

**Friction versus Frictionless Mechanics during maxillary En-  
masse Retraction in Adult Patients with Class I Bimaxillary  
dentoalveolar Protrusion: A Randomized Clinical Trial**

A Protocol Submitted To  
The Faculty of Oral and Dental Medicine,  
Cairo University  
In Partial Fulfillment of the Requirement  
For The PhD Degree in Orthodontics

By

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## **Administrative Information**

**Trial registration:** trial is not registered yet but is to be registered at ClinicalTrials.gov.

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### **Authors' contributions:**

**Sally Magdi Riad (S.M)**, BDS, MSc (Principal Investigator) will be responsible for recruitment of sample, application of different interventions, follow up of patients, writing the thesis, interpretation of results and drawing out conclusions.

**Fatma Abdo Abd El Said (F.A)**, BDS, MSc, PhD helped with developing the idea of the research and will help in monitoring the process of the study, reviewing the data and the results.

**Fady Hussein (F.H)**, MS, BDS, MSc, PhD initiated the study design, will help in sequence generation for randomization, follow up of patients, data verification and will help the principal investigator in interpretation of the results.

## **Introduction**

### **A] Background and Rationale:**

Protrusion of the maxillary and mandibular incisors with increased procumbency of the lips is considered one of the major chief complaints of adult patients seeking orthodontic treatment. This condition is known as bimaxillary dentoalveolar protrusion<sup>(1)</sup>.

The usual objective of treatment in such condition is the retraction of anterior teeth with a resultant decrease in soft tissue convexity<sup>(2)</sup>. And so, the treatment of choice for these patients is to extract the first premolars. In this case, maximum anchorage of the posterior teeth become of great importance for two reasons; to retract the anterior teeth to their greatest extent and to increase the chances of correcting the profile.

With the introduction of mini-screws/implants<sup>(3) (4)</sup> as anchorage, it has become possible to achieve absolute anchorage<sup>(5)</sup> during anterior teeth retraction<sup>(6)</sup>.

However, there have been controversies about how to achieve maximum retraction with anchorage preservation in first premolar extraction cases. Proffit and Fields<sup>(1)</sup> recommended separate canine retraction followed by incisors retraction for maximum anchorage, stating that this approach would decrease the load on the posterior teeth. However, they agreed that closing the space in two steps would take nearly as twice as long than closing it in a single step. On the other hand, Staggers and Germane<sup>(7)</sup> described anchorage as "being taxed twice with a two-step retraction, as opposed to once with en masse retraction". They mentioned that "the posterior segment is unaware of how many teeth are being retracted and simply responds to the force acting on it". So, studies were done to compare both techniques. The debate came to an end when no significant differences were found in the amount of retraction of anterior teeth and the degree of anchorage loss associated with both techniques<sup>(8)(9)</sup>. This fact suggests that en-masse retraction is an adequate alternative to two-step retraction during space closure specially that it is esthetically more acceptable<sup>(10)</sup>.

Space closure can be done either by Friction or Frictionless mechanics. In Friction or sliding mechanics; the space site is closed by means of coil springs or elastics allowing the brackets to slide on the orthodontic archwire. On the other hand, frictionless mechanics uses loop and

bends to generate force to close the space site which allow differential moments in both active and reactive units<sup>(11)</sup>.

It is well known that orthodontic treatment is time consuming, and so, the speed by which treatment is completed is considered a primary concern to every patient and orthodontist. But despite the large number of studies dealing with mechanics of space closure, no enough evidence was found in the orthodontic literature regarding the best technique for anterior teeth retraction<sup>(17)</sup>. And by searching the literature, no study was found to measure the patient satisfaction regarding the different techniques of retraction. Therefore, a recent systematic review<sup>(18)</sup> has recommended additional studies to determine the best way for anterior segment retraction.

From the mentioned background, we can find a gap in knowledge regarding the effectiveness of friction and frictionless mechanics during maxillary en-masse retraction that need further properly designed randomized controlled trial to achieve conclusive results.

Accordingly, conducting a well-designed Randomized Clinical Trial, evaluating the effects of the two systems with respect to space closure, will provide detailed information about tooth movement and so; will guide the orthodontists in their choice for the suitable treatment mechanics to be used and will shed a light on the expected treatment outcome and duration. Also, this will allow more patient satisfaction and cooperation during the treatment period.

### **Choice of comparator:**

Friction or Sliding mechanics is commonly<sup>(12)</sup> used due to its simplicity. However, the efficiency of this technique in space closure may be compromised due to binding between the bracket and archwire slowing the tooth movement. Theoretically, this can be overcome by the use of a frictionless system. The well-designed loops and bends provide the required moment to force ratio with great predictability but need more wire-bending skills. In addition, minor errors can result in major differences in tooth movement, and some patients may find the loop uncomfortable<sup>(13)</sup>.

## B] Aim of the Study:

The aim of this study is to compare the effectiveness of friction and frictionless mechanics during maxillary en-masse retraction regarding patient satisfaction, rate and duration of retraction, molar anchorage loss, anterior teeth inclination and soft tissue changes.

And so the research question of this trial is :*" In adult with Class I bimaxillary dentoalveolar protrusion; how does the use of friction and frictionless mechanics during maxillary en-masse retraction affect the rate of retraction of anterior teeth and other treatment outcomes?"*

### PICO format:

**P**-> adult patients with Class I bimaxillary dentoalveolar protrusion<sup>(14)</sup>.

**I**-> frictionless mechanics using closing T- loops.

**C**-> friction mechanics using NiTi coil springs.

**O**->outcome measures (1ry, 2ry):

|                          | <b>Outcome name</b>                 | <b>Measuring Device</b>              | <b>Measuring Unit</b>       |
|--------------------------|-------------------------------------|--------------------------------------|-----------------------------|
| <b>Primary<br/>(1ry)</b> | -Patient Acceptance <sup>(19)</sup> | -Questionnaire <sup>(20)</sup>       | - Scoring scale from 0 to 5 |
|                          | -Retraction duration                | -Clinical Evaluation <sup>(16)</sup> | -months                     |
|                          | -Retraction rate                    | -dental models <sup>(21)</sup>       | -millimeter (mm)            |

|                        |  |   |  |
|------------------------|--|---|--|
| <b>Secondary (2ry)</b> | <ul style="list-style-type: none"> <li>- Molar Anchorage</li> <li>-Inclination of ant teeth.</li> <li>- Soft tissue changes</li> </ul> | <ul style="list-style-type: none"> <li>- Lateral Cephalometric radiographs<sup>(8)</sup>.</li> <li>-Lateral Cephalometric radiographs<sup>(9)</sup>.</li> <li>- Lateral Cephalometric radiographs <sup>(15)(20)</sup>.</li> </ul> | <ul style="list-style-type: none"> <li>- Degree(°) and millimeter (mm).</li> </ul> |
|------------------------|--|---|--|

**Research Hypothesis:**

The null hypothesis for the study is that both friction and frictionless mechanics have the same efficiency in retracting the anterior segment following first premolars extraction in adult patients with class I bimaxillary dentoalveolar protrusion.

**Objectives:**

*Primary Objectives:* to compare between the use of friction and frictionless mechanics during en-masse retraction regarding patient's satisfaction and speed of retraction.

*Secondary Objectives:* to determine which technique will provide minimal anchorage loss with better anterior teeth inclination and better soft tissue after space closure.

**C] Trial Design:**

The design of this randomized controlled trial is a parallel group, two arms trial with 1:1 allocation ratio. In one group, frictional mechanics will be applied during anterior segment retraction while the other will receive non-frictional mechanics during retraction to compare the results of space closure.

## **Materials and Methods:**

### **I] Participants, Interventions and outcomes**

#### **A] Study Setting:**

The study will take place in the clinic of the Orthodontic Department at the Faculty of Oral and Dental Medicine, Cairo University. The recruited sample would be from the Egyptian population.

#### **B] Eligibility criteria:**

##### **➤ Inclusion criteria:**

1. Male or female adult patients with age range 18-30 yrs old<sup>(22)</sup>.
2. Class I bimaxillary dentoalveolar protrusion <sup>(23)</sup> .
3. Full permanent dentition<sup>(24)</sup>.
4. Good oral hygiene<sup>(25)</sup>.
5. Maximum anchorage is required<sup>(26)</sup>.
6. Healthy bone between first molars and second premolars is needed<sup>(27)</sup>.

