Effect of maxillary third molars extraction and non-extraction on distalization of first molars in a group of adolescent patients using infra-zygomatic gear distalizer

A Randomized Clinical Trial

Protocol submitted for the partial fulfilment of Master's degree in Orthodontics and Dentofacial Orthopedics Department.

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Submitted by

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Roles and responsibilities:

Principal investigator:

Nadeen hafez, BDS, will be responsible for applying the sample recruitment, clinical procedures of both interventions that will be carried out, follow up of patients, data management, results interpretation and writing the thesis as well as protocol registration.

Main supervisor:

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Co-supervisor:

Dr. Amr El-Dakroury (AD), BDS, MSC, PHD, (Co-supervisor): Helped with developing the idea of the research, will help in diagnosis of the sample, interpretation of results and drawing conclusion.

Dr. Mostafa Mohamed El-Dawlatly (ED), BDS, MOrth, (RCSEd) MSc, PhD, (Co-supervisor): Initiated the idea of the project and helped in designing the mechanics of the new appliance. Also, will be responsible for interpreting the outcomes and aide in the writing phase.

All authors contributed to refinement of the study protocol

Committees:

- Orthodontics Department Council.
- College Board Committee
- Ethics Committee

Introduction

Statement of the problem:

Class II malocclusion is characterized by an incorrect relationship between the maxillary and mandibular arches due to skeletal or dental problems or a combination of both. The prevalence of this malocclusion was recently found to be 20.6% in the Egyptian population between 11 and 14 years [1,2] with mandibular retrusion as its most typical characteristic.

Non extraction Treatment of Class II malocclusions frequently requires distalization of maxillary molars into a Class I relationship by means of extraoral or intraoral forces. Several writers have studied the impact of the second molar eruption stage on the distalization of the first molar for many years[3,4]. However, there is a paucity of research on the effects of third molar existence when distalization of the first molars.

In adults with erupted maxillary third molars, it is suggested to remove the third molars so that the extraction site may accommodate distalization and the regional acceleratory phenomena can aid in molar distalization. In contrast, adolescents often have unerupted third molars with partly developed roots the average age of third molar alveolar eruption is 20 years[5]. Kinzinger et al. suggested a germectomy of the third molars prior to distalization using a pendulum appliance in young children in order to accomplish physical distalization of the molars. However, surgical extraction of adolescents' unerupted third molars may be challenging and unpleasant. To our knowledge, no research has assessed the impact unerupted third maxillary molars on distalization.

Rationale for carrying out the trial:

Non extraction Treatment of Class II malocclusions frequently requires distalization of maxillary molars into a Class I relationship using extraoral or intraoral forces. Several methods and devices can be used to distalize maxillary molars and to correct Class II malocclusions. The most conventional method for distalizing the maxillary molars was the headgear [6,7], which can be used for orthodontic or orthopedic corrections. It is easy to apply and may distalize the maxillary first molars and the first and second premolars via transeptal fibers. However, the success of the treatment depends heavily on patient cooperation, lack of patient cooperation results in anchorage loss and unsatisfactory treatment results.

The disadvantages of the extraoral appliances have motivated many investigators to develop the mechanics of intraoral molar distalization. Several intraoral appliances have been used to distalize the maxillary molars in Class II patients without the patient's cooperation [8–12]. All these intraoral distalization appliances distalize the maxillary molars. However, anchorage loss was unavoidable, characterized by the protrusion of maxillary incisors, an increase in overjet, and a decrease in an overbite.

Consequently, skeletal anchorage units were introduced and proven effective in molar distalization[13–15] and other treatment protocols. The most common site for implant placement is in the maxillary body be-tween the roots of teeth[16,17]. Many working groups have recommended the zygomatic buttress as a site for mini-plate insertion, referred to as zygomatic anchorage systems[18]. With its thick cortical plate, the zygomatic process of the maxilla enables the anchorage de-vice to be placed at a distance far from the developing teeth in a growing patient while maintaining better stability for anchor units under high forces[19]. Yet, the lengthy surgical inter-vention required to insert mini-plates with the techni-cal difficulties and high sensitivity in its insertion area have made this technique unpopular.

In recent decades, certain researchers have proposed the infra-zygomatic crest (IZC) as an anchorage area for maxillary molar distalization using mini-implants [20]. The advantage of IZC is that it has a thick cortical bone that can withstand high strains. However, the treatment effects of maxillary dentition distalization with mini-screws implanted in the IZ crest have not yet been adequately evaluated in the literature.

In addition, several scientists have studied the influence of the second molar eruption stage on the distalization of the first molar for many years. However, there is a lack of research on the effects of third molar existence when distalization of the first molars is necessary. Therefore, the purpose of this research was to compare the effect of maxillary third molar presence versus extraction on distalizing first maxillary molars utilising Infra -zygomatic gear distalizer.

Literature Review:

The review of literature is divided under the following headings:

I. Techniques for maxillary molar distalization.

1-Extra oral appliances.

2- intra oral appliances.

II. Anchorage and TADS.

III. Distalizers with skeletal anchorage.

IV. Accuracy and reliability of 3D digital model and CBCT.

V. Distalization efficacy with respect to the third molar presence

I-Techniques for maxillary molar distalization.

1-Extra oral appliances.

Kingsley in (1880)[6], introduced the headgear appliance as a source of extraoral forces and anchorage. This appliance was made from a cloth covering the back and top of the head with the use of elastics to transmit the pulling force, it was designed to distalize the maxillary teeth without extraction.

Kloehn in (1947)[7], earned great popularity for the use of headgears, which have been used ever since. He reported great success in treatment of class II using an occipital headgear attached to hooks o the arch wire. For controlled force, the arch wire had stops mesial to maxillary first molar.

D. E. J. Bowden (1978)[21] , provided a literature review to examine theories of mechanical principles of tooth movement and anchorage control achieved by headgear therapy. This study stated that the antero-posterior, vertical, and lateral positions of the outer face bow hooks in relation to the centre of resistance of upper first molars which approximates the trifurcation of the roots define the direction and moment system generated by the headgear. An intrusive effect was created when a line of force passed upwards from the occlusal plane, whereas an extrusive effect was created when a line of force passed downwards. When worn for 12 to 14 hours per day with 350 to 450 g (12 to 16 ozs) applied force to molar teeth, all types of headgear have been proven to generate acceptable tooth movement.

Doruk et al (2004)[22]**,** investigated headgear cooperation using an objective measurement tool, the Compliance Science System (CSS). The study comprised 46 individuals, 32 girls and 14 boys between the ages of 10 and 15. (with a mean of 13 years). The patients, who were not aware that they were being watched, were asked to wear the headgear for 16 hours each day, with an electronic module timer connected to the neck-strap. Only the uncooperative patients were told that they had been watched, and both groups were given a four-month therapy term. Patients who were unwilling to cooperate raised their daily headgear use to about 4.5 to 6 hours. During the four-month period, all cooperative patients also wore their headgear as advised.

2-Intraoral appliances.

Hilgers (1992)[9]**,** introduced a new intra-oral distalizer and called it "Pendulum appliance". It was a hybrid that used a large Nance acrylic button in the palate for anchorage, along with 0.032" TMA springs that delivered a light continuous force to the upper first molars without affecting the palatal button. Pendulum appliance produced force of 200 to 250 grams in a swinging arc like pendulum from midline. He observed a tendency for the bite to open anteriorly as the Pendulum appliance drove the upper molars distally quite rapidly. Hilgers found that the molars could be moved much more effectively when they were being actively expanded by opening the screw of the Hybrid. The average amount of molar distalization was 5 mm in three to four months.

Carano and Testa (1996)[11]**,** used the distal jet appliance to distalize the molars bodily. The appliance consisted of bilateral tubes of 0.036" internal diameter attached to a Nance appliance soldered to the second premolars bands, a coil spring and a screw-clamp soldered over each tube. In this study they used either stainless steel or nickel titanium coil springs (150 gm for children, and 250 gm for adults). The wire extending from the acrylic through each tube ended in a bayonet bend that inserted into a lingual sheath of the first molar band. The appliance was activated by sliding the clamp closer to the first molar once a month. They achieved 5 mm of bodily molar distalization in a 10-year-old child in 4 months.

Fortini et al (1999)[12]**,** developed the First-Class appliance which consisted of a buccal component of a formative screw soldered to the first molar band and split rings welded to the second premolar or deciduous molar bands. From the palatal side there was a butterfly extended Nance button for more stability. NiTi coil springs were compressed between the premolar solder joints and molar tubes. The tubes prevented the distal tipping during distalization. This appliance showed rapid molar distalization even with fully erupted second molar and the distalization was bodily with no tipping or anchorage loss.

Keles et al (2001)[23], introduced the Keles Slider for the distalization of the maxillary first molar. Fifteen patients with mean age of 13.32 years were selected for unilateral molar distalization. The maxillary first molars and first premolars were banded. The anchorage unit was a Nance button with an anterior bite plane. From the palatal side, the point of distal force application was carried towards the level of center of resistance of the maxillary first molar. A Ni–Ti coil spring was used and activated every month, and 200 grams distal force was applied. The molars were distalized bodily on average 4.9 mm with no extrusion or tipping but showed distobuccal rotation. The first premolars showed bodily mesial movement of 1.3mm, incisor protrusion was 1.8 mm and incisor proclination was 3.2 degrees. The overbite was reduced by 3.1 mm and the overjet increased 2.1 mm.

II. **Anchorage and TADS**.

In 1999 Umemori et al[17]**,** defined skeletal anchorage as the mechanism where the patient's skeletal component is utilized using attachments as mini-implants and mini-plates to reinforce the anchorage during various orthodontic tooth movements. Intraoral skeletal anchorage provides absolute anchorage, eliminates the need for patient cooperation and anchorage preparation, and gets predictable treatment results more rapidly.

Park et al (2006) [24]**,** examined the success rate and factors affecting the clinical success of mini-implants used as orthodontic anchorage. Eighty-seven consecutive patients (35 males, 52 females; mean age, 15.5 years) with a total of 227 screw implants were examined. The screw implants were placed at 30°to 40° angles to the long axes of the teeth in the maxillary arch and at 10° to 20° angles in the mandibular posterior area. The screw implants in the retromolar area and the distobuccal bone to the mandibular second molars were placed at 90° to the bone surface, the different angulation was to reduce root contact by the mini screws without reducing the length of the screw. Results showed that the overall success rate was 91.6%. The clinical variables of mini-implant factors (type, diameter, and length), local host factors (occluso-gingival positioning and management factors, angle of placement, onset and method of force application, ligature wire extension and exposure of screw head) did not show any statistical differences in success rates. General host factors (age, sex) had no statistical significance, while Mobility, jaw (maxilla or mandible), side of placement (right or left), and inflammation around the screws due to bad oral hygiene showed significant differences in success rate. This study concluded that, to minimize the failure of screw implants, inflammation around the implant must be controlled, especially for screws placed in the right side of the mandible.

Poggioa et al (2006)[25]**,** provided a clinical indication for a safe application of the mini-screws as well as the ideal miniscrews features. The volumetric tomographic images of 25 maxillae and 25 mandibles taken with the New Tom System were examined. The results showed that in the maxilla, the greatest amount of mesiodistal bone was on the palatal side between the second premolar and the first molar. The least amount of bone was in the tuberosity. The greatest thickness of bone in the buccopalatal dimension was between the first and second molars, whereas the least was found in the tuberosity. In the mandible, the greatest amount of mesiodistal dimension was between first and second premolar. The least amount of bone was between the first premolar and the canine. Buccolingually, the greatest thickness was between first and second molars. The least amount of bone was between first premolar and the canine.

