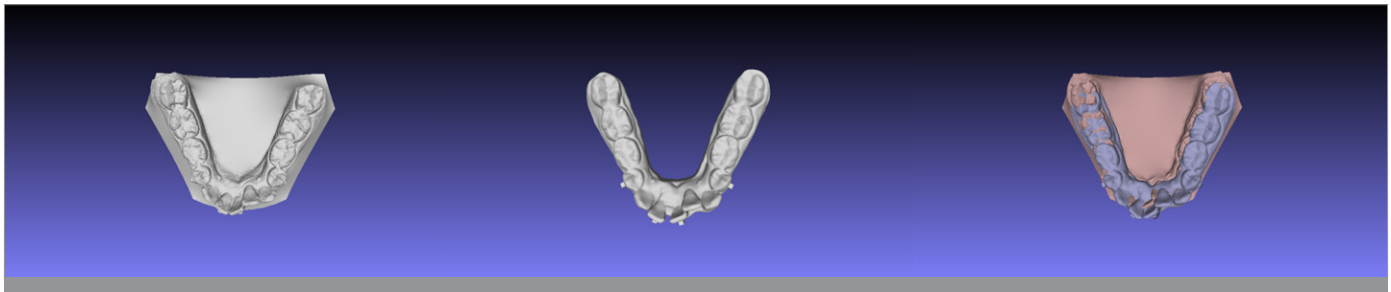

Figure 5. Clinical models, software models, and their superimposition at T4

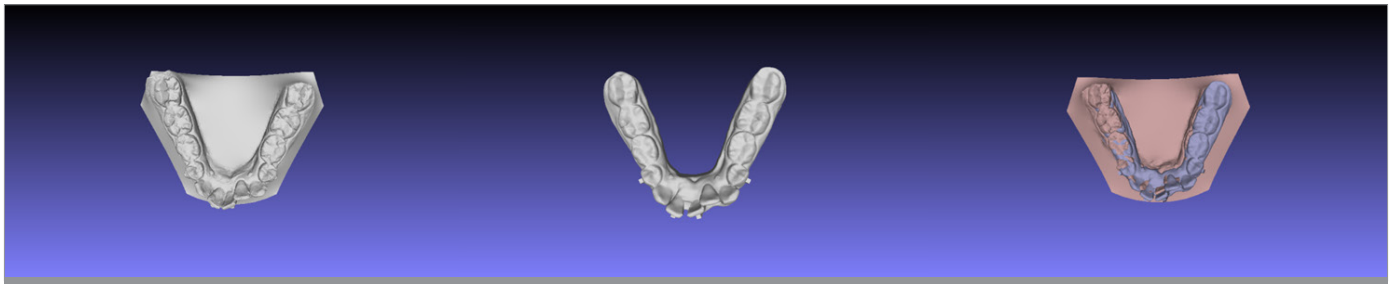

Figure 6. Clinical models, software models, and their superimposition at T6

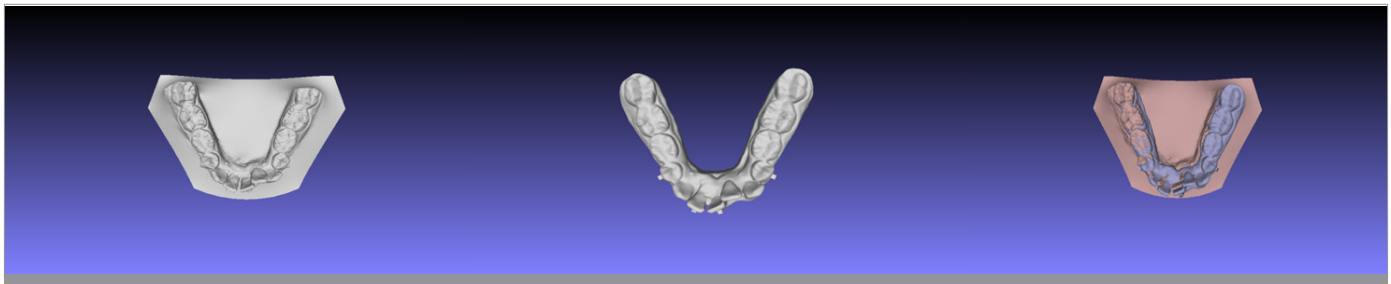

Figure 7. Clinical models, software models, and their superimposition at T8

Statistical Analysis

Data were entered into Microsoft Excel spreadsheet and were checked for any discrepancies. Summarized data were presented using tables. The software used for statistical analysis was Statistical Package for Social Sciences version 21.0 (IBM Corp.; Armonk, NY, USA) and Epi-info version 3.0. Shapiro–Wilk test was used to check which all variables were following normal distribution. Paired or dependent t-test was used for comparison of two mean values obtained from the same group or a pair of values obtained from the same sample when the data follow normal distribution. A p-value <0.05 was accepted as significant with 95% CI.