##### **➤ Exclusion Criteria:**

1. Systemic disease<sup>(28)</sup>.
2. Severe crowding<sup>(23)</sup>.
3. Extracted or missing upper permanent tooth/teeth (except for third molars)  
<sup>(24)</sup>.
4. Any signs or symptoms or previous history of temporomandibular disorders  
(TMD) <sup>(29)</sup>.
5. Previous orthodontic treatment<sup>(30)</sup>.

## **C] Interventions:**

- S.M will fill a medical history questionnaire for every patient to exclude the presence of any systemic condition interfering with orthodontic treatment. (Appendix 1)
- Proper examination of the oral structures is needed to identify caries, fracture or missing teeth. S.M will be carefully examine gingival tissues for any gingivitis, periodontitis, recession or lesions.
- S.M will check the potential patient to fulfill the previously mentioned inclusion criteria. Then will ask every participant to sign an informed consent about the study. Full set of records ( study models, lateral cephalometric radiographs, photos) will be taken by S.M for every patient as part of the routine procedure for treatment of patients in the outpatient clinic of the Orthodontic Department, Cairo University.

### **➤ Clinical Procedure:**

After pre-treatment records were taken, every patient will receive:

1. Banding of upper and lower first molars\*.
2. Bonding of upper and lower arch with MBT prescription 0.022 slot brackets\*.
3. Leveling arch wires in sequential order starting from round NiTi flexible arch wires according to the need of the case then the sequence will be continued .The leveling and alignment stage of the upper arch will be considered completed when a 0.019×0.025 StSt arch wire could be placed passively in all upper arch.
4. Once leveling and alignment stage is completed, the principal operator S.M will refer the patient the uptake of pre-intervention records.

### **➤ Acquisition of pre-intervention records:**

- S.M will take dental models before treatment as a part of the patient's records and every month during the follow up period. The models will be poured in dental stone and trimmed according to orthodontic standards.

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\*Ormco bands, Medicime glass ionomer for bands

\*Ormco 0.022 slot MBT brackets

- S.M will refer the patient for the uptake of Lateral cephalometric radiograph after the leveling and alignment stage before the first premolars extraction to identify the pre-retraction position of anterior teeth and molars.

➤ **Insertion of miniscrews:**

- S.M will place two miniscrews\*<sup>‡</sup>; 8mm in length and 1.4 mm in diameter<sup>(23)</sup>, made of biocompatible pure titanium between the maxillary second premolars and the first permanent molars bilaterally in the buccal alveolar bone using the appropriate screw driver. These miniscrews are used to ensure maximum anchorage during en-masse retraction.
- Before implantation of miniscrews; S.M will assess the space between the roots of maxillary second premolar and first permanent molar by periapical radiograph.

➤ **Implantation procedure:** Under the supervision of F.H, the principal investigator S.M will;

1. Give few drops of local anesthesia to the patient to ensure a pain-free procedure.
2. Use a periodontal probe to induce a bleeding point at the predetermined area of miniscrews insertion to facilitate implantation.
3. Swap the implantation area between the roots of maxillary second premolar and the first permanent molar by cotton soaked with Betadine solution for disinfection.
4. Use a screw driver to drill the miniscrews into the bone manually in a clockwise direction until fully engaged. This procedure will be repeated bilaterally.
5. Give strict oral hygiene instructions to the patients including regular mouthwash for 3 days and proper tooth brushing.

➤ **Extraction of the first premolars**

At this stage, S.M will refer the patient to the oral surgery department, Faculty of Oral and Dental medicine, Cairo University for extraction of both upper first

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\*Rocky Mountain Orthodontics, USA

premolars. All dental extractions will be done by the same dental surgeon for all the patients under local anesthesia and using upper premolar forceps.

➤ **Begin of Retraction**

**Friction group:** The principal investigator will:

- Secure the upper six anterior teeth together by mean of ligature wire to allow en-masse retraction during space closure.
- Fix a crimpable hook\* on the main archwire (0.019×0.025 StSt) between the upper lateral and canine bilaterally<sup>(31)</sup>.
- Bend a small piece of 0.019''x0.025''stst wire and insert it passively in the auxiliary tube of first molar band. The wire will be attached to the screw head to ensure proper anchorage control,.
- Use light cure composite\* to secure the wire in the screw head properly<sup>(23)</sup> to avoid wire disengagement.
- Extend NiTi coil spring from the molar band to the crimpable hooks bilaterally.
- Apply a force of 150 g for both sides . The force is measured by a force gauge\* and activated each visit to keep it constant all over the retraction phase.

**Frictionless group:** The principal investigator will:

- Secure the upper six anterior teeth together by mean of ligature wire to allow en-masse retraction during space closure.
- Bend a small piece of 0.019''x0.025''stst wire and insert it passively in the auxiliary tube of first molar band. The wire will be attached to the screw head to ensure proper anchorage control .
- Use light cure composite\* to secure the wire in the screw head properly<sup>(23)</sup> to avoid wire disengagement.
- Bend a 0.019×0.025 TMA wire to T-loops distal to upper canine bilaterally<sup>(32)</sup>.
- Add a gable angle of 45° in the canine area and anti-rotational angle of 45° in the retraction archwire<sup>(33)</sup>.

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\*Ormco Crimpable arch hook

\*Grenlo (Ormco) for metal brackets \*IMD, Orthodontic force gauge

- Cinch back the wire distal to upper first molars bilaterally.
- Apply force of 150 g for both sides. The force is measured by a force gauge and activated each visit to keep it constant all over the retraction phase.

➤ **Appliance activation**

At each visit, S.M will check the force magnitude using the same force gauge. Re-activation of the appliance is necessary to maintain 150 g force<sup>(34)</sup> delivery throughout the follow up period.

➤ **Follow up visits**

The principal investigator S.M will;

See the patient on a monthly basis until complete anterior segment retraction is observed.

Assess the miniscrews for mobility at every clinical appointment.

Take alginate impression for the patient at each visit to construct the dental models to assess the rate retraction. At each visit, S.M will remove the arch wires and coil springs before impression procedure. Alginate impression will be poured in dental stone. After setting, S.M will trim the dental casts and label it with the patient name, number and date.

➤ **Criteria for discontinuing or modifying the allocated intervention:**

In case of prolonged swelling or pain related to the miniscrews, S.M will give the patient strict oral hygiene measures and may wait for three weeks before the beginning of retraction.

In case of loose or broken any of the miniscrews, S.M will remove and replace the miniscrews after total resolution of the inflammation.

➤ **Post-retraction Questionnaire:**

S.M will ask the patients of both groups to fill in questionnaires regarding their experience with both techniques.

➤ **Post-retraction records**

Following retraction of the anterior segment, S.M will refer the patient to the same radiology center to acquire the final lateral cephalometric radiograph to assess the movement and inclination of anterior teeth as well as the changes in soft tissue post-retraction . (Appendix 2)

The final dental model will assess the rate of retraction and molar anchorage loss achieved throughout the study. ( Appendix 3)

**D] Outcomes**

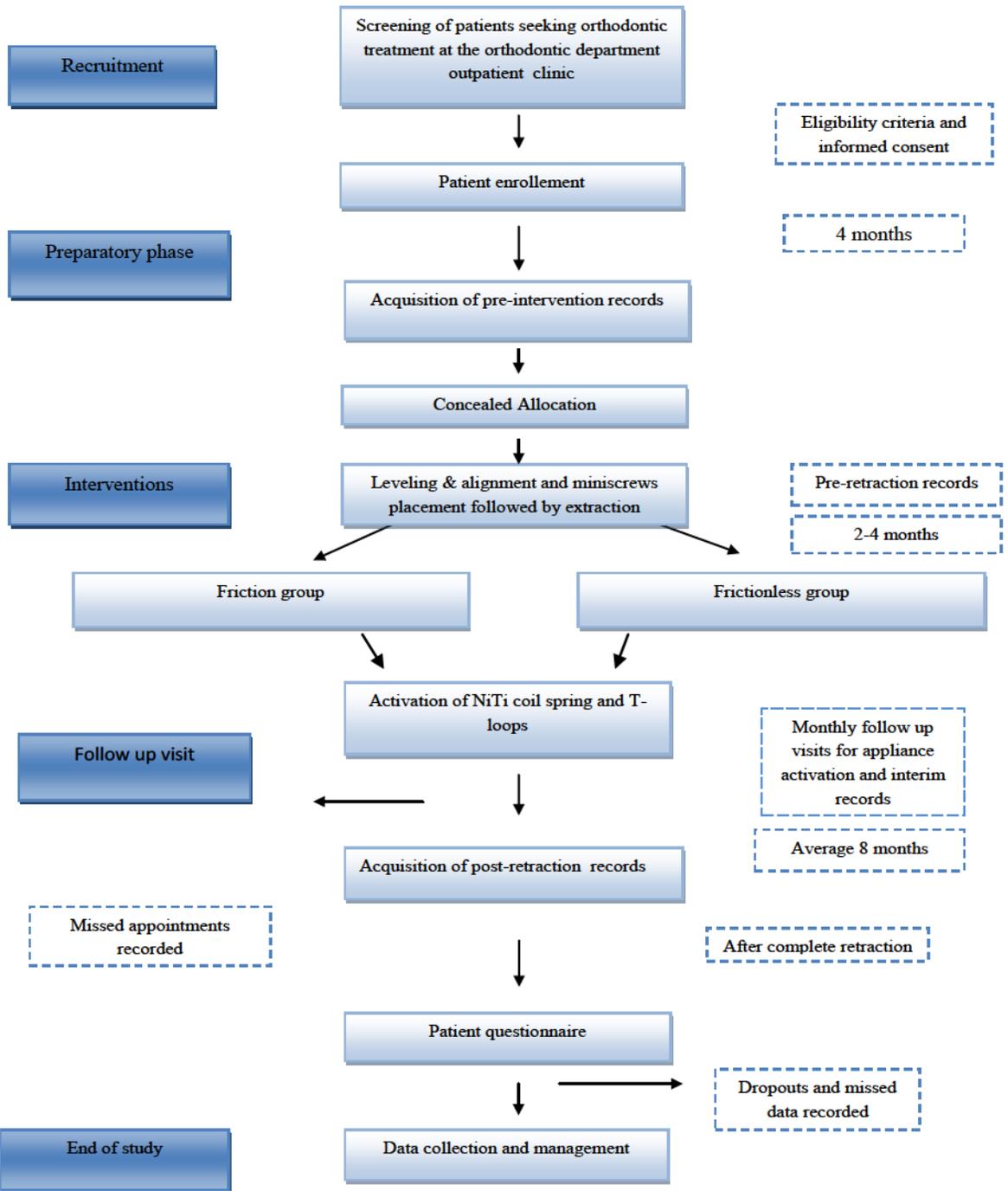
*Primary outcomes:* is to monitor the degree of patient satisfaction with the different methods used for anterior segment retraction as well as the rate and speed of space closure following first premolars extraction to help in the choice of treatment.

*Secondary outcomes:* include the molar anchorage loss associated with each technique during retraction as well as the final anterior teeth inclination which affect the soft tissue at the end of treatment. S.M will assess all the outcomes as the difference between T<sub>1</sub> at the start of en-masse retraction after first premolars extraction and T<sub>2</sub> after complete space closure.

**E] Participant time line:**

1. S.M will screen the potential patients through careful clinical examination of patients at the orthodontic department , Faculty of Oral and Dental Medicine, Cairo University.
2. All recruited patients should fulfill the previously mentioned inclusion and exclusion criteria.
3. S.M will ask every participant to sign an informed consent before the beginning of the study.
4. After patient's enrolment, S.M will ask each participant for pre-intervention records to ensure proper diagnosis.
5. S.M will randomly allocate the patients to one of the intervention group.

6. Active intervention will begin by proper leveling and alignment of the upper and lower arches.
7. S.M will send the patients for extraction of upper first premolars.
8. S.M will take pre- retraction records for every participant.
9. In Friction mechanics group, NiTi coil spring is used for maxillary en-masse retraction while in Frictionless group, T-loop is used for retraction.
10. Each patient will come every month for follow up visit, for appliance activation and uptake of impression for interim records.
11. After complete space closure, S.M will take post-retraction records for each participant.
12. Every patient will fill up a questionnaire regarding his experience during treatment.
13. S.M will continue the normal treatment and achieve proper finishing for every patient after the end of the study.





### E] Sample size calculation:

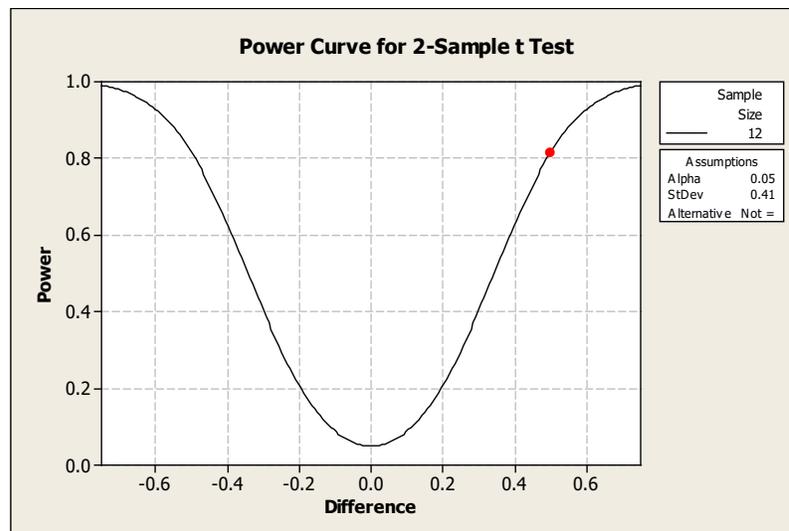
Our sample size calculation is based on a previous study<sup>(36)</sup> comparing the effect of friction and frictionless mechanics on maxillary canine retraction. The mean change in both groups is  $1.41 \pm 0.62$  mm and  $1.91 \pm 0.41$  mm respectively. The minimum clinical difference is 0.5mm/month. A t- test assuming equal variance for two independent groups is used. The power is set as 0.8, allocation ratio of 1:1 and the Type I error probability (alpha) associated with this test is set as 0.05. Results of the test showed that the group sample sizes of 12 is needed to reject the null hypothesis of equal means with a significance level of 0.05 . For consideration of drop out a sample size of 15 cases per group is considered.

#### *Computer output*

#### **Sample Target**

| <b>Difference</b> | <b>Size</b> | <b>Power</b> | <b>Actual Power</b> |
|-------------------|-------------|--------------|---------------------|
| <b>0.5</b>        | <b>12</b>   | <b>0.8</b>   | <b>0.814515</b>     |

**The sample size is for each group.**



**F] Recruitment strategy:**

The principal investigator will recruit the patients from the clinic of Orthodontic department, Faculty of Oral and Dental Medicine- Cairo University.

Screening of patients will continue until the total number of participants for the study is collected. Recruitment period is expected to be 4 months.

**III] Assignment of interventions:****A] Sequence generation:**

The supervisor of the study F.H will apply Computer generated random numbers to randomly assign patients to group A (Friction) or B (frictionless) using Microsoft Office Excel 2007 sheet. F.H will write the patient numbers in the first column, and 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:**

F.H will write the randomization numbers of the patients in opaque white papers folded three times to form sealed envelopes and store it inside a box. Then will keep the Codes for randomization at the secretary office.

**C] Implementation:**

At time of intervention, the main operator S.M will send the patient to the secretary office. Then, the assigned employee will open the box and ask the patient to select one envelope. S.M will assign each participant for the corresponding intervention either (friction or frictionless group) according to the list of codes of randomization.

Assignment to either intervention will occur before leveling and alignment stage.

#### **D] Blinding:**

**Blinding of the operators:** Blinding will not be possible for the operators during the application interventions and during the follow up visits. The principal operator S.M is responsible for assigning subjects to interventions according to the concealed allocation, insertion of miniscrews, appliance activation at follow up visits, dental impressions and acquisition of dental casts.

**Blinding of the outcome assessors:** It is a single blinded study, the outcome assessors only will be blind. The patients name will be sealed from pre and post radiographs and study models. Then two assessors will carry on, blindly and independently, the measurements and analysis of the study.

### **III] Data collection, management and analysis:**

#### **A] Data collection methods:**

##### **Primary outcomes:**

- 1. Parent's satisfaction:** Each patient will fill a questionnaire regarding his treatment experience in a scale from 0-5. The questionnaire will include several questions related to oral hygiene, pain and discomfort experienced throughout the trial .The design of the questionnaire to be used in this study is following what was used in similar study by Baxmann et al 2010<sup>(35)</sup>. The questionnaire will be filled at the end of the retraction phase.
- 2. Retraction duration:** S.M will assess the whole duration of retraction by clinical observation of space closure from the distal surface of the canines to the mesial surface of the first molars and will record it in months.
- 3. Retraction Rate:** in order to assess the antero-posterior movement of anterior teeth and first molar, S.M 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.

**Secondary outcomes:**

**4. Molar anchorage loss, change in anterior teeth inclination and soft tissue changes:** will be accessed by S.M via Lateral cephalometric radiograph taken before and after the completion of retraction. The principal investigator will identify the landmarks, reference lines and planes, then will interpret the measurements in degrees and millimeters.

**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:**

- S.M will be responsible for the extraction of the required data from the lateral cephalometric radiographs 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 supervisors (F.A and F.H) will choose a well-experienced inter-examiner during the study.
- F.A and F.H will provide a training session 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 supervisors will compare the measurements of the two assessors for disagreement with a difference of more than one millimeter.
- F.H 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 (F.A and F. H), 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 S.M will document and report any harms or unwanted effects during the study intervention to the trial supervisors (F.A and F.H). Also any unpleasant

experience will be reported by the patient in the final questionnaire at the end of the retraction. S.M will be responsible for the management of any adverse effects or unfavorable side effects resulting from the appliance.

**D] Auditing:** The supervisors (F.A and F.H) will follow up and review the different interventions and resulting data. The supervisor (F.H)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 (F.A) will be set every 3 months to monitor the progress of the study and the need for any adjustments.

## **V] Ethics and dissemination:**

### **A] Research Ethics Approval:**

The CEBD [Center for Evidence Based Dentistry CU] Cairo University, Egypt will review the protocol and the Ethics Committee [Research Ethics Committee Cairo University Faculty of Oral and Dental Medicine] will 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:**

S.M 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 Council of Orthodontics department, Faculty of Oral and Dental Medicine, Cairo University and the Ethics Committee will approve such amendment before proceeding in the study .

### **C] Consent:**

S.M 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:**

S.M 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 (F.A and F.H) responsible for auditing and analysis. Also, will keep the files in the Department Of Orthodontics, Faculty of Oral and Dental Medicine, Cairo 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 principle operator. This study is a part of a PhD degree in Orthodontics, faculty of oral and dental medicine, Cairo University and it is self-funded by the principal investigator.

**F] Access to data:**

The supervisors (F.A and F. H) and the principal investigator (S.M) 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 (S.M). Then the two group of patients will continue their regular orthodontic treatment according to the treatment plan described for each case. S.M will proceed in bonding of the lower arch, leveling and alignment, finishing and will apply proper retention protocol for each individual 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. S.M will present a copy of the thesis at the faculty of Oral and Dental Medicine, Cairo University library and will distribute additional copies among the main universities in Egypt.

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# Appendix 1

## Diagnostic chart

  
Faculty of Oral & Dental Medicine

**CASE HISTORY :**  
Name : \_\_\_\_\_ Sex : \_\_\_\_\_  
Date of birth : \_\_\_\_\_ Contact number : \_\_\_\_\_  
Address : \_\_\_\_\_  
Chief complaints : \_\_\_\_\_  
Relevant medical history : \_\_\_\_\_  
Relevant dental history : \_\_\_\_\_

**CLINICAL EXAMINATION :**  
**I ) EXTRA-ORAL EXAMINATION**

Facial Type :  Mesocephalic  Brachycephalic  Dolicocephalic  
General Profile :  Straight  Convex  Concave  
Symmetry :  Symmetric  Asymmetric  
Lower Facial Height :  Normal  Decreased  Increased  
Lips :  Competent  Incompetent  
Teeth show : \_\_\_\_\_ mm at rest \_\_\_\_\_ mm at smile  gummy smile  
Smile arc :  Normal  Flat  Reversed  Accentuated  
Upper Lip :  Normal  Protruded  Retruded  
Lower Lip :  Normal  Protruded  Retruded  
Mentolabial Sulcus :  Normal  Acute (Deepened)  Obtuse (Flat)  
Chin Button :  Orthognathic  Prognathic  Retrognathic  
Chin throat Angle :  90°  105°-120°

\* Antero-posterior : \_\_\_\_\_  
\* Vertical : \_\_\_\_\_  
\* Transverse : \_\_\_\_\_  
\* Frontal soft tissue assessment : \_\_\_\_\_  
\* At rest : \_\_\_\_\_

- On smile : \_\_\_\_\_  
\* Other findings : \_\_\_\_\_

**II ) INTRA-ORAL EXAMINATION**

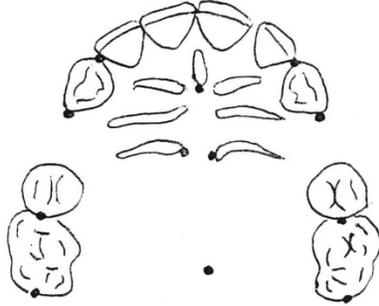
\* Soft tissue : \_\_\_\_\_ Oral hygiene : \_\_\_\_\_  
\* Erupted teeth present : \_\_\_\_\_  
\* Eruption problems : \_\_\_\_\_  
\* General dental condition : \_\_\_\_\_  
\* Crowding / spacing : Maxilla : \_\_\_\_\_  
Mandible : \_\_\_\_\_  
\* Bolton's discrepancies : Anterior ratio (78.48 ± 0.21%) : \_\_\_\_\_  
Overall ratio (91.94 ± 0.18%) : \_\_\_\_\_  
\* Other findings : \_\_\_\_\_

**III ) STATIC AND FUNCTIONAL OCCLUSAL EXAMINATION**

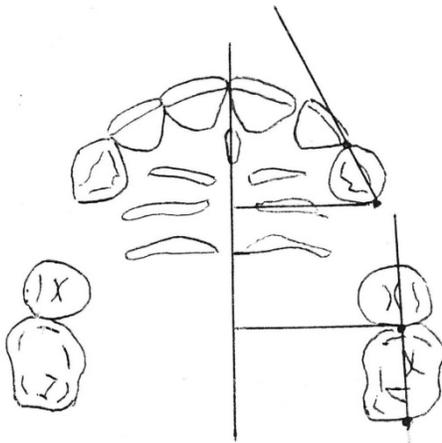
\* Incisor relation : \_\_\_\_\_  
British Classification : \_\_\_\_\_ Overjet (mm) : \_\_\_\_\_ Overbite (mm) : \_\_\_\_\_  
\* Angle's classification : \_\_\_\_\_ Molar relation : R \_\_\_\_\_ L \_\_\_\_\_  
\* Canine relation R \_\_\_\_\_ L \_\_\_\_\_  
\* Midlines discrepancies (mm) : Upper \_\_\_\_\_ Lower \_\_\_\_\_  
\* Cross - bites : \_\_\_\_\_  
\* Displacements (CO / CR discrepancy) : \_\_\_\_\_  
\* Abnormal Habits :  Digit Sucking  Mouth Breathing  Finger biting  Lip Sucking  
\* Swallowing :  Normal  Simple tongue thrust  Complex tongue thrust  
\* Mentalis Muscle :  Normal  Hyperactive  Hypoactive  
\* Other findings : \_\_\_\_\_



### Appendix 3



**Dental cast landmarks**



**Lines for linear and angular measurements**