Evaluation of the Rate of 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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Principal investigator:

Leena A. Shibl, BDS, will be responsible for the clinical procedures that will be carried out, sample recruitment, follow up of patients, writing the thesis, data management and results interpretation.

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Co-supervisor:

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All authors contributed to refinement of the study protocol.

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All authors contributed to refinement of the study protocol.

Committees:

- Orthodontics Department Council
- College Board Committee
- Ethics Committee

Introduction

Statement of the problem:

One of the common chief complaints of orthodontic patients is protrusion of the upper teeth resulting in an increased lip procumbency and poor facial esthetics. This problem is encountered in patients with bimaxillary protrusion as well as class II division 1 cases. These cases require extraction of first premolars and retraction of the anterior teeth, thus decreasing the soft tissue convexity. Several techniques of space closure are used in the orthodontics. The most frequently used ones are: Two-step retraction (retraction of canine teeth followed by retraction of all four incisors) and en-masse retraction (retraction of the canines and incisors as one unit)[1]. The en-masse technique can be done in one of two ways: through friction or frictionless mechanics. Both are viable options, but, ideally, we want to retract and complete the orthodontic treatment as quickly as possible, in order to decrease the negative effects that may occur during treatment. Long treatment time has been associated with greater susceptibility to iatrogenesis. This includes, but not limited to, root resorption, white spots, carious lesions, and gingival inflammation[2,3]. Which of these mechanics results in a decreased treatment time is still up for debate.

Rationale for carrying out the trial:

Improvement in appearance is the primary reason adults seek orthodontic care[4]. In regards to increased procumbence of the lips, extractions and retraction is the ideal treatment choice.

The first premolars are usually the main choice for extraction for maximum retraction of anterior teeth into the extraction space[5]. One method of space closure is the two-step technique, where the canines are retracted alone into the extraction space, followed by retracting the four incisors. Another method of space closure is the en-masse technique, where the six anterior teeth are retracted in as one unit. The "two-step technique" was recommended by Proffit and Fields[6], stating that this method would minimize anchorage loss, as the amount of force on the posterior teeth is reduced, unlike the "en-masse technique". On the other hand, it is seen as complicated and time consuming by some practitioners who claim that dividing up the strain does not eliminate its overall effect on the anchorage[1]. Moreover, with the advent of mini-implants, better anchorage preservation can be achieved in both methods compared to the traditional means of anchorage reinforcement[7].

Several studies have been conducted to determine whether the "two-step technique" trumped the "en-masse technique", or vice versa. It was determined that both were effective methods for retraction[8]. However, the question arises of which results in faster results. It is well known that orthodontic treatment is time consuming, especially in extraction cases. The average orthodontic treatment duration for extraction therapy is 31 months[9]. Furthermore, prolonged orthodontic treatment may lead to negative consequences to the overall oral health. Thus, reduction of the treatment duration is of primary concern to both the patient as well as the orthodontist. Theoretically, en-masse retraction is expected to be superior in terms of treatment time, as a smaller number of steps are required.

Several methods have been proposed to reduce the treatment duration of space closure[10], including implementing different retraction mechanics. Space closure can be done with two forms of mechanics: Friction or Frictionless mechanics.

In friction mechanics (sliding), the brackets slide against the orthodontic wire, creating friction between both. This is accomplished using elastics or coil springs. Frictionless mechanics, also called "Segmented Mechanics", utilizes loops and bends to generate a force to close the space, which allow differential moments in both active and reactive units[11].

Sliding mechanics are more commonly used due to its simplicity. However, in this kind of mechanics, the force of friction is encountered, which tends to reduce the force available eventually for effective tooth movement[1]. To overcome this friction encountered, a high magnitude of force has to be applied[12,13].

On the other hand, the drawbacks faced by the friction mechanics can be overcome by the use of segmented mechanics. With the use of loops, light, constant levels of force are provided, leading to an optimum force and decreased force decay[1,14]. It can be assumed that these benefits would lead to an increased rate of retraction. Despite this, frictionless systems tend to be less used in practice, due to the complexity of forming the loop. Minor errors may lead to major differences in tooth movement. In addition, some patients may find the use of loops uncomfortable[15].

Presumably, sliding mechanics takes more of a toll on the overall rate of retraction, due to the friction that occurs between the bracket-wire interface[16,17]. Despite the large number of studies dealing with mechanics of space closure, there isn't enough evidence in the literature regarding which is faster, especially while using the en-masse technique.

There's a scarcity in literature concerning en-masse retraction and its effect on the rate of tooth movement. Therefore, a randomized clinical trial has been chosen

to evaluate the rate of En-masse Retraction in orthodontic patients with maxillary protrusion using friction versus frictionless Mechanics

Literature Review:

Patients who seek orthodontic treatment seek a favorable esthetic outcome[18]. However, the time it takes to complete orthodontic treatment, especially in extraction cases, can be offsetting to patients. Several approaches have been implemented to achieve the treatment that will result in proper mechanics with an increased rate of tooth movement.

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- **Lateral Cephalometric for measurement and its reliability**
3- **3D digital model scanning and its reliability**
4- **Anchorage control during en-masse retraction**

1) Friction Vs Frictionless Mechanics

a. Friction mechanics

Barlow and Kuala (2008)[19] conducted a systematic review concerning the factors that affect the efficiency of closing an extraction space using sliding mechanics. Ten prospective clinical trials that compare the rates of closure under different variables and focus only on sliding mechanics were selected. The results showed that the clinical research was supported by laboratory results, where NiTi coil springs produce a more consistent force and a faster rate of closure when compared with active ligatures as a method of force delivery to close extraction space. Elastomeric chains produced similar rates of closure compared to Ni-Ti

Springs. Finally, arch wire size has no effect on the rate of closure, although the larger wire sizes control tipping more effectively.

Kojima and Fukui (2010)[12] calculated the long-term tooth movements in en-masse sliding mechanics. Although tipping of the anterior teeth occurred with the initial force system, they moved bodily after a long time elapsed. Therefore, long-term tooth movement could not be predicted from the initial force system. During the bodily movement, friction occurred at the bracket-wire interface and dissipated the applied force. As a result, the net force became one fourth of the applied force. It was also demonstrated that friction was not detrimental to anchorage.

Chaudhari and Tarvade (2015)[20] compared the clinical effectiveness of nickelt titanium (NiTi) closed coild spring and elastomeric chain on the rate of space closure, taking into account the anterior retraction and the anchorage loss. Forty patients undergoing orthodontic treatment for bimaxillary proclination were randomly selected after first premolar extraction. They were then allocated to two groups: NiTi closed coil spring group versus Elastomeric chain group, with 20 candidates in each group. The results of the study showed that faster space closure with significant anchorage loss was achieved using NiTi closed coil spring compared to the elastomeric chain.

b. Frictionless mechanics

Almeida et al. (2016)[21] compared force systems that are produced by Ni-Ti 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. 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.

Chen et al. (2000)[22] measured the moments and forces produced by various orthodontic T-loop spring designs (with varying vertical and horizontal dimentsions). The effects of dimension changes (within clinically used ranges) and the addition of gable bends with heat treatment were assessed. They found that increasing the vertical or horizontal dimension reduced the spring's load-deflection rate and its moment-to-force ratio. Moreover, gable preactivation with heat treatment had the opposite effects.

c. Friction vs. Frictionless

Ziegler and Ingervall (1989)[23] conducted a clinical study where the efficiency of maxillary canine retraction was observed by means of sliding mechanics along an 0.018-inch labial arch and an powerchain (AlastiK chain) compared to the use of retraction springs (frictionless mechanics) by Gjessing. Twenty-one subjects were included in the study where the upper first premolars were extracted. It was shown that the canine was retracted faster and with less distal tipping through frictionless mechanics than with the sliding mechanics. The canine retraction spring (Gjessing Spring) was not

superior to the sliding mechanics in controlling canine rotation during the retraction. However, this disadvantage is outweighed by the fact that the correction of rotation after the retraction is less time-consuming than the up-righting of a tipped canine

Dincer et al (2000)[24] evaluated the effect of application of Poul Gjessing (PG) Spring for retraction of upper incisors on the dento-alveolar structure compared to the effect of closed coil spring. 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. They concluded that mesial movement of buccal segment and distal movement of root apex of incisors were accompanied with the incisor retraction in both groups. Moreover, a significant incisors intrusion in PG group and a significant increase in deep bite in coil spring group. Plus, the PG spring produced three-dimensional control in the movement of upper incisors, so that application of additional intrusive mechanics after competition of the incisor retraction became unnecessary.

2) Lateral Cephalometric for measurement and its reliability

Ellis and McNamara (1986)[25] evaluated seventeen measurements of incisor angulation and position for their applicability in describing the incisor relationship to maxilla and mandible. They concluded that most of the measurements are better descriptors of other relationships that could confound interpretation of relationships to the supporting bones.

Ceylan et al. (2002)[26] evaluated the longitudinal growth changes in the incisor position, overjet, and overbite between 10 and 14 years of age using serial lateral cephalographs. Radiographs of 63 patients were taken at 10, 11, 12, and 14 years old. The results showed age affected the measurements of overbite, upper incisor-NA (mm), lower incisor-NB (mm), upper incisor-NA (angle), and the interincisal angle. Gender affected the overbite, upper incisor-NA (mm), upper incisor-NA (angle) and upper incisor-SN (angle).

Weyrich and Lisson (2009)[27] evaluated the effect of premolar extractions on incisor position and soft tissue profile in patients with Class II, Division 1 malocclusion using cephalometry. The concluded that patients who have undergone camouflage treatment exhibit significantly more retruded upper central incisors than those with extractions in both jaws, and that their upper incisors are highly significantly more retruded and their mandibles significantly more retrognathic than those of patients who have not undergone extraction therapy.

Yang and Qian (2016)[28] investigated the relationship of torque control and type of dental movement, as well as the relationship between reconstruction of the alveolar bone and retraction of the anterior teeth during anterior segment retraction. Lateral cephalometric radiographs as well as CBCT were used to evaluate the inclination degree of the upper anterior teeth, the horizontal and vertical displacement of edge and apex,and the thickness of the alveolar bone at the apex. The study concluded that, during retraction, cases who received torque control showed less inclination degree change of the upper anterior teeth, less lingual displacement of the edge, more lingual displacement of the apex.

3) 3D digital model scanning and its reliability

El-Beialy et al. (2010)[29] compared the accuracy of dental measurements taken with calipers on 34 orthodontic plaster dental casts to those from computed tomography scans of the same dentition. 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. The results showed high correlation between the conventional method and the 3DD in all the 3 planes of space. Thus, 3D dental measurement programs (such as the one used in this study) can be a valid alternative to conventional stone dental models.

Radeke et al. (2014)[30] compared the traditional manual technique of using calipers to take orthodontic measurements on plaster dental casts versus a digital measuring technique on 3D scans of casts. Plaster casts of 55 patients who had not undergone orthodontic treatment were scanned and measured using OnyxCeph3T program. The results showed that any tooth-width measurements taken on 3D scans are similar to measurements taken using calipers directly on actual casts, including that of reproducibility. Taking manual measurements with the caliper took significantly longer time compared to that of a computer software, but it would be negligible in clinical practice. Moreover, inexperienced examiners take mesiodistal tooth measurements faster using the software than when using calipers.

Moreira et al. (2014)[31] evaluated the reliability of linear measurements in virtual models versus physical plaster model by comparing measurements

performed on virtual models obtained from scanning alginate impression and plaster models. Twenty-six randomly selected patients had alginate impressions taken of their upper and lower jaws and both the impression and the plaster models were scanned. Measurements were performed using 3Shape software, and included: mesiodistal tooth measurements, arch perimeter, intercanine distance, and intermolar distance. The results showed no significant difference in measurements taken in the anterior tooth width, the maxillary intercanine and intermolar width, and the mandibular dental arch perimeter. The greatest differences were found in the maxillary and mandibular posterior tooth width. Overall, virtual models from wither plaster model scans or alginate impression scans are reliable and sufficiently accurate for orthodontic diagnosis and treatment planning.

4) Anchorage control during en-masse retraction

Upadhyay et al. (2008)[32] conducted a study to determine the overall efficiency of mini-implants as anchorage for en-masse retraction compared with conventional methods of anchorage preservation. A total of 30 patients with divided into two equal groups, each group allocated to either mini-implants (Group 1) or conventional means of anchorage (Group 2). They found that no anchorage loss was observed in group 1, compared to 1.95 mm of anchorage loss in group 2, thus concluding that mini-implants are an efficient method for anchorage.

Hedayati et al. (2019)[33] compared two positions of miniscrew placement (mesial and distal to the second premolar) with 4 different levels of anterior hook heights (0, 3, 6, and 9 mm) and their effect on tooth movement during en-masse

retraction. According to the study, the best control in the saggital plane was achieved by mesial placement of the mini-implant at 9mm anterior hook. Control in the vertical plane was best controlled by 6mm hook with a distal placement of the miniscrew.

Database search:

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

Aim of the study

A-PICO format:

Population:

Orthodontic patients requiring 1st premolar extractions.

Intervention:

En-masse retraction (canines and incisors) using segmental mechanics (frictionless) with miniscrews used as anchorage.

Comparator:

En-masse retraction (canines and incisors) using sliding mechanics (friction) with miniscrews used as anchorage.

Outcome measure:

	Outcome Name	Measuring Tool	Measuring Unit
Primary Outcome	Rate of space closure	Digital scanned dental models	- Scanned digital models in (mm) o Models taken every month o Analysed using 3 Shape Software

Secondary Outcome	Anchorage loss	Digital scanned dental models	Linear measurement in scanned digital models (mm)
	Molar Rotation	Digital scanned dental models	Degrees
	Vertical position	Lateral Cephalometric Xray	Mm
	Torque of anterior teeth	Lateral Cephalometric Xray	Degrees
	Pain	Pain scoring sheets given to patients	VAS scoring from 1-10 (Fig 1)

B-Research question:

In orthodontic patients with maxillary protrusion, can frictionless mechanics offer a faster rate of retraction compared to frictional 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 rate of retraction during en-masse retraction following 1st premolar extraction.

Primary objective:

Evaluating the rate of En-masse retraction using frictionless vs friction mechanics.

Secondary objectives:

Assessing the amount of anchorage loss, 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 vs 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 group will receive frictional mechanics. The rate of retraction 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 Orthodontic Department at the Faculty of Oral and Dental Medicine, Future University. The recruited sample would be from the Egyptian urban and rural population.

B] Eligibility criteria:

- **Inclusion criteria**: for the participants include the following:
  1. Adults and Adolescent patients (both genders)
  2. Age range (14-24)
  3. Patients with maxillary protrusion requiring first premolars extraction (Bimaxillary Protrusion or Class II division 1 cases).
  4. Patients with fully erupted permanent teeth (not necessarily including the third molar).
  5. Cases requiring maximum anchorage during retraction.
  6. Good general and oral health

- **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 Orthodontic Department, Future University.

- **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 premolar and first molar.

*American Orthodontics

** Jeil Miniscrews

- 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 NiTi, 0.016×0.022 NiTi and 0.017×0.025 StSt.
- After levelling and aligning is completed (right before retraction), the patient will be referred for the uptake of pre-intervention records.

➢ **<u>Acquisition of pre-intervention records:</u>**

- The patient will be referred for the uptake of a Lateral Cephalometric radiograph, which will be considered the T0 record.
- Impressions will be taken before retraction (without the archwire in place) followed by digital scanning of produced models.

➢ **<u>Begin of Retraction:</u>**

Frictionless group:

- A ligature wire extended between the second premolars and miniscrews will be used for proper 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. [35,36].
- A gable angle of 45˚ will be added.
- Distal activation of 4 mm will be done with cinch back the wire distal to 2nd molars bilaterally.[37]

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.
- Retraction will start on a 0.017”x0.025” Stainless steel wire using elastomeric chain (force applied will be 212 g per side)[38] extending between the crimpable hooks and the miniscrew.
- The force will be measured by a force gauge and reactivated every 4 weeks maintaining constant force of retraction all over the retraction phase.

➢ **Follow up visits**

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 212 gm per side.
- Reactivation of the T-loop by further distal activation and cinch back.
- Impression taking to determine the overall rate of retraction.

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

In cases of prolonged swelling or pain related to the miniscrew, 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 complete resolution of the inflammation.

- **Post-retraction Questionnaire:**

The patients of both groups will be asked to fill in questionnaires regarding their experience with their allocated technique

- **Retraction records**

Following en-masse, patients will be referred to the same radiology center to acquire the final lateral cephalometric x-ray to assess the movement and inclination of anterior teeth.

The final dental model will assess the rate of retraction, molar rotation, and molar anchorage loss achieved throughout the study.

- **Material Used**

- American Orthodontics Brackets, Roth prescription, 22 slot size.
- American Orthodontics Elastomeric power chains
- American Orthodontics Elastomeric O-ties
- American Orthodontics Ligature wire.

- Jiel Miniscrew, 8 mm TAD
- American Orthodontics Arch wires.
- American Orthodontics Molar bands/tubes.

D] Outcomes

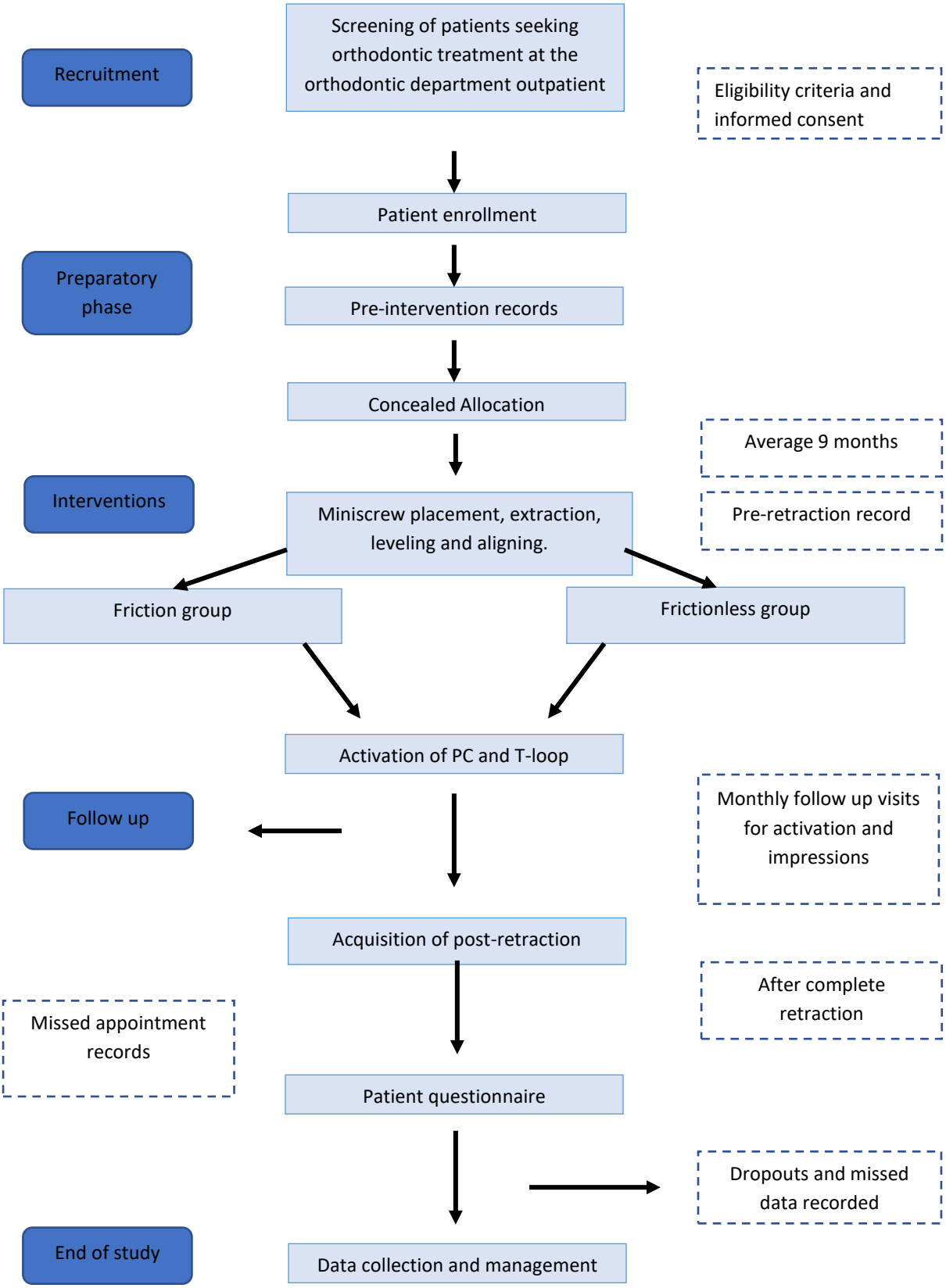
Primary outcome: is to monitor the rate of space closure during en-masse retraction. All outcomes will be assessed as the difference between T0 at the start of retraction and T1 after complete space closure.

Secondary outcomes: is to monitor the changes in the anterior teeth position (torque and vertical position), molar rotation, anchorage loss, 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 orthodontic department, Faculty of Oral and Dental Medicine, Future University.
2. All recruited patients should fulfil the previously mentioned inclusion and exclusion criteria.
3. Every participant will be asked to sign an informed consent before the beginning of the study.
4. After patient's enrolment, each participant will be asked for pre-intervention records to ensure proper diagnosis.

5. The 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 the upper arch.
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 orthodontic department outpatient
Eligibility criteria and informed consent
Patient enrollment
Preparatory phase
Pre-intervention records
Concealed Allocation
Average 9 months
Interventions
Miniscrew placement, extraction, leveling and aligning.
Pre-retraction record
Friction group
Frictionless group
Activation of PC and T-loop
Follow up
Monthly follow up visits for activation and impressions
Acquisition of post-retraction
After complete retraction
Missed appointment records
Patient questionnaire
Dropouts and missed data recorded
End of study
Data collection and management

E] Sample size calculation:

Our sample size calculation is based on a previous study comparing the effect of friction and frictionless mechanics[24]. 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.

F] Recruitment strategy:

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

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 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 outcome:

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, The models will be digitalized and the landmarks, reference lines and planes will be identified on the pre, interim and post-retraction digital dental models for measurements reading.

Secondary outcomes

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

2. 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.

3. Pain: Each patient will fill a questionnaire regarding his treatment experience in a VAS scoring from 1-10. The questionnaire will include several questions related to oral hygiene, pain and discomfort experienced throughout the trial.

4. Anterior teeth torque, extrusion/intrusion: will be accessed by the principle investigator via lateral cephalometric radiographs 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:

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

B] Protocol amendments:

The main investigator will be responsible to complete a formal amendment in case of any modifications or adjustments to protocol that may affect the conduct of the

study, as changes in the study design or intervention procedures. The Orthodontics department, Faculty of Oral and Dental Medicine, Future University and the Ethics Committee will approve such amendment before proceeding in the study.

C] Consent:

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

D] Confidentiality:

The main investigator will store any personal information about the participants collected during the study separately from study records in locked files in areas with only access to the supervisors responsible for auditing and analysis. Also, will keep the files in the Department Of Orthodontics, Faculty of Oral and Dental Medicine, Future University and will identify all the reports, data and administrative forms by a coded ID number to maintain participant confidentiality. Participant information won't be used outside the study except with written permission of the participant.

E] Declaration of interests:

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

F] Access to data:

The supervisors and the principal investigator will only have access to the data of the study. All the data will be secured by a password to maintain confidentiality. No other parties are allowed to assess the results until the study is terminated and the conclusions are revealed.

G] Ancillary and post-trial care:

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

H] Dissemination Policy:

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

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Appendix

Fig 1: