

**Effect of Bilateral Distalization of Upper First
Molars in a Group of Patients after extraction
of Maxillary Second Molars Using Infra
Zygomatic Mini Implants**
Prospective clinical trial

Protocol submitted for the partial fulfillment of master's degree in
Orthodontics

Faculty of Dentistry, Future University in Egypt

Submitted by

Name: **Hosam Abdullah Mohamed Zaza**

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I. Administrative Information

1. Title:

Effect of bilateral distalization of upper first molars in a group of patients after extraction of upper second molar using infra zygomatic mini implants

2. Trial registration:

Trial will be registered in www.clinicaltrials.gov

3. Protocol version:

July -2020, First version.

4. Funding:

This research is self-funded.

5. Roles and responsibilities:

Main supervisor: -

- **Prof. Nagwa Al Mangoury (NM)**, BDS, MSC, PHD, FDS(RCSEd). Professor of orthodontics at the faculty of oral & dental medicine, Future university: Helped in developing the idea of the research, will help in interpretation of results and drawing conclusions.

Co-supervisor: -

- **Dr. Amr El-Dakrouy (AD)**, BDS, MSC, PhD, Associate professor – Department of Orthodontics and Dentofacial Orthopedics, Cairo University, (Co-supervisor): Calculated the sample size, also will help in following up of patients, creating analysis and interpretation of the results.

Co-supervisor: -

- **Dr. Mostafa Mohamed El-Dawlatly (ED)**, BDS, MSC, MOrth, PhD (RCSEd), Lecturer of orthodontics at the faculty of dentistry, Cairo University, (Co-supervisor): Initiated the idea of the project and helped in designing the mechanics of the new appliance. Also, will be responsible for clinical part of the study, interpreting the outcomes and aide in the writing phase.

Principle investigator: -

• **Hosam Abdullah Mohamed Zaza (HZ)**, BDS, (Principal Investigator): Will be responsible for the clinical part of the study, sample recruitment, follow up of patients, writing the thesis, interpretation of results.

Committees:

- Department of Orthodontics and Dentofacial Orthopedics Council
- College Board Committee
- Ethics Committee

II. INTRODUCTION

Class II malocclusion is considered to be a prevalent type of malocclusion, which can be observed in almost 1/3 of the population¹. Class II malocclusion can be either dental and/or skeletal, each having their own characteristics. These characteristics are usually expressed simultaneously, but to different extents. The dental component is expressed when the buccal groove of the mandibular first molar is distally positioned to the mesio-buccal cusp of the maxillary first molar. As for the skeletal component, it is expressed through the antero-posterior disproportions of the jaws relative to each other². Individuals with Class II Malocclusion usually suffer from functional defects & impaired masticatory function^{3,4}, which is directly related to this type of malocclusion⁵.

The skeletal disproportion is usually due to either mandibular retrusion, maxillary protrusion, or both. The total and lower face heights could be either decreased, normal or increased. However, an increased vertical height is more likely associated with skeletal class II cases². The anteroposterior relationships of teeth with Class II malocclusion doesn't improve spontaneously with age². Therefore, correction of this type of skeletal problem in preadolescents is advocated.

Treatment of Class II malocclusion could be divided into four different treatment methods: Growth modification with the use of either extraoral headgears or functional orthopaedic appliances; distalization of maxillary molars; Retraction of maxillary anterior teeth into extraction spaces of premolars (camouflage treatment); Combination of distalization of maxillary teeth and protraction of mandibular teeth. The latter 3 methods of treatment involve dental movement only, while the first method encompasses both dental and skeletal alterations¹.

Conventionally, to treat class II in adult patients with an increased overjet, we would extract the upper first premolars and retract the anterior segment into the extraction space. However, the therapeutic option of extracting the upper second molar would enable faster first molar retraction⁶. Furthermore, the impact of extracting the upper second molar on patient profile is minimal compared with conventional treatments performed with first premolar extraction. Also, when the second molar is extracted the possibility of third molar impaction is decreased, the third molar usually comes into occlusion and in most cases spontaneously assumes a favorable position relative to the first molar⁶.

Furthermore, in some class II cases extraction is not an option because of the patient's profile such as naso-labial angle & lip thickness as extraction will result in an improper soft-tissue profile because of maxillary incisors up righting⁷. In such cases distalization of maxillary arch using mini-implants has been introduced in order to achieve a proper class I relation without jeopardizing the harmony of the soft tissue profile⁸.

In adults with erupted maxillary third molars & badly decayed or unilaterally extracted second molars, extraction of these upper second molars is recommended to provide sufficient space for arch distalization instead of maxillary third molars⁹. The extraction site will provide sufficient space for distalization. The extraction socket, if recent, will also result in regional acceleratory phenomena, which can help with accelerating molar distalization¹⁰. Furthermore, distalization of maxillary molars after extracting the second molar will have the added benefit of achieving a Class I molar relationship¹⁰.

Distalization of the first molar can be done by using means of extraoral or intraoral forces. Several methods and devices can be used. The most conventional method for distalization involves the use of cervical headgear, which can be either used for orthodontic or orthopaedic corrections. It is easy to apply and may distalize not only the maxillary first molars but also the first second premolars via trans-septal fibers¹¹.

However, the short comings of using cervical headgear was apparent in the undesirable lateral forces that tend to move maxillary molars into crossbite, which is unavoidable¹². In addition to this, the success of the treatment depends heavily on patient cooperation, and lack of patient cooperation results in loss of anchorage and unsatisfactory treatment results.

The disadvantages of the extraoral appliances have motivated many researchers to develop several mechanics of intraoral molar distalization. Numerous intraoral appliances have been used to distalize the maxillary molars in Class II patients without relying on patient's cooperation; these include nickel-titanium spring¹³⁻¹⁵, magnet¹³, distal jet^{16,17}, first class¹⁸, Jones jig^{19,20}, pendulum^{19,21}, and Keles slider^{12,22} appliances. All of these intraoral distalization appliances were used to distalize the maxillary molars; however, in most of these appliances mentioned above, anchorage loss was unavoidable, characterized by the protrusion of maxillary incisors, increase in overjet, and decrease in overbite^{23,24}. Recent studies have suggested the use of mini implants^{25,26}, and plates^{27,28} as anchorage units in orthodontic patients requiring distalization, which also eliminated the dependence on patient co-operation.

With our proposed distalizer using infra-zygomatic mini screws, the orthodontic fixed appliance is postponed till after the stage of distalization. Delaying the bonding procedure will decrease the risk of adverse effects of fixed orthodontic appliances, such as enamel decalcifications as well as labial flaring of the anterior teeth.

There is a scarcity in the current literature regarding such appliance and its effect on distalizing the first maxillary molar in absence of the second molar. Therefore, this study was made to evaluate the effect of bilateral distalization of upper first molars in a group of patients after extraction of maxillary second Molars using infra zygomatic mini implants.

Statement of the problem:

The appliances available for distalization used to be mainly extraoral distalizing appliances which depended entirely on patient cooperation and compliance²⁹. Even after the emergence of intra-oral distalizing appliances they had adverse dentoalveolar effect such as anchorage loss and flaring of the upper anterior teeth³⁰. Thus, this study was made in order to evaluate the efficiency of our proposed appliance in the treatment of Class II patients while avoiding the adverse effects mentioned above.

Rationale for carrying out the trial:

To evaluate the efficiency of the proposed appliance in distalizing maxillary 1st molars in adults after extraction of upper second molars to achieve class I molar relation. Furthermore, to evaluate all the dentoalveolar changes that will occur while using the proposed appliance.

Literature Review:

A) Class II:

Angle (1907), Classified malocclusion by dividing it into class I, class II and class III malocclusion according to maxillary first permanent molar & its relation to the mandibular first permanent molar³¹.

Moyers et al (1980), Studied the differential diagnosis of class II malocclusions by means of computer-based statistical methods, several types of Class II malocclusion have been discovered with defining horizontal and vertical characteristics. Of the six horizontal types, four are severe syndromes, one is a loose, ill-defined grouping of cases with mild skeletal features, and one has only the dental features of Class II. Five vertical types associate with Class II were also revealed, although each vertical is not associated with all horizontal types. A simplified simulation of the computerized procedures has been developed for routine use in clinical practice³².

B) Maxillary molar distalization:

Joydeep Ghosh et al (1996), determined the effects of the pendulum appliance on distalization of maxillary molars and the reciprocal effects on the anchor premolars and maxillary incisors. Initial and follow-up cephalometric radiographs were obtained on 41 subjects (26 girls and 15 boys) who were treated with the pendulum appliance for bilateral distalization of the maxillary first molar teeth. Dental casts were available on 31 patients. Dental, skeletal, and soft tissue changes were determined. The mean maxillary first molar distalization was 3.37 mm, with a distal tipping of 8.36. The maxillary second molars were also distalized 2.27 mm. it was concluded that the pendulum appliance is an effective and reliable method for distalizing maxillary molars, provided the anchor unit is adequately reinforced. Its major advantages are minimal dependence on patient compliance, ease of fabrication, one-time activation, adjustment of the springs if necessary, to correct minor transverse and vertical molar positions, and patient-acceptance³³.

Pavlick C. T. (1998), Concluded that Superb clinical results, supported by research indicate that cervical headgears, when used correctly according to the principles of the Bioprogressive philosophy, will produce the most desirable and predictable orthopedic desirable orthopaedic changes in growing faces³⁴.

Sugawara et al. (2006), reported that the zygomatic process of the maxilla could be used to prevent the anchorage loss. He used mini plates placed in the zygomatic buttress for molar distalization in non-growing patients²⁸.

Nur et al. (2012), designed an intraoral appliance, named the Zygoma-Gear Appliance (ZGA), for bilateral maxillary molar distalization using the titanium anchor plates placed in the zygomatic process of the maxilla. The authors demonstrated that an effective maxillary molar distalization without anchorage loss could be achieved in a short time using the ZGA³⁵.

El Dawlatly et al. (2014), Suggested the use of Orthodontic mini implants placed in the zygomatic buttress to act as anchorage for the distalization. The authors recommend this treatment technique for growing class II patients with increased upper incisors and gingival display³⁶.

C) Reliability of scanned models:

Nalcaci et al (2014), The aim of this study was to evaluate 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. No significant difference was observed regarding the amount of molar distalization among the three groups, therefore 3D digital models are reliable to assess the results of upper molar distalization and can be considered a valid alternative to conventional measurement methods³⁷.

L. S. Lemos et al. (2015), The aim of this study was to evaluate the reliability of measurements made on digital cast models scanned in the 3Shape R700 scanner (3Shape, Copenhagen, Denmark) that uses a non-destructive laser beam to reproduce model surfaces so that the plaster model is not destroyed. The sample consisted of 26 cast models. Six linear measurements were made on the cast models and then compared on the digitalized cast models. The study concluded that The digital models obtained from the 3 Shape R 700 scanner are reliable and can be considered an alternative to cast models for performing measurements and analyses in orthodontic practice³⁸.

D) Reliability of CBCT:

Periago et al. (2008), He compared the accuracy of linear measurements made on cone beam computed tomographic (CBCT) derived 3-dimensional (3D) surface rendered volumetric images to direct measurements made on human skulls and concluded that While many linear measurements between cephalometric landmarks on 3D volumetric surface renderings obtained using Dolphin 3D software generated from CBCT datasets may be statistically significantly different from anatomic dimensions, most can be considered to be sufficiently clinically accurate for craniofacial analyses³⁹.

E) Mini-implants:

Shingo Kuroda et al. (2007), Evaluated the clinical usefulness of mini-implants as orthodontic anchorage. examined their success rates, analyzed factors associated with their stability, and evaluated patients' postoperative pain and discomfort with a retrospective questionnaire. Seventy-five patients, 116 titanium screws of 2 types, and 38 miniplates were retrospectively examined. The success rate for each type of implant was greater than 80%. He concluded that miniscrews placed without flap surgery have high success rates with less pain and discomfort after surgery than miniscrews placed with flap surgery or miniplates placed with either procedure⁴⁰.

Database research:

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

III- Aim of the study

The aim of this study is to evaluate the Effect of Bilateral Distalization of Upper First Molars in a Group of Patients after extraction of Maxillary Second Molars Using Infra Zygomatic Mini Implants.

A-PICO format :

Patient/Population :

Adult patients having Class II molar relation. And indicated for maxillary molar distalization.

Intervention:

Infra-zygomatic mini implant supported maxillary intra oral appliance & extraction of maxillary second molars.

Comparator:

Pre-treatment and post treatment maxillary and mandibular changes.

Out-come mesure(s):

Prioritization of the outcome	outcome	Method of measurement	Unit of measurement
primary	Anteroposterior Dental changes in the upper buccal segment	Scanned dental cast e.g. (MB cusp of U6-MB groove of L6) CBCT	Millimeters
secondary	other dental changes in upper buccal segment including (intermolar width, molar inclination,)	Scanned dental cast CBCT	Millimeters and degrees
	dental changes in mandibular teeth.	Scanned dental cast	Millimeters

B-Research question :

Will the proposed appliance be able to induce dental effects for correction of class II malocclusion in adult patients after extraction of upper second molars within the duration of eight months?

IV-Objectives of the study

•Research hypothesis:

The null hypothesis of this research is that there are no dental changes associated with the use of proposed appliance.

•Primary objective (s):

Amount and rate of maxillary 1st molar Distalization.

•Secondary objective:

Evaluate the other dental changes in the upper buccal segment accompanying the Distalization technique and the consequent dental changes in the mandibular arch.

•Study design

Prospective clinical trial.

V- Methods (-participants, interventions and outcomes)

•Study settings:

The study will be performed in the outpatient clinic of the Orthodontics and Dentofacial Orthopedics Department at the Faculty of Oral and Dental Medicine, Future University in Egypt. The recruited sample would be from the Egyptian population.

Eligibility criteria:

Inclusion criteria:

- 1-Patients with CVMI index 5 & 6.
- 2-From quarter unit to 3\4-unit class II molar relationship.
- 3-An overjet of an average 6mm.
- 4-Full set of permanent dentition except for the maxillary second molar.
- 5-Favorable path of eruption for the maxillary third molar.

Exclusion criteria:

- 1- Medically compromised Patients.
- 2-Patients under long term medications.
- 3- Patients having sever periodontal disease.
- 4-Any other age group.
- 5-Full unit class II cases.

•Intervention:

A) Medical History Questionnaire will be filled by the patient to exclude the presence of any systemic condition.

B) Clinical Examination:

Proper examination of the oral structures including teeth which will be examined for caries, fracture or missing teeth and Gingival tissues which will be examined for gingivitis, periodontitis, attachment loss, gingival recession, oral lesions and the nature of the gingival biotype.

C-Diagnosis:

The patient is checked to fulfil the previously mentioned inclusion criteria.

Full set of records will be taken for every patient as part of the routine procedure for treatment of patients in the outpatient clinic of the Department of Orthodontics and Dentofacial Orthopedics, Future University in Egypt.

D-Clinical Procedures:

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, dentaurem, Germany).

Bands will be cemented to 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, and U loop at 1st premolar region, and bends acting as 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 anterior teeth.

Orthodontic force 350 mg per side Will be delivered by Niti closed coil spring which is attached from infra zygomatic mini screw to the hook soldered to the wire framework.

Patient will wear mandibular thermoform retainer at night only.

E-Follow up period:

The patient will be asked to attend follow up visits every 4 weeks to check the following:

- A) The stability of the mini implants
- B) The activity of the appliance (force recalibration is required).
- C) The amount of correction achieved.
- D) Any inflammation related to the appliance or the mini implants

Impressions and wax bite will be taken (without the appliance in place) followed by digital scanning of produced models).

F-Criteria for discontinuing intervention:

Any harmful effects to the patient from any of the treatment modalities

Lack of patient co-operation

Outcomes:

Primary: Anteroposterior position changes of upper first molars.

Secondary: Other dental changes in upper post segment and mandibular dental arch.

Methods of measuring of all outcomes:

Linear and angular measurements Will be made on the pre, post and follow-up dental scanned casts and on the CBCT to assess the dental changes in intervention group.

Units of measurement:

Millimetres and degrees

Blinding:

•Due to the nature of the study, the operator and patients can't be blinded. Blinding of the outcome assessors can be done by sealing the name of the patient in the pre and post treatment radiographs used for analysis.

VI- Sample size

Our sample size calculation is based on a previous study³¹ evaluating the dentoalveolar, skeletal, and soft tissue effects of the Zygoma-Gear Appliance (ZGA) when used for bilateral distalization of the maxillary molars. as the Primary outcome values was:

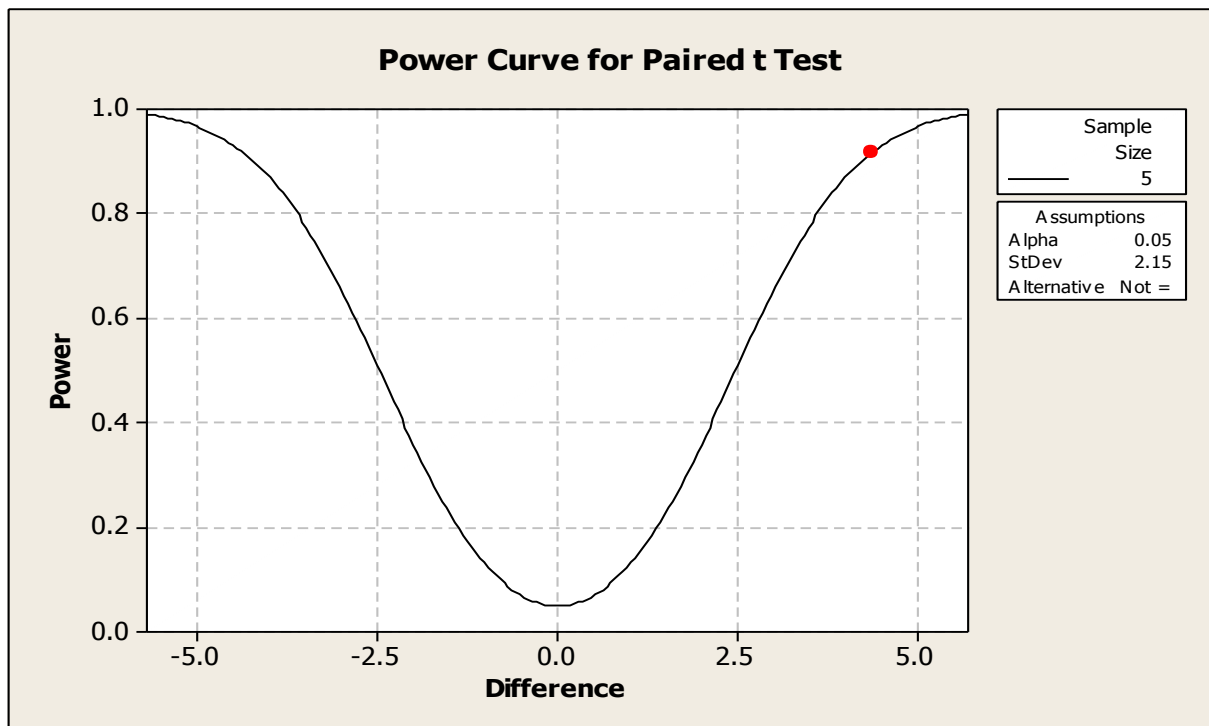
	Before	After	Difference
VRL-U6	32.05 ± 4.01	27.66±4.17	-4.36± 2.15

The plan of the study is a continuous response variable from matched pairs of study subjects. Prior data indicate that the difference in the response of matched pairs is normally distributed with standard deviation 2.15. If the true difference in the mean response of matched pairs is 4.36, we will need to study 5 pairs of subjects to be able to reject the null hypothesis that this response difference is zero with probability (power) 0.8. The Type I error probability associated with this test of this null hypothesis is 0.05. So, to count for drop out or missing data a sample of size of 8 pairs of subjects is recommended

Type of test: Paired t Test

Minitab software output.

	Sample	Target	
Difference	Size	Power	Actual Power
4.36	5	0.8	0.915696



To count for drop out or missing data a sample of size 8 is recommended

VII-Data collection, management and analysis:

Patients recruited from the clinic at the department of orthodontics at Future university in Egypt

The data collection for the primary and secondary outcomes will be done by taking scanned dental casts and CBCT.

Pre and post treatment/ observation period in the treatment

Plans to promote participants retention and complete follow-up:

- Telephone numbers of all patients included in the study will be recorded as a part of the written consent.
- All patients will be given reminder phone calls at the time of the predetermined follow updates.
- Patient punctuality at appointments, number of missed appointments will be regularly monitored.
- **Data management:**
- All data will be electronically entered in the computer at the Department of Orthodontics and Dentofacial Orthopedics. The data should include all photographs, models and radiographs.
- Resulted data from scanned cast analysis will be organized in excel sheets that will be electronically entered and backed up in a google drive for permanent storage.
- The patients' data should have sequential numbers that will be revised at each step to avoid any mixing of data between patients.

Statistical analysis:

The principle 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.

VIII-Monitoring:

A) Data monitoring:

Monitoring of the study will be strictly done by the supervisors periodically. They will monitor all the steps of the followed protocol and find solutions to all troubles that have occurred during the trial performance.

B) Harms:

If any harm occurs to the patient before entry to the study, it will be reported as unrelated. If it happens after, it will be recorded and documented by the primary investigator. Severity of harms and potential causal relationship with intervention will be addressed. In cases of inflammation of the tissue around the mini-implant, immediate removal of the mini-implant and prescription of anti-inflammatory drugs will be done in order to subside the inflammation followed by replacement of the mini-implant after the resolution of the inflammation.

C) 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, adherence to interventions and reporting of harms. A meeting with the senior supervisor will be set to monitor the progress of the study and the need for any adjustments.

Research ethics approval:

This protocol and the template informed consent form will be reviewed by the Ethics Committee of Scientific Research –Faculty of Oral and Dental Medicine-Future University in Egypt.)

Protocol amendments:

Any modification to the protocol which may have an impact on the conduct of the study, potential benefit of the patient or may affect patient safety will require a formal amendment to the protocol. Such amendment will be agreed upon by the Department of Orthodontics and Dentofacial Orthopedics, Faculty of Oral and Dental Medicine, Future University in Egypt and the Ethics Committee will approve such amendment before proceeding in the study.

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.

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 and Dentofacial Orthopedics, Faculty of Oral and Dental Medicine, Future University in Egypt 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.

Declaration of interests:

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

Ancillary and Post Trial Care:

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

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 in Egypt library and will distribute additional copies among the main universities in Egypt.

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