International Journal of Applied Dental Sciences

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To determine the effect of material fatigue of aligners in oral environment and to describe and quantify the type and amount of Orthodontic tooth movement produced by clear aligners

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DOI: https://doi.org/10.22271/oral.2020.v6.i1d.896

Abstract
Introduction: The following observations regarding tooth movement with Invisalign aligners resulted from a randomized and controlled clinical trial
1. In a two-week prescription cycle of wearing an aligner, more orthodontic tooth movement (OTM) was seen in the first week as compared to the second week.
2. The exact expected result from the comparison was not obtained.
3. Different individuals depicted different OTM.
The results in this study have certain clinical implications which require further research and a more thorough study.
Aim: The primary aim of this study was to determine whether these observations were due to material fatigue of the aligners in the oral environment. The secondary aim of this study was to describe and quantify the type and amount of OTM produced by clear aligners.
Material and Method: A single centre prospective clinical trial was completed, comparing 15 subjects treated over a course of eight weeks with a control group of 37 subjects study with similar population demographics and nearly identical study design. An upper central incisor was programmed to move two mm over eight weeks, or 0.5 mm every two weeks, using Invisalign® aligners. The treatment subjects changed to a fresh aligner with the same prescription after one week, and the control subjects wore each aligner for the prescribed two weeks. Every week impressions were taken with polyvinyl siloxane (PVS) and models were fabricated digitally to measure OTM. In addition, initial and final cone beam computed tomography (CBCT) images were obtained from the treatment subjects only, to describe and measure OTM.
Result: No significant difference was seen found in OTM in individuals who were wearing the initial aligner for a period of two weeks vs. those individuals who switched to a fresh aligner after a period of one week. The OTM variability in the second week was seen due to the material wear and fatigue present. There was, however, a significant difference in OTM during the first week vs. the second week of any given two-week cycle, for both groups. When OTM was measured from the centre of the clinical crown, the two mm prescription of the aligners was not fully expressed in any of the 15 treated subjects.
Conclusion: High variability was observed. In addition, CBCT data indicated that: 1) the target teeth experienced tipping that was uncontrolled in nature, with the median rotation center at 41% of the length of the root apical to the alveolar crest, 2) although only one central incisor was planned to move, the contralateral central incisor felt a reactive force and got rotated in the direction opposite that of the target tooth, 3) seven of the 15 subjects experienced a net anteroposterior (A-P) change of less than 1.9 mm between the midpoint of the incisal edge of the target tooth and the contralateral central incisor, and 4) the results of an exploratory data analysis attempting to correlate biologic variables with OTM revealed some trends, but additional research is required before making conclusions.

Keywords: Orthodontic Tooth movement, environment, clear aligners, OTM

Introduction

Research involving the Invisalign® system is lacking. Sufficient literature supporting the OTM by use of the clear aligners is not available. As per the available data it is suggestive that

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the movement is by tipping which is uncontrolled in nature, also suggesting that the rotation center is present between apex of the tooth and the resistance center of the tooth.

In a tooth with a single root the resistance center is present on the long axis of the tooth between one third and one half of the root length apical to the alveolar crest [1].

Duong et al. [2] studied the comparison of stainless steel (SS) and Nickel Titanium (NiTi) wires having the load-deflection rates (LDR) 0.017x0.017'' vs 0.030 mm polyurethane material over a 0-10% range of strain in vitro. The LDR of the NiTi wire was less than polyurethane but this it was greater than the stainless steel wire. Therefore, the aligner delivers lower initial force than the SS wire. Further studies should be carried out to check the force related to Invisalign®. Currently patients are instructed to wear each aligner for 2 weeks [3]. Though degradation of aligner causing the OTM is unclear, but certain evidences suggest that there is a decrease in the magnitude of force transferred to the teeth over time. Both the clinician as well as the patient would be benefited with a proper knowledge of the degradation and fatigue of the appliances on OTM [4].

Methods
Study design
The following study was a single center prospective clinical trial involving subjects with minor malalignment of incisors, who were otherwise medically fit and wanted comprehensive orthodontic treatment.

16 patients were selected and 1 out of this left the study before starting of the treatment, making the sample size fifteen (six males and nine females) between the ages of 18 and 40 years (mean age 25.13). The ones selected were all medically sound and had acceptable malocclusions as defined by the inclusion and exclusion criteria (Table 1). Comparison of demographics of treatment with control group is depicted in Table 2.

The target tooth considered was the maxillary right or left central incisor. Random tooth selection was made. During this study, selected subjects were handed over with 4 upper aligners, which were designed in such a way that the respective target tooth would move 0.5 mm every two weeks. No intrusion, extrusion or rotation was programmed but only bodily movement of the single target tooth in the A-P dimension was programmed. Also, for the treatment group, 4 aligners as that of the first aligner were formed for replacing the given aligner at the beginning of each odd-numbered week. Therefore, new aligners were delivered each week (Weeks one-seven). This is in contrast to the control group, where subjects wore only 4 aligners, each for a period of 2 weeks. The study lasted for a period of 8 weeks after which the data was collected.

An instruction was given to the patients to wear the aligner for full-time. However, the appliance had to be removed before eating, drinking, or brushing their teeth. Subject compliance played an important in role in this and to check the compliance the subjects were asked to maintain a daily dairy.

Enrolment
To determine subject eligibility, two screening visits were required.
Screening 1 (Initial Screening)
In this all the patients were assessed, the ones needing minor incisor alignment, medically fit and not having any diseases related to the oral cavity were selected, rest were eliminated.

The selected patients proceeded with Screening 2.

Screening 2 (Second screening)
In this the patients were finalized and all records were collected. The following procedures were performed: 1) Poly-Vinyl Silicon impressions, 2) intraoral and extra oral pictures, and 3) CBCT imaging. For women, a negative urine pregnancy test immediately prior to radiographic procedures was required. After the investigator reviewed all information and confirmed eligibility, the subject was enrolled into the study and the target tooth was identified according to the above criteria.

Study visits
Week 0
At the initial week of the study (Week 0) the first aligner was delivered and all the subjects were instructed to wear the aligner for full-time and were also told to remove it while eating, drinking and brushing. The acceptable visit window for Weeks 0 - 8 was ± one day, and all 15 treatment subjects successfully satisfied this requirement.

Weeks 1, 2, 3, 4, 5, 6 and 7
At these visits maxillary PVS impressions as well as frontal and occlusal photographs were taken, and the next aligner was delivered.

Week 8 (Study termination)
At the final study visit (Week 8) maxillary PVS impressions and final photographs were taken as well CBCT imaging of the maxilla.

Collection of data
Weekly digital models were fabricated from PVS impressions. Models from Weeks 1-8 were then superimposed with the initial model from Screening 2, according to the best fit of the posterior teeth (Figure 1), using Align Technology's ToothMeasure® software, Version 2.3. The centroid of the clinical crown of the target tooth was established, and the amount of A-P and vertical OTM of the target tooth was then measured for each time point relative to baseline. ClinCheck® was used to evaluate the direction of programmed OTM and A-P axis was determined.

Examiner 1 (a consultant orthodontist) measured the models of the 15 treatment subjects, and Examiner 2 (a dental practitioner) measured the 37 control subjects.

CBCT images were obtained during Screening 2 and Week 8. Examiner 1 adjusted the pictures taken above by using the Anatomage's In Vivo Dental® software, version 4.1 to correspond those images with the digital models obtained. Both the initial and final images were ran through the software, curvature of the palate was registered and best fit of maxillary bony structures was obtained. Different readings were recorded (Table 3 and Figure 2).

Δ U1 (x) refers to the distance between lines drawn through the midpoint of the incisal edges of the superimposed target tooth perpendicular to the A-P axis (the plane of prescribed tooth movement). Δ U1 (s) is the length of the line connecting the midpoint of the incisal edges of the superimposed target tooth. Δ Apex refers to the length of a line connecting the change in apex of the superimposed target tooth. Rotation angle is the angle created by the intersection of lines drawn from the midpoint of the incisal edge to the apex of the target tooth. The apex of this angle is considered the center of rotation. Tooth length refers to the distance from the midpoint

of the incisal edge to the apex of the target tooth from the initial x-ray.

Crown length is the portion of the tooth length that is coronal to the bone. Bone to C-rot. Is the section of tooth length between the center of rotation and a line connecting the most coronal aspect of the faciolingual crestal bone. Δ U1 (o) refers to the A-P change in the midpoint of the superimposed incisal edge of the opposite central incisor, the one that was not the target tooth. From these measurements, additional ratios and measurements were calculated.

CBCT used to determine the quality of bone was also used to calculate a fractal analysis score [5]. In all planes CBCT slices were taken and were compared. Images were subjected to histogram equalization using a reference image, and a region of interest (ROI) adjacent to the apex of the target tooth was selected for use on all images. Fractal analyses were carried out for each of the different ROIs using the power spectrum method employed by the TACT® workbench. 32 bit complex floating point representations of the ROIs were cropped, and subject to 2D Fast Fourier transform (FFT), followed by plotting the log of the magnitude versus frequency component that was generated by the FFT. A regression line was fit to this plot, and the slope of this line was used to generate a fractal dimension (FD) for each of the ROIs. The higher the FD, the higher the morphological complexity at the ultra-structural level of bone. FD was assessed with the strength of bone with the previous literature so obtained.

Calibration
Both the examiners were made well versed with the ToothMeasure® software on the initial day, and the following measurement protocol was agreed upon:
1) allow the software to ignore teeth according to its "statistical filtering" protocol, 2) always ignore teeth immediately adjacent to the target tooth as well as the target tooth itself, and 3) instruct ToothMeasure® to superimpose the models according to the best fit of the remaining teeth. Eight superimpositions per subject was obtained from six randomly selected subjects to calculate the interexaminer reliability. Results were identical between Examiners 1 and 2, who later measured superimposed digital models for the treatment and control groups, respectively [6].

For the CBCT data, Examiner 1 re-measured the following variables on a different day to determine reproducibility: ΔU1 (s), rotation angle, tooth length, and crown length. The intraclass classification coefficient (ICC) of Flies [7, 8]. Was determined, using R software® [9]. To quantify the strength of relationship between the duplicate measurements. ICC values ranged from 0.90 to 0.99, which demonstrated excellent reliability.

Statistical management of data
The amount of A-P OTM of the target tooth from baseline to Week 8 was assessed for the 15 treatment subjects that completed the study. One subject dropped out after enrolment but prior to initiating OTM and thus had no data to analyse. A sample of 37 individuals was taken and model data from the treatment sample was compared with data from the control group. The null hypothesis of no difference in OTM from baseline to Week 8 between control group and treatment group was tested, using a two sample t-test with a level of significance set at 0.05. Mixed modelling analysis was used to test the difference between the first week of any given two-week interval vs. the second week, and differences with treatment group over the four two-week cycles. OTM was

quantified using descriptive statistics from CBCT data. Correlations between tooth movement and possible covariates were analysed using Pearson correlation coefficients

Table 1: Inclusion and exclusion criteria

|	Inclusion criteria		Exclusion criteria
1	Males or females between the ages of 18 and 40	1	Must not have active caries
2	Must have adult dentition with all upper front teeth present	2	Must not be a chronic user of NSAIDS or steroid medication
3	Must have at least one maxillary central incisor that has sufficient space between it and adjacent teeth to allow AP movement (crown tipping only) of 2 mm	3	Must not have smoked in the last six months
4	Must have normal pulp vitality, gingival attachment, papillary bleeding score index (PBS index), and pocket depth	4	Women must not be pregnant
5	Must be in good health as determined by medical history		
6	Must be willing and able to participate		
7	Must understand and sign a written informed consent form		

Table 2: Comparison of demographics of treatment and control groups

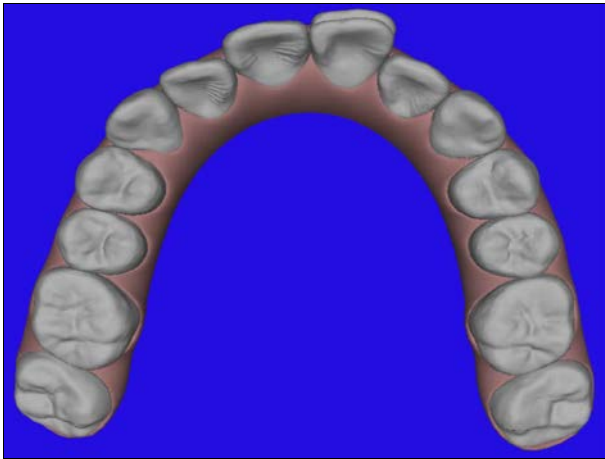|	Treatment			Control			
	N	Mean ± SD	Range	N	Mean ± SD	Range	p-value
Age (yr)	15	25.5 ± 4.8	20.5 - 34.9	37	26.7 ± 5.1	18.6 - 40.5	0.50*
Sex							
Male (%)	6(30)			11(30)			
Female (%)	9(60)			26(70)			0.52**

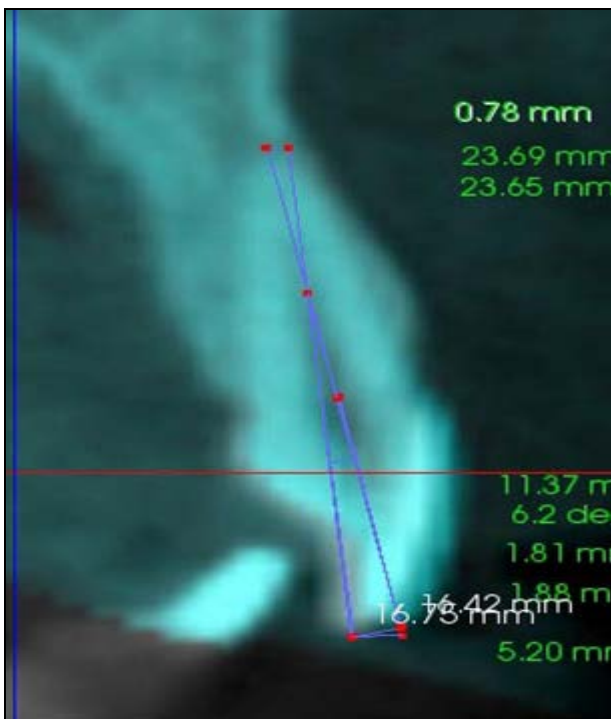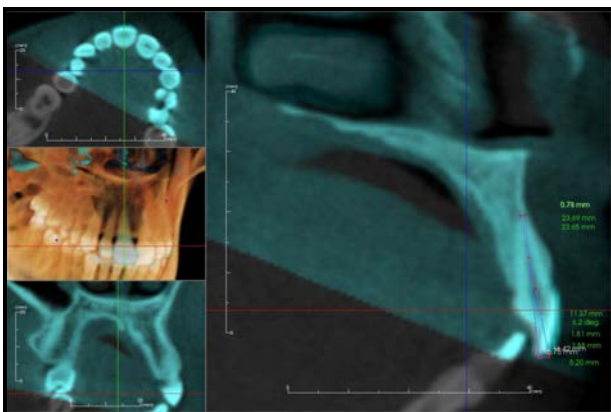* Wilcoxon rank sum test
** Fisher exact test

Table 3: Superimposed CBCT measurements. Blue is initial and red is final
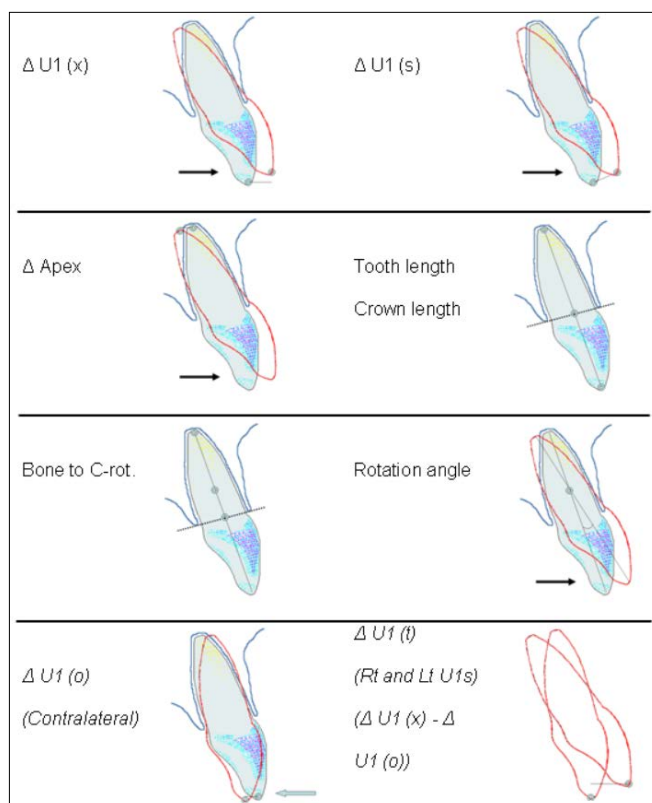
Fig 1: Superimposed digital models

Fig 2: Superimposed CBCT (A) and close-up of target tooth with measurements (B), Gray is initial and blue is final

Results

Results from model measurements are summarized in Table 4, and a comparison of mean values for the treatment and control groups is illustrated in Figure 3. No overall difference in OTM was detected between the groups, with mean total OTM of 1.11 mm (standard deviation (SD) 0.30) and 1.07 mm (SD 0.33) for the treatment and control groups,

respectively (p=0.72). Also, no difference was detected in weekly OTM of the treatment vs. control groups overall (Table 5) (p=0.812) or between any two-week prescription cycle (Table 6) (p's=0.176 and 0.297). However, as shown in Table 7, 4.4 times more OTM occurred during the first week than the second week of aligner wear (p<0.001) after combining the groups. Measurements from superimposed CBCT images confirmed that the target tooth experienced uncontrolled tipping (Table 8). The center of rotation, on average, was located a distance of 41% of the root length apical to the faciolingual crestal bone. The incisal edge of the target tooth moved more than the centroid of the clinical crown in all cases, with a mean of 1.56 mm for Δ U1 (x) compared with 1.1 mm measured from the centroid. Δ U1 (s) had a mean of 1.63 mm, compared with the mean Euclidian mean value of 1.11 mm measured from the centroid of the clinical crown on the models. The apex of the target tooth moved in the opposite direction with a mean of -0.73 mm. The contralateral central incisor experienced a loss of anchorage measured from the incisal edge, with a mean OTM of -0.28 mm. Mean FD determined from the CBCT of each treatment subject was 1.71 ± SD 0.20. Pearson Correlation Coefficient values between OTM and CBCT measurements are listed in Table 9.

Table 4: Weekly statistics from treatment and control groups, respectively

Tx Group	n	Median	Mean	Std Error	SD	Min	Max
Wk 0	15	0	0	0	0	0	0
Wk 1	15	0.240	0.239	0.0174	0.0674	0.100	0.370
Wk 2	15	0.310	0.297	0.0228	0.0883	0.130	0.450
Wk 3	15	0.430	0.458	0.0295	0.114	0.330	0.670
Wk 4	15	0.450	0.497	0.0418	0.162	0.230	0.770
Wk 5	15	0.620	0.701	0.0536	0.207	0.430	1.060
Wk 6	15	0.770	0.793	0.0534	0.207	0.530	1.130
Wk 7	15	1.040	1.033	0.0648	0.251	0.530	1.420
Wk 8	15	1.160	1.108	0.0768	0.297	0.350	1.460
Control	**n**	**Median**	**Mean**	**Std Error**	**SD**	**Min**	**Max**
Wk 0	37	0	0	0	0	0	0
Wk 1	36	0.210	0.206	0.0122	0.0735	0.0300	0.320
Wk 2	36	0.240	0.234	0.0122	0.0735	0.0500	0.390
Wk 3	37	0.440	0.445	0.0228	0.138	0.100	0.680
Wk 4	36	0.530	0.495	0.0255	0.153	0.0700	0.790
Wk 5	36	0.775	0.726	0.0380	0.228	0.120	1.100
Wk 6	36	0.830	0.737	0.0416	0.250	0.0700	1.100
Wk 7	37	1.080	1.009	0.0519	0.316	0.100	1.410
Wk 8	37	1.180	1.072	0.0536	0.326	0.220	1.550

Table 5: Mixed modelling comparing mean OTM per week from baseline to Week 8 for treatment vs. control group

Group	Mean ± SD	P value (t-test)
Treatment	0.14 ± 0.11	0.812
Control	0.14 ± 0.15	

Table 6: Mixed modelling comparing the mean magnitude of OTM per week expressed during each two-week prescription cycle

Group	Interval	Mean/Wk ± SD	P value
Treatment	Week 1-2	0.15 ± 0.11	0.176
	Week 3-4	0.10 ± 0.09	
	Week 5-6	0.15 ± 0.11	
	Week 7-8	0.16 ± 0.13	
Control	Week 1-2	0.12 ± 0.11	0.297
	Week 3-4	0.13 ± 0.13	
	Week 5-6	0.13 ± 0.17	
	Week 7-8	0.16 ± 0.19	

Table 7: Mixed modeling comparing OTM during the first week vs. second week for the treatment and control groups, both separately and combined

Group	Interval	Mean ± SD	P value
Treatment	1st week	0.21 ± 0.09	< 0.0001
	2nd week	0.07 ± 0.08	
Control	1st week	0.23 ± 0.13	< 0.0001
	2nd week	0.04 ± 0.11	
Total	1st week	0.22 ± 0.12	< 0.0001
	2nd week	0.05 ± 0.10	

Table 8: CBCT measurements from treatment group

Variable	n	Mean	SD	Max	Min
Δ U1 (x)	15	1.56	0.38	2.02	0.80
Δ U1 (s)	15	1.63	0.40	2.09	0.80
Δ Apex	15	-0.73	0.26	1.32	0.39
Tooth Length	15	24.87	2.02	30.32	21.67
Crown Length	15	12.27	0.74	13.27	10.84
Bone to C-rot.	15	5.14	1.25	7.7	2.9
Δ U1 (o)	15	-0.28	0.16	0.52	0
Δ U1 (t)	15	1.85	0.36	2.4	1.08

Table 9: Pearson correlation coefficient of week 8 OTM vs. biologic variables

Variable	N	R	P value
Age	15	-0.25	0.37
Crown/Root ratio	15	-0.01	0.97
Fractal Dimension	15	0.38	0.10

Table 10: Comparison of Model and CBCT mean A-P OTM

	n	Mean	Max	Min	SD
Model (x)	15	1.09	1.44	0.35	0.28
Δ U1 (x)	15	1.56	2.02	0.8	0.38
Δ U1 (t)	15	1.85	2.4	1.08	0.36
Ratio (x/x)	15	0.7	0.92	0.44	0.11
Ratio (x/t)	15	0.59	0.73	0.32	0.1

Discussion

This trial reinforced the previous literature assessments that the majority of OTM during any two week aligner prescription cycle occurred during the 1st week of the cycle. In this the selected target tooth did not undergo the usual cycle of tooth movement illustrated by Krishnan *et al.* [10]. This occurred because of the inability of the removable polyurethane aligner to deliver continuous force and also by the fact that the aligner took two weeks for activation. According to model data, there was an excess of 1mm in the aligner given in the eighth week as there was incomplete expression seen during the previous seven weeks. This likely resulted in the tooth feeling a greater force during the last week than after delivery of the first and second aligners, when the amount of activation was 0.5 mm or less. However, significantly less OTM occurred at Week 8 than Week 1, and there was no significant difference in the amount of OTM observed at Week 8 and Week 2. This indicated that the discrepancy in the amount of OTM achieved during the 1st and 2nd week of each prescription cycle cannot be explained by force magnitude. This is further supported by our finding that the use of fresh aligners did not increase the amount of OTM.

The study was designed in such a way that only bodily protraction of the target tooth would occur but uncontrolled tipping was also seen in certain cases which had other clinical implications. To be more precise, the last outcome would be different when assessed by Clincheck®, and aligner retention and tracking may be negatively affected. Moving the maxillary incisors in the A-P dimension with aligners, there was vertical changes of the incisal edges, which made the treatment more desired and reduced the midcourse modifications. The amount of relative intrusion and extrusion to program can be determined by estimating the location of the center of rotation of the teeth (determined to be approximately 41% of the root length apical to the faciolingual crestal bone).

The full prescription was not seen in any of the 52 subjects according to model data. In fact, the mean OTM for both groups was only 1.1 mm, or 55% of the prescription. It is important to remember that the prescribed amount of OTM was twice the maximum rate per aligner currently prescribed by Invisalign®. There were evidences that a larger portion of the prescription could be achieved if the maximum two-week activation was decreased to 0.25 mm instead of 0.5 mm.

The difference in the amount of OTM prescribed and that obtained from the study could be partially explained by the uncontrolled observed and the readings obtained in the study. The largest amount of OTM recorded from baseline to Week 8 from model data was 1.44mm, or 72% of the prescription. This same subject had 1.98 mm of OTM from baseline to Week 8 when measured from the incisal edge of the target tooth of superimposed CBCT images. See Table 10 comparing model and CBCT mean OTM values. Given this information, one would not expect 100% of the prescription at the centroid of the crown to be fulfilled since OTM at the incisal edge was already fully achieved [11].

One must also consider anchorage loss of the contralateral central incisor when interpreting this data. The prescribed protraction of the target tooth relative to the contralateral central incisor at Week 8 was 2 mm for each subject, and the difference between Δ U1 (o) and Δ U1 (x), or Δ U1 (t), indicates that a mean of 1.85 mm of this 2 mm distance was actually fulfilled, an average of 92.3% of the prescription. In addition, 8 of the 15 subjects showed a total OTM greater than 1.9mm, which indicates that OTM at the incisal edge of these subjects was nearly fully expressed.

A difference was seen in the programmed OTM and the observed OTM as per the model data. However, a vast discrepancy was seen in the selected patients, and in some cases the result predicted for the target tooth at the incisal edge was not achieved. Some factors that could influence the rate of OTM described by Krishnan *et al.*, [12] were not included in the study. Factors not in control of the examiner were gender of the subject, age, quality of the bone, length of the tooth and the point of center of resistance (determined by root length, root width, and bone height) [13, 14].

The result of the exploratory data analysis attempting to correlate several of these biologic variables with OTM was statistically insignificant with low powers of explanation. Some trends were noted, however, and future research with larger sample sizes will be necessary to explore these findings. There was considerable variability of OTM in this study, which is a problem that practicing orthodontists often

encounter [15].

Conclusion
Invisalign was used to study the OTM in one place. No significant difference was found in the amount of OTM between those who wore the same aligner for two weeks vs. those who changed to a fresh aligner after one week. Therefore, the above study concluded that the decrease in the amount of OTM observed during the 2nd week of wearing the aligner was not due to material fatigue. Factors that could have an impact on movement of the tooth such as age of the subject, sex, location of root and quality of bone were also assessed. However, number of persons selected in the study was very less due to which reaching on any conclusion was not possible. Further studies with a larger sample size could yield a proper result.

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