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Comparitive Assessment of the Clinical Treatment Outcome and the Predicted Treatment Outcome of Clear Aligner Treatment; *In Vivo* Study

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Abstract

Objectives: The objective of this clinical study was to assess the predicted treatment outcome and actual treatment outcome and compare the 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 STL models at various stages by using MeshLab software (Developed at the Visual Computing Lab at ISTI-CNR with the support of the 3D-co-form project).The predicted software models showing orthodontic tooth movement was compared with the actual movement achieved clinically.
Results: The results of this 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 more in Clinical STL group at each stage such as 2.55 at T4, 1.65 at T6 and 1.0 at T8 whereas 2.0 at T4. 0.90 at T6 and 0.25 at T8 in the Software model group. Also, on comparing mean accuracy these three stages, the analysis of data showed the mean accuracy at T4 is 62.5%, mean accuracy at T6 is 68.8% and the mean accuracy at T8 is 78.1%.
Conclusions: The predicted software models do not accurately reflect the patient's tooth position .There is an overestimation by predicted software as compared to the actual 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: Aligner, Comparison, Clinical Outcome, Predicted Outcome

1. Background

Tooth movement without the use of conventional techniques using bands, brackets and wires was reported in early 1945 by Dr. Kesling (1). He described about a flexible appliance that induces minor tooth movement which he termed as tooth positioning appliance. Later, Nahoum (2) and others also described about different types of invisible appliances that served the purpose of retention of teeth and acted as overlay appliance.

Raintree Essix (New Orleans, LA) also developed an alternative technique to induce minor orthodontic tooth movement, in which invisible clear appliances were formed on the cast of teeth. It was found that the appliance was effective in correcting minor discrepancies in the alignment and correction of teeth (3-5). Though movements are limited to 2 - 3 mm (4) and beyond this range, another impression and a new appliance are advocated.

Today, in the 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 factors such as cost, treatment time, aesthetics, comfort and so on. Owing to these factors, more and more numbers of adult patients are demanding orthodontic treatment and demand for aesthetic appliances has increased in recent years (6).

With further advancement in orthodontic technology, Align Technology introduced Invisalign™ in 1998, which was a series of removable, clear aligners, as an aesthetic alternative to fixed appliances. Usually scanned images are converted to physical models by using different stereolithography techniques to fabricate series of aligners that sequentially reposition the teeth (7, 8). Stereolithographic models are constructed at every stage (9). Each aligner is designed to induce tooth movement by 0.25 to 0.33 mm every two weeks (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 patient, bone levels, medications, bone density, root length, few systemic conditions and chronic illnesses can have variable effects on tooth movement (11). Variability among patients can affect orthodontic tooth movement (OTM). Hence, it is necessary to evaluate the difference between the predicted and actual teeth movement achieved.

There is 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. Also 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 main goal of this study was to compare the clinical treatment outcome and the predicted treatment outcome of clear aligners.

2. Objectives

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

3. Methods

The cases were selected among the ones visiting the department, who were indicated for comprehensive orthodontic treatment. Ten orthodontic patients having mild to moderate crowding in lower incisors were scheduled for regular evaluation using Little's irregularity index (12). The sample size was calculated using the nMaster 2.0 software. The power of the study was taken to be 80% and confidence interval (C.I.) of 95% was taken.

Cases were selected among healthy and adult compliant and motivated patients who can visit the department regularly. They had mild to moderate lower anterior crowding according to Little's irregularity index which were decided to be treated with a non-extraction approach.

The tray should not be altered with scissors or thermopliers for treatment.

Exclusion criteria were: severe crowding, large restorations in lower anterior teeth, prosthetic replacements in lower anterior teeth, gross gingival / periodontal problems in lower anterior teeth and recent extraction and tooth trauma.

Patients were selected on the basis of inclusion criteria. A sample of 10 patients was selected using Little's irregularity index. Clear aligners were given to the patients with mild to moderate anterior crowding and instructed to record the duration of wear. Aligners were changed every 2 weeks. Impressions were taken repeatedly with polyvinylsiloxane at different stages and sent to laboratory for 3D scan of dentition and to make a virtual model of the cast. After the initial set of aligners, silicon impressions were taken (13, 14), at various stages starting from stages T4, T6 and T8, and mailed to Kline Technology. The clinical models were scanned using the Extra oral dental scanner- Maestro 3D MDS400 (Figure 1) and converted to a stereo lithography (STL) format. A STL file was made for every set of models for maxillary and mandibular arch separately. The software model files were also converted to the STL format. Mesh lab software (Figure 2) with the support of the 3D-co-form project program used to make digital measurements and derive the alignment, irregularity scores on both the models and compare the achieved teeth position at different stages. The Mesh Lab software allowed the measurements to be made using a measuring tool, a software application. The software enables to superimpose 2 digital models on reference points, such as untreated posterior teeth. The digital models at various stages are superimposed over the untreated stationary premolars and molars. With the help of measuring tool, it measured the resolution of crowding, rotation and alignment of anterior teeth (Figure 3). The mean change between the clinical and the software model was calculated and the discrepancy was measured.

The clinical and software STL models of zero aligner at T0 stage, aligner at T4, aligner at T6, aligner at T8 are taken and superimpositions are done (Figures 4 - 7).

Once 2 models are superimposed, software performed an efficacy analysis showing quantitative measurements of predicted and achieved tooth movements. The accuracy is determined by the following equation:

$$Percentage\ of\ accuracy = 100\% - \left[\left(\frac{|predicted - achieved|}{|predicted|}\right) \times 100\%\right] \quad (1)$$

3.1. Statistical Analysis

The findings were entered into Microsoft Excel and were checked for any discrepancies. Summarized data was presented using tables and graphs. The software used for

the statistical analysis was SPSS (statistical package for social sciences) version 21.0 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 2 mean values obtained from a same group or a pair of values obtained from the same sample when the data follows normal distribution. The p-value was taken significant when less than 0.05 ($P < 0.05$) and confidence interval of 95% was taken.

The statistical tests used in the study were Paired or Dependent *t*-test. It was used as the data follows normal distribution. Paired or Dependent Student's *t*-test and Shapiro-Wilk tests

4. Results

This study was done to assess the difference between the stage clinical outcome and the predicted outcome of clear aligners and also percentage of accuracy. In this study the mean change from T0 to T4, T0 to T6 and T0 to T8 was compared with 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 around 78% at T8.

The mean change from T0 to T4 was compared between clinical and software models using the Paired *t*-test. The mean change from T0 to T4 was significantly more in software model that is 1.25 in comparison to clinical model which is 0.70 (Figure 8). The mean change from T0 to T6 was compared between STL and Software models using the Paired *t*-test. The mean change from T0 to T6 was significantly more in software model that is 2.35 in comparison to clinical model which is 1.60 (Figure 9). The mean change from T0 to T8 was compared between STL and software models using the Paired *t*-test. The mean change from T0 to T8 was significantly more in software model that is 3.00 in comparison to clinical model which is 2.25 (Figure 10). Also, the evaluation of the mean accuracy of clear aligners in clinical models at T4 was found to be 62.5, 68.83 at T6 and 78.12 at T8 (Figure 11).

Moreover, the comparative evaluation of the irregularity score of clinical and software models has been depicted at T0 which is 3.25 and 3.25, respectively, at T4 2.55 and 2.00, respectively, at T6 1.60 and 0.90, and at T8 stage which is 1.00 and 0.25, respectively (Figure 12).

5. Discussion

Although clear aligner treatment has been presented as esthetic, and comfortable orthodontic treatment for adult patients, very few investigations (6) have studied the predictability of orthodontic tooth movement. Lagravere and Flores-Mir (15) published a systematic review in which there were only two studies that met their inclusion criteria related to Invisalign™ aligners efficacy (16, 17). As per this study, the treatment effects of this kind of orthodontic treatment, no strong conclusions could be made. Thus, those who intend to use clear aligner treatment (CAT) on the patients have to depend on their clinical acumen, logical reasoning and very limited published literature. This 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 orthodontic tooth movement. And it also enunciates that these variables could alter the predictability of the aligner treatment.

