Evaluation of the Anchorage loss during En-masse Retraction in Orthodontic patients with Maxillary Protrusion Using Friction versus Frictionless Mechanics: A Randomized Clinical Trial

Protocol submitted for the partial fulfillment of Masters' degree in Orthodontics

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Submitted by

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Roles and responsibilities:

Principal investigator:

Amr M. Attia, BDS, will be responsible for the sample recruitment, applying clinical procedures of both interventions that will be carried out, follow up of patients, data management, results interpretation, writing the thesis and protocol registeration.

Main supervisor:

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Co-supervisor:

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Co-supervisor:

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All authors contributed to refinement of the study protocol.

Committees:

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

Introduction

Statement of the problem:

One of the most common complaints of orthodontic patients is proclination of anterior teeth where there is an increase in facial convexity and as well as incompetent lips. Bimaxillary dentoaleveolar protrusion and class II division I cases always have this appearance. Frequently this situation requires extraction of the first premolars followed by fixed orthodontic appliance for space closure and retraction of anterior teeth. Different techniques are used including “Two-step retraction” where canines are retracted as a first step followed by anterior four incisors as a second step and “En-masse retraction” where anterior teeth are retracted as one unit. However, the method of “En-masse retraction” is controversial - whether to use frictionless or friction mechanics.

Rationale for carrying out the trial:

The main reasons of extraction in orthodontics is to correct severe crowding, achieve proper facial profile, improve lip competence and to adjust buccal relationships[1-3]

At the beginning, first premolars are extracted , initial bonding is done followed by leveling and alignment procedures. After this step, there are two general techniques to retract the six anterior teeth with less mesial drifting of the maxillary first permanent molar.

The first approach is a regular procedure where the canines and incisors are retracted in two separate steps. Primary, the canine in the extraction quadrant is retracted until it comes in contact with the tooth distal to the extraction space then canines are anchored to the teeth distal to them where they are used as single

anchor units to retract the incisors. This procedure is called “Two-step retraction’’ technique.[4-6]

The main advantage of this approach is that the load on the posterior teeth is reduced, thus minimal anchorage loss would be expected. The second step, where the posterior segments are anchored with the canines to retract anterior teeth without loosing anchorage [7].However, Closing the extraction space in two steps increases treatment time and also the medial displacement tendency of maxillary first molars is high, thus requiring further time and effort [8]

A second technique was introduced to overcome the disadvantage of the “Two-step retraction” technique where the incisors and canines are retracted separetely. This approach is called ‘‘En-masse retraction’’. Bennett and McLaughlin developed the MBT system in which they used this technique [9,10].

“En-masse retraction” technique has become popular because of its simplicity, but theoretically might be expected to have more load on the posterior segment than the "Two-step retraction” technique.

The use of Temporary Anchoring Devices (TADs) as anchorage is superior to conventional molar anchorage in maximum anchorage and hence attaining better treatment [11,12,13]

Space closure is a tough process in orthodontics, as it requires a strong basis of biomechanics in order to close a space efficiently with minimal unwanted side effects. It can be done with two forms of mechanics: Friction or Frictionless mechanics.

Understanding and predicting the difficulties involved in the way teeth respond to the forces and moments isn’t an easy challenge to many orthodontists. On one hand, sliding mechanics is widely used due to its simplicity, but on the other

hand it shows lack of force control due to friction between arch wire and brackets and lack of vertical and horizontal control over anterior teeth thus making the system indeterminant [14,15,16].

Moreover, Previous studies have demonstrated that the sliding mechanics might lead to uncontrolled tipping or extrusion of the anterior segment[17,19]. On the other hand, theories have suggested that the drawbacks encountered with the sliding mechanics for incisors retraction can be overcome by the use of well-designed loops providing a better control over the moment/ force ratio and thus the position of anterior teeth. However, minor errors in the loops design can result in major differences in tooth movement, and some patients may find the loops uncomfortable [17]

Uncontrolled orthodontic tooth movement can have various adverse effects including root resorption as well as Anchorage loss if posterior segments aren't stabilized and well-anchored [18]. Accordingly, vertical and horizontal control of posterior segments is considered a primary concern to all orthodontists.