III. Distalizers with skeletal anchorage.

Gelgor et al. (2004)[26] investigated the effectiveness of intraosseous screws for anchorage in maxillary molar distalization. The study included twenty-five participants (18 girls and seven boys; 11.3 to 16.5 years of age). The screw was placed behind the incisive canal at a safe distance from the mid-palatal suture following the palatal anatomy. The amount of force used was 250 g per side The average distalization time to achieve an overcorrected Class I molar relationship was 4.6 months. In the cephalograms, the upper first molars were tipped 8.88°and moved 3.9 mm distally on average. The upper molars showed distopalatal rotation. Mild protrusion (mean 0.5 mm) of the upper central incisors was also recorded. However, there was no change in overjet, overbite, or mandibular plane angle measurements. They concluded that immediately loaded intraosseous screw–supported anchorage unit was successful in achieving sufficient molar distalization without major anchorage loss.

Kinzinger et al. (2005)[13]**,** conducted a study where the standard pendulum appliance was modified by integrating a distal screw into its base and by special pre-activation of the pendulum springs. The suitability of this Pendulum K for the translatory distalization of maxillary molars was investigated in children and adolescents. The study with its collective of 66 patients confirmed that the Pendulum K allows a virtually translatory molar distalization with slight tipping of

4.75° to the palatal plane and 4.25° to the anterior basal plane. Palatal movements of the first molars were avoided. The proportion of molar distalization in the total movement was 73.53%.

Erverdi et al. (2006)[27]**,** presented the fabrication and application of a new generation of posterior intrusion appliances using zygomatic anchorage. The use of zygomatic anchorage enabled en masse impaction of the posterior segment without any side effects such as labial flaring. A 14-year-old, female Class II patient with an anterior open bite was treated with the new generation posterior intrusion appliance. At the end of treatment, a Class I canine and molar relationship and a correction of the anterior open bite were achieved. The molars were impacted 3.6 mm, and this impaction was maintained throughout the treatment. The mandibular plane showed a counter-clockwise autorotation of 48. This case report demonstrates that zygomatic anchorage could be used effectively for molar intrusion and anchorage maintenance.

Sugawara et al (2006)[19]**,** examined the treatment effects when using the skeletal anchorage system (SAS) in order to distalize the maxillary molars in non-growing patients. The SAS consists of titanium anchor plates and monocortical screws that were temporarily placed. The sample size consisted of 25 non growing patients with average age at the beginning of treatment of 23 years 11 months. The average amount of distal movement of the maxillary first molars was 3.20 mm at the root level and 3.78 mm at the crown level in about 19 months. The authors also concluded that the maxillary first molar was distalized with no regard to the extraction of the third or second molars.

Polat-Ozsoy et al (2008)[15]**,** performed a retrospective study to investigate the dentoalveolar and skeletal effects obtained from 2 types of pendulum appliance with different anchorage designs: bone-anchored pendulum appliance (BAPA) and conventional pendulum appliance (CPA). The BAPA group included 22 patients while the CPA group included 17 patients with mean age 13.61 ± 2.01 years.

Approximately 230 g of distalizing force was used. Lateral cephalograms before treatment and at the end of distalization were measured. For the BAPA group, the distalization was 4.8mm in 6.8 months and 9.1° distal tipping, while for the CPA group, the distalization was 2.7 mm in 5.1 months and 5.3° distal tipping. The BAPA group also showed distaliazation in upper 1st and 2nd premolars by 2.7 ± 1.6 mm and 4.1 ± 2.1 mm respectively, with retraction of maxillary incisors by -0.1 ±1.7 mm, -1.7° ± 2.9°, while in the CPA there was significant loss of anchorage showed as mesialization in upper 1st and 2nd premolars by 4.0 ± 2.7 mm and 2.3 ± 2.1 mm respectively, together with proclination of upper incisors by 1.2 ± 1.7 mm, 0.9° ± 2.4°.

Fudalej et al (2011)[28]**,** performed a systematic review without meta-analysis, to analyze studies that used temporary anchorage devices during distalization. Several databases including Pub Med, Embase and Cochrane Central Register of Controlled Trials were searched until August 2010. This systematic review included only nonrandomized prospective and retrospective studies. Twelve articles met the inclusion criteria out of which 4 were of medium quality and 8 of low quality. The results showed that maxillary molars were distalized by 3.3 to 6.4 mm with the mean distal movement of the maxillary molars was 0.7 mm (SD, 0.3 mm) per month (range, 0.2-1.2 mm). with distal tipping from .080° to 12.20°. The maxillary incisors remained in the same position during distal movement of the molar with only 2 studies showed statistically significant retraction of the central incisors.

Nur et al (2012)[29]**,** utilized the zygoma gear appliance to bilaterally distalize the maxillary molars and performed research to determine its dentoalveolar, skeletal, and soft tissue effects. The research group included fifteen patients (mean age, 15.87 1.09 years; range, 14–18 years), and lateral cephalometric images were obtained before and after distalization. A distalization force of 300 g per side was applied to the maxillary molars via the closed coil springs which replaced the heavy elastics in the previous design. The findings of the study showed that the maxillary molars were effectively distalized into a Class I relationship in all patients in a short time despite the presence of the maxillary second and third molars, the rate for the distal movement of the molars was 0.84 mm per month by total distalization of 4.37 ± 2.15 mm without anchorage loss, while distal tipping measured only 3.30º,maxillary first molars showed a slight intrusion (0.50 mm) and there were insignificant changes in both skeletal and soft tissue measurements.

Kilkis et al (2016)[30]**,** conducted a study to evaluate the dentoskeletal effects of the zygoma-gear appliance used for unilateral maxillary molar distalization, this study consisted of 21 patients with mean age 15.68 ± 2.18 years and concluded that it was effective with significant amount of distalization for the maxillary first molar (5.31 ± 2.46 mm) in (0.45 ± 0.12 years), a 0.98 mm distalization rate per month

Aline Rode Santos et al (2017)[31]**,** conducted a tomographic study to evaluate the infra-zygomatic crest region thickness, in adult (male and female) patients. CBCT images from 40 patients were used to assess cross-sectional measurements of the infra-zygomatic crest region. Measurement 1 considered thickness 2 mm above the distobuccal root of the permanent maxillary first molar, while measurement 2 was taken 2 mm above the first measurement. The mean thickness of the infra-zygomatic crest in males was 3.55 mm for measurement 1 and 2.84 mm for measurement 2, while in females these were 2.37 mm and 2.24 mm, respectively. The authors concluded that the overall mean thickness of the infra-zygomatic crest was 2.49 mm with respect to measurement 1, and 2.29 mm for measurement 2, with no statistically significant differences between genders.

IV. Accuracy and reliability of 3D digital model and CBCT.

Mavropouls et al (2005)[32] used three dimensional digitized models to evaluated the treatment changes that occurred after modifying the Jones Jig appliance with a Nance button for anchorage demand. Ten patients with bilateral class II molar relationship, that requires distalization, and fully erupted upper second molars were involved in this study. Dental casts and lateral cephalometric radiographs were taken immediately before placement and after removal of the appliance. The 3D models were superimposed on the anterior part of the palate comprising the palatal rugae and a zone in the palate along the midline raphe. The study proven that noncompliance simultaneous distalization of the first and second maxillary molars can be an efficient option for the correction of Class II molar relationship. The cast assessment of 3D sagittal and vertical tooth movements was more reliable than the cephalometric record.

Peck et al (2007)[33] performed a study to compare between the accuracy of CBCT and panoramic x-ray in detection of mesiodistal root angulation. This study included five patients in which at first a plaster study model was prepared for each patient, then a radiographic stent containing radiopaque markers was fabricated for each of these models. Panoramic and cone beam computed tomography (CBCT) scans were taken on each patient with the radiographic stent seated on the dentition. Root angulations for each of the radiographic scanned images were measured. This study showed that CBCT scans produced very accurate measurements of root angulation compared to plaster model measurements (the gold standard), while panoramic projections did not provide reliable data on root angulation.

EL-Zanaty et al. (2010) conducted a study comparing the dental measurements obtained from CBCT scans and plaster dental models using 3-dimentional-based dental measurements program. The measurements were done in 3planes of space, they found out there is excellent agreement between 3D based dental measurement program and the conventional method which can substitute the conventional plaster model.

El-Beialy et al. (2011)[34] conducted a study to find out the accuracy and reliability of measurements obtained from CBCT for various head orientations. Stainless steel wires were fixed to a dry skull at different places which was then scanned by using CBCT in a central position and 5 other positions. Six landmarks were placed by two operators and compared to the true length of the wires glued on the skull which is considered as the gold standard. The results showed that the CBCT measurements were very accurate producing a 1:1 ratio to the real size measurements and that the accuracy and reliability were not affected by changing the skull orientation. The authors therefore recommended that the upper-lip and chin rests are not needed during CBCT scan.

Nalcacia et al. (2015)[35] investigated the reliability of measurements obtained after the superimposition of three-dimensional (3D) digital models by comparing them with those obtained from lateral cephalometric radiographs and photocopies of plaster models for the evaluation of upper molar distalization, Data were collected from plaster models and lateral cephalometric radiographs of 20 Class II patients who's maxillary first molars were distalized with an intraoral distalizer. The posterior movements of the maxillary first molars were evaluated using lateral cephalometric radiographs (group CP), photocopies of plaster models (group PH), and digitized 3D models (group TD). The pre- and post-treatment scans of the dental models were superimposed on three points in the incisive papilla area (the most anterior point, the most prominent point, and the most posterior point of the incisive papilla). frontal line perpendicular to the midsagittal plane and passing through the most prominent point of the incisive papilla was constructed on the superimposed 3D models to determine the distalization amounts of the central incisors, canines, premolars, and molars. It was concluded that 3D digital models are reliable to assess the results of upper molar distalization and can be considered a valid alternative to conventional measurement methods.

V. Distalization efficacy with respect to the third molar presence

Kinzinger et al (2004)[4]**,** evaluated the efficiency of a pendulum appliance for molar distalization related to second and third molar eruption stage. The studied sample included 36 adolescent patients in various stages of the molar dentition. The patients were divided into 3 groups (PG 1-3) according to the stage of eruption of their second and third molars. In PG 1 (18 patients), eruption of the second molars had either not yet taken place or was not complete. In PG 2 (15 patients), the second molars had already developed as far as the occlusal plane, with the third molars at the budding stage. In PG 3 (3 patients), germectomy of the wisdom teeth had been carried out, and the first and second molars on both sides had completely erupted. A modified pendulum appliance, including a distal screw and special preactivated pendulum springs was used for bilateral maxillary molar distalization. The study showed that the degree of tipping of maxillary second molar was greater when a third molar bud was in the direction of movement. Moreover, the study concluded that third molar bud could sometimes act as a fulcrum, affecting the efficiency of upper 1st molar distalization. After previously completed germectomy of the wisdom teeth, almost exclusively bodily distalization of both molars is possible. In the presence of both 2nd and 3rd molars the duration of distalization will be longer, greater forces will have to be applied, and more anchorage will be lost. This study recommended germectomy of wisdom teeth prior to ditalization.

Flores-Mir et al (2013),[3] conducted a systematic review to evaluate the efficiency of molar distalization associated with the second and third molar eruption stage. A systematic computerized database search was done using several databases and out of the thirteen initially identified articles, only four fulfilled their final selection criteria. The results showed that three of the four studies showed no statistical significance in the linear amount of maxillary first molar distalization based on the eruptive stage of the second and/or third molars, while the last study showed that the amount of distal movement of the first molars was significantly greater in the group with unerupted second molars. The study also noted that tipping of the first molar was greater when a third molar bud was located in the direction of movement. As a result, they concluded that effect of maxillary second and third molar eruption stage on both linear and angular maxillary molar distalization appears to be minimal. But this conclusion was based only on low–level of evidence clinical trials.

Jin Lee et al (2019)[36] **,** evaluated changes in the position of maxillary third molars with cone-beam computed tomography images in adolescents after total arch distalization using a modified C-palatal plate (MCPP) and to compare them with the changes in a matched control group. Forty adolescent patients (mean age, 12.6 years) were divided into MCPP and control groups. Cone-beam computed tomography images were taken before and after molar distalization (mean duration,14.4 months) in the MCPP group and in the control group (mean duration, 12.9 months). The changes in the position, angulation, and rotation of the third molars were assessed, and the volumes of maxillary tuberosity were measured. The results showed that after distalization, the third molars moved backward (1.2 mm) and upward (0.5 mm) in the MCPP group with a significant difference ($P<0.003$), and they moved downward and forward in the control group. The changes in rotation and angulation were insignificant. The volumes of maxillary tuberosity increased in both groups. The study concluded that maxillary total arch distalization caused unerupted third molars to move backward and upward, with an insignificant difference in the posttreatment volume of maxillary tuberosity. Therefore, it may be possible to perform maxillary total arch distalization in adolescents with unerupted third molars without a germectomy, at least in the short term.

Database research:

A search was performed on electronic databases (PubMed, Cochrane library).

Aim of the study

A-PICO format:

Population:

Adolescent patients having Class II molar relation with full permenant dentition including unerupted third molar. And indicated fore maxillary molar Distalization.

Intervention:

Distalization of maxillary first molars using infra-zygomatic gear distalizer after extraction of maxillary third molars.

Comparator:

Distalization of maxillary first molars using infra-zygomatic mini-implants as anchorage unit without extraction of maxillary third molars.

Outcome measure(s):

	Outcome name	Measuring device	Measuring unit
Primary outcome	The total anteroposterior distance moved by the maxillary first molars.	Digital models using 3- shape scanner and program.	mm

		CBCT images using Anatomage software.	mm
Secondary outcomes	1-Maxillary first molar distalization rate.	Digital models using 3 shape scanner and program.	mm/month
	2-Maxillary first molar rotation	Digital models using 3 shape scanner and program.	Degree
	3- Intermolar width	Digital models using 3 shape scanner and program.	mm
	4-Maxillary first molar tipping and torque	CBCT images using Anatomage software.	Degree
	5-Maxillary first molar vertical changes	CBCT images using Anatomage software	mm

	6- Total anteroposterior distance moved by maxillary first and second premolars.	Digital models using 3 shape scanner and program.	mm
	7- Maxillary second molar tipping.	CBCT images using Anatomage software	Degree
	8-Maxillary third molar tipping	CBCT images using Anatomage software	Degree
	9-Maxillary third molar vertical changes	CBCT images using Anatomage software	mm
	10-Maxillary four incisors anteroposterior and vertical linear measurements.	CBCT images using Anatomage software	mm
	11- Maxillary four incisors torque.	CBCT images using Anatomage software	mm

B-Research question:

Does extraction of the upper third molars have a different impact than non-extraction on distalizing maxillary first molars in Class II adolescents?

Objectives of the study research

Research hypothesis:

The null hypothesis was that the presence and extraction of unerupted maxillary third molars would have a similar effect on the distalization amount of maxillary first molars and the other dental changes.

Primary objective (s):

Amount of maxillary fitst molar Distalization.

Secondary objective:

Evaluate the other dental changes in the upper buccal segment accompanying the Distalization technique and dental changes in the incisors.

Study design

This research was a single-cantered, 2-arm parallel group randomized controlled clinical trial 1:1 allocation ratio, performed following the Consolidated Standards of Reporting Trials guidelines.

Material and Methods

I) Participants, Interventions, and Outcomes

A) Study Setting:

The study will be performed in the clinic of the Orthodontic Department at the Faculty of Oral and Dental Medicine, Future University in Egypt. The recruited sample would be from the Egyptian urban and rural population.

B) Eligibility: for the participants include the following:

(1) Adolescent patients aged 16-19 years.

(2) skeletal Class I (0°<ANB< 4).

(3) bilateral Class II molar relationship. defined by at least an end-to-end molar relationship.

(4) normal vertical growth pattern.

(5) full permanent dentition with unerupted upper third molars.

Exclusion criteria included:

(1) a skeletal Class II or Class III relationship.

(2) past orthodontic treatment.

(4) poor oral hygiene.

(5) Increased vertical dimension.

C) Interventions:

- **Medical History Questionnaire:**

will be filled by the patient to exclude the presence of any systemic condition.

- **Clinical Examination:**

Proper examination of the oral structures including;

- Teeth will be examined for caries, fracture or missing teeth.
- Gingival tissues will be examined for gingivitis, periodontitis, attachment loss, gingival recession, oral lesions and the nature of the gingival biotype.
- Thorough intraoral examination is needed to evaluate the need for referral for consultation or intervention before the initiation of treatment.

Diagnosis

The patient is checked to fulfil the previously mentioned inclusion criteria. Full set of records will be taken for every patient (study models, lateral cephalometric radiographs, and photos as part of the routine procedure for treatment of patients in the outpatient clinic of the Orthodontic Department, future University in Egypt.

Clinical Procedure:

After taking pre-treatment records, every patient will receive:

- The third molars will be extracted surgically in the third molar extraction group four weeks before intervention commenced.
- Proper disinfection will be performed with a local disinfectant, BETADINE povidone-iodine 10%, at the area of mini-implant insertion.
- Two infra zygomatic mini-implants will be placed (Screw Tomas pin 10mm, dentaurum, Germany).
- Bands will be cemented to the upper first molars.
- The inner bow (1.2mm) is a modified version of the inner part of a conventional face bow. Two hooks were soldered onto the inner bow distal to the lateral incisor teeth regions. A U loop at the first premolar region and bends acting as a mesial stop will be bent in front of the maxillary first molars.

- The inner bow will be adjusted to the headgear tubes on the maxillary first molar bands, as the anterior component of the inner bow is 3 mm free from the labial surface of the anterior teeth.
- A distalization force of 300 gm/per side was applied to the maxillary molars via a closed coil spring (Tomas-coil spring, Dentourum, Germany). According to the desired activation length, the distal end of the coil spring was set to the IZ mini-screw, while the mesial end was linked to the wire framework hook either directly or with a 0.01-inch stainless-steel ligature

<u>Follow up period</u>

The patient will be asked to attend follow up visits every 4 weeks

<u>1-to check the following:</u>

1. The stability of the mini-implants
2. The activity of the appliance (force recalibration is required).
3. The amount of correction achieved.
4. Any inflammation related to the appliance or the mini-implants

2- <u>Impressions will be taken</u> (without the appliance in place) followed by digital scanning of produced models).

- **<u>Criteria for discontinuing or modifying the allocated</u>**

In cases of prolonged swelling or pain related to the mini-screw, the patient will be given strict oral hygiene measures and may wait for three weeks before the beginning of retraction.

-In cases of loose or broken mini-implant, the screw will be removed and replace the mini-implant after total resolution of the inflammation.

-In case of non-compliant patients.

- **<u>Criteria of ending the distalization phase.</u>**

- Class I molar relation or at the end of pre-determined treatment duration (eight months).

D] Outcomes

1) **<u>Primary outcome</u>**

The primary outcome of the current study was to determine the total Anteroposterior position changes of upper first molars.

2) **<u>Secondary outcomes:</u>**

The secondary outcomes were the changes in upper first molars rotation, intermolar width, tipping, torque, and vertical position, the upper first molars distalization rate, the changes in the anteroposterior position of the upper first and second premolars, tipping of upper second molars, tipping and vertical position of the upper third molars, and anteroposterior, vertical, and torque changes of the upper incisors.

3) Methods of measuring of all outcomes:

Linear and angular measurements will be made on the pre, post and follow-up digital models and on the pre-and post distalization CBCT to assess the dental changes in intervention group.

Participant timeline:

1. The principal investigator will screen the potential patients through careful clinical examination of patients at the orthodontic department, Faculty of Oral and Dental Medicine, Future University in Egypt.

2. All recruited patients should fulfil the previously mentioned inclusion and exclusion criteria.

3. Every participant will be asked to sign an informed consent before the beginning of the study.

4. After patient's enrolment, each participant will be asked for pre-intervention records to ensure proper diagnosis.

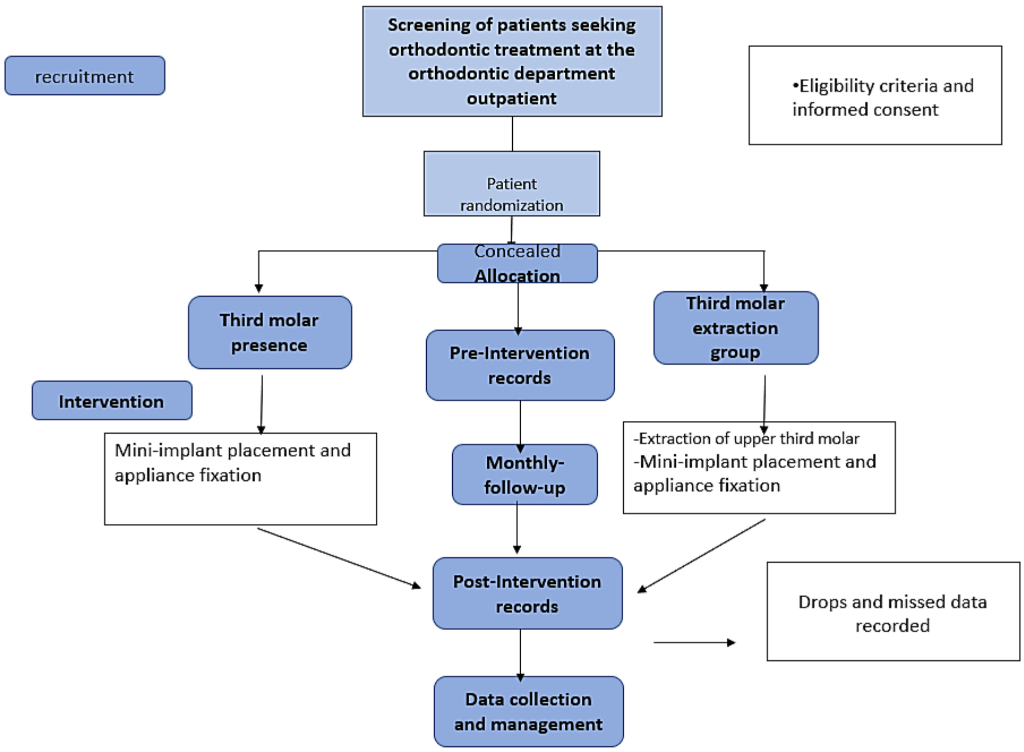
5. The principal investigator will randomly allocate the patients to one of the intervention groups.

6. After patient's enrolment, pre-intervention records will be taken for each participant to ensure proper diagnosis (T0).

7. Every 4 weeks Each patient will have follow up visit, for appliance activation, uptake of impression for interim records and checking for mini-screws stability (T1-T7).

8. Post- records for each participant will be taken after duration of eight months (T8) at the same visit of appliance removal.

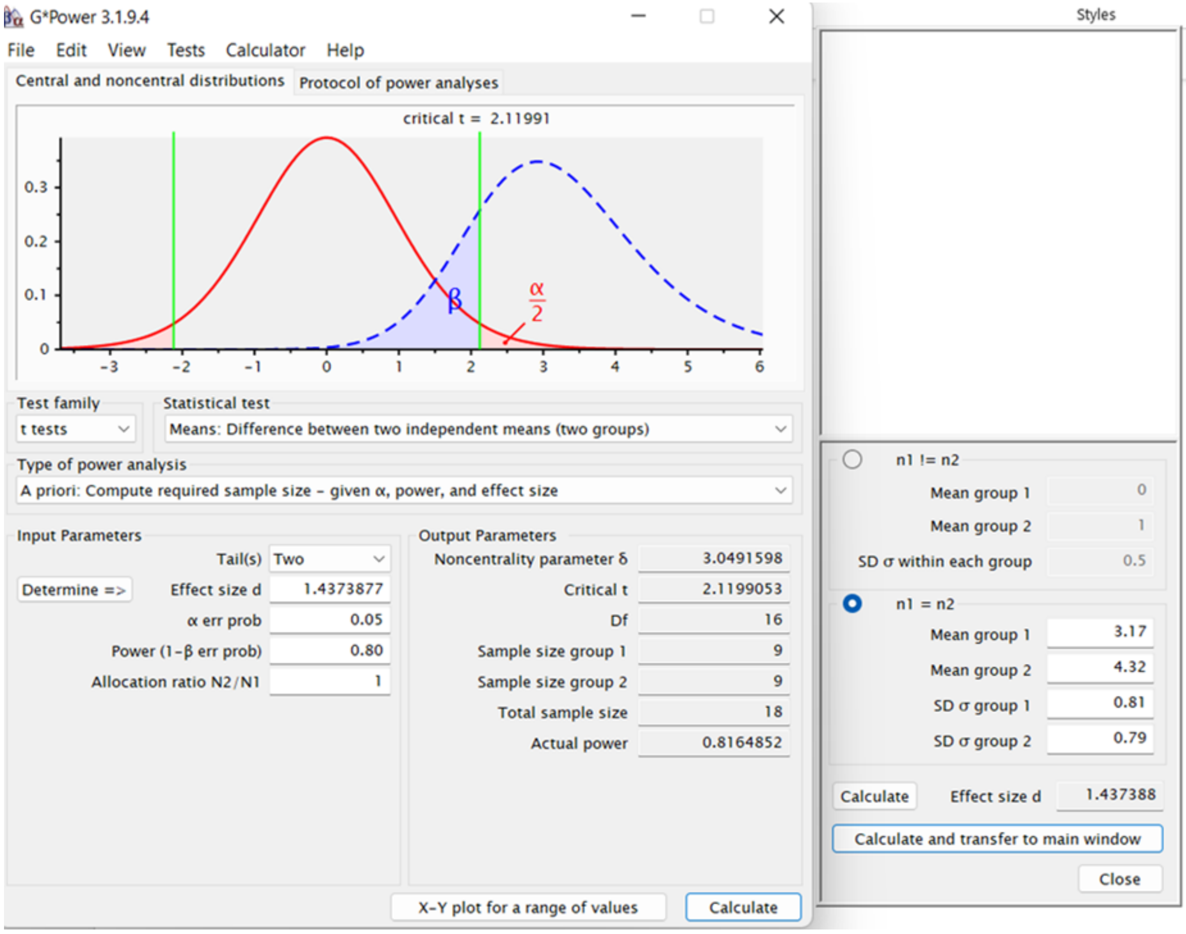
9. The principal investigator will continue the normal orthodontic treatment and achieved proper finished occlusion for every patient after the end of the study.



E] Sample size calculation:

The sample size calculation is based on the findings of a pilot study, including three patients from each group, in which the upper first molar distalization amount was the primary outcome. The mean (standard deviation) values were 3.17(0.81) mm and 4.32 (0.79) mm in the TMP and TME groups, respectively. The effect size was 1. 437. With alpha level of 0.05 and a test power of 80%, the minimum estimated sample size was 18 patients (9 patients per group). Considering drop out a sample size of 11 per group is appropriate.

Sample size calculation is performed Using G*Power version 3.1.9.2.



F] Recruitment strategy:

The principal investigator will recruit the patients from the clinic of Orthodontic department, Faculty of Oral and Dental Medicine- Future University in Egypt. Screening of patients will continue until the total number of participants for the study is collected.

II) Assignment of interventions

A] Sequence generation:

The supervisor of the study will apply Computer generated random numbers to randomly assign patients to group A (En-masse) or B (two steps) using Microsoft Office Excel 2007 sheet. The patient numbers will be written in the first column and the supervisor will select function RAND to generate the randomization number in the second column. These numbers will be sorted according to the randomization number so the first column numbers will be randomly distributed.

B] Allocation concealment mechanism:

The Co-supervisor of the study (Dr.Mostafa El-Dawlatly) will write the randomization numbers of the patients on opaque white papers folded three times to form sealed envelopes and store it inside a box. The codes for randomization will be securely held at the secretary's office.

C] Implementation

At the time of intervention, the main operator will send the patient to the secretary's office. Then, the assigned employee will open the box and ask the patient to select one envelope. The main operator will contact the supervisor to know the order and then the main operator will allocate each patient to assign each participant for the corresponding intervention either (extraction or non-extraction) according to the list of codes of randomization.

D]Blinding:

Because both the operator and the patient are aware of the clinical intervention, double-blinding is not feasible. However, the digital dental models and CBCT will be assessed blindly by a trained external assessor.

III) <u>Data collection, management and analysis:</u>

A] Data collection methods:

to assess the primary and secondary outcomes, the principal investigator will take study models for every participant monthly during the follow up visits. Then will digitize the models and identify the landmarks, reference lines and planes on the pre, interim and post-retraction digital dental models for measurements reading. Also, by identifying the landmarks, reference lines and planes using CBCT taken before and after the completion of retraction.

B] Data management:

A colleague outside the research team will enter the data and organize it in excel sheets in the computer of the orthodontic department. Data will include all photographs, models, radiographs and filled questionnaire.

C] Statistical Analysis:

- The principal investigator will be responsible for the extraction of the required data from the CBCT taken before and after retraction as well as the study models taken at every follow up visit. The data will be sent to a specialized statistician.
- The specialized statistician will be responsible for the statistical analysis of the study by:

1. Presenting the data as mean, standard deviation (SD) and Standard error (SE) values.
2. Using Paired t-test to compare between the friction and the frictionless group of retraction as well as to compare between the pre-and post -treatment data for each group.

3. Using Anova test to determine the rate of anterior segment retraction.

4. Statistically evaluate the patient acceptance for both techniques.

- For this study, the specialized statistician will use IBM11 SPSS12 Statistics Version 20 for Windows to perform the required statistics.
- The significance level will be $P \leq 0.05$. Highly significant variables are detected when P value is less than 0.01.

Assessors Reliability:

- To achieve high reliability for measurements, the supervisor will choose a well experienced inter-examiner during the study.
- A training session will be provided for the examiners to ensure standard measurements techniques.
- Each examiner will complete the measurements on a model and will repeat the procedure after one week to assess the intra- and inter-examiner reliability.
- The supervisor will compare the measurements of the two assessors for disagreement with a difference of more than one millimetre.
- The supervisor will evaluate the amount of variation in measurements among and between examiners to test the performance of each assessor.
- The examiner with less reliability will receive additional training but will be replaced during the study.
- The specialized statistician will calibrate the intra and inter-examiner reliability for the measurements of the study by the Intra-

class correlation coefficient (ICC). The closer the ICC to 1.0, the higher reliability between assessors. According to Fleiss:" ICC values between 0.7 and 0.9 represent good reliability." The kappa scores between study examiners will be calculated, a range of 0.60-0.80 will represent acceptable reliability.

IV) Method Monitoring:

A] Data Monitoring: An independent Data Monitoring Committee (DMC) will monitor the results of the study. The Committee will include the trial’s supervisors, who will periodically review the trial data and identify the need for any adjustments or modifications during the study.

B] Interim Analysis: no interim analysis will be performed during the study.

C]Harm: The main operator will document and report any harms or unwanted effects during the study intervention to the trial supervisors. Also, any unpleasant experience will be reported by the patient in the final questionnaire at the end of the retraction. The main operator will be responsible for the management of any adverse effects or unfavorable side effects resulting from the appliance.

D]Auditing: The supervisor will follow up and review the different interventions and resulting data. And he will periodically follow up the trial progress including recruitment of patients, allocation of participants to study groups; adherence to interventions and reporting of harms. A meeting with the senior supervisor will be set every 3 months to monitor the progress of the study and the need for any adjustments.

IV) Ethics and dissemination:

A] Research Ethics Approval:

The Ethical committee in Future University, Egypt will review the protocol before they approve it. The research Ethics committee will evaluate the different interventions of the study to ensure its ethical validity and the potential benefits to the participants.

B] Protocol amendments:

The main investigator will be responsible to complete a formal amendment in case of any modifications or adjustments to protocol that may affect the conduct of the study, as changes in the study design or intervention procedures. The Orthodontics department, Faculty of Oral and Dental Medicine, Future University in Egypt and the Ethics Committee will approve such amendment before proceeding in the study.

C] Consent:

The main investigator will be in charge for detailed explanation and elaboration of the different steps of the study interventions for each patient. Then will ask every participant to sign a written consent before they begin treatment. The consent will be written in Arabic.

D] Confidentiality:

The main investigator will store any personal information about the participants collected during the study separately from study records in locked files in areas with only access to the supervisors responsible for auditing and analysis. Also, will keep the files in the Department Of Orthodontics, Faculty of Oral and Dental Medicine, Future

University and will identify all the reports, data and administrative forms by a coded ID number to maintain participant confidentiality. Participant information won't be used outside the study except with written permission of the participant.

E] Declaration of interests:

No financial interests are to be declared by the supervisors and the principal operator. This study is a part of a Masters' degree in Orthodontics, Faculty of Oral and Dental Medicine, Future University and it is self-funded by the principal investigator.

F] Access to data:

The supervisors and the principal investigator will only have access to the data of the study. All the data will be secured by a password to maintain confidentiality.

No other parties are allowed to assess the results until the study is terminated and the conclusions are revealed.

G] Ancillary and post-trial care:

Any complication associated with the intervention will be managed by the principal operator. Then the two group of patients will continue their regular orthodontic treatment according to the treatment plan described for each case.

H] Dissemination Policy:

The trial results will be available to the participants, health care professionals and the public by publication of the study in high quality national and international journals. The principal investigator will present a copy of the thesis at the Faculty of Oral and Dental Medicine, Future University library and will distribute additional copies among the main universities in Egypt.

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