Figure 1. Maestro3MDS400

The objective of this study was to compare a software model with the clinical model to determine the tooth movement at various stages of aligners such as aligner no 4, 6, and 8. The results of this study shows that mean change from T0 to T4, T0 to T6 and T0 to T8 comparing both the groups was significantly more in software models in comparison to clinical models.

The result gave an inference that the clinical models showed resolution of crowding when it is assessed individually at different stages. But, when it is compared with the software models at different stages the mean change is lesser in clinical models as compared to software models, which helps us to conclude that resolution of crowding is better in the software models and it overestimates the correction of the crowding and misalignment.

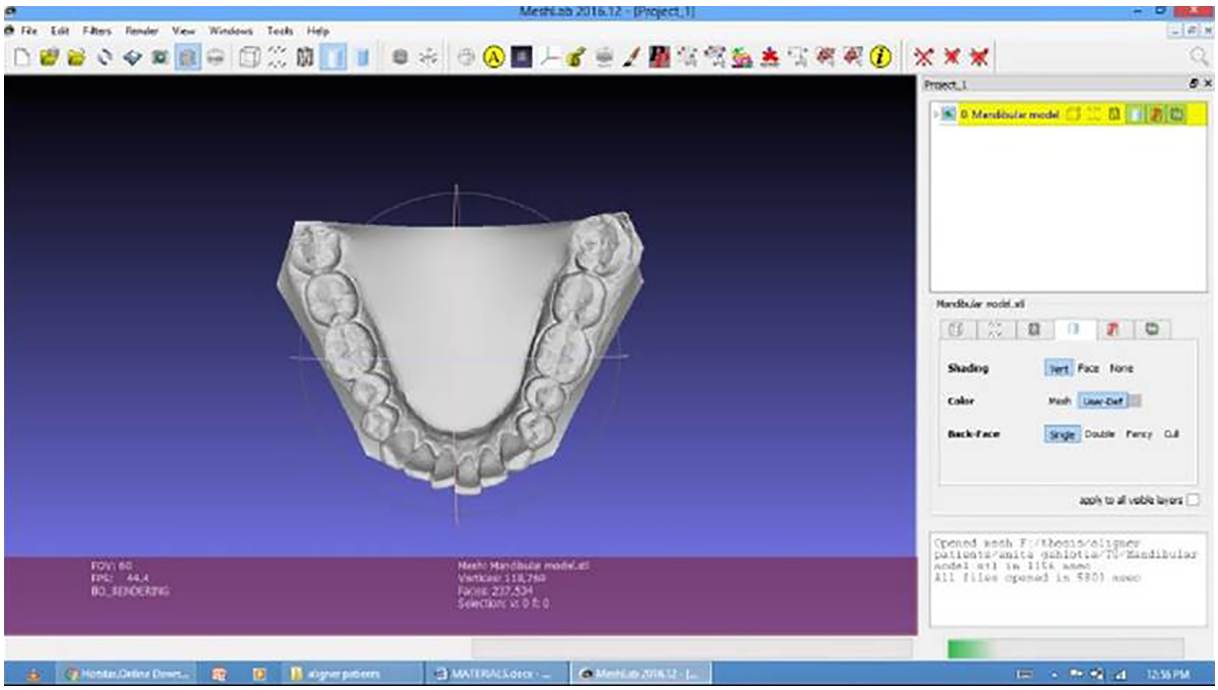

Figure 2. Meshlab

Figure 3. Measuring tool software

The comparison was made for the mean accuracy of the clear aligners at the different stages of aligners. The analysis of data showed the mean accuracy which 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 done using the Invisalign™ with their proprietary system. Kravitz et al. (10) conducted a study to assess the efficacy of tooth movement with Invisalign™. The amount of tooth movement predicted by ClinCheck™ software was compared with the clinical tooth movement achieved after Invisalign™ therapy. It concluded that mean accuracy with Invisalign treatment was 41% (18,19). Buschang et al. (7) conducted a prospective study which compared patients' models taken before and after treatment, in the study. ClinCheck™ models overestimated the corrections of the occlusion.

If the clear aligner therapy has to be reliable and effective, the predicted and clinical outcomes should be comparable. 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.

This 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. Also, the comparison showed that the accuracy of the appliance is around 78%, which is more than quoted by other authors in their study. It should be taken into consideration that there must be some variables or biologi-

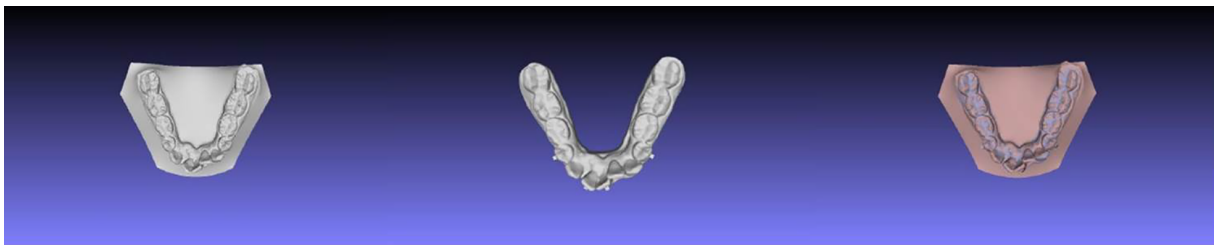

Figure 4. Clinical, software models & superimposition at T0

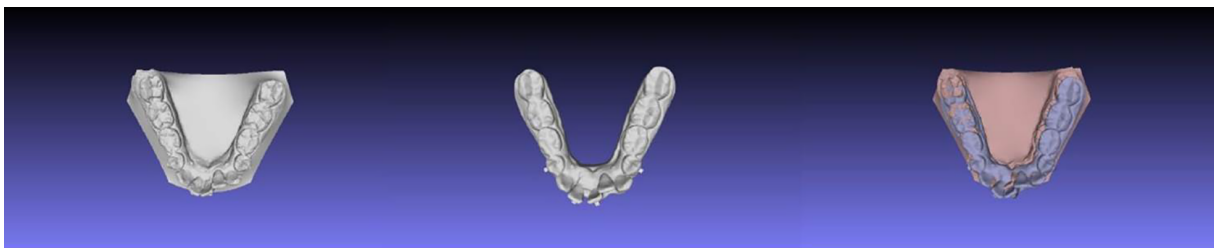

Figure 5. Clinical, software models & superimposition at T4

Figure 6. Clinical, software models & superimposition at T6

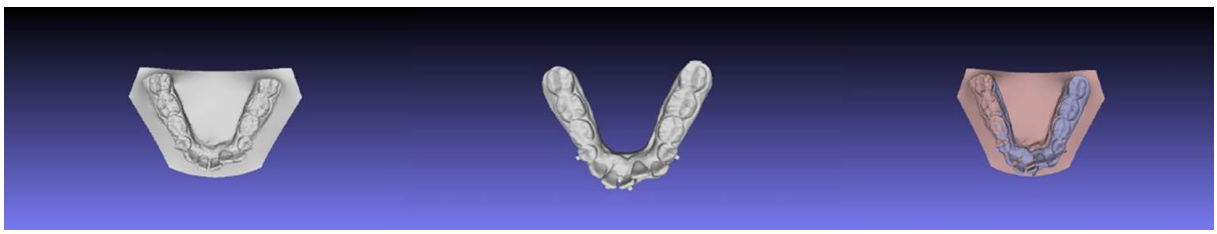

Figure 7. Clinical, software models & superimposition at T8

cal restraints that affected the mean accuracy of the treatment, as it has affected the clinical treatment outcome at every stages.

Also, a study by Drake et al. stated that translational movement is not achievable by the CAT (20); the aligners can tip the tooth crown but cannot torque the tooth effectively due to inadequate torque control movement with aligner system. Although, the tooth movement programmed by the software is bodily movement, tipping of the teeth occurs. Hence, the end result will vary from the programmed or predicted result.

Another study was done by Clements et al. (21) using Align Technology to compare 2 different materials of the aligner (soft and hard). The hard material group showed

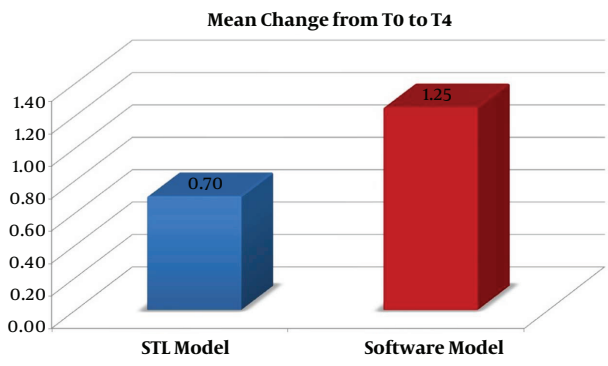

Figure 8. Comparison between two groups at stage T0 - T4. Group 1, STL models; group 2, software models.

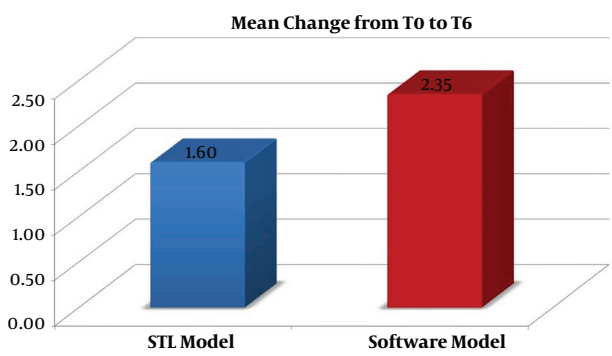

Figure 9. Comparison between two groups at stage T0 - T6. Group 1, STL models; group 2, software models.

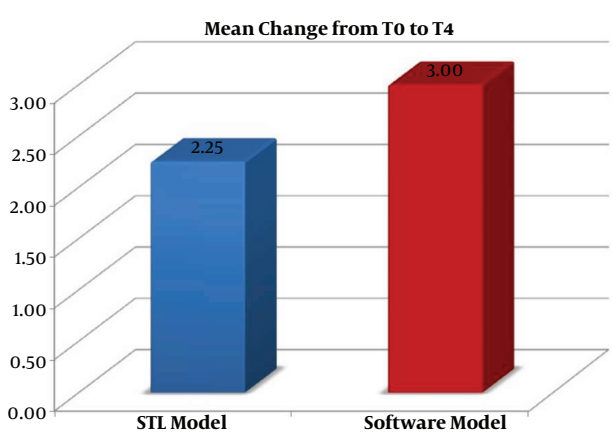

Figure 10. Comparison between two groups at stage T0 - T8. Group 1, STL models; group 2, software models.

the best results in PAR 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 which 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 the patients with difficult or different malocclusion. These variables diminish the clinical outcome of the aligners as to which it was predicted and reduces the mean accuracy of the clear aligner treatment. 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 this study: (a) mild to moderate crowding cases were included, excluding the posterior segment which was taken as reference for superimposition; (b) restraints such as the thickness of material that can alter the tooth movement was not taken into account; (c) no adjuncts / auxiliaries were used; (d) overcorrection was not incorporated in the software; (e) torque expression was not accounted for.

Emphasizes should be given to the need of overcorrection to be built in the software, effective attachment designs so as to make aligners more reliable in terms of treating difficult malocclusions and in order to get the desired result. This study was done using an aligner system with the same proprietary software so as to maintain uniformity on all patients and results. However, more studies should be done on similar pattern involving more number of patients and also further studies needs to be done to evaluate the expression of the torque with the aligner system and also the material qualities.

5.1. Conclusions

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

1. The mean change from T0 to T4, T0 to T6, and T0 to T8 was significantly more in software models, when they were compared with the clinical models.

2. The software models overestimated the alignment and the resolution of crowding in comparison with the actual clinical models. Software models at present do not accurately predict the final occlusion at the end of the treatment.

3. The mean accuracy is 62% at T4, 68% at T6, and 78% at T8, concluding that it is efficient appliance for correcting mild to moderate crowding. In addition, there are variables or biological restrains that alter the accuracy of the clear aligner treatment.

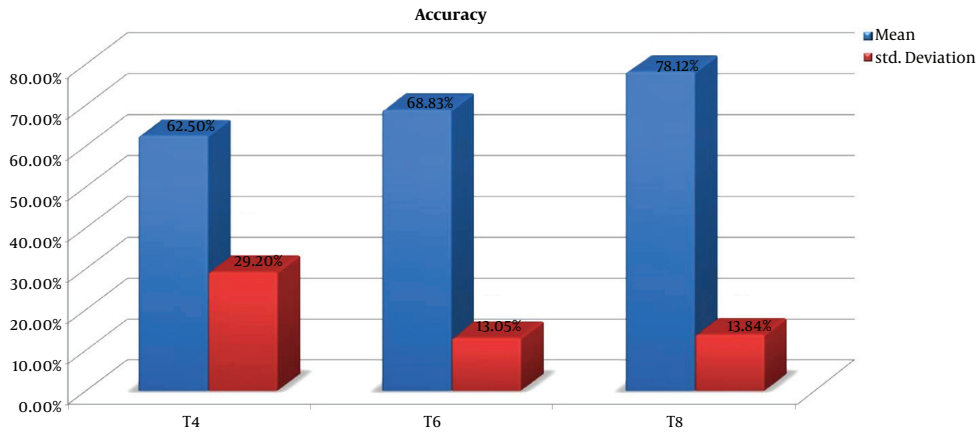

Figure 11. Mean accuracy of aligners at T4, T6, and T8 stages

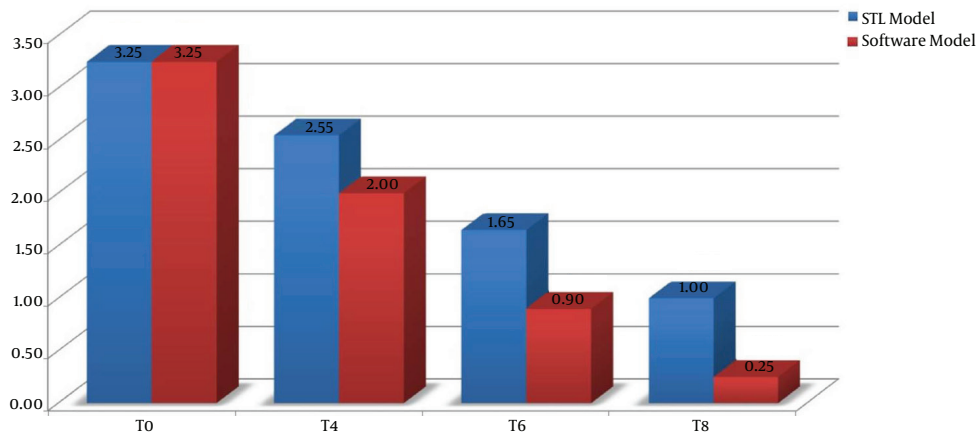

Figure 12. Comparison of irregularity score (crowding) between two groups. Group 1, STL models; group 2, software models.

4. 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.

Footnotes

Conflict of Interests: There is no conflict of interest.

Ethical Approval: the study has been approved by Institutional Ethical Committee SRCDSR.

Funding/Support: There is no funding/support.

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