There is scarcity in literature regarding the effectiveness of friction and frictionless mechanics during ''En-masse retraction''technique on anchorage loss of posterior segment. Moreover there is deficiency in studies measuring the patient pain and satisfaction regarding the different techniques of retraction[20].

Accordingly, the aim of the current randomized clincal trial (RCT) is to evaluate the effects of friction versus frictionless mechanics, implemented during "En-masse retraction", on anchorage loss. Additionally, assessment of both techniques regarding their rates, effects on root resorption as well as patient satisfaction and scoring will be done.

Literature Review:

One of the primary concerns of individuals seeking orthodontic treatment is to improve their smile, facial esthetics and accordingly their social well being [21].

Many approaches have been applied to accomplish the treatment of those who have bimaxillary protrusion and class I division I cases without any adverse consequences on the teeth that might happen due to the mechanics used. "En-masse retraction" has been applied to acquire better control of posterior teeth and adjusting the position of buccal segment. Multiple studies have been conducted to evaluate the potency of different techniques in relation to the horizontal and vertical position of posterior teeth.

The review of literature will be discussed under the following titles:

1. **Friction and frictionless Mechanics**
    - **a.** Friction Mechanics
    - **b.** Frictionless Mechanics
    - **c.** Friction vs. Frictionless Mechanics
2. **CBCT**
    - **a.** Reliability of CBCT compared to 2D x-ray.
    - **b.** Accuracy of CBCT landmarks for assessment of anchorage loss
    - **c.** Accuracy of CBCT for assessment of root resorption
3. **3D digital model scanning and its reliability**
4. **Anchorage control during "En-masse retraction"**

1) Friction Vs Frictionless Mechanics

a. Friction mechanics

Moore and Waters (1993)[22] Examined analytically the force system bracket and wire in sliding mechanics spot the light on the reason of bracket binding. The results were checked on an enlarged model system, and reasonable agreement between theory and experiment was obtained. The results revealed that for a given bracket tip the restoring couple varies with the flexural rigidity of the wire, the bracket width, span length and the position of the bracket along the span. Moreover, as tipping happened intial intrusive force was brought then it turned out to be extrusive as retraction continues.

Barlow and Kula (2008)[23] carried out systematic review to evaluate the power of clinical evidence concerning the effect of several factors on the efficiency of closing extraction spaces using sliding mechanics. Ten prospective clinical trials comparing rates of closure under different variables and only focusing on sliding mechanics were selected for reviewing. Of these ten trials, two compared arch wire variables, seven compared material variables used to apply force, and one examined bracket variables. Their final conclusion was that arch wire properties, type, size, diameter, along with bracket design, material, and force delivery system all affected friction and hence tooth movement. Elastomeric chain produced similar rates of closure when compared with nickel-titanium springs where there was a little advantage of 200 g nickel-titanium springs over 150 g springs. Lastly, arch wire size has no effect on the rate of closure, although the larger wire sizes had better control on tipping.

Almuzian *et al.* (2018)[24] conducted a systematic review and meta-analysis to explore the effectiveness of nickel titanium closing springs

(Niti-CS) and elastomeric power chains (EPC) in orthodontic space closure and patient-centered outcomes between both of these methods. Only randomized clinical trials (RCTs) were included. Only 4 RCTs met the criteria out of 187 records and were included in the quantitative synthesis featuring 290 test quadrants. The results showed moderate quality evidence assuming that NiTi closing spring produces a faster rate of space closure than the elastomeric chain. Finally, the study couldn't find any difference in terms of anchorage loss between NiTi closing spring and elastomeric chain.

b. Frictionless mechanics

Kuhlberg and Burstone (1997)[25] evaluated the effect of off-center positioning on the force system produced by segmented 0.017 x 0.025 inch TMA T-loops. The spring was tested in 7 positions, centered, 1, 2, and 3 mm toward the anterior attachment, and 1, 2, and 3 mm toward the posterior attachments. The horizontal force, vertical force, and alpha and beta moments were measured over 6 mm of spring activation. The results showed that centered T-loop produces equal and opposite moments with minimal vertical forces. Off-center positioning of a T-loop produces differential moments where more posterior positioning produces an increased beta moment and anterior positioning produces an increased alpha moment.

Chen *et al*. (2000)[26] experimentally measured the load components produced by T-loop springs and the effects of design variations and the addition of gable bends with heat treatment. They used 0.016 inch × 0.022–inch stainless steel wire, bent the T-loop springs on a template jig. The vertical (v) and horizontal (h) dimensions were 6 or 7 millimeters and 6, 7, or

8 millimeters, respectively. six spring geometries are identified, ten specimens of each design (60 total) were made-up. The same springs were also tested with 30° gable preactivation and stress-relieving heat treatment (GPH). They concluded that increasing the vertical or horizontal dimension, the spring's load-deflection rate and its moment-to-force ratio was reduced. Additionally , gable preactivation bends with heat treatment was found to have the reverse result .

Almeida *et al.* (2016)[27] compared force systems that are produced by Ni-It T-Loop springs made with wires of different dimensions. Thirty T-Loop springs were divided into 3 groups according to their dimensions: 0.016 X 0.022 and 0.017 X 0.025 and 0.018 X 0.025 inches respectively. It was concluded that the larger wires produced higher forces with slight increase on the moments. However, the moment to force ratio produced by the 0.016 X 0.022 wire was the highest.

c. Friction vs. Frictionless

Ziegler and Ingervall (1989)[28] conducted a clinical study of maxillary canine retraction with a retraction spring and with sliding mechanics to assess the efficiency of maxillary canine retraction by means of sliding mechanics along an 0.018-inch labial arch and an elastic chain was compared with the canine retraction spring designed by Gjessing. Twenty-one subjects were included in the study where the upper first premolars were extracted. Results showed that rate of canine was increased and with minimal distal tipping with the spring group than with the sliding mechanics group. No

significant difference between canine retraction spring and sliding mechanics regarding canine rotation control in the retraction phase. However, the correction of rotation after the retraction is less time-consuming than the up-righting of a tipped canine

Dincer *et al.* (2000)[29] carried out a clinical study to evaluate the applicability and effects on the dentoalveolar structures of Poul Gjessing (PG) springs when used for retraction of the upper incisors, and to relate the results with the effect of a closed coil spring retraction system. 63 subjects with angle Class I or Class II were selected and divided into two groups, the PG group with 17 subjects and the closed coil spring group with 19 subjects. The results showed that three-dimensional controlled movement of the upper incisors can be obtained by application of the PG universal retraction spring as the active element of segmented arch mechanics. The amount of overbite reduction at completion of the incisor retraction makes the use of additional intrusive mechanics unnecessary

2) CBCT

a. Reliability of CBCT compared to 2D x-ray.

Chung How Kau *et al.*(2009) [30] conducted a study to determine if measurements obtained from digital models from cone beam computed tomography (CBCT) images were comparable to the traditional method of digital study models by impressions. Digital models of 30 subjects were used. InVivoDental software was used to analyze CBCT scans taken by a Galileos cone beam scanner. OrthoCAD software was used to analyze

impression scans of patients at different stages of orthodontic treatment. Impressions were taken using alginate and were mailed to OrthoCAD for digital conversion. The results showed that digital models generated from CBCT imaging are as accurate as OrthoCAD digital models in making linear measurements for overjet, overbite, and crowding measurements. Moreover CBCT digital models offer other information such as bone levels, root positions, and TMJ status.

McNamara *et al.* (2011) [31] Carried out a study to evaluate the accuracy and reliability of craniometric measurements made on CBCT scans and lateral cephalograms using fiducial markers and dry skulls. Ten fiducial markers were placed on known craniometric landmarks of 25 dry skulls with stable occlusions. CBCT scans and conventional lateral headfilms consequently were taken of each skull. They conlcluded that CBCT craniometric measurements computed by a dedicated "3D Cephalometric module" are more accurate than lateral cephalograms and can be used for craniofacial analysis. Moreover, lateral cephalograms have intrinsic limitations that result in distorted images, enlarged in some areas and reduced in others.

b. Accuracy of CBCT landmarks for assessment of anchorage loss

Chaudhary *et al.*(2014) [32] conducted a study to compare the rate of movement of canine using conventional method on one side and skeletal

anchorage (micro implants) on the other side of the same patient. 17 subjects were included for extraction of all first premolars. Micro implants were placed between the roots of the second premolar and the first molars on right side, in both the arches. Retraction was done using sliding mechanics using stainless steel arch wire. They concluded that the movement is equal on the both sides although anchorage loss is seen on the conventional side using molar as an anchorage unit. The retraction was primarily achieved by tipping and partly by translation. Maxillary canine retraction was more on the implant side (6.51 mm). However, Distal tipping was also more on the implant side (9.51°)

c. Accuracy of CBCT for assessment of root resorption

Dudic *et al.* (2009)[33] carried out a study to evaluate the orthodontically induced apical root resorption using panoramic radiograph in one group and cone-beam computed tomography (CBCT) in the other group. They examined 275 teeth in 22 patients just before the end of their orthodontic treatment. Root Resorption was assessed as no, mild, moderate, severe and extreme. Additionally, apical root resorption was underestimated when the teeth were examined on a panoramic radiograph. Finally, they found out that CBCT would be a helpful added diagnostic tool, especially when the orthodontist decides to continue or modify treatment due to orthodontically induced root resorption.

Ren *et al.*(2013)[34] compared the accuracy of CBCT and periapical radiograph as diagnostic tool for spotting external apical root resorption. The study included 160 single rooted extracted premolars with predetermined

simulated root resorption. Two x-rays were taken for each tooth ,CBCT and periapical radiograph, and were blindly evaluated by two observers. The found out that for all external apical root resorption, the sensitivity and specificity values of CBCT (75.8% and 96.3%, respectfully) were greater than that of periapical radiographs (67.5% and 82.5%, respectfully). Therefore, CBCT was a reliable diagnostic for external root resorption, at the same time as periapical radiographs underestimated it.

3) 3D digital model scanning and its reliability

Alcan, Ceylanoğlu and Baysal (2009)[35] They conducted an experimental study to assess the accuracy of digital models produced by the 3Shape system and to test the dimensional stability of three different brands of alginates for durations of 1, 2, 3, and 4 days in a laboratory environment investigated. 105 impressions were taken from a master model with three different brands of alginates. 21 stone models were poured and 21 digital models were prepared while the remaining 84 impressions were poured after 1, 2, 3, and 4 days, correspondingly. They found that Both the stone models and the digital models were highly correlated with the master model. Significant deformities in the alginate impressions were noted at different storage periods of 1 to 4 days. Therefore, Digital orthodontic models are as reliable as traditional stone models. Storing alginate impressions in sealed plastic bags for up to 4 days caused statistically significant deformation of alginate impressions, but the magnitude of deformation of alginate impression did not appear to be clinically relevant and had no adverse effect on digital modeling.

El-Beialy and Mostafa (2010)[36] compared the accuracy of dental measurements taken with calipers on 34 orthodontic plaster dental casts and those from computed tomography scans of the dentition with a dental measurement program (3DD, Biodent, Cairo, Egypt). The mesiodistal widths of teeth, arch widths, arch lengths, arch perimeters, and palatal depths were made with the calipers on a plaster cast. The patients were also scanned with computed tomography, and measurements were made digitally with 3DD, a 3-dimensional-based dental measurements program. They found a strong agreement in most measurements between the conventional method and the 3DD in the 3 planes of space. The mesiodistal measurements of the maxillary right and left second premolars, left central incisor, and right first molar, and the mandibular left and right central incisors, right canine, and left first premolar had fair agreement. Therefore, 3DD can be an alternative to conventional stone dental models.

4) Anchorage control during ‘‘En-masse retraction’’

Hedayati and Shomali(2016)[37] conducted a study to detect the type of anterior segment movement during en masse retraction using different antero-posterior positions of the mini screw with different vertical heights of the anterior power arm. Micro implants were placed in two different positions, mesial and distal of the second premolar. Forces were applied to four different levels of anterior hook height: 0, 3, 6, and 9 mm. Initial tooth movement in eight different conditions was examined and estimated with ANSYS software.

They concluded that placement of micro implants distal to second premolar had minimum adverse effect on anterior dentition.

Reint Meursinge Reynders & Luisa Ladu(2017)[38] conducted a systematic review to compare the effectiveness of TADs as anchorage devices with conventional anchorage methods in patients whom treatment includes space closure of extracted maxillary first premolars with minimal loss of molar anchorage. Fourteen studies; seven RCTS and seven CCTs were included. In total 303 patients received TISADs with 313 control patients. The results showed that TADs are superior to conventional methods of anchorage. The average difference of 2mm is both statistically and clinically significant.

