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Evaluation of Two Bone Anchored Appliances During En Masse Distalization of Maxillary Buccal Segment with Class II Patients; A Comparative Clinical Study

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Abstract

***Objective**: to assess quality of orthodontic tooth movement during distalization by two different skeletally anchored distalizing appliances* ***.Patients and methods**: the current study was applied on 22 orthodontic patients with class II molar relationship. Patients were divided into two active groups; group I: include 11 patients treated by modified sagittal screw distalizer and group II: include 11 patients treated by modified distal jet distalizer. Quality of distalization was assessed by the following measurements; first and second premolars root horizontal distance (mm), first and second molars root horizontal distance(mm), SNA, SNB, U1 to FH* ***.Results**: The highest change (%) in first molar root horizontal distance (mm) was recorded in group II with a decrease by -11.5 % in the left side and -11.4 % in the right side* ***.Conclusion**: Bone anchored Distal Jet and modified Sagittal screw distalizer provide an effective tool for treating mild to moderate class II malocclusion. But the modified distal jet produces high quality of distalization than the modified Sagittal screw distalizer.*

Keywords: *Distalization; Modified Distal; Modified Sagittal Screw Distalizer; Bone Anchored Distalizer; En Mass Distalization.*

1. Introduction

The quest of modern Orthodontics for novel conservative treatment modalities is relentless(1). This quest pursues treatment plans that veers away from more invasive approach such as extractions(2). These conservative treatments are made possible thanks to modern appliances capable of increasing sagittal and/or transverse dimension of the dental arch.

Patients with class II malocclusion account for about 35% of cases in the American and European population(3) Class II malocclusions have also been correlated to temporomandibular joint dysfunctions(4, 5) and wrong posture in children.(6)

There are numerous types of equipment to treat this malocclusion, from functional therapy (applied in growing patients) to fixed mechanicals, correlated not only to the degree of musculoskeletal maturation of the patient(7) to the oral functional habits as oral breathing(8) but also to the psycho-social state of the patient and to their compliance.(9-11)

For class II patients with a normal position of the mandible and maxillary dento-skeletal class II malocclusion, even during the growing period, molar distalization is an efficient strategy of treatment, to achieve a correction of the molar relationship by attempting to elongate the dental arch from the distal end.

Conventional appliances of distalization such as headgear, despite of being successful for tooth movement, highly depend on patient compliance(12). Utilizing bone-borne appliances for Distalization either of single molar, posterior segment or entire dental arch has been a relatively new and enticing prospect (13). Utilizing bone-borne distalization at once avoids the issue of compliance as well as anchorage loss(14)

This study aims to evaluate the type of movement achieved by two bone-borne appliances used for en masse distalization of the posterior maxillary buccal segment. One of the appliances is a bone-borne Distal Jet, whereas the other is an inverted skeletally anchored sagittal screw distalizer.

Patients and methods:

Study design:

A randomized comparative clinical study

Study setting and sample size:

Sample size calculation was based on mean U5/ANS-PNS angle change before and after treatment by Mini-screw-anchored pendulum appliance in maxillary molar distalization retrieved from previous research (15) Using G*power version 3.0.10 to calculate sample size, based on t test for mean value before and after treatment (83.2 & 79.8, respectively), 2 tailed test , α error =0.05 and power =80.0% ,with effect size =0.89 ,the calculated sample size was 12 patients per group

Eligibility criteria

Inclusion criteria

Patient with age range from 14-16 years old.

All permanent teeth present (except for third molar).

Bilateral class II malocclusion with a mesial migration of maxillary posterior teeth.

Healthy systemic condition/no systemic illness, as reported by patients.

No previous orthodontic treatment.

Good oral hygiene.

No prolonged use any form of anti – inflammatory drugs

Sample collection and attrition

The subjects selected for the study were collected from the outpatient clinic of the Department of Orthodontics, Faculty of dental medicine, Al-Azhar University (Boys, Cairo). Initially 50 patients were considered for the study, 23 of whom were excluded for not meeting one or several of the eligibility criteria. Further attrition of the sample occurred as 2 more patients refused to participate in the study upon realizing that TADs will be inserted as part of the treatment plan. One more patient elected to refuse treatment as he could not commit to periodical follow up visits required for participation in the study.

Twenty-four patients (8 males, 14 females) were eligible and willing to participate in the study. However, only 22 patients actually completed the treatment duration up to T2 (i.e. distalizer removal) while two patients dropped out; one patient had to travel outside the country for an extended period of time and the other failed to respond to phone calls or any other means of communication shortly after starting treatment.

Ethical Consideration

This study was independently reviewed and approved by the ethics committee of Faculty of dental medicine Al-Azhar University (Cairo, boys) and issued code number 558/2307. The study was also registered at clinicaltrials.gov under the identifier code of NCT05245929.

Patients' records

The following routine records were obtained for each patient prior to distalizer appliance insertion (T1)

Extra-oral photographs: A set of four extra-oral photographs; frontal, frontal with smile, right profile, and left profile.

Intra-oral photographs: A set of five intra-oral photographs, frontal view, right and left side views, and upper and lower occlusal views.

Orthodontic study cast: Extra hard stone was used to pour the upper and lower alginate impressions that were taken. A squash bite was used for bite registration.

Standardized lateral cephalometric radiograph and panorama

Full skull CBCT: (90 Kvp/11 mA, over 27 seconds, field of view 17x20) immediately before start of treatment (T1) and after diztalizer removal (T2)

Performing the randomization

Two sets of randomized numbers from 1 to 24 were generated via Research Randomizer website1 (Appendix V). Each set consisted of 12 patients. Using opaque, identical, sealed envelopes, a total of 24 envelopes contained standard-sized treatment allocation papers (modified Distal Jet or modified sagittal screw distalizer). Before the intervention, an individual unrelated to the study was asked to pick one of the sealed envelopes. The allocation paper was shown to the patient and then kept in a different place.

Blinding

Coded system was used to ensure blindness of the allocator. After allocation of the patients, it was not feasible to blind the patients to the nature of the appliance they were about to receive, after follow up the statistician was also blind to the patients result analysis sides.

Treatment Procedures

All patients in the study underwent intensive prophylaxis procedures including scaling and gingival treatment to standardize as possible the pre-treatment periodontal status for all patients. Besides the standard oral hygiene procedures (i.e. toothbrushing 4 to 5 times daily, floss and mouth wash), special appliance care and cleaning were provided to the patient in a written form.

Bonding

The right and left premolars were bonded using Dentaurum Discovery Smart brackets, Roth prescription, size 22 mil and Ormco Greenglo orthodontic composite. The first and second molars were banded using appropriately fitting band

A 19x25 mil Stainless Steel archwire was inserted to consolidate the posterior segment as one unit. Bonding positions were carefully selected to ensure passive insertion of the Archwire.

The ortho eyelet

The ortho eyelet is a cylindrical metallic component that can adapt to the head of the miniscrew with an internal O-ring.. The eyelet is custom precision milled to fit the diameter of the shaft of the miniscrew implant but not the collar to prevent over-insertion into the soft tissue. The position of the eyelet was selected to guide the insertion of the miniscrew into the ideal anatomic position in the palate(16) (Fig. 1).

Figure (1): The ortho eyeletModified Distal Jet Appliance design

The modified Distal Jet design incorporates the Ortho Eyelet anteriorly instead of premolars bands and skeletal anchorage is achieved via the miniscrews inserted through the eyelet (Fig. 2).

Figure (2): Modified Distal Jet Appliance

Modified sagittal screw distalizer design

The design of a traditional tooth-borne sagittal screw distalizer is palatally positioned incorporating four extension arms, which are soldered bilaterally to the first and second maxillary molar bands in a similar way to the expansion screw. The modified version for the study is comprised of a sagittal expansion screw anchored by palatal miniscrews inserted through ortho eyelet (Fig. 3).

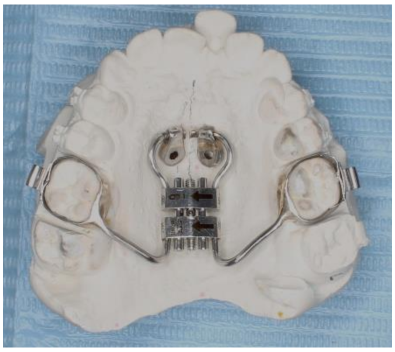

Figure (3): Modified sagittal screw distalizer design

Anchorage preparation

In this study, Orthodontic Anchor Screw were used. The ACR is an immediate loading 1.8 mm in diameter implant made of titanium alloy. It was available in three different lengths: 10 mm, 11 mm and 13 mm long. It consists of two parts: threaded part and O-Ball head. Two lengths of miniscrews were used in this study: 11 mm and 13 mm. The length of the two miniscrews used for each case was chosen according to the available amount of bone in the anterior part of the palate. The amount of bone available was measured in the pretreatment CBCT. An additional factor was achieving bicortical engagement for better skeletal anchorage preparation.

Selecting insertion site:

The safest zone for the placement is the anterior para-median region at 6-9 mm posterior to the incisive foramen and 3-6 mm paramedially as it has the greatest amount of ossified tissue in the palate and is away from the roots of neighboring teeth(17) . The first miniscrew was placed at the level of the maxillary first premolars, 1-2 mm lateral to the midpalatal suture. Palatal bone thickness is greatest in an area within 1 mm of the midpalatal suture, at the level of the first premolars.

The miniscrew with the contra angle driver was placed angulated 20-30° to the vertical and pointing towards the anterior. This ensured that the entire length of the screw was in bone, without contact with the incisive foramen and the apices of the maxillary incisors.

The second miniscrew was placed at the level of the first one and parallel to it. Miniscrews mobility was assessed after insertion using tweezers and back-end of intraoral mirror to test primary stability.

Appliance insertion

At the insertion appointment, the distalizer assembly was placed and fixed in place with the miniscrews. The assembly was checked for accuracy and minor chair-side adjustments of the wire were made if necessary to ensure a passive fit of both the miniscrews into the eyelets and the molar bands. The bands were fitted and cemented on the maxillary first molars.

Active molar distalization

As for modified distal jet, active molar distalization was started for all patients. Bilateral open coil springs were inserted between the grid lock screw and maxillary first permanent molar bands with a continuous force of 240g per side, this is the maximim force possible as mentioned in the manufacturer's brochure. The patients were examined at every two weeks for appliance, and the force level of the coil springs were checked and activated every 4 weeks.

As for the modified sagittal screw distalizer, it was also commenced within the insertion visit with a quarter turn (0.2 mm) of the screw. The patients were checked weekly for appliance inspection and periodic activation (one quarter turn per week)

All patients were fitted with a vacuum Essex retainer (2mm thickness) for the lower arch to provide disarticulation and facilitate the distalization movement

Data collection and measurements

The pre-insertion (T1) and 8-month follow up (T1) CBCT ((90 Kvp/11 mA, over 27 seconds, field of view 17*20)) data were exported in a digital imaging and communications in medicine (DICOM) multifile format and imported into Dolphin Imaging version 11.0. for 3-dimensional volume rendering. Reorientation of the head position of each scan was performed as follows. The Frankfort horizontal plane was defined through the right and left orbitales and the left porion(18), and the midsagittal plane (y) was defined as the plane passing through Sella, Nasion and anterior nasal spine(19). The Coronal (transporionic plane) was defined through right and left porions and perpendicular to the midsagittal plane(20). All measurements and landmark selection was in accordance with previous studies(18, 19, 21)

Then, using the Digitize/Measure module in Dolphin Imaging software, certain anatomical landmarks were recognized on the 3D rendering(22). Each image was then traced using the same software.

All tracings and digitization were made by the same examiner to minimize operator-generated variation in the measurements. The software calculated the linear and angular dimensions between specified landmarks. The landmark chosen were Sella,Nasion, Porion, Orbitale,Point A, Menton, Point B, Gonion, Maxillary Central incisor, Anterior nasal spine, Posterior nasal spine

The planes used for orientation and measurement were: Frankfort horizontal plane, Midsagittal plane, Coronal plane, Mandibular Plane, and Sella Vertical Line. The following linear measurements were chosen: first and second premolars root horizontal distance (mm) , first and second molars root horizontal distance(mm), SNA, SNB, U1 to FH.

Results

First premolar root horizontal distance (mm)

In group-I, treated with sagittal screw Distalizer, the average first premolar root horizontal distance (mm) recorded an average (±SD) of 56.7±2.2, and 53.9±2.5 pre- and post- intervention with a highly significant difference ($p<0.001$) between pre and post in the first group as revealed by paired t-test (table. 1).

In group-II, Modified Distal Jet, the average first premolar root horizontal distance (mm) recorded an average of 58.2±3.4, and 55.0±3.1 pre and post intervention with a highly significant difference ($p<0.001$) between pre and post in the first group as revealed by paired t-test (table. 1).

The highest change (%) in first premolar root horizontal distance (mm) was recorded in group II modified distal Jet with a decrease by -5.7 % in the left side and -5.5 % in the right side (table. 2).

Second premolar root horizontal distance (mm)

In group-I, treated with sagittal screw Distalizer, the average second premolar root horizontal distance (mm) recorded an average (±SD) of 45.2±7.4, and 42.5±7.7 pre- and post- intervention with a highly significant difference ($p<0.001$) between pre and post in the first group as revealed by paired t-test (table. 1).

In group-II, Modified Distal Jet, the average second premolar root horizontal distance (mm) recorded an average of 45.7±6.0, and 42.7±6.0 pre and post intervention with a highly significant difference ($p<0.001$) between pre and post in the first group as revealed by paired t-test (table. 1).

The highest change (%) in second premolar root horizontal distance (mm) was recorded in group II modified distal Jet with a decrease by -7.2 % in the left side and -7.0 % in the right side (table. 2).

First molar root horizontal distance (mm)

In group-I, treated with sagittal screw Distalizer, the average first molar root horizontal distance (mm) recorded an average (±SD) of 26.4±2.7, and 23.6±3.1 pre- and post- intervention with a significant difference ($p<0.001$) between pre and post in the first group as revealed by paired t-test (table. 1).

In group-II, Modified Distal Jet the average first molar root horizontal distance (mm) recorded an average of 28.0±3.2, and 24.8±3.0 pre and post intervention with a highly significant difference ($p<0.001$) between pre and post in the first group as revealed by paired t-test (table. 1).

The highest change (%) in first molar root horizontal distance (mm) was recorded in group II with a decrease by -11.5 % in the left side and -11.4 % in the right side (table. 2).

Second molar root horizontal distance (mm)

In group-I, treated with sagittal screw Distalizer, the average second molar root horizontal distance (mm) recorded an average (±SD) of 19.6±2.7, and 16.8±2.9 pre- and post- intervention with a highly significant difference ($p<0.001$) between pre and post in the first group as revealed by paired t-test (table. 1).

In group-II, Modified Distal Jet, the average second molar root horizontal distance (mm) recorded an average of 21.5±4.8, and 18.3±4.4 pre and post intervention with a highly significant difference ($p<0.001$) between pre and post in the first group as revealed by paired t-test (table. 1).

The highest change (%) in second molar root horizontal distance (mm) was recorded in group I with a decrease by -15.5 % in the left side followed by -14.8% in group II in the right side followed by -14.7% in group-II left side (table.2).

SNA

In group-I, treated with Modified Veltri Distalizer, the average SNA recorded an average (±SD) of 79.5±0.8, and 79.5±0.9 pre- and post- intervention in with a non-significant difference ($p>0.05$) between pre and post in the first group right side as revealed by paired t-test.

In group-II, Modified Distal Jet, the average SNA recorded an average of 79.3±1.1, and 79.3±1.1 pre and post intervention in the right side with a non-significant difference ($p>0.05$) between pre and post in the first group as revealed by paired t-test.

The difference between group I and group II were non-significant ($p>0.05$) in pre and post intervention in both right side and left side as revealed by independent t-test.

There was no change recorded in SNA between pre and post in both right and left sides in both groups I and II.

SNB

In group-I, treated with Modified Veltri Distalizer, the average SNB recorded an average (±SD) of 79.5±0.8, and 79.5±0.9 pre- and post- intervention in with a non-significant difference ($p>0.05$) between pre and post in the first group right side as revealed by paired t-test.

In group-II, Modified Distal Jet, the average SNB recorded an average of 79.3±1.1, and 79.3±1.1 pre and post intervention with a non-significant difference ($p>0.05$) between pre and post in the first group right side as revealed by paired t-test.

The difference between group I and group II were non-significant ($p>0.05$) in pre and post intervention in both right side and left side as revealed by independent t-test.

There was no change recorded between pre and post in both right and left sides in both groups I and II.

U1 to FH

Regarding group-I, treated with Modified Veltri Distalizer, the average U1 to FH recorded an average (±SD) of 113.3±3.6, and 113.5±3.6 pre- and post- intervention with a non-significant difference ($p>0.05$) between pre and post in the first group right side as revealed by paired t-test.

In group-II, Modified Distal Jet, the average U1 to FH recorded an average of 111.8±4.4, and 111.8±4.4 pre and post intervention with a non-significant difference ($p>0.05$) between pre and post in the first group right side as revealed by paired t-test.

The difference between group I and group II were non-significant ($p>0.05$) in pre and post intervention in both right side and left side as revealed by independent t-test.

There was no change recorded in the U1 to FH between pre and post in both right and left sides in both groups I and II.

Table (1): Comparison of the measurements within each group and between the two groups:

		Group	Before Distalization		After distalization		P value
			Mean	SD	Mean	SD	
1	U4 root to SVL	Sagittal screw distalizer	56.7	2.2	53.9	2.5	<0.001***
		Modified distal jet	58.2	3.4	55.0	3.1	<0.001***
		P value	0.110 ns		0.167 ns		
2	U5 root to SVL	Sagittal screw distalizer	Mean	SD	Mean	SD	<0.001***
			45.2	7.4	42.5	7.7	
		Modified distal jet	45.7	6.0	42.5	6.2	<0.001***
			0.426 ns		0.495 ns		
3	U6 root to SVL	Sagittal screw distalizer	Mean	SD	Mean	SD	<0.001***
			26.4	2.7	23.6	3.1	
		Modified distal jet	28.0	3.2	24.8	3.0	<0.001***
		P value	0.101 ns		0.174 ns		
4	U7 root to SVL	Sagittal screw distalizer	Mean	SD	Mean	SD	<0.001***
			19.6	2.7	16.8	2.9	
		Modified distal jet	21.5	4.8	18.3	4.4	<0.001***
		P value	0.133 ns		0.181 ns		
5	U1 to FH	Sagittal screw distalizer	Mean	SD	Mean	SD	0.276 ns
			113.3	3.6	113.5	3.6	
		Modified distal jet	111.8	4.4	111.8	4.4	0.276 ns
		P value	0.202 ns		0.175 ns		
6			82.0	1.4	82.0	1.4	
		Modified distal jet	81.7	1.3	81.7	1.3	<0.001***
		P value	0.292 ns		0.396 ns		
7	SNB	Sagittal screw distalizer	Mean	SD	Mean	SD	0.500 ns
			79.5	0.8	79.5	0.9	
		Modified distal jet	79.3	1.1	79.3	1.1	0.500 ns
		P value	0.333 ns		0.339 ns		

***, significant at p<0.05, <0.010, <0.001; ns nonsignificant at p>0.05

Table 2: Amount of change within each group and between the two groups:

	Variable	Group	P value	
			Mean	
1	U4 root to SVL	Sagittal screw distalizer	-2.8	<0.001***
		Modified distal jet	-3.2	<0.001***
2	U5 root to SVL	Sagittal screw distalizer	-2.7	<0.001***
		Modified distal jet	-3.2	<0.001***
3	U6 root to SVL	Sagittal screw distalizer	-2.8	<0.001***
		Modified distal jet	-3.2	<0.001***
4	U7 root to SVL	Sagittal screw distalizer	-3.1	<0.001***
		Modified distal jet	-3.4	<0.001***
5	U1 to FH	Sagittal screw distalizer	0.2	0.257 ns
		Modified distal jet	0.0	0.500 ns
6	SNA	Sagittal screw distalizer	0.0	0.500 ns
		Modified distal jet	0.0	0.500 ns
7	SNB	Sagittal screw distalizer	0.0	0.500 ns
		Modified distal jet	0.0	0.500 ns

***, significant at p<0.05, <0.010, <0.001; ns nonsignificant at p>0.05

Discussion

A total of 22 participant in current study was tested in two groups Group-I treated with sagittal screw Distalizer and Group-II treated with Modified Distal Jet each presented by 11 patients. In group I, 5 males (22.7%) and 6.0 females (27.3%), however in group II, 1 male patient (4.5%) and 10 Female patients (45.5%). The difference between groups I and II based on gender was non-significant as revealed by Chi-square test (p=0.074). As an overall, males presented by 6 patients in both groups (27.3%) and females by 16 (72.7%).

In this study the posterior maxillary segment was consolidated via heavy archwire (19x25) in an attempt to achieve en msasse distalizatoin with the diztalizer force acting on a single center of resistance to produce bodily movement.

The results of this study reveal that the mean amount of distalization of The root of first maxillary premolar, measured by the change of the linear distance from the root apex of U4 to Sella Vertical Line (SVL) using Sagittal screw distalizer was 2.8 mm . These results reflect the type of movement of the U4 to be mainly a bodily movement since the amount of distalization of both crown and root was largely similar. the same was observed in the 2d premolar, 1st and 2nd molars as seen in table 2

The findings of this study indicate that reinforcement of anchorage with orthodontic miniscrews increased the amount of molar distalization. The distal movements of the maxillary molars in the studies with comparable distalization techniques were from 3.9 to 6.4 mm(23-25)

A systematic review with meta-analysis(14) suggested that the palatally placed TSADs supportingappliances with pendulum-like arms produced a large amount of distal tipping (11.17°) compared to the buccally placed TSADs. This could be attributed to the design of the appliance in the included studies, since both of them had pendulum-like arms extending from a TSAD-supported appliance. However, several studies on palatally placed TSADs with different appliance designs such as MCPPs reported minimal distal tipping(26-28)

A distal movement of the molars is the effect of bodily tooth movement and tipping, which is usually not desired clinically. The findings of the studies that used similar techniques of distalization showed that the distalization of molars was associated with 3.0_ to 12.20_ of distal tipping(25). Only Gelgor et al(23) found minimal molar tipping (0.80_) in 1 of their 2 study groups. This was also found by Antonarakis and Kiliaridis, (29) who reported 5.40_ of molar distal tipping after the use of tooth-borne distalizing appliances.

4. Conclusion

Bone anchored Distal Jet and modified Sagittal screw distalizer provide an effective tool for treating mild to moderate class II malocclusion. The appliances were well-tolerated by the patients with minimal complications or pain following insertion. But the modified distal jet produce high quality of distalization than the modified Sagittal screw distalizer.

Limitations

Controlled studies with larger samples are still required to test other activation protocols with different intervals and forces of activation to elect the most efficient protocol.

Conflict of interest

None of the authors has received any grants for this study nor is any of them affiliated with any of the manufacturers of the materials used.

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