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Evaluation of Dental and Skeletal Changes with Sequential Distalization of Maxillary Molars Using Clear Aligners: A preliminary study

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EVALUATION OF DENTAL AND SKELETAL CHANGES WITH SEQUENTIAL DISTALIZATION OF MAXILLARY MOLARS USING CLEAR ALIGNERS: A PRELIMINARY STUDY

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ABSTRACT

EVALUATION OF DENTAL AND SKELETAL CHANGES WITH SEQUENTIAL DISTALIZATION OF MAXILLARY MOLARS USING CLEAR ALIGNERS: A PRELIMINARY STUDY

Minh Nguyen, D.D.S., M.S.

Introduction: Class II malocclusions in non-growing patients can be treated by orthognathic surgery or camouflaged with tooth movement. Fixed appliances such as the pendulum appliance or distal jets have been used to distalize maxillary molars to achieve a Class I molar relationships. Recently, removable clear aligners have been reported to achieve similar results with better oral hygiene. It is not clear in the literature whether these removable appliances can distalize maxillary molars dental tipping or translation. The objective of this study was to evaluate the dental and skeletal changes in three planes spaces using CBCT scans and compared the treatment changes with a control group of subjects with comparable Class II craniofacial morphology. **Methods:** A total of 8 patients (mean age = 16, SD = 5) with Class II division 1 malocclusions treated with maxillary molar distalization using clear aligners were recruited for the study. Four of these subjects had bilateral molar distalization. A total of 12 maxillary molars were evaluated for tooth movement in three planes of space using CBCT scans. These patients were compared with a control group of untreated subjects from the Bolton Brush study who were matched in craniofacial morphology, gender, and treatment length. The average treatment time for the treatment group was 24 months and the average time between the Bolton-Brush Growth Study. Sagittal and vertical changes were measured using the Pancherz analysis (Pancherz, 1982). Transverse changes were measured by intermolar widths of the maxillary and mandibular molars. Data were analyzed using paired t test. **Results:** Significant sagittal changes were found with the forward movement of the mandibular incisors (Ii/OLP, 3.4mm), forward movement of the mandibular molars (Mi/OLP 3.6mm), and the change in molar relationship (-2.3mm). When the treatment changes were compared to control subjects, significant differences were found with the mesial movement of the maxillary molars (Ms/OLP, 0.5mm vs. 5.0mm, $p<.0005$). The change in molar relationship was -2mm vs. 0.5mm, $p<.0004$. The treatment group showed a reduction in overjet of -2mm compared to the control group of 0mm, $p<.04$. No significant vertical changes were found except for the maxillary incisor extrusion. No significant changes were found with transverse changes. **Conclusions:** Significant dentoalveolar changes including restraint in the forward movement of the maxillary molars can be expected to with sequential molar distalization with clear aligners.

DEDICATION

I would like to dedicate this thesis to my family who have supported me on my extended academic career. It’s been a long road that will come to a promising end and I looking forward to moving onto the next chapter of my life.

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CHAPTER 1: INTRODUCTION

BACKGROUND

The most common alternative treatment method to bonding orthodontic braces is aligner treatment. There are several brands that manufacture aligner treatment: Align and Clear Correct. Other companies who are more known by their manufacturing of braces have entered the aligner market space such as Dentsply with SureSmile, 3M with Clarity, and Ormco with Spark Clear Aligner System. This aesthetic method of treatment is growing in demand by patients that's reformed the orthodontic industry. Initially aligners were used to treat class I mild crowding cases but over the past 20 years research and development of new materials, software, case reports, and providers attempting more complex cases allows aligner treatment to be a viable treatment option for several types of cases. Class II malocclusions is a very common malocclusion in North America. There are many methods to correcting such malocclusions such as extractions of bicuspids, advancement of the mandible, and dentoalveolar correction with elastics or forsus. A complex movement but conservative treatment option is distalization of maxillary molars specifically sequential distalization with aligners which involves moving posterior teeth one at a time distally to correct a class II malocclusion into class I, reduce overjet, or eliminate crowding. Challenges with distalization include loss of anchorage leading to forward movement of anterior dentition, shifting of maxillary midline with unilateral distalization, and predictability of tracking with aligners.

STATEMENT OF THE PROBLEM

An orthodontist today cannot sustain a successful practice without having incorporation of aligner treatment technique as a comprehensive orthodontic treatment modality. This study observes dental and skeletal changes with CBCT. The primary benefit of using CBCT scan instead of a 2D lateral cephalometric for measurements is the ability to extract a scan to isolate the left and right maxillary molars and measure transverse changes. The benefit if isolating left and right molars is some subjects were prescribed unilateral sequential distalization. Although distalization is a complex movement not often prescribed, this study explores the movement of maxillary molar distalization to observe:

1. Skeletal and dental changes with sequential molar distalization in all three planes of space
2. Anchorage loss using lower aligner and class II elastics as anchorage
3. Class I correction was due to treatment, growth of patients, or a combination of both.

<u>SIGNIFICANCE OF THE PROBLEM</u>

The objective of this study was to evaluate the dental and skeletal changes in three planes spaces using CBCT scans and compared the treatment changes with a control group of subjects with comparable Class II craniofacial morphology.

Null Hypothesis

1. There is no significant differences in the sagittal dental and skeletal changes after treatment with clear aligners.
2. There is no significant differences in the vertical dental and skeletal changes after treatment with clear aligners.
3. There is no significant differences in the transverse dental changes after treatment with clear aligners.

ASSUMPTIONS

1. The variability in Clincheck prescription was kept to a minimum with only one provider for the entire sample.
2. The number of aligners prescribed were not significantly different between treated patients

LIMITATIONS

1. The subjects were recruited over a period from 2006 to 2019 was limited
2. The attachments prescribed by the provider were not the same from patient to patient.
3. The length of treatment time in patients varied.
4. The number of refinements prescribed by the provider.
5. Advancement and changing in plastic materials by Invisalign.
6. The treated subjects have CBCT records vs the untreated control group were 2D lateral cephalograms.
7. CBCT records of subjects allow for evaluation of left and right molars individually where as 2D lateral cephalogram is more difficult to locate molars.

DELIMITATIONS

1. All cephalometic measurements were done by one investigator
2. All cephalometric images extracted from CBCT were done by one investigator
3. All patients included in this study were treated by one provider.

CHAPTER 2: REVIEW OF THE LITERATURE

CLASS II MOLAR DISTALIZATION

A common method to correct Class II malocclusions by a non-extraction protocol is to move the maxillary molars distally to correct the Class II molar relationship to a Class I.[1] One method in conjunction with braces was using a nance appliance with bands on first premolars and distalizing with superelastic NiTi coils. This study found indicates that first molar crowns are moved distally at the rate of approximately 1mm/month. Two key factors need to be taken into consideration when performing molar distalization include: 1) anchorage loss when retracting premolars, canines, and incisors; and 2) molars that are moved distally will cause the crown to tip more posteriorly than the root.

Anchorage is a prime factor when it comes any translational movements in orthodontics meaning after distalizing molars during retraction of anterior teeth, the first molars may move anteriorly in a reciprocating fashion taking up the space needed to retract anterior teeth. Future studies led to the ability to maintain anchorage with skeletal support and not just dental support. The study by Duran et al, 2016 evaluated molar distalization with a palatal miniscrew supported fixed appliances and assessed pre and post treatment casts.[2] The study consisted of 21 patients with bilateral class II molar relationships; digital casts were acquired before and after treatment and evaluated. The study found in the sagittal direction the first molars showed a mean movement 4.1 mm with distal tipping of 11.02 degrees, the central incisors distal movement was 0.95mm. The study concluded that with support from anterior palatal region the maxillary molars were distalized without anchorage loss.

Although the Duran et al 2016 study was able to distalize molars without anchorage loss, the treatment requires a relatively invasive treatment and large appliance on the palate. This may lead to decrease acceptance of treatment or compromised treatment. This study evaluated patients based on the superimposition of dental casts, not lateral head films, and not 3-Dimensional CBCT imaging.

Various types of molar distalization appliances are available to correct dental class II malocclusion, such as distal jet and the pendulum appliance.[3] The Carriere Motion or Carriere Distalizer is marketed as a class II corrector that rotates and upright maxillary first molars while distalizing the posterior segment a unit.[4] This previous study evaluated the comparison of Carriere Distalizer to class II intermaxillary elastics and Forsus. The research revealed the time of class II correction for Carriere motion was significantly shorter than class II elastics and no difference when compared to Forsus. The amount of class II correction was significantly lower when compared to Forsus appliance. No significant skeletal correction was induced by Carriere motion in growing patients.

CLEAR ALIGNER TECHNIQUE

Orthodontists used thermoplastic removable appliances to correct minor tooth movements as early as 1945.[5] The objective of the tooth positioning appliance was to influence the movement of all teeth to move to best position with relation to one another without any interference from bands or wires. Comprehensive treatment was impractical due to multiple impressions and laboratory time required to fabricate each aligner. Orthodontic laboratories would use the initial cast model and change the tooth movements by removing stone or adding wax to the cast to influence the predicted tooth movement. Followed by fabrication of a thermoplastic appliance modeled after the each stage of tooth movement. The Invisalign appliance was introduced by Align Technology in the late 1990s as a means to straighten teeth without braces. Stanford student Zia Chishti and his partners learned how to simulate a solid object with computer-aided design model and then digitally recreate that object with 3-dimensional printing technology. The ability to with this technology and sequential staging of tooth movements was capable of generating orthodontic forces. The marketing of major aligner companies to the public has increased its demand for clear aligner treatment leading to this treatment modality as an essential part to an orthodontic practice today.

Initially, clear aligners were used to treat mild to moderate crowding. Recently, aligners are used for complex cases such as treatments involving extractions, open bite, and class II malocclusion.[6] The study presents two case reports; it compared the treatment of unilateral class II malocclusion with Invisalign and elastics compared with bilateral Carriere distalizer followed by aligner appliances. The study found that the combination of distalizer pretreatment (carriere) with clear aligner therapy reduced treatment time. Case 2 spent four months distalizing and 10 months treatment with clear aligners. The study shows that it is capable of correct class II movements. Questions that need to be answered when treating with clear aligners is if the treatment time just as efficient as fixed appliances, and is 3D computer rendering ClinCheck predictable.

The study by Simon et al. 2014 was to investigate three predefined movements with aligners.[7] The study retrospectively assessed 30 patients between 2011 and 2012. The study also was assessing influence of auxiliaries such as attachments, and power ridges. Pre-treatment and final plaster models were scanned, segmented into single teeth, super imposed with the ending ClinCheck to determine predicted tooth movement. The study assessed 60 tooth movements and found the overall efficacy was 59.3%. The highest accuracy was molar distalization, while lowest was premolar derotation. The study concluded that all three movements can be accomplished with Invisalign. The study did not present any cephalometric records which is an additional method of evaluating post treatment records when superimposing pre and post records of treatment. This method of evaluation will observe changes in reference to skeletal landmarks.

The study by Ravera et al. 2016 evaluated distalization with class II elastics with aligners in adult patients.[8] The study assessed 20 subjects with pre and post lateral cephalograms. The study evaluated patients who underwent bilateral distalization of maxillary dentition. The study found the first molar distalized 2.25 mm without significant tipping and the second molar distalized 2.52 mm without significant tipping. The study concluded that clear aligner therapy with composite attachments and class II elastics can distalize maxillary molars.

An additional study evaluated the accuracy of specific tooth movements with Invisalign. Charalampakis et al, 2018 evaluated 20 Class I adult patients treatment with clear aligners and had a "refinement" series of aligners.[10] The predicted model from the initial ClinCheck was superimposed with the start point of the refinement ClinCheck at the posterior teeth. The study found that the horizontal movements were accurate with insignificant differences, vertical movements specifically intrusion were less accurate. The study concluded that the most inaccurate movements of identified movements in the study were intrusion of incisors and rotation of canines. This study was basing their assessments on the clincheck and could superimpose because they were all Class I molars. This method would not work for complex tooth movements.

CHAPTER 3: METHODS AND MATERIALS

TREATMENT SAMPLES

EXPERIMENTAL GROUP

Subjects in the experimental group consisted of patients treated by one of the investigators (T.S.) between 2006 and 2019. The inclusion criteria included patients with a class II division 1 malocclusion (half-step and full-step) who were treated with clear aligners, sequential distalization was observed in the Clincheck unilaterally or bilaterally correcting into class I occlusion, no history of previous orthodontic treatment, no pre-treatment transverse discrepancy, and complete pre- and post-treatment CBCT. Exclusion criteria included distalization of segments of posterior teeth instead of sequentially and extraction treatment plans. A total of 1300 patients together with their Clinchecks were evaluated. Eleven subjects (4 males, 7 females) were prescribed sequential distalization. One patient was full step bilateral, three were full step unilateral, four were bilateral end-on, three were unilateral end-on class II. Upon acquisition of records, three subjects did not have complete pre and post CBCT records due to practice transition during patient treatment from 2D lateral cephalogram to CBCT. A total of 8 subjects had complete pre and post treatment CBCT records. A total of 12 maxillary molars can be isolated as the treatment group. The provider had elastics prescribed as anchorage on all subjects.

CBCT SCANS

Left and right halves of subjects were isolated and 2-Dimensional Lateral Cephalograms were extracted from pre and post treatment CBCTs with Dolphin Imaging Systems. Coronal sections were evaluated of maxillary and mandibular first molars for transverse changes.

CONTROL GROUP

Treated patients were matched to untreated patients in the Bolton Brush Growth Study database based on initial malocclusion, gender, craniofacial morphology, time of treatment initiated and time at treatment completion. The control group consisted of cephalometric radiographs of 12 subjects with no history of orthodontic treatment from the Bolton-Brush Study.

CEPHALOMETRIC ANALYSIS

SAGITTAL AND VERTICAL MEASUREMENTS

CBCT full head scans were oriented in a natural upright position. The 3-Dimensional scans were isolated into left and right halves at the midline, sella, and anterior cranial base. Left and right lateral cephalograms halves were extracted from CBCT. Sagittal and vertical measurements were made using the cephalometric systems described by Pancherz.[10] Registration of the lateral cephalograms was performed on a 0.003-in matte cephalometric acetate tracing film. The measurement for each variable was made with cephalometric protractor and ruler. Sagittal and vertical measurements were evaluated to the nearest 0.1mm. Analysis of the sagittal, skeletal, and dental changes were recorded along the occlusal plane (OLs), palatal plane (NL), mandibular plane (ML), and to the occlusal plane perpendicular from the first cephalogram; this formed a reference grid. The grid was transferred into subsequent cephalograms by superimposing the tracings on midsagittal cranial structures. A sample of cephalometric landmarks and constructions are seen in Figure 1.[11]

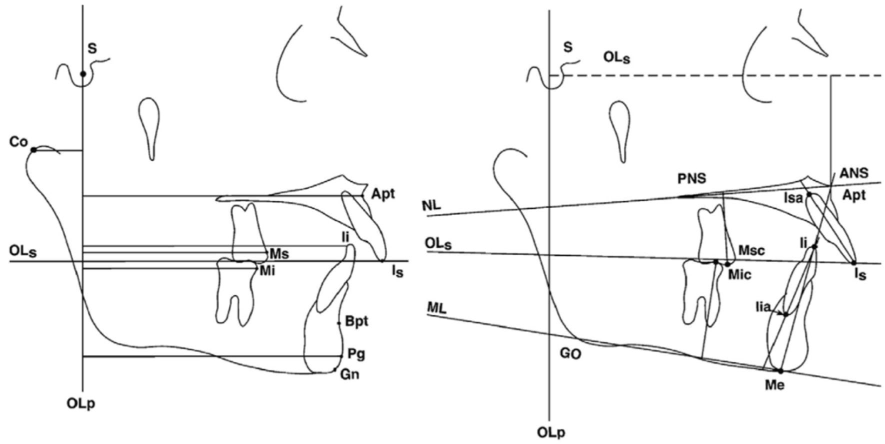

Figure 1. The reference grid OLp and OLs is for sagittal changes. The reference grid lines NL and ML is for vertical changes.[11]

TRANSVERSE MEASUREMENTS

CBCTs were oriented in the natural upright postion. The maxillary first molar was isolated in the sagittal plane, lingual cusp was iolsated in the vertical plane. Coronal slices in the CBCT from the treatment group were taken at T1 and T2. The transverse changes were measured at the width between palatal cusp tip of maxillary first molars and width between the central fossae of mandibular first molars.[12]

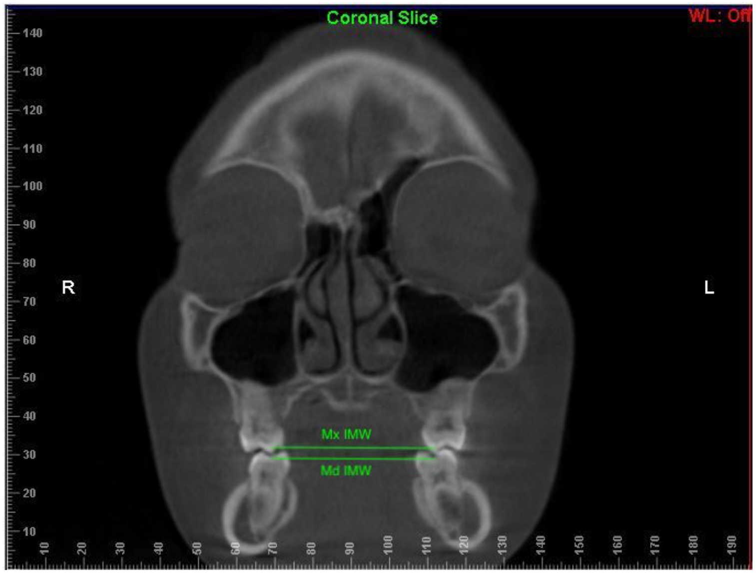

Figure 2. Coronal Slice of CBCT. Transverse measurements of maxillary inter molar width (Mx IMW) and mandibular inter molar width (Md IMW)

INTRA-RATER RELIABILITY OF MEASUREMENTS

A total of 13 subjects were measured by the same researcher a second time with two week interval in between to determine the intra-rater reliability of measurements for T1 and T2.

DATA ANALYSIS

All statistical tests in this study were conducted using SAS (version 9.4, 2013, SAS Institute Inc. Cary, NC). We used paired t test or Wilcoxon signed rank test to exam the sagittal and vertical changes between T1 and T2. The difference in starting morphology and sagittal and vertical changes between treatment and control groups were compared with Mann Whitney U test. Intra-class correlation coefficient was calculated to exam the reliability of the measurements. All tests were two sided, p-value of less than 0.05 was considered statistical significance.

CHAPTER 4: RESULTS

CRANIOFACIAL MORPHOLOGY

The starting craniofacial morphology of treatment and controls subjects is shown in Table 1. The only significant difference was found in the measurement ANS-Me between treatment and control subjects.

Variables	Treatment		Control		Z	p-value
	Median	95% CL	Median	95% CL		
SNA angle (º)	80.5	77.6-82.8	81.3	80.1 – 83.3	0.81	.43
SNB angle (º)	77.7	75.6 – 79.7	76.4	74.3 - 80.7	0.06	.97
ANB angle (º)	3.2	1.6 – 4.7	3.5	2.9 – 5.8	1.50	.14
PP angle (º)	0	-0.7 – 3.9	0.5	-0.1 – 4.4	0.41	.70
MP angle (º)	32.8	24.5 – 35.6	30.1	29.0 – 32.1	-0.99	.34
ANS-Me (mm)	66.5	62.3 – 68.7	63.1	53.2 – 64.6	-2.08	.04*
OP angle (º)	17.0	16.4 – 20.8	18.9	18.1 – 19.5	1.39	.17
U1/SN angle (º)	104.9	97.0 – 111.7	107.4	97.0 – 110.2	0.35	.74
L1/MP angle (º)	96.1	90.8 – 101.3	91.1	87.5 – 109.2	0.17	.88
U1/L1 angle (º)	128.6	117.1 – 141.3	127.2	111.3 – 145.5	-0.17	.88
Wits (mm)	1.3	-0.3 – 5.1	3.4	2.6 – 4.4	1.56	.12

Z= Z value from Mann Whitney U test, *p<.05, **p<.01, ***p<.001

Table 1. Comparison of starting craniofacial morphology of treatment and control subjects

TREATMENT CHANGES

SAGITTAL CHANGES

Dental and skeletal changes of subjects in the treatment group post treatment (T2) V. pretreatment (T1) are compared in the sagittal dimension in Table 2. The paired t tested indicated the treatment and growth group showed a forward movement of the mandibular incisal edge position (li/Olp, 3.4mm, p-value 0.0005), forward movement of mandibular molars (Mi/Olp, 3.6mm, p-value 0.003), and molar relationship change (-2.3mm, p-value 0.0004). There are no significant changes in the sagittal dimension in all other variables between T1 and T2.

VERTICAL CHANGES

Changes in subjects in the treatment group post treatment (T2) V. pretreatment (T1) are compared in the vertical dimension in Table 1. The paired t test indicated the treatment showed downward movement of maxillary incisal edge position (2.8mm, p-value 0.02). There are no significant changes in the vertical dimension in all other variables between T1 and T2.

Variables	**T1**		**T2**		**T2-T1**			
	Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**	**t**	**p-value+**
Sagittal (mm)								
OLp-A Pt	79.7	5.3	81.3	6.1	1.6	4.0	1.37	.20
Olp-Pg	83.1	5.8	85.2	7.6	2.0	5.9	1.17	.27
Olp-Co	12.8	5.0	13.5	4.2	0.8	1.8	1.43	.18
Co-A pt	92.3	5.6	94.5	5.0	2.2	3.6	2.06	.06
Co-Gn	93.7	6.2	96.3	8.8	2.7	6.5	1.42	.18
Co-Gn minus Co-Apt	1.3	4.0	1.8	6.7	0.5	5.6	0.31	.76
li/Olp	81.7	6.2	85.2	6.7	3.5	3.4	3.54	.005**
Ms/Olp	57.8	5.9	59.4	5.8	1.7	3.5	1.65	.13
Mi/Olp	56.9	6.3	60.8	6.3	3.9	3.6	3.73	.003**
Molar Rel	0.8	1.8	-1.4	1.4	-2.3	1.5	-5.05	.0004***
Vertical (mm)								
Ols-A pt	35.5	4.8	36.3	4.7	0.8	2.2	1.33	.21
ANS-Me	65.9	7.8	66.1	5.4	0.2	3.5	0.16	.87
ls-NL	28.6	3.9	31.3	2.7	2.8	3.4	2.83	.02*
li-ML	41.1	5.6	41.6	6.4	0.5	5.9	0.30	.77
Overbite	3.1	1.7	2.3	1.2	-0.8	1.5	-1.75	.11
Mic-ML	31.8	4.3	30.8	5.9	-1.0	2.7	-1.27	.23
Variables	**Median**	**IQR**	**Median**	**IQR**	**Median**	**IQR**	**S**	**p-value#**
Sagittal (mm)								
Wits	0	-1.5-1.0	-1.0	-2.0-0.5	0	-1.5-0	-6.5	.22
ls/OL-P	86.0	82.5-87.5	86.5	84.0-91.0	1.5	-1.0-3.5	17.5	.12
Overjet	4.0	3.0-5.5	3.0	2.0-4.0	-2.0	-3.0-0.5	-14.5	.17
Vertical (mm)								
Msc-NL	21.5	19.5-23.5	23.0	21.5-24.5	1.0	0-4.0	14	.06

SD=standard deviation, IQR=inter quantile range, t=t value, S=S value, +p-value for paired t test, #p-value for Wilcoxon signed rank test. *p<.05, **p<.01, ***p<.001

Table 2. Sagittal and vertical changes between T1 and T2 for treatment subjects.

CONTROL CHANGES

SAGITTAL CHANGES

Changes in the untreated control group T2 vs T1 are compared in the sagittal dimension in Table 2. The Wilcoxon signed rank test showed there was a significant difference in the forward movement of A point (Olp-Apt, 4.8mm, p-value 0.005), forward movement of pogonion (Olp-Pg 6.9mm, p-value 0.0006), condylar lengthen (Co-Apt, 4.4mm, p-value 0.04), forward movement of maxillary incisal edge (ls/OLp, 4.9mm, p-value 0.004), forward movement of mandibular incisal edge (li/Olp, 5mm, p-value 0.004), forward movement of mandibular molars (Mi/Olp 5.3mm, p-value 0.0001), forward movement of maxillary molars (Ms/Olp, 5mm, p-value 0.0005), forward movement of gonion (Co-Gn and Co-Gn minus Co-Apt, 3mm and 0.5mm, p-value 0.01 and 0.03). There are no significant changes in all other variables between T1 and T2 control.

VERTICAL CHANGES

Changes in subjects in the control group T2 V. T1 are compared in the vertical dimension in Table 2. There were no significant changes in variables between T1 and T2

Variables	T1		T2		T2-T1			
	Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**	**t**	**p-value**$^{+}$
Sagittal (mm)								
OLp-A Pt	71.3	3.9	76.1	5.0	4.8	4.6	3.55	.005**
Olp-Pg	74.2	5.0	81.1	8.6	6.9	7.0	3.41	.006**
Olp-Co	11.8	2.1	11.6	3.1	-0.2	3.1	-0.18	.86
Co-A pt	83.3	5.3	87.7	5.1	4.4	6.4	2.37	.04*
Wits	1.9	2.1	0.9	2.9	-1.0	3.30	-1.05	.32
ls/OL-P	76.8	2.7	81.7	5.6	4.9	4.7	3.59	.004**
li/Olp	72.4	3.9	77.4	6.5	5.0	4.7	3.68	.004**
Mi/Olp	50.8	4.4	56.1	5.6	5.3	2.5	7.20	<.0001***
Molar Rel	0.3	1.0	1.0	2.1	0.8	2.0	1.33	.21

Vertical (mm)								
Ols-A pt	34.2	6.3	35.8	4.6	1.6	4.0	1.36	.20
ANS-Me	59.9	4.4	62.4	5.0	2.5	6.4	1.35	.20

Variables	**Median**	**IQR**	**Median**	**IQR**	**Median**	**IQR**	**S**	**p-value#**
Sagittal (mm)								
Co-Gn	85.0	79.5-88.5	91.0	88.0-97.5	3.0	0-12.5	23.5	.01*
Co-Gn minus Co-Apt	1.0	1.0-3.0	2.5	1.0-5.5	0.5	0-4.0	10.5	.03*
Overjet	3.0	2.0-3.0	3.0	3.0-5.0	0	0-1.0	5.00	.13
Ms/Olp	52.0	47.0-56.0	57.1	56.0-61.0	5.0	4.0-8.0	39	.0005**
Vertical (mm)								
Is-NL	26.0	25.0-27.0	26.0	24.5-30.5	0	-2.5-4.5	2.5	.81
Ii-ML	39.0	36.5-39.0	39.0	35.5-43.0	1.50	-2.0-4.0	14	.27
Overbite	3.0	2.0-4.5	4.0	3.0-4.0	1.0	-1.5-1.0	1.00	1.0
Msc-NL	21.0	19.0-22.0	21.5	19.0-23.5	2.0	-2.0-3.5	19	.13
Mic-ML	29.0	27.0-30.5	32.0	28.5-32.0	3.0	-2.0-5.0	21	.10

SD=standard deviation, IQR=inter quantile range, +p-value for paired t test, #p-value for Wilcoxon signed rank test. *p<.05, **p<.01, ***p<.001

Table 3. Sagittal and Vertical changes between T1 and T2 for control subjects.

TREATMENT VS. CONTROL CHANGES

SAGITTAL

Changes in the differences in the subjects in the treatment and control groups from T2-T1 are compared in Table 3. The result of Mann Whitney U test showed the treatment induced a restriction of the forward movement of maxillary molars (Ms/Olp), treated group was 0.5mm, compared to the control group of 5.0mm with a p-value of 0.002. The treatment group showed a molar relationship difference of -2.0mm in compared to the control group of 0.5mm with a p-value of 0.0004. The treatment showed a reduction in overjet of -2.0 mm when compared to the control group of 0mm, with a p-value of 0.04

VERTICAL CHANGES

Changes in the subjects in the treatment group and the control group are compared in Table 3. There were no significant differences in changes between T1 and T2 between the treatment and control subjects in the sagittal and vertical dimension.

Variables	Treatment Median	95% CL	Control Median	95% CL	Z	p-value
Sagittal (mm)						
OLp-A Pt	1.5	-1.0 - 5.0	5.0	-2.0 – 9.0	1.84	.07
Olp-Pg	0.5	-3.0 – 5.0	5.0	1.0 - 14.0	1.77	.08
Olp-Co	1.5	0 – 2.0	-1.0	-1.0 – 1.0	-1.26	.22
Co-A pt	2.0	-1.0 – 5.0	3.0	-1.0 – 10.0	0.67	.52
Co-Gn	1.0	-3.0 – 7.0	3.0	0 – 14.0	1.33	.19
Co-Gn minus Co-Apt	-1.0	-2.0 – 6.0	0.5	0 – 4.0	1.23	.23
Wits	0	-2.0 - 0	-1.0	-3.0 – 1.0	-0.53	.61
ls/OL-P	1.5	-1.0 – 5.0	5.0	0 – 10.0	1.25	.22
li/Olp	3.0	0 – 6.0	5.0	0 – 11.0	0.67	.52
Overjet	-2.0	-3.0 – 1.0	0	0 – 1.0	2.05	.04*
Ms/Olp	0.5	-1.0 – 3.0	5.0	4.0 – 9.0	3.05	.002**
Mi/Olp	3.5	0 – 6.0	5.0	3.0 – 8.0	1.13	.27
Molar Rel	-2.0	-3.0 – -1.0	0.5	-1.0 – 2.0	3.39	.0004***
Vertical (mm)						
Ols-A pt	0.5	0 – 2.0	2.0	0 – 3.0	0.86	.41
ANS-Me	-0.5	-2.0 – 4.0	2.0	-5.0 – 8.0	1.19	.25
ls-NL	2.5	0 – 5.0	0	-3.0 – 8.0	-1.27	.21
li-ML	0	-5.0 – 4.0	1.5	-2.0 – 4.0	0.41	.70
Overbite	-1.0	-2.0 - 0	1.0	-2.0 – 1.0	1.24	.24
Msc-NL	1.0	0 – 5.0	2.0	-2.0 – 4.0	-0.38	.72
Mic-ML	-1.5	-3.0 - 0	3.0	-3.0 – 6.0	1.55	.13

Z= Z value from Mann Whitney U test, *p<.05, **p<.01, ***p<.001

Table 4. Sagittal and vertical changes between T1 and T2 between the treatment and control subjects

TRANSVERSE CHANGES

Intermolar width of maxillary molars and mandibular molars of the treatment group between T1 and T2 was compared in Table 5. The study found there was a significant difference in mandibular intermolar width between T1 and T2 with a median increase of 1.5mm, p-value 0.0008. No significant difference was found in maxillary intermolar width of treated subjects.

Variables	T1		T2		T2-T1			
	Median	**IQR**	**Median**	**IQR**	**Median**	**IQR**	**S**	**p-value#**
Transverse (mm)								
Upper intermolar width	40.0	39.5-41.0	41.5	39.5-43.5	1.0	0-2.5	7.5	.06
Lower intermoloar width	40.0	38.5-41.5	42.0	40.0-43.5	1.5	1.0-3.0	18	0.008**

IQR= IQR=inter quantile range, S=S value, #p-value for Wilcoxon signed rank test. *p<.05, **p<.01, ***p<.001

Table 5. Transverse change from T1 to T2 for treatment subjects (n=8).

INTRA-RATER RELIABILITY OF MEASUREMENTS

13 subjects were measured by the same researcher a second time with two week interval in between. Intra-class correlation coefficients of all measurements except two, li-ML at T1 (0.585) and Ols-A pt (0.719), were higher than 0.80, indicating a high level of agreements between the two measurements (Table 6).

Variables (T1)	**ICC**	**Variables (T2)**	**ICC**
Sagittal (mm)		**Sagittal (mm)**	
OLp-A Pt	0.941	OLp-A Pt	0.921
Olp-Pg	0.981	Olp-Pg	0.915
Olp-Co	0.978	Olp-Co	0.970
Co-A pt	0.974	Co-A pt	0.949
Co-Gn	0.935	Co-Gn	0.985
Co-Gn minus Co-Apt	0.971	Co-Gn minus Co-Apt	0.893
Wits	0.848	Wits	0.955
ls/OL-P	0.985	ls/OL-P	0.970
li/Olp	0.989	li/Olp	0.944
Overjet	0.960	Overjet	0.851

Ms/Olp	0.993	Ms/Olp	0.963
Mi/Olp	0.988	Mi/Olp	0.971
Molar Rel	0.935	Molar Rel	0.834
Vertical (mm)		**Vertical (mm)**	
Ols-A pt	0.877	Ols-A pt	0.719
ANS-Me	0.934	ANS-Me	0.899
ls-NL	0.849	ls-NL	0.907
li-ML	0.585	li-ML	0.977
Overbite	0.931	Overbite	0.952
Msc-NL	0.959	Msc-NL	0.936
Mic-ML	0.962	Mic-ML	0.970

ICC=Intra-class Correlation Coefficient

Table 6. Reliability of measurement

CHAPTER 5: DISUCCSION AND CONCLUSION

DISCUSSION

Orthodontists have used aligners to correct minor tooth movements as early as 1945; however, comprehensive treatment was impractical due to the number of impressions and laboratory time required to fabricate each aligner.[13] Clear aligners are currently more feasible for comprehensive treatment with the rise of 3D printing technology and software that is capable to recreate staging of tooth movements. This retrospective study was performed with 8 untreated and 8 patients with dental class II malocclusions treated with sequential distalization of maxillary molars with aligner treatment. The average treatment time was 24 months. All patients were treated by one provider. Treated patients were prescribed class II elastics as anchorage therefore, loss of anchorage could not be evaluated. Maxillary molars of treated patients were evaluated for dental and skeletal changes in all three planes of space.

SAGITTAL CHANGES WITH TREATMENT

In the sagittal dimension, this study revealed that treated patients with sequential distalization had a net median maxillary molar movement mesially of 0.5mm. When compared to the control group of 5.0mm mesially, the treated patients had restriction of maxillary molars. The patient's all started with a positive molar relationship, class II malocclusion, and finished with a negative molar relationship, class I molars or end-on occlusion. The median change in treated patient's molar relationship was -2.0 mm compared to the control group of 0.5mm and creating a net change of -1.5mm molar relationship change. The molar changes in treated patients was mostly due to the forward movement of the mandibular dentition with a mandibular median mesial movement of 3.5mm. This study contrasts with net molar distalization amount of 1.7mm with a Herbst appliance as reported by Vanlaecken et al 2006.[11] This current study had similar unpredictable results comparable to the reports of Patterson et al.[13] The study found that in class II malocclusion patients treated with Invisalign and class II elastics had an AP correction that was 6.8% of the predicted amount. The report found that Invisalign system was successfully achieved certain tooth movements but failed to show any significant class II correction. Rossini et al showed an AP movement maxillary molar distalization of 1.5mm with 88% accuracy.[14] These findings and this study cannot be directly compared because the previous study used lateral cephalograms which may induce measurement errors because of superimposition of contralateral molars. In addition, this study was able to isolate left and right molars from the CBCT records by extracting a 2D cephalogram which won't have any contralateral molar tracing errors. Treated patients with aligners showed a net overjet correction of 2mm whereas patients without treatment showed 0mm of overjet correction. This study is comparable to Carriere motion class II corrector study that resulted in a mean overjet reduction of 2.1mm with class II elastics from pretreatment to post removal of Carriere motion appliance.[15] The previous study also found that the correction was overjet correction had an increase in lower incisor proclination of 4.2 degrees.

Conventional appliances for distalization include distal jet and pendulum. The study by Chiu et al., compared the result of distal jet versus pendulum and the results showed comparable findings similar to this study.[3] The study sampled a growing patient pool and observed the skeletal dental effects at three times points, pretreatment (T1), post distalization (T2), and post treatment (T3). Lateral cephalograms were traced, superimposed, and analyzed. The study found that during distalization phase the maxillary molars distalized with both appliances. At the end of comprehensive treatment, the study found that the molars ended 0.6mm mesial to their original position with distal jet and 0.5mm distal in the pendulum. Similar to this aligner study which showed mesial movement of 0.5mm of maxillary molars. The total molar correction was 3.0mm in both groups meaning most of the class II correction was due to the forward movement of mandibular dentition; which is very comparable to this study and found a 3.5mm mesial movement of mandibular dentition. Both distal jet and pendulum appliances lost anchorage and produced significant maxillary and mandibular incisor flaring. This study observes the effects of sequential distalization as a class II correction with Invisalign. Biomechanically, as a posterior force is placed on the molars during distalization, an equal and opposite force is placed on the anterior teeth. These forces result in an increased overjet if class II elastics are not prescribed.[13] In the Chiu et al. study, observed the amount of true bodily movement vs tipping.[3] The study revealed the amount of distal tipping relative to Frankfort horizontal was 5 degrees in the distal jet group and 10.7 degrees in the pendulum group. This resulted in molar tipping of 1.8 degrees per millimeter in both groups. Despite initial claims of the distal jet producing better bodily movement because the distalizing force is directed close to the level of maxillary molar center of resistance, this study resulted in molar tipping. This study with aligners cannot be directly compared with Chiu et al. because the cephalometric analysis was not superimposed on cephalometric landmarks as well as the previous study analyzed hand-tracing of lateral cephalograms introducing increased error of tracing the contralateral molar.

VERTICAL CHANGES WITH TREATMENT

In the vertical dimension, no significant differences were found between the treatment group and the control group except for the downward movement of maxillary incisal edge position. The goal of this study was focused on movement of maxillary molars but no overcorrections of overbite were observed in the clinchecks of the treated patients. The study by Patterson et al. revealed that overbite corrections were predicted 38.9% of the time in class II malocclusion patients. Another study by Haouli et al., provided an update on the accuracy of tooth movement with Invisalign.[16] The study superimposed initial and final Clincheck models to determine predicted values were compared to achieved values by superimpose the initial Clincheck models with digital models post treatment. That study found that any predicted vertical intrusion of mandibular incisors was only 35% and relatively low. Despite continued advances in research and development with Invisalign, the strengths and weaknesses of tooth movement with Invisalign remained relatively the same with their first study in 2009.

TRANSVERSE CHANGES WITH TREATMENT

Expansion was not prescribed as part of the protocol for sequential distalization in the treatment subject. The control group was composed of lateral cephalograms and transverse could not be measured. The study found a that a significant difference in mandibular intermolar width of 1.5mm. This is likely due to an increased curve of Wilson in the mandibular dentition as compensation for a typically narrower maxillary dentition. The study by Uysal et al. found that in Class II division 1 malocclusion untreated subjects, the maxillary intermolar width was significantly narrower than Class I normal occlusion subjects.[17] It is likely there when Invisalign is used to expand the arch perimeter; it is mostly dentoalveolar changes and not skeletal as observed when a rapid palatal expander creates a diastema. Clear aligners is often used in adults who are not candidates for traditional expanders so buccal lingual tipping will be observed during transverse corrections. The study by Haouli et al observed a variety of predicted tooth movements compared to achieved tooth movements with invsialign. The study found that the highest overall accuracy was achieved with buccal-lingual crown tip of 56%.[16]

FUTURE RESEARCH

The primary limitation with this study was the limited number of treated subjects. Distalization movement is not a common movement; in addition, limiting the number of subjects to those treated with Invisalign. Access to a serial growth study with CBCTs of untreated patients will likely never be in existence in the future. The Carriere motion appliance, formerly known as Carriere Distalizer, claims to establish class I relationship at the beginning of treatment by distalizing and rotating the maxillary molars while using intermaxillary elastics on mandibular molars as anchorage. The study by Kim-Berman et al found that appliance is an effective way of correcting class II malocclusion.[15] The changes were mostly dentoalvoelar but some skeletal changes occurred. This study is also limited because records were lateral head films of each patient were analyzed at the time points of treatment. When compared to other studies, this study is able to observe dental and skeletal in all three planes of space due to 3-Dimensional imaging of CBCT. The benefits are less probably of tracing error of contralateral molars, and able to observe changes in the transverse dimension which is where traditional lateral cephalograms lack. Some providers due to the unpredictability of sequential distalization, multiple refinement scans, increased chair time, have elected to use the Carriere motion appliance as the sagittal first class II corrector. After patients were corrected to “super class I,” patients then moved onto full fixed appliances or aligners for comprehensive treatment. A study with Carriere motion using the protocol in this research can be easily repeatable and raises questions. The Carriere motion claims to distalize maxillary molars, which can be evaluated by isolated left and right molars. The appliance also rotates the molars, which may introduce not necessarily skeletal transverse changes but dentoalveolar tooth position changes. It may be possible the final molar rotational position may be result in distal aspect rotating in and mesial aspect rotating out and leaving the patients in a compromised unpredictable crossbite.

Moving forward, class II corrector studies of the past can be repeated using CBCT for pre and post treatment records. With the use of CBCT, one can separate the left and right molars which eliminates inducing tracing error bias. The molars can be evaluated in all three planes of space. This study may be able to observe molar tipping in the future by adding additional landmarks on the maxillary root structures that were no included in Pancherz analysis of roetgenograms, such as the using the most apical mesial aspect of the mesial buccal root for sagittal changes and the most apical aspect of the palatal root of maxillary first molars for vertical changes.

CONCLUSIONS

Significant dentoalveolar changes including a restraint in the forward movement of the maxillary molars can be expected with sequential molar distalization with removable clear aligners.

NULL HYPOTHESIS TESTING

1. Rejected: There is no significant sagittal dental and skeletal changes after treatment with clear aligners. The treatment group between T1 and T1, showed a forward movement of the mandibular incisal edge position of 3.4mm, forward movement of mandibular molars of 3.6mm, and a molar relationship change of 2.3mm. When the treatment group was compared to the control group, the study showed a 0.5mm mesial movement of maxillary molars compared to the control group of 5.0mm. The treatment group showed a

significant molar relationship of -2mm compared to the control group of 0.5mm. The treatment showed a reduction of overjet by 2mm whereas the control group showed 0mm overjet change.

2. Accepted: There is no significant vertical dental and skeletal changes after treatment with clear aligners. Even though, the treatment group between T1 and T2 showed a downward movement of maxillary incisal edge position, when compared to the control group there was no significant difference.
3. Rejected: There is no significant transverse dental and skeletal changes after treatment with clear aligners

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