Database search:

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

Aim of the study

A-PICO format:

Population:

Orthodontic patients requiring 1st premolars extraction followed by anterior segment retraction.

Intervention:

‘‘En-masse retraction’’ using frictionless mechanics with miniscrews used as anchorage.

Comparator:

‘‘En-masse retraction’’ using sliding mechanics (friction) with miniscrews used as anchorage.

Outcome measure:

	Outcome Name	Measuring Tool	Measuring Unit
Primary Outcome	Anchorage loss	CBCT	- Linear measurement in mm Angular measurement in degrees
Secondary Outcome	Rate of space closure	Digital scanned Dental Model	- Scanned digital models in (mm) o Models taken every month o Analysed using 3 Shape Software
	Pain	Pain scoring sheets given to patients	VAS scoring from 1-10 (Fig 1)

	Root resorption	CBCT	Scoring system of Levander and Malmgren[39] (5 grades classification)
	Torque of anterior teeth	CBCT	Degrees
	Tip of anterior teeth	CBCT	Degrees
	Vertical position	Digital scanned Dental Model	Mm
	1st Permenant Molar rotation	Digital scanned Dental Model	Degrees

B-Research question:

In Orthodontic patients requiring 1st premolars extraction followed by ‘‘En-masse retraction’’, can frictionless mechanics offer a better control of anchorage loss compared to friction mechanics?

Objectives of the study

Research hypothesis:

The null hypothesis (H_0) of this research is that there’s no difference between both frictionless and friction mechanics on anchorage loss during ‘‘En-masse retraction’’ following 1st premolar extraction

Primary objective (s):

Measuring anchorage loss during ‘‘En-masse retraction’’using frictionless versus friction mechanics.

Secondary objective:

Evaluating the rate of ‘‘En-masse retraction’’using frictionless Versus friction mechanics, root resorption, pain and discomfort during retraction. In addition to this, changes in vertical position (extrusion/ intrusion), tip and torque of anterior teeth will be measured following ‘‘En-masse retraction’’ using frictionless versus friction mechanics.

Study design:

This is a randomized clinical trial with two arms parallel group, and 1:1 allocation ratio. In one group, frictionless mechanics will be applied during ‘‘En-masse retraction’’ while the other will receive frictional mechanics during retraction. The anchorage loss will then be compared between both interventions.

Material and Methods

I)participants, interventions, and outcomes

A] Study Setting:

The study will be performed in the 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 urban and rural population.

B] Eligibility criteria:

➢ **Inclusion criteria**:for the participants include the following:

1. Orthodontic patients (both genders)
2. Age range (14-24)
3. Patients requiring 1st premolars extraction followed by ‘‘En-masse retraction’’ (Bimaxillary Protrusion or Class II division 1 cases).
4. Patients with fully erupted permanent teeth (not necessarily including the 3rd molar).
5. Cases requiring maximum anchorage during anterior segment retraction.
6. Cases with minimal crowding (2-3) mm

➢ **Exclusion Criteria:** for the involved subjects included:

1. Patients suffering from any systemic diseases interfering with tooth movement.
2. Patients with extracted or missing permanent teeth. (except for third molars).
3. Patients with badly decayed teeth.
4. Patients with any parafunctional habits (i.e. Bruxism, tongue thrusting, mouth breathing, etc.…).
5. Patients with previous orthodontic treatment

C] Interventions:

➢ **Medical History Questionnaire:**

For every patient, to exclude the presence of any systemic condition interfering with orthodontic treatment.

➢ **Clinical Examination:**

Oral structures will be examined to identify caries, fracture or missing teeth. Gingival tissues will be carefully examined for any gingivitis, periodontitis, recession, or lesions.

➢ **Diagnosis**

Check the potential patient to fulfill the previously mentioned inclusion criteria. Every participant will be asked to sign an informed consent about the study. Full set of records (study models, panorama radiograph and lateral cephalometric radiographs, photos) will be taken for every patient as part of the routine procedure for treatment of patients in the clinic of the Orthodontics and Dentofacial Orthopedics Department, Future University in Egypt.

