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Evaluation of Dento-Skeletal Vertical Changes Associated with En Masse Skeletally Anchored Distalization of the Maxillary Posterior Segment in Class II Patients: A Randomized Clinical Trial

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ABSTRACT

Distalization is now a ubiquitous Orthodontic non-extraction treatment option for Class II that benefits from novel anchorage options by miniscrews and other temporary anchorage devices. **Objectives:** is to assess vertical changes during en masse distalization of the maxillary posterior segment using two different skeletally anchored distalizers.

Methodology: A22 subjects(8 males, 14 females, average age 15.3 ± 1.2 years) were assigned in a randomized assortment to 2 groups, group I modified Hyrax, group II received modified Distal Jet distalizer, both appliances were anchored by miniscews to the palate and a 2 mm thickness Essix retainer was fitted to the lower dentition. Full skull cone beam computed tomography (CBCT) were taken before insertion of distalization devices (T1) then later at 8 months of distalization (T2). **Results:** show that in group-I, average right first upper molar crown vertical distance decreased by 2.3 mm($p \leq 0.001$), and average of 4.1 ($p \leq 0.001$) in the left side. In group-II, average right first molar crown vertical distance (mm) decreased by 3.2 ($p \leq 0.001$), and an average of difference 3.4 ($p \leq 0.001$) in the left side. FMA decreased by 2.8±1.3 (p 0.04) and 2.6±2.05 (p 0.039) in Groups I and II respectively. **Conclusion**, both distalizers can produce intrusion movement to the maxillary first molar when used with Essix retainer in the lower arch, with a noted decrease in FMA.

KEYWORDS: Orthodontics, Distalization, Class II malocclusion, CBCT.

1. INTRODUCTION

All orthodontists envision achieving precise and predictable tooth movements. However, the constraints of human biology and biomechanics tend to interfere with fulfilling that goal [1, 2]. The recent advances in Temporary Anchorage Devices (TADs) have inspired many novel biomechanical systems to help alleviate the limitations dictated by conventional anchorage [3] and resurrect longstanding methods of treatment such as distalization [4]. Distalization is one of the more ubiquitous and resurging treatment options for Angle class II cases. It aims to resolve arch space deficiency by elongating the dental arch through moving the posterior segment distally [5]. This study aimed to appraise the alterations or lack thereof in vertical position of maxillary permanent first molar as it's being distalized along with the posterior buccal segment, as well as the Frankfort mandibular plane angle (FMA). The null hypothesis of our study was that neither appliance will produce dentoskeletal vertical effects expressed as changes of the upper permanent first molar position and/or FMA.

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2. METHODOLOGY

2.1. Sample Size Calculation

Calculation of sample size was performed from mean U5/ANS-PNS angle difference in degrees before distalization and afterwards using palatal miniscrew -anchored pendulum device which was a similar approach to this study [6]. G*power version 3.0.10 was used to compute the size of the sample, based on t test for average value prior to and following distalization (83.2 & 79.8, respectively), two tailed test, α error =0.05 and power =80.0%, the effect size was =0.89 with the calculated size of the sample of 12 subjects assigned to each group (Fig. 1) .

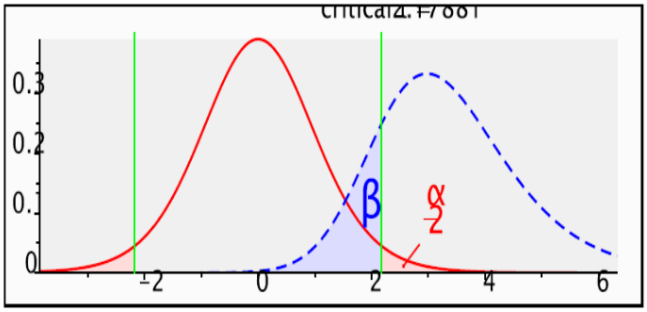

Fig. 1: Sample size calculation.

2.2. Patients

The current study's design was conceived as a two-arm randomized clinical trial. Initially it was conducted on 24 selected patients from the clinic of Orthodontics department, Faculty of Dental Medicine, Al-Azhar University (Cairo, Boys). The risks, benefits and procedures of the study were clearly explained to the patients and/or their guardians and a written informed consent document was thereby signed. The study procedures were independently reviewed by the faculty's ethical committee and given the identifier code 558/2307.

2.2.1. Inclusion Criteria

1. The age of the patients to be between fourteen and sixteen years old.
2. The presence of a full set of permanent teeth, third molar being the only exception.
3. Angle's class II either division 1 or 2, but no subdivision.
4. Self-reported general healthy condition of the patients with no reported systemic diseases.
5. No previous orthodontic treatment as reported by the patient.
6. Excellent maintenance of adequate oral hygiene procedures.
7. No extended usage of any kind of anti-inflammatory drugs.

2.2.2. Exclusion Criteria

1. Cases of skeletal malocclusion requiring growth modification or surgery.
2. Cases with syndromes affecting their dentition or craniofacial structures.
3. Individuals who have compromised periodontal health or poor dental hygiene.

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2.2.3. Discontinuation Criteria

1. Patients who exhibit a lack of compliance with instructions
2. Patients frequently missing agreed upon appointments
3. Patients frequently damaging or dislodging the appliance.
4. Patients ignoring oral hygiene measures.

Twenty-four subjects (9 males, 15 females) qualified through the selection process and agreed to take part in the study. Even though, only twenty-two subjects fulfilled the study period till reaching T2 (i.e. appliance removal) and two subjects failed to complete the study; one subject mentioned that they had to move residence and couldn't travel to the clinic regularly, and the other stopped responding to numerous calls and other channels of communication. (Fig. 2).

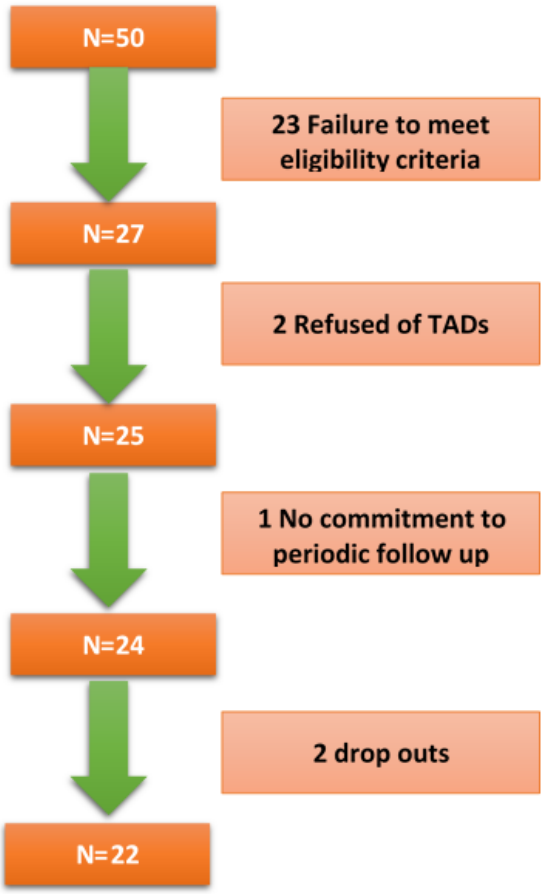

Fig. 2: Consort flowchart.

2.2.4. Case History and Clinical Examination

An extensive examination sheet for each subject as well as a thorough extra-oral and intra-oral inspection were completed.

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2.2.5. Patients' Records

The ensuing records were collected for each subject before appliance insertion (T1) and immediately after its removal (T2)

A- Extra-Oral Photographs

6 extra-oral photographs; frontal view, frontal view with smile, right profile view, left profile view.

B- Intra-Oral Photographs

5 intra-oral photographs, frontal view, right and left side views, upper occlusal view and lower occlusal view.

C- Orthodontic Study Cast

A condensation silicon impression of the upper and lower arches was taken and poured with extra hard stone material. A squash bite was also taken, and the models were Angle-trimmed and positioned according to the registered bite.

D- Full skull CBCT

(90 Kvp/11 mA, over 27 seconds, field of view 17*20) before distalizer insertion (T1) and following distalizer removal (T2)

2.2.6. Randomization

The Research Randomizer website was utilized to produce two sets of random numbers between 1 and 24. Each group contained twelve subjects. Standard-sized intervention allocation pieces of paper (Group I modified Hyrax, Group II modified Distal Jet[1]) were inserted into 24 opaque, identical, carefully closed envelopes. An individual not familiar with the details of the study was told to pick a random sealed envelope before the visit of distalizer insertion. The chosen paper would determine the subject's allocation and so the type of the distalizer used. Afterwards the chosen paper was kept somewhere else.

2.2.7. Blinding

To ensure the allocator's blindness, a randomized coded process was used. It was not conceivable to blind the subjects to the type of distalizer they would be receiving, the same issue goes for the operator as well. However, the radiologist making the measurements was blinded to the type of appliance used.

2.2.8. Treatment Procedures

In order to standardize the patients' pretreatment periodontal condition. Prophylactic measures were undertaken as scaling and polishing for all patients and gingival therapy if needed.

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Bonding

The bonded brackets used were Dentaurum DiscoverySmart system, with the Roth prescription, and the slot size of 22 mil *and the adhesive used for bonding the brackets was Ormco Greenglo adhesive paste**. Only the maxillary first premolar and second premolar were bonded. The maxillary first and second molar were fitted with adequately fitting Leone bands*** . A 19x25 mil archwire made from stainless steel e was selected to help establish the buccal upper teeth as consolidated unit with a common center of resistance.

Modified Hyrax Design

A repurposed expansion screw*** was used in the sagittal, anteroposterior direction instead of its usual transverse placement. Its posterior arms were welded to the bands around the upper first molar. The anterior arms were inserted through one opening of an eyelet that was custom made to modify the appliance into a skeletally anchored device. The eyelet was also used in the planning stage to help direct the path of the miniscrew passing through it into the most appropriate and safe insertion site of the anterior palate [6] (Fig, 3).

Fig. 3: Modified Hyrax design.

Modified Distal Jet Design

The Nance acrylic button part of the traditional Distal Jet appliance was discarded since the design used in the study relies on skeletal anchorage not tissue anchorage. The appliance was" skeletonized" with the posterior pistons ending into the palatal sheath of the upper first permanent molar. The anterior part of the appliance was fitted with an eyelet similar to the modified Hyrax which fulfilled the same purpose of directing the miniscrew, later to be inserted into its appropriate position (Fig, 4).

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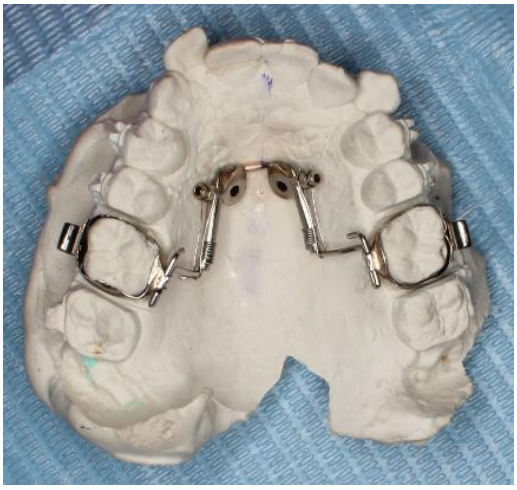

Fig. 4: Modified Distal Jet design.

Preparation of anchorage

For our study, Orthodontic Anchor Screw* ACR were used (Fig. 5). It's a titanium alloy miniscrew with a diameter of 1.8 mm and a length of 11 mm.

Disarticulation

The entirety of the subjects received a lower Essix retainer with a sheet thickness of 2mm to help disarticulate the occlusion and facilitate distalization movement.

Fig. 5: ACR miniscrew.

Miniscrew Insertion Site

The safest choice for the insertion site was the paramedian anterior region, which is 6 to 9 mm behind the incisive foramen and 3-6 mm paramedially, because it has the most sufficient bone thickness palatally and is not close any roots of neighboring teeth [6].

[3] * (ACR.Biomaterials Korea, INC)

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Active Molar Distalization

Activation of both appliances commenced immediately after insertion. In the modified Distal Jet a continuous force of 240 g for each side—the maximum force specified in the manufacturer's provided guide— was exerted from the beginning. In the modified Hyrax the appliance was activated by one quarter turn every two weeks. During the follow up visits the patients underwent examinations for integrity and cleanliness of appliances, and the coil springs' force levels were tested and adjusted.

Study End Point

Attaining super Class, I molar relationship or 8 months from beginning of distalization was set as study end point (T2) at which a full skull CBCT was taken after distalizer removal.

2.2.9. Data Collection and Measurements

The pre-distalizer insertion (T1) and after 8-month of active distalization (T2) CBCT (90 Kvp/11 mA, over 27 seconds, field of view 17*20)) data were saved in a digital imaging and communications in medicine (DICOM) multifile format and exported into Dolphin Imaging version 11.0[4]. for three-dimensional volume rendering. Each scan was re-oriented as described in Table 1 [7, 8, 9]. The landmark identification and selection of relevant measurements was in accordance with similar studies [7, 10, 11]. Then, applying the “Measure” function in Dolphin Imaging software, specific anatomical landmarks were identified on the 3D rendering [12]. All images were then traced utilizing the same software Fig. 6. Digitization, tracing and measurements were performed by the same operator. The software computed the angular and linear dimensions between identified landmarks according to the definitions given in Tables 1-3.

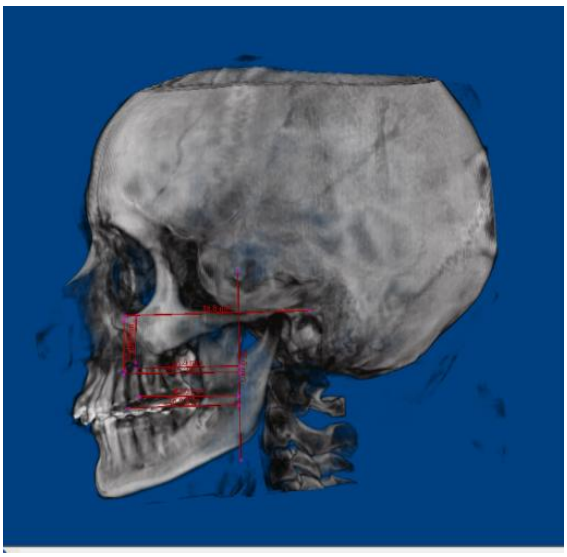

Fig. 6: 3D linear landmarks and measurement.

[4] (DI) (Dolphin Imaging, Chatsworth, Calif), Vistadent AT (GAC) (GAC International)

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Table 1: Planes used for measurements

Orientation and measurements planes and lines		
Landmark	**Name**	**Skeletal Plane definition**
Frankfort horizontal plane	FH	Left and right orbitales and left porion
Midsagittal plane	Y-axis	Anterior nasal spine, sella, and nasion points
Coronal plane	Transporionic plane	Left and right porion with a right angle on the mid-sagittal plane
Mandibular Plane	MP	Right and Left Gonion to Menton

Table 2: Landmarks used for measurements

Landmark	Name	Skeletal landmark definition
Porion	Porion_R; Porion_L	Superior midpoint of external auditory meatus
Orbitale	Orbitale_R;Orbitale_L	At the bottom border of the bony rim of the orbit

Table 3: The study measurements

Mandibular skeletal vertical measurements		
FMA^{0}	At the intersection of MP with FH ,it's the inferior anterior angle	
Maxillary dentoalveolar linear measurements		
First molar crown vertical distance (mm)	U6Cr-FH	Vertical measurement from distal end of crown of maxillary first molar perpendicular to FHP

3. RESULTS

In group-I, the average first maxillary molar crown vertical distance in mm was (±SD) 47.1±9.8, and 44.8±8.6 prior to and after distalization in the right side with a highly significant difference ($p \leq 0.001$) as indicated by paired t-test. It also recorded an average of 48.6±8.8, and 44.5±9.6 prior to and following distalization in the left side with a highly significant difference ($p \leq 0.001$) between before and after in Group I om left side as shown by paired t-test. This negative change denotes intrusion movement in the upper first molar.

Table 4: First molar crown vertical distance

Side	Time of investigation	Group-I		Group-II		Significance	
		Modified Hyrax		**Modified Distal Jet**			
		Mean	**SD**	**Mean**	**SD**	**t**	**p-value**

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Right	Pre	47.1	9.8	49.8	11.6	-0.6	0.279 ns
	Post	44.8	8.6	46.6	11.2	-0.4	0.342 ns
	Change	-2.2		-3.2			
	p-value	≤0.001***		≤0.001***			
Left	Pre	48.6	8.8	51.3	11.4	-0.6	0.269 ns
	Post	44.5	9.6	47.9	11.1	-0.8	0.227 ns
	Change	-4.1		-3.4			
	p-value	0.001***		≤0.001***			

In group-II the average maxillary first molar crown vertical distance in mm recorded 49.8±11.6, and 46.6±11.2 before and after distalization in the right side with a highly significant difference ($p \leq 0.001$) as indicated by paired t-test. It also recorded an average of 51.3±11.4, and 47.9±11.1 before and after distalization in the left side with a highly significant difference ($p \leq 0.001$) as revealed by paired t-test. It was also revealed that no significant difference was found between group I and group II in the right side. Moreover, there was also no significant difference existing between groups I and II in the left side both pre and post as shown by independent t-test. Regarding Group-I, the average FMA was (±SD) of 25.1±1.4, and 22.3±1.2 before and after- distalization with a significant difference ($p<0.05$) being shown by the paired t-test. In group-II, the average FMA was measured at 24.5±2.3, and 21.9±1.8 before and after distalization with a significant difference being shown ($p<0.05$) between before and after in the first group right side as shown by paired t-test. No significant difference was found between both groups ($p>0.05$) in pre and post distalization as shown by independent t-test. This decrease in FMA denotes counter-clockwise rotation of the mandible.

Table 5: measurements of FMA

FMA						
Time of investigation	**Group-I**		**Group-II**		**Significance**	
	Modified Hyrax		**Modified Distal Jet**			
	Mean	**SD**	**Mean**	**SD**	**t**	**p-value**
Pre	25.1	1.4	24.5	2.3	0.78	0.223 ns
Post	22.3	1.2	21.9	1.8	0.79	0.221 ns
Change	2.8		2.6			
p-value	0.04 n*		0.039*			

4. DISCUSSION

While the literature is replete with studies of the efficacy of skeletally anchored distalizers assessing the anteroposterior position of first molar [13-16], less attention has been given to measuring the vertical effect or lack thereof resulting from these TAD supported

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distalizers. The current study was conducted to assess such vertical changes via CBCT on both the dental and skeletal levels. The utilization of CBCT was valuable in assessing both sides of the upper arch independently without the interference and superimposition that usually hinder such assessment via lateral cephalometry [17]. This results from the 2D nature of lateral cephalometric radiographs as opposed to 3D visualization afforded by CBCT, this in turn offers superior isolation and measurements of bilateral points and segmented entities [18]. Established methods such as headgear in its variations and other appliances requiring no compliance from patients (e.g. The pendulum and First Class) were devised for upper molar distalization [19-22]. These appliances have been associated by problematic adverse effects such as extrusion, distal tipping, and the mesial in torsiversion of the upper first molars [23-25]. A key factor in these adverse effects is the design of the appliance and the line of action of the applied force. Appliances such as the pendulum and conventional distal jet apply their forces more palatal to the center of resistance of the molar, this results in the mesial in rotation associated with distalization [26]. The design used in this study attempts to solve this issue by consolidating the maxillary posterior segment into one unit with a common center of resistance.

In the current body of literature, it was noted that various contemporary distalization appliances resulted in unsought outcomes on the maxillary molars distalization movement and on the sagittal-vertical planes as clockwise rotation of the mandibular plane and elongation in the anterior facial height [26-30]. This notion denoted a contraindication of the upper molar distalization in patient with a pre-existing vertical or hyperdivergent growth pattern [31]. Such vertical adverse effects are probably related to the wedging effect of distalization [32] which extrudes the molars during their distal movements due to the converging anatomy of the upper and lower jaw in the posterior direction. This study attempted to lessen these vertical adverse effects by directing the line of action of the force more towards the palate to produce an intrusion effect.

The results of this study indicate that the average vertical distance between the crown of the upper left and right permanent first molar and FH plane has decreased by 3.15 mm, from which it could be surmised that intrusion of first molar was achieved. This result is contrary to previous studies [26, 27] where extrusion has occurred during distalization. The reasoning for this conflict could be traced to the use of Essix retainer in the lower arch in the current study which might cause intrusion of the opposing molar as a previous study have alluded to [33] while using clear aligners for distalization with vertical control. The current study also assessed the vertical skeletal effect of distalization by measuring FMA angle pre and post distalization, the results were in accordance with the dental measurements as the FMA decreased by 2.8 and 2.6 in Groups I and II respectively. These measurements further indicate that distalization using skeletally anchored appliances inserted palatally can produce intrusion effect which can justify their use in hyperdivergent cases. This result in contrary to another study which has used C-plate, also palatally inserted, resulting in an increased FMA in both hypo and hyperdivergent patients [34]. This discrepancy in results might be due to the use of the Essix retainer which could have decreased the extrusion effect and enabled free rotation of the mandible without interference from intercuspation of opposing molars. While most studies assessed molar distalization using lateral cephalometry or scanned models [35], To the best of this author's knowledge this study is the first to utilize CBCT imaging to assess the vertical effects of two palatally anchored distalizers for en masse distalization of the maxillary posterior segment in class II patients. Previous studies have measured change in angulation and tip of the molars

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[36] which can indirectly affect the vertical position, but measurement of the resulting skeletal effect is only made feasible by analysis of a full skull CBCT.

5. CONCLUSION

Both modified Distal Jet and modified Hyrax provided a predictable and effective method for maxillary molar distalization and intrusion which can allow their use in hyperdivergent class II patients.

6. STUDY LIMITATIONS

Limitations of the study are the relatively low sample size and the confined nature of distalization movement which incumbers accurate measurements even with the aid of CBCT.

CONFLICT OF INTEREST

Authors must declare all relevant interests that could be perceived as conflicting. Authors should explain why each interest may represent a conflict. If no conflicts exist, the authors should state this. Submitting authors are responsible for co-authors declaring their interests.

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None is declared

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