RESULTS

This study was conducted to assess the difference between the stage clinical outcome and the predicted outcome of clear aligners and also percentage of accuracy. In the present study, the mean change from T0 to T4, T0 to T6, and T0 to T8 was compared from clinical models and software models, and it was seen that the mean change was more in the software models at each stage, respectively. The mean accuracy of the clear aligners was approximately 78% at T8.

The mean change from T0 to T4 was compared between the clinical and software models using the Paired t-test. The mean change from T0 to T4 was significantly more in the software model with 1.25 than in the clinical model with 0.70 (Figure 8) (Table 1).

The mean change from T0 to T6 was compared between the STL and software models using the Paired t-test. The mean change from T0 to T6 was significantly more in the software model with 2.35 than in the clinical model with 1.60 (Figure 9) (Table 2).

The mean change from T0 to T8 was compared between the STL and software models using the Paired t-test. The mean change from T0 to T8 was significantly more in the software model with 3.00 than in the clinical model with 2.25 (Figure 10) (Table 3).

Table 1. Mean change from T0-T4 between both the groups

Change from T0 to T4	Mean	Std. Deviation	Mean Difference	t-test value	p
Clinical STL model	0.70	0.26	-0.55	-3.498	0.007
Software model	1.25				

Table 2. Mean change from T0-T6 between both the groups

Change from T0 to T6	Mean	Std. Deviation	Mean Difference	t-test value	p
Clinical STL model	1.60	0.32	-0.75	-6.708	0.000
Software model	2.35	0.41			

Table 3. Mean change from T0-T8 between both the groups

Change from T0 to T8	Mean	Std. Deviation	Mean Difference	t-test value	p
Clinical STL model	2.25	0.35	-0.75	-4.392	0.002*
Software model	3.00	0.82			

Table 4. Mean accuracy at different stages

Accuracy	Mean	Std. Deviation
T4	62.50%	29.20%
T6	68.83%	13.05%
T8	78.12%	13.84%

In addition, the evaluation of the mean accuracy of clear aligners in clinical models at T4 was found to be 62.5 and 68.83 at T6 and 78.12 at T8 (Figure 11) (Table 4).

Moreover, the comparative evaluation of the irregularity score of the clinical and software models has been depicted at T0 stage with 3.25 and 3.25, at T4 stage with 2.55 and 2.00, at T6 stage

Table 5. Comparison of irregularity score between both the groups at different stages

	Clinical STL model		Software models	
	Mean	SD	Mean	SD
T0	3.25	1.16	3.25	1.16
T4	2.55	1.26	2.00	1.11
T6	1.65	1.16	0.90	0.99
T8	1.00	0.91	0.25	0.42

SD: standard deviation

with 1.60 and 0.90, and at T8 stage with 1.00 and 0.25, respectively (Fig. 12) (Table 5).

DISCUSSION

Although clear aligner treatment (CAT) has been cited as a safe, aesthetic, and comfortable orthodontic procedure for adult patients, only a few investigations (6) have focused on the predictability of OTM. In 2005, Lagravère and Flores-Mir (15) published a systematic review in which only two studies met their inclusion criteria related to Invisalign™ therapy efficacy (16, 17). It was stated that no strong conclusions could be made regarding the treatment effects of this kind of orthodontic treatment. Thus, clinicians who plan to use the CAT on their patients have to rely on their clinical experience, the opinions of experts, and limited published evidence. The present study aimed to assess the effect of these variables on the clinical outcome along with the biological restraints in the patients and compared it with the software models that had no constraints to OTM. In addition, it also enunciates that these variables could alter the predictability of the aligner treatment.

The purpose of the present study was to compare a proprietary software model with the actual clinical outcome to determine whether overall occlusion and crowding at various stages of aligners, such as aligner nos. 4, 6, and 8, are comparable. The present study endeavored to establish the relative validity of predicted proprietary software models by determining whether the 3D treatment outcome of aligner therapy can be accurately predicted.

The results of the present study show that the mean change from T0 to T4, T0 to T6, and T0 to T8 comparing both the groups was significantly more in the software models than in the clinical models.

The result provided an inference that the clinical models showed resolution of crowding when it is assessed individually at different stages. However, when it is compared with the software models at different stages, the mean change is lesser in the clinical models than in the software models, thereby suggesting that resolution of crowding is better in the software models and it overestimates the correction of crowding and misalignment.

The comparison was made for the mean accuracy of the clear aligners at different stages of aligners. The analysis of data showed the mean accuracy that concluded from the data that the maximum accuracy matched for both the groups at the T8 stage, though the accuracy of this match was lesser in the initial stages of treatment; the accuracy between the predicted and clinical outcomes improves as the treatment progressed.

Moreover, a study was conducted using the Invisalign™ with their proprietary system. Kravitz et al. (10) conducted a prospective clinical study in 2009 to evaluate the efficacy of tooth movement with Invisalign™. The amount of tooth movement predicted by ClinCheck (Align Technology) was compared with the amount achieved after Invisalign™ treatment. Tooth movement was evaluated on Tooth-Measure, Invisalign's proprietary virtual model superimposition software. It concluded that the mean accuracy of tooth movement with Invisalign was 41% (18, 19).

In addition, Buschang[7] conducted a prospective study that compared the patients' models taken immediately after treatment, ClinCheck™ models overestimated alignment, buccolingual inclinations, occlusal contacts, and relations.

For aligner treatments to be valid and effective, the predicted and actual outcomes should be comparable. Digital computerization allows the visualization of the treatment plan at not only beginning and end but also step by step, and aligner by aligner throughout the treatment that purportedly reflects the treatment outcomes and hence the anticipated end result can be visualized. However, there is no study that correlates and compares the predicted software models and the clinical outcome at varied stages along with the variables in the patient's mouth into consideration, as they can alter the clinical outcome end results.

The present study was one of a kind where the comparison was made at different stages to assess the efficacy and the accuracy of the aligners and to correlate it with the predicted outcomes. In addition, the comparison showed that the accuracy of the appliance is approximately 78%, which is more than reported by other authors in their study. In addition, it should be taken into consideration that there must be some variables or biological restraints that affected the mean accuracy of the treatment, as it has affected the clinical treatment outcome at every stage.

In addition, a study by Drake et al. (20) stated that bodily movement is not achievable by the CAT; the aligners can easily tip the tooth crown but cannot tip the root because of the inadequate root control movement with the aligner system. Although the tooth movement programmed by the software is bodily movement, tipping of the teeth occurs. Therefore, the end result will vary from the programmed or predicted result.

Another study was conducted by Clements et al. (21) using Align Technology to compare two different materials of the aligner (soft and hard). The hard material group showed the best results in Peer Assessment Rating score reduction. The stiffness of the material is an important factor in achieving the desired result as it has better tooth control.

These variables along with wear of the aligners by the patient for requisite hour are an important factor in achieving the predicted

end result that should be taken into consideration. Clearly, successful aligner treatment is not limited to aligners alone; there are different adjuncts and auxiliaries that should be used to explore the horizons of aligner in treating patients with difficult or different malocclusion. These variables diminish the clinical outcome of the aligners as to which it was predicted and reduce the mean accuracy of the CAT. And so as to overcome this variability and hindrance in the accuracy and predictability to achieve as it was desired. Certain limitations are associated with the present study.[1] Mild to moderate crowding cases were included, excluding the posterior segment that was taken as a reference for superimposition (2). Restraints, such as the thickness of material that can alter the tooth movement, were not taken into account (3). No adjuncts or auxiliaries were used (4). Overcorrection was not incorporated in the software (5). Torque expression was not accounted for.

Emphasis should be given to the need of overcorrection to be built in the software, effective attachment designs so as to make aligners more reliable with respect to treating difficult malocclusions and to achieve the desired result. The present study was performed using the XYZ aligner system with the same proprietary software so as to maintain uniformity on all patients and results. However, more studies should be conducted on similar pattern involving more number of patients, and also further studies need to be performed to evaluate the expression of the torque with the aligner system and also the material qualities.

CONCLUSION

The present study was conducted to evaluate the clinical outcome and the predicted outcome and to compare the results of both outcomes. Data were evaluated, and statistical analysis was done to find the results. The present study concluded the following:

- The mean change from T0 to T4, T0 to T6, and T0 to T8 was significantly more in the software models than in the clinical models.
- The software models overestimated the alignment and the resolution of crowding in comparison with the actual clinical models. Software models do not accurately reflect the patient's final occlusion immediately at the end of active treatment.
- The mean accuracy is 62% at T4, 68% at T6, and 78% at T8, concluding that it is an efficient appliance for correcting mild to moderate crowding. In addition, there are variables or biological restrains that alter the accuracy of the CAT.
- Hence, there is a need of overcorrection to be built in the treatment planning stage itself and execution of the anticipated end result so as to achieve the desired correction as seen in software models.

Ethics Committee Approval: Ethics committee approval was received for this study from the Institutional Ethics Committee of Sudha Rustagi College of Dental Sciences and Research.

Informed Consent: Informed consent was obtained from the patients included in the study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept - A.I., G.S., V.G., R.S.; Design - A.I., G.S., N.G., P.P.; Supervision - A.I., G.S., V.G., R.S., N.G., P.P.; Materials - A.I., G.S., V.G., R.S., N.G., P.P.; Data Collection and/or Processing - G.S., N.G., P.P.; Analysis and/or Interpretation - A.I., G.S., V.G., R.S.; Literature Search - V.G., R.S., N.G., P.P.; Writing Manuscript - A.F., M.H.F.; Critical Review - G.S., N.G.

Conflict of Interest: The authors have no conflict of interest to declare.

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