➢ **Clinical Procedure:**

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

- Bonding of all teeth except for first premolars and banding/bonding the first and second molars will be done using Roth prescription brackets (0.022 x 0.028 slot)*.
- Miniscrews will then be placed in the upper arch between the second pre-molar and first molar**.
- The patient will be referred for extraction of first premolars.
- Anchorage will be secured, followed by Leveling and alignment for the bonded and banded teeth through following the wire sequence: 0.014 Nitti, 0.016×0.022 Nitti and 0.017×0.025 StSt.

*American Orthodontics
**Jeil

- After levelling and aligning is completed (right before retraction), the patient will be referred for the uptake of pre-intervention records:

  a- CBCT

  b- Impression and models

  c- photo (Extraoral & Intraoral)

  d- pain questionnaire

➢ **Acquisition of pre-intervention records:**

- The patient will be referred for the uptake of a CBCT, which are considered to be the T0 records.
- Impressions will be taken before retraction (without the archwire in place) followed by digital scanning of produced models.
- Photos (Extraoral & Intraoral)
- Pain questionnaire distributed with explainatory session on it

➢ **Beginning of Retraction:**

Frictionless group:

- A braided ligature wire extended between the second premolars and miniscrews will be used for proper indirect anchorage control.
- Closing retraction T-loops will be fabricated using 0.017 x 0.025 TMA wire. The loop will be positioned halfway the extraction space and the canine. [40,41].
- A gable angle of 45˚ will be added to the posterior segment.

- Distal activation of 4 mm will be applied with cinching back the wire to the auxillary tube distal to first molars bilaterally. [42]

Friction group:

- Crimpable hooks added to the arch wire (0.017”x0.025” Stainless steel) distal to the lateral incisor passing near the center of resistance of the anterior segment.
- A ligature wire extending between the second premolar and miniscrews will be used for proper anchorage control.
- Retraction will start on a 0.017”x0.025” Stainless steel wire using elastomeric chain (force applied will be 200 g per side) [43] extending between the crimpable hooks and the miniscrews.
- The force will be measured by a force gauge and reactivated every 4 weeks maintaining constant force of retraction all over the retraction phase.

➢ **<u>Follow up visits</u>**

Patients will be asked to attend for follow up sessions every 4 weeks for:

- Evaluation miniscrews stability.
- Replacement of the power chain to maintain a force of 200 gm per side.
- Reactivation of the T-loop by further distal activation and cinch back.
- Impression taking to determine the anchorage loss

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

In cases of prolonged swelling or pain related to the miniscrews, 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 miniscrews, the screw will be removed and replace the miniscrew after total resolution of the inflammation.

➢ **Criteria for Ending the retraction:**

a-class I canines

b-normal overjet

c- closure of extraction space

d- reaching good profile

Ø **Post-retraction Questionnaire:**

The patients of both groups will be asked to fill in questionnaires regarding their experience with their allocated technique during the whole retraction period from day of extraction till the end of retraction.

Ø **Retraction records**

Following ‘‘En-masse retraction’’, patients will be referred to the same radiology center to acquire the final cone-beam CT to assess the movement and inclination of anterior teeth.

The final dental model will be used to assess the rate of retraction and molar anchorage loss achieved throughout the study.

Ø Material Used

- American Orthodontics Brackets, Roth prescription, 22 slot size.
- American Orthodontics Elastomeric power chains
- American Orthodontics Elastomeric O-ties
- American Orthodontics Ligature wire.
- Miniscrew, 8 mm length × 1.6 mm diameter TAD (Jeil)
- American Orthodontics Arch wires.
- American Orthodontics Molar bands/tubes.

