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Three Dimensional Assessment of Maxillary Molars Following Distalization Using Two Different Approaches

A Research Informed Consent Form
In Partial Fulfillment of the Requirements of
Master's Degree in Orthodontics

Faculty of Dentistry,
Ain Shams University
2016

AIN SHAMS UNIVERSITY
FACULTY OF DENTISTRY
RESEARCH ETHICS COMMITTEE
(FDASU-REC Im 121606)

INFORMED CONSENT FORM

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Research Title: Three Dimensional Assessment of Maxillary Molars Following Distalization Using Two Different Approaches.

Scientific background and aim of the work: The idea of this study is to evaluate the effect of using coil spring and mini screw anchorage system during maxillary molars distalization.

Clinical procedure in details:

- Full orthodontic records will be taken for patients who meet the inclusion criteria. These records are:

  1-Extra-oral and intra-oral photographs.
  2-Orthodontic study casts.
  3-Panoramic radiograph: will be used to detect any dental or bone anomalies, general periodontal condition & bone level, stage of eruption & position of third molars.
  4-Lateral cephalometric radiograph: will be used to determine skeletal pattern & mandibular plane angle to verify fitting the inclusion criteria.
- Extra orthodontic records: Cone Beam Computed Tomography.
- The maxillary first and second molars will be banded. Brackets will be bonded to the maxillary first and second premolars.
- Leveling of these segments will be carried out using orthodontic wires sequentially, till 0.019˝x 0.025˝stainless steel archwire is reached.
- Segmented stiff 0.019˝x 0.025˝stainless steel archwire will be used to minimize the distal tipping and rotation of the molars. It will be extended from the maxillary second molar to the maxillary first premolar.
- In the first approach, a nickel titanium open coil spring will be inserted mesial to the maxillary first molar to provide distalizing force. In the second approach, two pieces

of nickel titanium open coil springs will be inserted mesial to the maxillary first molar and mesial to the maxillary second molar.
- Mini screw anchorage system will be used as a mean of indirect anchorage.
- The patients will be seen every four weeks for reactivation until Class I molar relationship is obtained, as assessed clinically.

Method of assessment:
- The rate of tooth movement will be analyzed using computer software on digital models obtained every four weeks. When a Class I molar relationship is obtained distalization will be considered achieved, which will be assessed clinically.
- Cone beam computed tomography (CBCT) will be taken for every patient pre-treatment and post-distalization.

Study time frame: 2 years.

Study setting: Operating room of the Department of Orthodontics and Dentofacial Orthopedics, at Faculty of Dentistry, Ain Shams University, Cairo, Egypt.

Total No. of cases: 20 patients.

Case selection methodology: This Randomized Clinical study will be conducted on 20 patients with age ranging from 18 to 25 years, selected from the outpatient clinic of the Orthodontic Department, Faculty of dentistry, Ain Shams University.

The subjects will be selected to fulfill the following inclusion criteria:
1. Skeletal class I, or mild to moderate skeletal class II malocclusion.
2. Full cusp or end to end class II molar relationship.
3. Mild to moderate crowding in the upper dental arch and/or increased overjet.
4. Any other indication requiring maxillary molar distalization unilaterally or bilaterally.
5. Full permanent dentition with exclusion of third molars.
6. Both first and second maxillary molars are in occlusion.
7. Normal or horizontal growth pattern.
8. Non-extraction treatment plan.
9. All subjects are free from any dental anomalies as well as periodontal and systemic diseases that may influence orthodontic treatment.

Exclusion criteria:
1. Previous orthodontic treatment.
2. Severe profile convexity requiring orthognathic surgery.
3. High mandibular angle.
4. Severe molar rotation.
5. Poor oral hygiene.
6. Severe carious lesions.

Adverse event reporting: Anticipated adverse effects regarding the use of mini screw and its remedy.

1. **Pain and discomfort:** If present, it may last 1–2 days and could be reduced by instructing the patient to use warm mouth rinse containing local anesthetic agent.
2. **Irritation to the buccal mucosa:** Bonding resin or a periodontal wound dressing could be applied to the head of the mini screw to smooth its surface and to minimize soft-tissue irritation.
3. **Inflammation around mini screw:** The screws need to be thoroughly cleaned. Mild infections can be controlled by using antiseptic mouthwash and by regular brushing.
4. **Mini screw mobility or failure:** The patient will be instructed to avoid manipulating the screw with fingers, tongue, or with foreign objects like pens. The mini screw could be tightened and left for 1–2 months with no loading, or light loading if necessary. If stability cannot be regained, the mini screw will be removed and replaced.

Participant's benefits and welfare:

1. Improvement of dental occlusion and achieving Angle's class I dental malocclusion.
2. Decrease the disfigurement of face, mouth, and teeth.

Availability of alternative treatment plan: If the patient refused to accomplish the study plan at any stage; another suitable treatment plane will be provided until Angle's class I malocclusion is achieved. Self-withdrawal at any time without disclosing the reasons is completely guaranteed, and without any adverse effects.

Medical confidentiality: medical confidentiality is completely maintained. Each case will be reported individually and privately regarding his/her health issues during the study in the proper time.

Declaration of interests:

- No financial competing interests: This study was part of a Masters' degree in Orthodontics, Faculty of Dentistry, Ain-Shams University.
- No financial conflicts of interest were declared. The study was self-funded by the principal investigator.

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I voluntarily agree to participate in this research project and I consent that all concerns and inquiries about this study have been addressed and has been explained to me in detail. I choose, voluntarily, to participate in this research project. I certify that I am at least 18 years of age.

Participant (or guardian) signature:
Date:
ID card No.: