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ORIGINAL RESEARCH

Evaluation of the dentoskeletal effects of maxillary molar distalization with clear aligners: Class II elastics *vs.* miniscrew anchorage

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Abstract

Background: To compare (1) the dentoskeletal effects of Class II elastics and infrazygomatic crest (IZC) miniscrew anchorage in sequential maxillary molar distalization using clear aligners and (2) the planned and achieved tooth movements of the maxillary molars and second premolars. **Methods**: A total of 22 patients with Angle Class II malocclusion treated with clear aligners and maxillary molar distalization were included. The patients were divided into two groups based on anchorage method: Class II elastics or IZC miniscrew. Lateral cephalometric radiographs and digital models were obtained from all patients before treatment (T_0) and after distalization of the second premolars (T_1) to assess skeletal and dental changes. Geomagic Control X was used to superimpose the digital models to evaluate dental movements. **Results**: Comparison of cephalometric measurements demonstrated significant differences between the groups in incisor mandibular plane angle (IMPA) and overbite. In the intermaxillary elastic group, the upper second molar was distalized by 1.72 $\pm$ 0.64 mm, upper first molar by 1.87 $\pm$ 0.78 mm, and upper second premolar by 1.55 $\pm$ 0.8 mm. In the IZC miniscrew group, the upper second molar was distalized by 2.24 $\pm$ 0.87 mm, upper first molar by 2.19 $\pm$ 0.74 mm and upper second premolar by 1.84 $\pm$ 0.71 mm. In both groups, greater than predicted maxillary molar intrusion was observed. **Conclusions**: More distal movement of the maxillary second molar was achieved with miniscrews than intermaxillary elastics. In cases where overbite reduction and control of lower incisor inclination are critical, miniscrew anchorage is more advantageous during maxillary molar distalization with clear aligners. **Clinical Trial Registration**: The study was registered with ClinicalTrials.gov as: NCT06631131.

Keywords

Class II malocclusion; Clear aligner; Distalization; Miniscrew anchorage

1. Introduction

Class II malocclusion, which is one of the most prevalent types of malocclusion, can be the result of the upper jaw being positioned forward, the lower jaw being positioned backward, or a combination of both [1, 2]. Treatment options for non-growing patients with Class II malocclusion include upper premolar extraction or intraoral/extraoral distalization focusing on the maxillary arch, whereas functional appliances are used for mandibular repositioning and/or dentoalveolar modifications in both the maxilla and mandible [3–5]. Orthognathic surgery is a treatment approach for non-growing patients with severe skeletal Class II malocclusions and includes mandibular advancement surgery for mandibular retrognathia, superior repositioning of the maxilla, or bimaxillary surgery [6]. In cases of dental Class II malocclusions with a good soft tissue profile, distalization is often preferred [7, 8]. Various intraoral and extraoral appliances are used in the process of distalizing the upper first molars [9, 10].

The rise in esthetic expectations and the increasing number of adult patients requiring orthodontic treatment have contributed to the popularization of clear aligners and lingual appliances in current orthodontic practice [11]. Clear aligners were initially used in simple malocclusion cases, but the evolution of aligner technology and the introduction of attachments has enabled the treatment of more complex cases [12].

Several case reports and studies have shown that Class II correction can be achieved with sequential molar distalization with clear aligners [13–16]. There are also studies and case reports in the literature documenting maxillary arch distalization with lingual appliances [17–19]. Simon *et al.* [14] reported that molar distalization using clear aligners was effective (mean 2.7 mm) and highly accurate. A systematic review indicated that clear aligners are effective in controlling parallel tooth movement during maxillary molar distalization in non-growing patients when a distalization of 2.6 mm is planned [20]. A multicenter retrospective study demonstrated mean distal movement of 2.25 mm and 2.52 mm respectively for maxillary first and second molars without significant vertical movement or tipping [21]. Saif *et al.* [16] evaluated the efficacy of clear aligners in maxillary molar distalization and reported that the movement accuracy for maxillary first and second molars was 75.5% and 72.2%, respectively, when an average of 2.6 mm distalization was planned. A recent study reported that temporary anchorage devices (TADs) can be used to prevent unwanted tooth movements, provide bone anchorage, and prevent anchorage loss during maxillary molar distalization [22]. Similarly, the use of TADs for skeletal anchorage was reported to be an effective method for correcting Class II malocclusions in adult patients without the need for extraoral appliances and with little risk of loss of anterior anchorage [23]. Jia *et al.* [24] showed that anchorage units like miniscrews, precision cuts, and patient-specific attachments were beneficial in preventing anchorage loss during clear aligner treatment for molar distalization. In a finite element study, the use of miniscrews to create force parallel to the occlusal plane was reported to be more advantageous than the use of Class II elastics when distalizing maxillary teeth with clear aligners [25].

To the best of our knowledge, there has been no prospective study to date assessing the dentoskeletal effects of sequential maxillary molar distalization using clear aligners with miniscrew anchorage in Class II patients. A recent two-center retrospective study comparing miniscrew anchorage with Class II elastic anchorage during distalization of the maxillary arch with clear aligners showed that the achieved distalization efficiency was 36.2%–43.9% in the posterior teeth with no statistically significant difference in maxillary arch distalization efficiency between the groups, although miniscrew anchorage showed better control of mesiodistal tipping in posterior teeth [26].

The purpose of this prospective clinical study was to compare (1) the dentoskeletal effects of Class II elastics and IZC miniscrew anchorage in sequential maxillary molar distalization using clear aligners and (2) the planned and achieved tooth movements of the maxillary molars and second premolars. The null hypothesis of our study was that there would be no dentoskeletal differences between the groups resulting from maxillary molar distalization with clear aligners supported by different anchorage mechanics (intermaxillary elastics *vs.* IZC miniscrews) in patients with Class II malocclusion.

2. Materials and methods

This prospective clinical study was confirmed by the Ethics Committee of Bezmialem Vakif University (approval no: 40173, 17 November 2021). An informed consent form was signed by all study participants, or by the parents/guardians in the case of minor patients.

The data for this study were obtained from patients who presented for treatment at the Department of Orthodontics at Bezmialem Vakif University Faculty of Dentistry between December 2021 and January 2023. The inclusion criteria were as follows: (1) skeletal Class I or mild skeletal Class II malocclusion with a balanced profile, (2) Class II molar relationship, (3) mild or moderate dental crowding on both arches, (4) previous extraction or absence of the upper third molars, (5) good compliance to orthodontic treatment, and (6) availability of initial and progress stereolithography (STL) files of intraoral scans and lateral cephalometric radiographs. Exclusion criteria were (1) severe dental crowding on both arches, (2) Class II subdivision malocclusion, (3) severe skeletal Class II malocclusion requiring orthognathic surgery, (4) presence of impacted or supernumerary teeth, (5) tooth extraction (except third molars), (6) poor compliance to orthodontic treatment, and (7) craniofacial and dentofacial disorders, syndromes, or systemic diseases impacting bone metabolism or tooth movement.

Analysis indicated that a minimum of 21 samples would be required to achieve 80% power for detecting significant differences at a significance level of $\alpha = 0.05$ with an effect size of 0.65 as calculated based on a previous study [16]. A total of 27 patients were initially included. However, 5 patients were excluded because they discontinued treatment (n = 2), had poor treatment compliance (n = 2), or had poor radiograph quality (n = 1). Consequently, the final sample comprised 22 individuals ranging in age from 15 to 25, with 11 individuals (22 second molars, 22 first molars, and 22 second premolars) in each group. All patients were treated with clear aligners (Invisalign®, Align Technology, CA, USA) by same certified orthodontist (ESA) at Bezmialem University Hospital. Sequential distalization (50%) was planned in the maxillary arch. For each aligner, a staging of 0.25 mm was determined. The sequential distalization protocol starts with the distalization of the second molar; when the second molar reaches 50% of the total movement, the first molar starts moving distally. This staging continues sequentially until the canine is distalized. After distalization of the posterior teeth is completed, en masse retraction of the upper incisors is started. In the ClinCheck plan, 3 or 4 mm vertical rectangular attachments were placed from the second molar to the canine and were beveled mesially to enhance the distalization forces.

The patients were divided into two groups, those who were treated with sequential distalization with aligners supported by Class II elastics or IZC miniscrew anchorage. In the intermaxillary elastic group, with the beginning of the movement of the upper first molars, Class II intermaxillary elastics (3/16” 4.5 oz, Ormco Inc., Glendora, CA, USA) were used from precision cuts on the upper canines to the buttons on the lower first molars (Fig. 1A). In the IZC miniscrew group, miniscrews (total length: 13 mm, diameter: 2 mm, SemiOss miniscrew system, Istanbul, Türkiye) were inserted in the IZC region between the upper molars in both sides before first molar movement started. The same intramaxillary elastics were used from precision cuts on the upper canine to the IZC miniscrew (Fig. 1B).

When a miniscrew failed (n = 3 miniscrews), the patient was immediately called in and the miniscrew was repositioned at a site either more distal or more mesial to the previous insertion point. The use of intra/intermaxillary elastics was started with the initiation of upper first molar movement to prevent anchorage loss and maxillary incisor proclination. Both groups were instructed to wear the elastics and aligners a minimum of 22 hours per day using a 10-day aligner wear protocol.

FIGURE 1. Intraoral photographs of the groups divided according to the use of elastic. (A) Class II elastics from precision cuts of the upper canines to the buttons on the lower first molars (Intermaxillary elastic group). (B) Intra-maxillary elastics from precision cuts of the upper canines to IZC miniscrews (IZC miniscrew group).

Maxillary third molars were extracted before treatment.

Patients were scanned using an iTero 5D Element intraoral scanner (Align Technology Inc., San José, CA, USA) and radiographs were taken before treatment (T_0) and after distalization of the upper second premolar (T_1). At T_1, the movement of the maxillary second premolars has been completed, but no planned movement of the maxillary incisors has started at this stage. Intraoral photographs of a representative case from each group at T_0 and T_1 are shown in Fig. 2.

2.1 Lateral cephalometric analysis

Digital tracing and measurements of the cephalometric radiographs were performed by the same investigator (EK) using NemoCeph version 6.0 software (Nemostudio 2020, Software Nemotech S.L., Madrid, Spain). Angular dental measurements were performed between the long axis of the teeth and the sella-nasion (S-N) plane using Image J software (version 1.53a, National Institutes of Health, Bethesda, MD, USA). The long axis was determined as a line through the incisal edge and root apex for incisors, through the buccal cusp tip and root apex for premolars, and through the centroid and furcation for molars. Dentoskeletal and soft tissue measurements are presented in Fig. 3.

2.2 Measurement of digital models

To assess the severity of Class II malocclusion before treatment, the molar relationship was measured from digital models in centric occlusion using OrthoCAD software (version 5.9.1.50, Align Technology Inc., San Jose, CA, USA). Reference landmarks for measuring the molar relationship were the buccal groove of the mandibular first molar and the mesiobuccal cusp of the maxillary first molar [27].

Digital models were exported from the OrthoCAD software as stereolithography (STL) files and imported into Geomagic Control X software (version 2018.1.0, 3D systems, Rock Hill, SC, USA) for three-dimensional (3D) model comparison. In this software, the pretreatment model was referred to as the "reference model", while the progress model is named the "measured model". All digital models were superimposed using the local best fit algorithm (Fig. 4).

For model superimposition, 50 iteration points were defined in a reference area in the palatal region. After model superimposition, changes in tooth position were determined by marking the mesiobuccal cusp tips of the maxillary molars and the buccal cusp tips of the premolars as reference points on the T_0 and T_1 models, and linear measurements were taken on all three axes (Fig. 5).

In linear measurements,

1. The X-axis represent buccolingual (transversal) differences (X+ in the buccal direction and X− in the palatal direction);
2. The Y-axis represent mesiodistal (sagittal) differences (Y+ in the distal direction and Y− in the mesial direction); and
3. The Z-axis represent vertical differences (Z+ indicating extrusion and Z− indicating intrusion).

For angular measurements, reference points and vectors were identified on the 3D models. These points were the mesiobuccal and mesiopalatal cusp tips of the molars and the buccal and palatal cusp tips of the premolars. The angles between reference vectors were measured (Fig. 6). Rotational movements were measured using the XY-axis, with positive values indicating mesiobuccal rotation and negative values indicating distobuccal rotation.

2.3 Statistical analysis

To determine intra-examiner reliability, 10 randomly selected patients were remeasured by the same investigator (EK) after 3 weeks and the intraclass correlation coefficient (ICC) was calculated.

Normality of the data distribution was evaluated using the Shapiro-Wilk test. Chi-square tests were performed to compare gender distribution between the groups. Paired t-test was used for intragroup comparisons, while Mann-Whitney U tests and independent t-tests were used for intergroup comparisons. All data were analyzed using SPSS software version 22.0 (IBM Corp, Armonk, NY, USA). Significance was defined as $p <$

FIGURE 2. Intraoral photographs of the groups at T_0 and T_1. Intermaxillary elastic group at pretreatment (A), and after the upper second premolar distalization completed (B), IZC miniscrew group at pretreatment (C), and IZC miniscrew group-after the upper second premolar distalization completed (D).

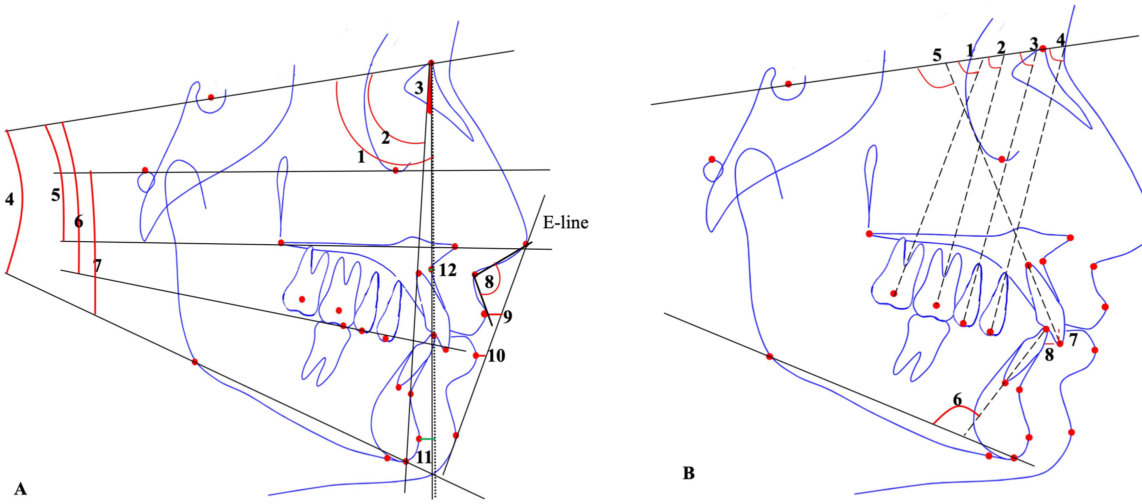

FIGURE 3. Cephalometric linear and angular measurements were used in this study. (A) Skeletal and soft-tissue measurements: 1, SNA (°); 2, SNB (°); 3, ANB (°); 4, SN-GoGn (°); 5, SN-PP (°); 6, SN-OP (°); 7, FMA (°); 8, Nasolabial angle (°); 9, Upper lip to E-line (mm); 10, Lower lip to E-line (mm); 11, N-Pog (mm); 12, N-A (mm); (B) Dental measurements: 1, U7-SN (°); 2, U6-SN (°); 3, U5-SN (°); 4, U4-SN (°); 5, U1-SN (°); 6, MP-L1 (°); 7, Overbite (mm); 8, Overjet (mm). (U7, maxillary second molar centroid; U6, maxillary first molar centroid; U5, maxillary second premolar buccal cusp tip; U4, maxillary first premolar buccal cusp tip; U1, maxillary incisor tip; L1, mandibular incisor tip; MP, mandibular plane.)

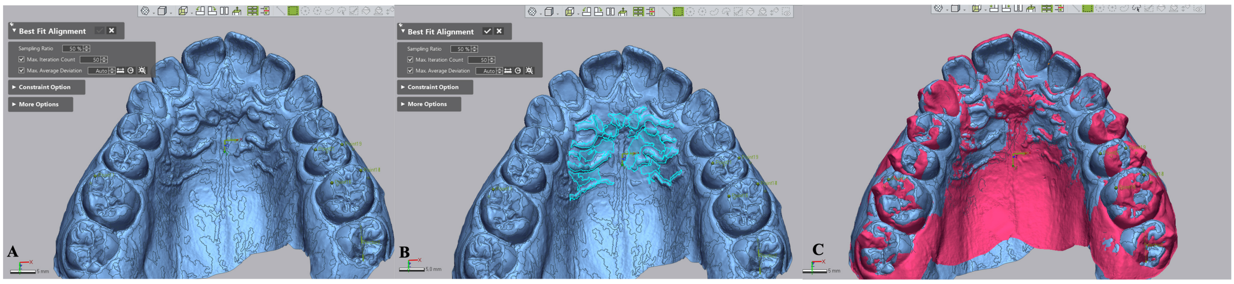

FIGURE 4. Superimposition of digital models. (A) Pretreatment model (T_0) is referred to as the "reference model". (B) A reference area in the palatal region for the model superimposition. (C) Superimposition of pretreatment and posttreatment models. Blue, pretreatment-reference model (T_0); Pink, achieved outcome-measured model (T_1).

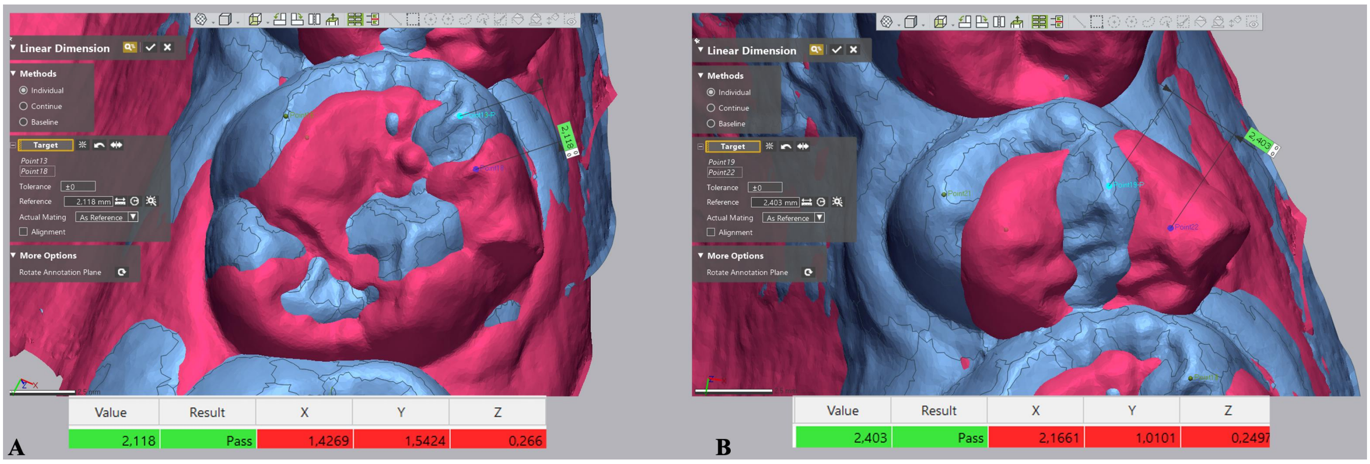

FIGURE 5. Linear measurements on superimposed digital models. (A) Displacement of the mesiobuccal cusp of the maxillary molar on the (transversal), Y-axis (sagittal) and Z-axis (vertical). (B) Displacement of the buccal cusp of the maxillary second premolar on the X-axis (transversal), Y-axis (sagittal) and Z-axis (vertical). Blue, pretreatment-reference model (T_0); Pink, achieved outcome-measured model (T_1).

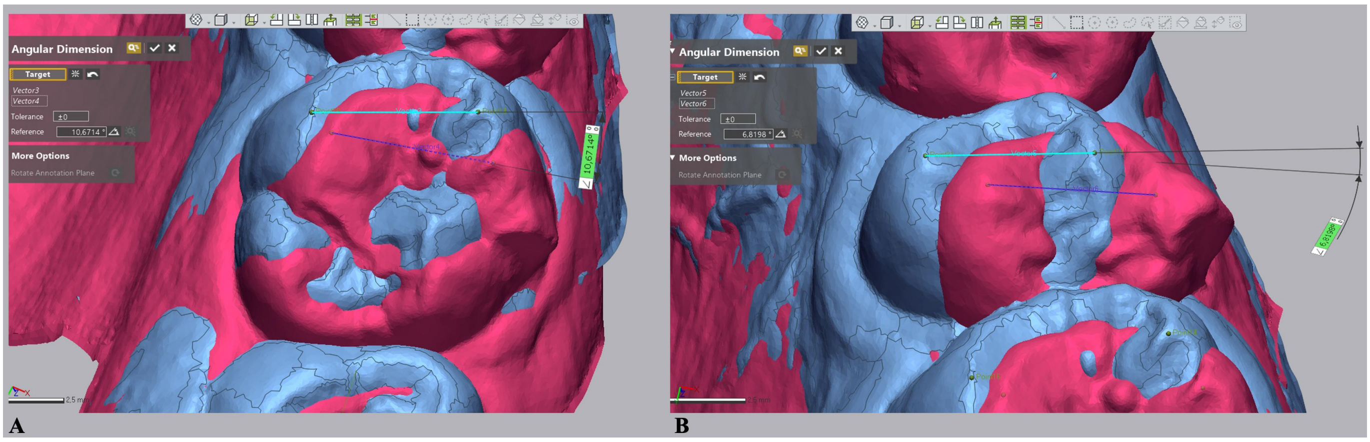

FIGURE 6. Angular measurements on superimposed digital models. (A) Vectors created by combining the mesiobuccal and mesiopalatinal cusp tips used to measure molar rotation. (B) Vectors created by combining the buccal and palatinal cusp tips used to measure premolar rotation. Blue, pretreatment-reference model (T_0); Pink, achieved outcome-measured model (T_1).

0.05. Sample size calculation was performed using G*Power software (version 3.1.9.2, Heinrich-Heine-Universität Düsseldorf, Düsseldorf, NRW, Germany).

3. Results

The ICC values ranged from 0.84 to 0.99 for cephalometric measurements and 0.94 to 0.99 for digital model measurements, demonstrating excellent intra-examiner reliability.

The descriptive data and recorded parameters of the groups are given in Table 1. The mean age and gender distribution did not differ between the groups. Statistically significant differences between the groups were found for total aligner number ($p = 0.015$), aligner number at the time of the T_1 scan ($p = 0.037$), and initial severity of the Class II molar relationship ($p < 0.001$).

The cephalometric data of the groups are reported in Table 2. In the intermaxillary elastic group, statistically significant changes in Wits, N-Pog (pogonion to nasion perpendicular plane) SN-OP (sella-nasion to occlusal plane angle), U1-SN (upper incisor to SN angle) and U5-SN (upper second premolar to SN angle) values were observed at T_1 ($p < 0.05$). Wits was decreased by 1.5 ± 1.4 mm, SN-OP was increased by 2.1 ± 1.6 degrees, and N-Pog was increased by 1.6 ± 1.9 mm. U1-SN increased by 2.2 ± 2.5 degrees, while U5-SN decreased by 6.2 ± 3.5 degrees. In the IZC miniscrew group, statistically significant decreases in U5-SN (5.8 ± 4.3 degrees, $p = 0.003$) and overbite (1.6 ± 1 mm, $p = 0.001$) were observed at T_1. Statistically significant differences were observed between the groups for IMPA ($p = 0.020$) and overbite ($p = 0.030$).

Linear movements of the teeth in the sagittal, transversal, and vertical planes are presented in Table 3. In the intermaxillary elastic group, significant differences were found between predicted and achieved distal movement of maxillary second molars ($p = 0.011$) and maxillary second premolars ($p < 0.001$). The maxillary second molar was distalized 1.72 ± 0.64 mm, with significant intrusion (0.19 mm extrusion predicted; 0.96 mm intrusion achieved). The maxillary first molar was distalized 1.87 ± 0.78 mm with greater than predicted intrusion (0.13 mm predicted; 0.54 mm achieved) and buccal movement

TABLE 1. Descriptive statistics for each of the groups.

	Intermaxillary elastic group		IZC miniscrew group		
Variables	Mean	SD	Mean	SD	*p* value
Age	19.46	4.15	20.35	4.21	0.680
	n	%	n	%	
Sex					
Female	9	82%	9	82%	1.000
Male	2	18%	2	18%	
	Mean	SD	Mean	SD	
Arch length discrepancy					
Upper Arch (mm)	−3.28	0.99	−2.96	2.57	0.717
Lower Arch (mm)	−2.93	1.42	−2.84	1.24	0.882
Amount of IPR					
Upper Arch (mm)	0.31	0.31	0.58	0.50	0.163
Lower Arch (mm)	2.34	0.90	1.99	0.64	0.330
Total number of aligners					
Upper	47.00	6.05	57.90	9.89	0.015*
Lower	43.30	7.33	52.60	11.67	0.060
Number of aligners (T_1 scan)	26.20	5.10	31.30	6.14	0.037*
Initial severity of the Class II molar relationship (mm)	2.20	0.78	3.40	1.10	<0.001***

$^*p < 0.05$; $^{***}p < 0.001$. IZC, infrazygomatic crest; IPR, interproximal reduction; SD, standard deviation.

(0.95 mm predicted; 1.4 mm achieved) and less than predicted distal rotation (9.95° predicted; 8.13° achieved). The maxillary second premolar was distalized 1.55 ± 0.80 mm.

In the IZC miniscrew group, significant differences were observed between predicted and achieved distal movement of maxillary second molars (p = 0.001), first molars (p = 0.024), and second premolars ($p < 0.001$). The maxillary second molar was distalized 2.24 ± 0.87 mm, with significant intrusion (0.25 mm extrusion predicted; 0.77 mm intrusion achieved) and greater than planned buccal movement (0.07 mm transversal movement predicted; 0.68 mm achieved). The maxillary first molar was distalized 2.19 ± 0.74 mm, also with significant intrusion (0.01 mm extrusion predicted; 0.41 mm intrusion achieved), greater than planned buccal movement (0.79 mm predicted; 1.41 mm achieved), and less than planned distal rotation (8.47° predicted; 5.71° achieved). The maxillary second premolar was distalized 1.84 ± 0.71 mm, with greater than planned buccal movement (1.01 mm predicted; 1.64 mm achieved).

When the predicted tooth movements were compared between the groups, the IZC miniscrew group had significantly larger predicted distal movement of the upper second and first molars and significantly less predicted distal rotation of the second molar. No significant difference was detected between the groups in achieved tooth movements except for distalization and rotation of the second molars. There was more distal movement and less distal rotation of the second molars in the IZC miniscrew group compared to the intermaxillary elastic group. No difference was observed between achieved and predicted tooth movements except for the vertical movement of the upper second and first molars.

4. Discussion

This prospective clinical study investigated the dentoskeletal effects of Class II elastics or miniscrew anchorage during maxillary molar distalization with clear aligners using intraoral models and lateral cephalometric radiographs. The linear movement and mesiodistal rotation of the teeth were measured by superimposing intraoral models using the local best-fit method in the palatal rugae region. A study comparing the effectiveness of landmark-based superimposition and a local best-fit algorithm for superimposition of maxillary digital models showed that applying the local best-fit algorithm was faster and more effective [28]. Another study found that semi-automatic best-fit registration software (Geomagic software) consistently demonstrated excellent agreement in the measurement of tooth movement [29]. Similarly, the digital model measurements in the present study showed excellent reliability. Along with other dentoskeletal measurements, mesiodistal angulation of the teeth was measured using lateral cephalometric films. This approach was used because of the inability to evaluate root movement with 3D models and the difficulty of determining the long axis of the crown in T_1 scans due to the attachments. However, cephalometric radiographic measurements are based on two-dimensional views of 3D structures, which has limitations such as magnification errors and loss of information due to the overlap of bilateral structures [30].

TABLE 2. Intra- and intergroup comparisons of linear and angular cephalometric measurements.

	Intermaxillary elastic group (n = 11)				IZC miniscrew group (n = 11)				
Measurements	T_0	T_1		T_1–T_0	T_0	T_1		T_1–T_0	Intergroup comparison
	Mean ± SD	Mean ± SD	Difference	*p* value	Mean ± SD	Mean ± SD	Difference	*p* value	*p* value
Skeletal									
SNA (°)	79.40 ± 5.51	79.40 ± 5.70	0.0 ± 0.8	1.000	78.40 ± 3.05	78.70 ± 3.43	0.3 ± 1.1	0.434	0.490
SNB (°)	75.50 ± 4.79	75.60 ± 4.61	0.1 ± 0.7	0.688	73.60 ± 2.88	74.10 ± 3.41	0.5 ± 0.9	0.138	0.279
ANB (°)	3.80 ± 1.65	3.60 ± 1.79	−0.2 ± 0.7	0.443	4.80 ± 2.00	4.70 ± 1.95	−0.1 ± 0.8	1.000	0.573
Wits (mm)	2.74 ± 2.13	1.22 ± 2.04	−1.5 ± 1.4	0.011*	4.35 ± 2.20	3.21 ± 1.90	−1.2 ± 1.9	0.099	0.632
N-A (mm)	−4.03 ± 5.00	−3.23 ± 5.26	0.8 ± 1.5	0.132	−4.16 ± 3.7	−3.70 ± 3.78	0.4 ± 1.4	0.336	0.614
N-Pog (mm)	−12.35 ± 8.10	−10.72 ± 7.75	1.6 ± 1.9	0.029*	−12.95 ± 6.60	−12.39 ± 6.80	0.5 ± 2.5	0.502	0.307
SN-GoGn (°)	34.30 ± 5.53	34.10 ± 5.74	−0.2 ± 1.3	0.662	32.30 ± 4.90	32.90 ± 5.91	0.6 ± 1.8	0.329	0.288
SN-PP (°)	7.70 ± 3.23	7.10 ± 2.96	−0.6 ± 1.1	0.111	8.90 ± 3.47	8.40 ± 3.65	−0.5 ± 1.1	0.213	0.625
SN-OP (°)	16.40 ± 5.70	18.50 ± 5.46	2.1 ± 1.6	0.003**	17.10 ± 4.45	17.70 ± 5.47	0.6 ± 2.6	0.489	0.145
FMA (°)	30.00 ± 4.90	29.30 ± 5.20	−0.7 ± 1.7	0.242	27.30 ± 4.90	27.60 ± 5.35	0.3 ± 2.1	0.475	0.186
Soft Tissue									
Nasolabial Angle (°)	111.50 ± 7.69	111.20 ± 7.89	−0.3 ± 6.9	0.894	104.50 ± 10.08	105.30 ± 10.15	0.9 ± 6.1	0.687	0.710
UL/E-line (mm)	−1.37 ± 1.06	−0.88 ± 1.38	0.5 ± 1.1	0.209	−0.12 ± 2.23	−0.31 ± 1.97	−0.2 ± 1.1	0.612	0.201
LL/E-line (mm)	0.06 ± 2.07	0.70 ± 1.90	0.6 ± 0.9	0.063	0.27 ± 2.81	0.57 ± 2.79	0.3 ± 1.7	0.604	0.225
Dental-angular (°)									
U1-SN (°)	102.10 ± 9.27	104.32 ± 8.68	2.2 ± 2.5	0.027*	103.82 ± 9.70	104.33 ± 7.97	0.5 ± 6.9	0.829	0.496
U4-SN (°)	85.79 ± 7.68	84.72 ± 6.32	−1.0 ± 3.9	0.411	82.75 ± 6.12	82.10 ± 7.29	−0.5 ± 4.8	0.712	0.811
U5-SN (°)	76.20 ± 5.60	71.00 ± 4.19	−6.2 ± 3.5	<0.001***	76.31 ± 5.05	70.58 ± 6.23	−5.8 ± 4.3	0.003**	0.850
U6-SN (°)	68.62 ± 6.38	66.60 ± 6.16	−1.9 ± 4.3	0.186	66.45 ± 5.85	64.98 ± 5.05	−1.4 ± 2.6	0.118	0.761
U7-SN (°)	59.81 ± 5.88	59.74 ± 8.57	0.0 ± 6.1	0.976	59.30 ± 5.86	58.61 ± 8.05	−0.7 ± 5.3	0.693	0.772
MP-L1 (IMPA) (°)	95.30 ± 7.20	98.70 ± 4.82	2.9 ± 4.4	0.067	99.60 ± 3.33	98.10 ± 3.92	−1.5 ± 3.1	0.169	0.020*
Dental-linear (mm)									
Overjet (mm)	5.13 ± 1.39	4.28 ± 1.89	−0.9 ± 1.2	0.055	6.43 ± 2.55	6.22 ± 3.21	−0.2 ± 2.3	0.746	0.468
Overbite (mm)	3.20 ± 1.78	2.71 ± 1.42	−0.4 ± 1.1	0.248	4.91 ± 1.19	3.37 ± 1.25	−1.6 ± 1.2	0.001**	0.030*

**p < 0.05; **p < 0.01; ***p < 0.001. IZC, infrazygomatic crest; SD, standard deviation; SN, Sella to nasion; SNA (°), Sella-nasion-A point angle; SNB (°), sella-nasion-B point angle; ANB (°), A point-nasion-B point angle ; N-A, nasion perpendicular to point A; N-Pog, nasion perpendicular to pogonion; SN-GoGn, SN to gonion-gnathion plane angle; SN-PP (°), SN to palatal plane angle; SN-OP (°), SN to occlusal plane angle; FMA (°), Frankfurt horizontal to mandibular plane angle; UL, upper lip; LL, lower lip; U1-SN (°), upper incisor to SN angle; U4-SN (°), upper first premolar to SN angle; U5-SN (°), upper second premolar to SN angle; U6-SN (°), upper first molar to SN angle; U7-SN (°), upper second molar to SN angle; IMPA (°), Incisor mandibular plane angle.*

TABLE 3. Predicted and achieved tooth movements in maxillary molar distalization with Class II elastic and miniscrew anchorage groups.

	Intermaxillary elastic group			IZC miniscrew group			Intergroup comparison	
Variables	Predicted tooth movement	Achieved tooth movement		Predicted tooth movement	Achieved tooth movement		Predicted–Achieved	Predicted
	Mean ± SD	Mean ± SD	*p* value	Mean ± SD	Mean ± SD	*p* value	*p* value	*p* value
Maxillary second molar (n = 22)								
Anteroposterior (mm)	1.95 ± 0.69	1.72 ± 0.64	0.011*	2.85 ± 0.80	2.24 ± 0.87	0.001**	0.067	0.001**
Vertical (mm)	0.19 ± 0.33	−0.96 ± 0.58	<0.001***	0.25 ± 0.35	−0.77 ± 0.98	<0.001***	<0.001***	0.663
Transversal (mm)	0.19 ± 0.47	0.46 ± 0.80	0.124	0.07 ± 0.73	0.68 ± 0.71	0.003**	0.168	0.533
Rotation (°)	−6.56 ± 5.33	−5.34 ± 3.54	0.090	−3.02 ± 5.25	−3.01 ± 3.39	0.999	0.301	0.038
Maxillary first molar (n = 22)								
Anteroposterior (mm)	1.94 ± 0.88	1.87 ± 0.78	0.509	2.64 ± 0.80	2.19 ± 0.74	0.024*	0.084	0.001**
Vertical (mm)	−0.13 ± 0.30	−0.54 ± 0.40	<0.001***	0.01 ± 0.39	−0.41 ± 0.69	0.019*	<0.001***	0.205
Transversal (mm)	0.95 ± 0.68	1.40 ± 0.65	0.022*	0.79 ± 0.90	1.41 ± 0.99	0.001**	0.459	0.538
Rotation (°)	−9.95 ± 5.23	−8.13 ± 4.83	0.014*	−8.47 ± 5.20	−5.71 ± 3.94	0.003**	0.377	0.376
Maxillary second premolar (n = 22)								
Anteroposterior (mm)	2.15 ± 0.89	1.55 ± 0.80	<0.001***	2.72 ± 0.79	1.84 ± 0.71	<0.001***	0.169	0.039
Vertical (mm)	−0.06 ± 0.37	−0.23 ± 0.26	0.086	−0.09 ± 0.41	−0.18 ± 0.74	0.650	0.225	0.782
Transversal (mm)	1.36 ± 0.77	1.59 ± 0.78	0.138	1.01 ± 0.80	1.64 ± 0.66	<0.001***	0.067	0.175
Rotation (°)	−0.64 ± 9.29	−1.28 ± 7.83	0.494	−1.63 ± 5.13	−1.81 ± 4.85	0.860	0.752	0.683

For linear measurement positive values indicate distalization (anteroposterior), extrusion (vertical) and buccal movement (transversal). Negative values indicate mesialization (anteroposterior), intrusion (vertical) and palatal movement (transversal). For angular movement positive values indicates mesiobuccal rotation and negative values indicates distobuccal rotation in XY-axis.

**$p < 0.05$; **$p < 0.01$; ***$p < 0.001$. IZC, infrazygomatic crest; SD, standard deviation.*

It was found that the IZC miniscrew group used a higher total number of maxillary aligners during distalization treatment and had a higher aligner number at the time of the T_1 intraoral scan ($p < 0.05$). In addition, the Class II molar relationship was more severe and the planned amounts of distalization for the maxillary first and second molars was higher in IZC miniscrew group ($p < 0.001$). This is due to the fact that group assignment was not completely random; three patients with a full-cusp Class II molar relationship were included in the IZC miniscrew group because the planned amount of distalization was greater and better anchorage control would be required.

In this study, the amount of distalization achieved in both groups was statistically significantly less than planned, except for maxillary first molars in the intermaxillary elastic group. In the study by Saif *et al.* [16], no Class II elastics or additional mechanics were used during molar distalization with clear aligners, and progress models were obtained immediately after distalization of the first and second molars was complete. Similar to our study, they observed less than planned distalization of the maxillary molars. Li *et al.* [31] also observed a discrepancy between planned and achieved maxillary molar distalization with clear aligners. In their study, miniscrews or Class II elastics were used for anchorage during distalization and the second scan was performed at the end of treatment. Similarly, Liu *et al.* [26] reported that achieving predicted distalization was difficult, even with miniscrew anchorage.

In the present study, both groups showed significant intrusion of the teeth despite planning extrusion in the ClinCheck plan. This is thought to be a result of the "bite block" effect on the posterior teeth caused by the thickness of the clear aligners used [32]. In a similar study by Liu *et al.* [26], intrusions were observed in the posterior region rather than extrusion movements. This was also explained by the "bite block" effect of the clear aligner. However, in the present study, achieved buccal movement was greater than planned for maxillary first molars in the intermaxillary elastic group and second premolars and first and second molars in the IZC miniscrew group. Supporting the findings of our study, several studies reported that Class II treatment with maxillary molar distalization using the Invisalign system significantly increased inter-premolar and molar widths [31, 33].

When achieved tooth movements were compared between the groups, the only significant difference was in the amount of distalization and rotation of the second molars. The maxillary second molars showed greater distalization in the IZC miniscrew group using miniscrew anchorage during sequential distalization than in the intermaxillary Class II elastic group. This may be because the IZC miniscrew group had more planned distalization and better anchorage with miniscrews compared to Class II elastics.

Proclination of the upper incisors was 2.1° in the intermaxillary elastic group versus 0.5° in the IZC miniscrew group, with the maxillary incisor proclination observed in the intermaxillary elastic group found to be statistically significant. The reason for the lesser proclination in the IZC miniscrew group may be that the force produced by the intra-arch elastics used in this group is only in the sagittal direction, which better prevents upper incisor proclination, whereas the Class II elastics used in the intermaxillary elastic group apply force in both the sagittal and vertical directions, resulting in less prevention of incisor proclination.

In this study, molar distalization without tipping was achieved in both groups, whereas statistically significant distal tipping was observed in the second premolars. Similarly, several other studies also reported distalization of the first and second molars without significant tipping [21, 34]. The authors attributed this to the self-limiting 0.25 mm activation of each clear aligner and the presence of vertical attachments placed on the buccal surfaces of the teeth to counter the tipping movement [21]. In addition, it has been reported that the sequential distalization protocol applied prevents excessive spaces between the teeth during distalization and thus plays a role in reducing uncontrolled tipping by maintaining maximum contact between the clear aligners and the teeth [35]. The significant tipping of the second premolars in both groups may have been observed because the uprighting movement of the second premolars had not yet occurred and the scans were obtained at an intermediate stage, before first premolar and canine distalization and incisor retraction were completed.

When changes in the skeletal vertical dimension were analyzed, SN-GoGn (°) (sella-nasion to gonion-gnathion plane angle) showed less than 1° of variability in both groups, similar to the literature, indicating that clear aligners ensure good vertical control during maxillary molar distalization [21, 34]. Similar to the study by Caruso *et al.* [34], the SN-OP angle increased in both groups but the difference was significant only in the intermaxillary elastic group, which may be related to the direction of the force applied by the Class II elastics. This idea is supported by a finite element analysis study demonstrating that the extrusive force applied to the maxillary incisors increased as the direction of the elastic force shifted from posterior-apical to posterior-incisal to enhance distalization from the canine precision cut [25].

Although this study included postpubertal patients with no difference in age between the groups, there were statistically significant decreases in Wits and increase in N-Pog in the intermaxillary elastic group, while no significant difference in sagittal measurements was observed in the IZC miniscrew group. Clockwise rotation in the occlusal plane may contribute to the decrease in Wits value. The increase in N-Pog may be attributed to mandibular growth stimulation [36] or remodeling at the symphysis [37], as no mandibular rotation was observed.

In this study, the amount of overbite decreased significantly more in the IZC miniscrew group. This result can be explained by the fact that the vertical force vector of the elastic was slightly apical in the IZC miniscrew group and thus supported the reduction in overbite. Despite the molar intrusion observed in both groups, the planned lower incisor intrusion also plays a role in the reduction of deep-bite.

The change in IMPA also differed significantly between the groups. IMPA increased in the intermaxillary elastic group and decreased in the IZC miniscrew group, although these changes were not significant within the groups. The statistically insignificant decrease in IMPA in the IZC miniscrew group may be explained by not using intermaxillary elastics and performing the interproximal reduction (IPR) in the lower anterior region. In the literature, it is stated that treatment with clear aligners provides good control of mandibular incisor inclination despite the use of Class II elastics [38]. Similarly, we observed no significant increase in the intermaxillary elastic group.

Based on the results of our study, although more distal movement was achieved in the IZC miniscrew group compared to the intermaxillary elastic group, the planned tooth movement was not fully achieved. To achieve more effective distalization with clear aligners and miniscrew anchorage, force can be applied directly from the teeth to the miniscrew, rather than through the precision cuts on the aligners.

The most obvious limitation of our study is the need for full-time patient compliance and the use of aligners and elastics at the specified times during treatment with clear aligners, as with any removable appliance. Other limitations of the study are that root movements were not evaluated with 3D imaging methods, sample sizes were small in both treatment groups, and the amount of planned distalization differed between the groups. Additionally, possible individual differences in miniscrew insertion angles due to the absence of a guide during insertion were not controlled. Moreover, the amount of anchorage loss in the posterior region during incisor retraction was not considered, as the final records were obtained immediately after distalization of the upper molars and second premolars was completed.

Randomized clinical trials are needed to more comprehensively evaluate the effects of Class II elastics and miniscrew anchorage during distalization with clear aligners and to assess the amount of anchorage loss in the posterior region that may occur during incisor retraction using post-treatment records.

5. Conclusions

- There was a discrepancy between the achieved and planned distalization of upper molars with clear aligners both with Class II elastics and miniscrew anchorage. The upper molars distalized without tipping but showed more intrusion and buccal movement than planned in both groups.
- More distal movement of the upper second molars were achieved with miniscrew anchorage than with Class II elastics.
- Miniscrew anchorage during maxillary molar distalization with clear aligners is preferable to Class II intermaxillary elastics in cases where overbite reduction is desired and lower incisor proclination is not desired.

AVAILABILITY OF DATA AND MATERIALS

The data presented in this study are available on reasonable request from the corresponding author.

AUTHOR CONTRIBUTIONS

EK—contributed to data collection, investigation, methodology, performed to analysis writing and review. ESA—contributed to design of the study, methodology, investigation, supervision, writing-review and editing. All authors read and approved the final manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The protocol of this study was approved by the Ethics Committee of Bezmialem Vakif University (Approval Number: 2021/40173). An informed consent form was signed by all study participants, or by the parents/guardians in the case of minor patients.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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