D] Outcomes

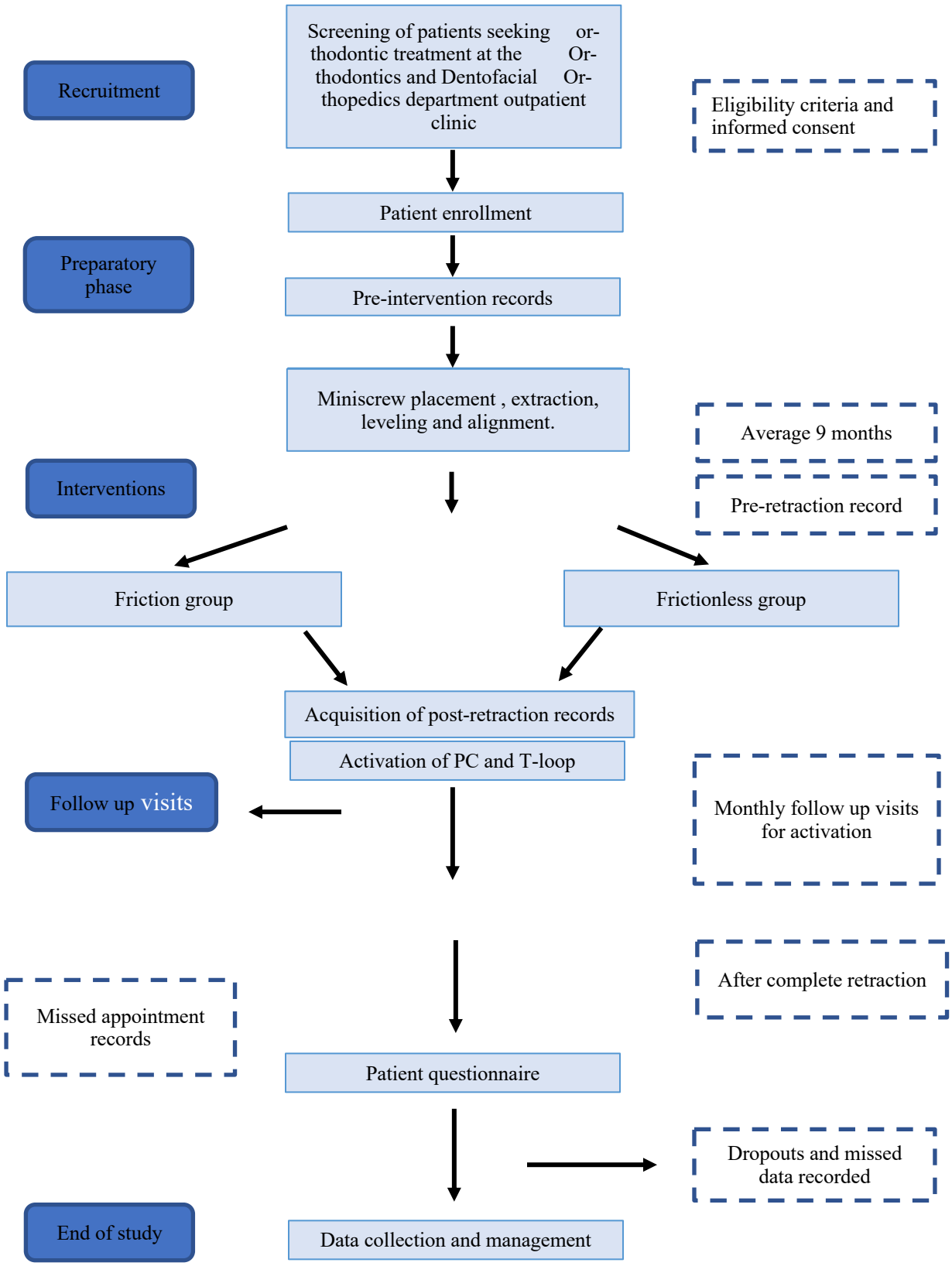
Primary outcome: is to monitor the anchorage loss during ‘‘En-masse retraction’’. All outcomes will be assessed as the difference between T0 at the start of retraction and T1 after complete space closure.

Secondary outcomes: is to monitor the changes in the anterior teeth position (final anterior teeth tip, torque and vertical position), rate of space closure, presence of any root resorption and pain associated with the different methods used for retraction.

E] Participant timeline:

1. The principle investigator will screen the potential patients through careful clinical examination of patients at the Orthodontics and Dentofacial Orthopedics department, Faculty of Oral and Dental Medicine, Future University in Egypt.
2. All recruited patients should fulfill 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. Pre-intervention records will be taken for each participant after enrollment to ensure proper diagnosis.
5. The principle investigator will randomly allocate the patients to one of the intervention groups.
6. Anchorage will be secured by placement of miniscrew, followed by extraction of the first premolar.
7. Active intervention will begin after proper levelling and alignment of teeth through following the wire sequence: 0.014 NiTi, 0.016×0.022 NiTi and 0.017×0.025 StSt.
8. The principle investigator will take pre-retraction records for every participant T0.
9. In Friction mechanics group, Power chain is used for anterior segment retraction while in Frictionless group, T-loop is used for retraction.
10. Each patient will come every 4 weeks for follow up visit, for appliance activation and uptake of impression for interim records.
11. After complete space closure, the principle investigator will take post-retraction records for each participant T1.

12. Every patient will fill up a questionnaire regarding his experience during treatment.
13. The principle investigator will continue the normal treatment and achieve proper finishing for every patient after the end of the study.


Recruitment
Screening of patients seeking orthodontic treatment at the Orthodontics and Dentofacial Orthopedics department outpatient clinic
Eligibility criteria and informed consent
Patient enrollment
Preparatory phase
Pre-intervention records
Miniscrew placement , extraction, leveling and alignment.
Average 9 months
Interventions
Pre-retraction record
Friction group
Frictionless group
Acquisition of post-retraction records
Activation of PC and T-loop
Follow up visits
Monthly follow up visits for activation
After complete retraction
Missed appointment records
Patient questionnaire
Dropouts and missed data recorded
End of study
Data collection and management

F] Sample size calculation:

Our sample size calculation is based on a previous study comparing the effect of friction and frictionless mechanics[29]. Using PS software output, we are planning a study of a continuous response variable from independent Group I and Group II subjects with 1 Group I(s) per Group II subject. In a previous study the response within each subject group was normally distributed with standard deviation 0.76. If the true difference in the Group II and Group I means is 1.0, we will need to study 10 Group II subjects and 10 Group I subjects to be able to reject the null hypothesis that the population means of the Group II and Group I are equal with probability (power) 0.8. The Type I error probability associated with this test of this null hypothesis is 0.05. Considering drop out a sample size 15 per group is appropriate.

G] Recruitment strategy:

The principal investigator will recruit the patients from the clinic of Orthodontics and Dentofacial Orthopedics 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 (Frictionless) or B (friction) 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 supervisor of the study (Dr. Heba M. Dehis) 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 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 levelling 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 is responsible for assigning subjects to interventions according to the concealed allocation, appliance activation at follow up visits, dental impressions and acquisition of dental casts.

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

III) Data collection, management and analysis:

A] Data collection methods:

Primary outcomes:

1. Anchorage loss: will be accessed by the principal investigator via CBCT taken before and after the completion of retraction by identifying the landmarks, reference lines and planes, then will interpret the measurements in degrees and millimeters.

Secondary outcomes:

1. Retraction rate: to assess the antero-posterior movement of anterior teeth and first molars, the principle 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.

2. Pain: each patient will fill a questionnaire regarding his treatment experience in a Visual Analog Scale (VAS) scoring from 1-10 by making a handwritten mark on a 10-cm line that represents a continuum between "no pain" on the left end (0 cm) of the scale and the "worst pain" on the right end of the scale (10 cm). The questionnaire will include several questions related to oral hygiene, pain and discomfort experienced throughout the trial.

3. Root resorption: will be accessed by the principle investigator via CBCT taken before and after the completion of retraction. The resorption will be identified using

scoring system of Levander and Malmgren[34] that classifies it into 5 grades: 0, no root resorption; 1, mild resorption, with the root of normal length and only an irregular contour; 2, moderate resorption, with small areas of root loss and the apex having an almost straight contour; 3, severe resorption, with loss of almost one third of root length; and 4, extreme resorption, with loss of more than one third of the root length.

4. Anterior teeth torque: will be accessed by the principle investigator via CBCT 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.

5. Anterior teeth extrusion/intrusion: will be accessed by the principle investigator via CBCT 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 millimeters.

6. Anterior teeth tip: will be accessed by the principle investigator via scanned digital models taken before and after the completion of retraction.

7. Molar Rotation: will be accessed by the principal investigator via digitalized dental models. These records will be taken before and after the completion of retraction by identifying the landmarks, reference lines and planes, then will interpret the measurements of the angles in degrees.

B] Data management:

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

C] 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.

• 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 millimeter.

• 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.

V) Ethics and dissemination:

A] Research Ethics Approval:

The Ethical committee in Future University in 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 and Dentofacial Orthopedics 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 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.

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 Masters' degree in Orthodontics and Dentofacial Orthopedics department, Faculty of Oral and Dental Medicine, Future University in Egypt 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 in Egypt library and will distribute additional copies among the main universities in Egypt.

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Appendix

Fig 1: