Evaluation of treatment duration of En-masse versus Two steps Retraction in Patients having Maxillary Protrusion :

A Randomized Clinical Trial

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

Faculty of Oral and Dental Medicine, Future University in cairo

Submitted by

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Funding:

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Roles and responsibilities:

Principal investigator:

Aya A. El Ashwal, BDS, will be responsible for applying the sample recruitment, clinical procedures of both interventions that will be carried out, follow up of patients, data management, results interpretation and writing the thesis as well as protocol registration.

Main supervisor:

Dr. **Nagwa El Mangoury,** BDS, MSc, PhD - Department of Orthodontics and Dentofacial Orthopedics – Future University. Helped in developing the idea of the research, will help in interpretation of results and drawing conclusions.

Co-supervisor:

Dr. **Faten H.K. Eid,** BDS, MSc, PhD, professor - Department of Orthodontics and Dentofacial Orthopedics – Cairo University. Helped in setting the study design, will help in follow up of patients, creating analysis, interpretation of results and drawing conclusions and help writing thesis and supervision.

Co-supervisor:

Dr. **Heba M. Dehis,** BDS, MSc, PhD, Lecturer - Department of Orthodontics and Dentofacial Orthopedics – Cairo University. Will be responsible for implementation of random sequence generation, as well as allocation concealment. Additionally, will help

in follow up of patients, interpretation of results, drawing conclusions, as well as writing Thesis and protocol registration.

All authors contributed to refinement of the study protocol.

Committees:

- Orthodontics Department Council
- College Board Committee
- Ethics Committee

Introduction

Statement of the problem:

Several orthodontic techniques have been used to treat patients with bimaxillary protrusion as well as class II division 1 cases. To resolve this problem extraction of first premolars and retraction of the anterior teeth is usually done, thus improve esthetics and lips competence. It is still debatable which technique is superior to the other, Two-step retraction (retraction of canine first followed by retraction of all four incisors) versus en masse retraction (retraction of the canines and incisors as one unit) (1) both techniques can be done by implementing either friction or frictionless mechanics.

Rationale for carrying out the trial:

In order to achieve patient satisfaction and shortest treatment duration, there is no gold standard guidelines which technique achieves the most efficient results at the shortest period of time of retraction. The first premolars are usually the main choice of extraction in bimaxillary protrusion cases, maximum anchorage of the posterior teeth become of great importance for two reasons; first to retract the anterior teeth to their greatest extent and second to increase the chances of correcting the profile maximum retraction of anterior teeth into the extraction space and retraction is the ideal treatment choice. (2,3)

Space closure can be achieved by two methods either the two-steps (4) or by en-masse technique. A debate was raised between the two methods regarding friction mechanics.

It has been recommended that two steps techniques would provide less load on the posterior teeth thus minimal anchorage loss but on the other hand, separate canine retraction followed by incisors retraction would take longer time than closing it in a single step and it is aesthetically unacceptable (5) for some patient as there is a space after canine retraction and it persists up until the full retraction of anterior segment, for these reasons en-masse retraction is expected to be superior treatment option as retraction will be done by one step (6).

Nowadays, Orthodontists prefer using the en-masse technique because of its simplicity and the extraction space will be closed in one step so better aesthetics. But theoretically this technique may provide more loads on posterior segment so more risk of anchorage loss.

In general orthodontic treatment takes long time especially in extraction cases by average two years treatment time (7). So the longer treatment duration, the greater risks on the dentition by a way of root resorption (8), periodontal disease and enamel decalcifications (9). Thus, reduction of the treatment duration is of prime concern to both the patient as well as the orthodontist.

For many years, practitioners have been looking for an efficient force system that can close extraction spaces quickly, aesthetically, accurately, and effectively. It was determined that both were effective methods for retraction (10). However, there is no evidence which technique offers shorter treatment duration with best retraction and space closure.

Space closure can be done with two forms of mechanics: Friction or Frictionless mechanics, so knowing well biomechanics of force system is of great importance to close the extraction space without anchorage loss of posterior segment and avoiding any adverse effects on teeth roots.

Accordingly, the aim of the current randomized clinical trial (RCT) is to evaluate duration of en-masse retraction versus two steps retraction in adult patient having maxillary protrusion using friction mechanics. In addition to recording effects on root resorption and anchorage loss for both techniques.

Literature Review:

Improvement in esthetic and facial profile is the main target of patients who seek orthodontic treatment to fulfill their satisfaction (11). Several approaches have been implemented to achieve the treatment that will result in proper mechanics with an increased rate of tooth movement. However, extraction cases take time to be completed. Long treatment time to patients and orthodontics is one of drawbacks. Multiple studies have been conducted to evaluate the potency of different retraction methods.

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

1- **En masse retraction and two steps retraction**
2- **Friction Mechanics**
3- **3D digital model scanning and its reliability**

1) En masse retraction and two steps retraction

Heo W. *et al.* 2007 (12) compared the amount of anchorage loss of the maxillary posterior teeth and amount of retraction of the maxillary anterior teeth between en masse retraction and two-step retraction of the anterior teeth, 30 female adult patients with Class I malocclusion and lip protrusion that needed maximum posterior anchorage. There were no significant differences in the degree of anchorage loss of the maxillary posterior teeth between the two groups. Bodily and mesial movements of the upper molars occurred in both groups. Approximately 4 mm of the retraction of the upper incisal edges resulted from 1 mm of anchorage loss in the upper molars in both groups.

Rizk MZ *et al.* 2018 (13) conducted a systematic review and meta-analysis to evaluate the the effectiveness of en masse and two-step retraction methods during orthodontic space closure regarding anchorage preservation and anterior segment retraction and to assess their effect on the duration of treatment and root resorption. An electronic search for potentially eligible randomized controlled trials and prospective controlled trials was performed in five electronic databases up to July 2017. The process of study selection, data extraction, and quality assessment was performed by two reviewers independently. A narrative review is presented in addition to a quantitative synthesis of the pooled results where possible. They conclude that Both en masse and two-step retraction methods are effective during the space closure phase. The en masse/miniscrew combination is superior to the two-step/conventional anchorage combination with regard to anchorage preservation and amount of retraction. Limited evidence suggests that

anchorage reinforcement with a headgear produces similar results with both retraction methods. Limited evidence also suggests that en masse retraction may require less time and that no significant differences exist in the amount of root resorption between the two methods.

Khlef HN *et al.* 2019 (14) carried out a systematic review and meta-analysis To evaluate the efficacy of accelerated and non-accelerated methods of en-masse retraction of the upper anterior teeth in terms of skeletal, dental, and soft-tissue variables, as well as the duration of retraction or overall orthodontic treatment.
An electronic search of PubMed and nine other major databases for randomized controlled trials (RCTs) and clinical controlled trials (CCTs) was performed between January 1990 and April 2018. There is a weak to moderate evidence that using accelerated and non-accelerated methods would improve the facial profile and lead to similar skeletal corrections so according to the quality of evidence, there is a need for more well-conducted RCTs, and more work to be oriented towards en-masse retraction with the use of other acceleration methods.

2) Friction Mechanics

Barlow and Kuala 2008 (15) carried out 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. Moreover elastomeric chains was found to produce 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.

Kanuru RK *et al.* 2014 (16) carried out clinical study to investigate the amount of space closure by movement of canines into the extraction spaces using four brands of elastomeric power chains (EPCs) by intraoral application with pre-adjusted appliance for 6 weeks, namely the Ormco, 3M Unitek, Rocky Mountain, and Highland, which were closed-link with five loops delivering less than or equal to 250 g were used. The rates of canine retraction were measured between the attachment points on the canine bracket hook and first molar hook using a Mitutoyo Digital Vernier Caliper at the time of first application, after 3 weeks of use, and at the end of 6 weeks of use, and were subjected to statistical calculations. Although all brands of the EPCs produced space closure of canines, it was observed that not much of a significant difference existed among the products tested.

Chaudhari and Tarvade 2015 (17) compared the clinical effectiveness of nickelt titanium (NiTi) closed coil 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.

Al muzian *et al.* 2017 (18) conducted meta-analysis to explore the effectiveness of nickel titanium closing springs and elastomeric power chains (EPC) in orthodontic space closure and to assess the adverse periodontal effects, cost efficiency and patient-centred outcomes between both of these methods, and they concluded that both of NiTi closing springs and elastomeric chains are efficient force delivery systems in closing extraction space with space closure being the resultant of anterior teeth retraction, anchorage loss or combination.

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3) 3D digital model scanning and its reliability

El-Beialy and Mostafa Y.A. 2010 (19) 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.

Kim *et al.* 2016 (20) analysed the accuracy of Bolton analysis obtained from digital models scanned with Ortho Insight (3D) laser scanner system in comparison to those obtained from cone beam computed tomography (CBCT)

images and traditional plaster models. CBCT scans and plaster model's scans were obtained from fifty patients. Botlon ratios were calculated with the Ortho Insight 3D laser scanner software, CBCT scans were imported and analyzed using AVIZO software and plaster models were measured with a digital caliper. Laser scanned digital models were found to be highly accurate compared to physical models and CBCT scans for assessing the spatial relationship of dental arches for orthodontic diagnosis.

Database search:

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

Aim of the study

A-PICOS format:

Population:

Adolescent and adult orthodontic patients requiring first premolars extraction.

Intervention:

En-masse retraction using sliding mechanics (friction) with mini screws used as anchorage.

Comparator:

Two-steps retraction using sliding mechanics (friction) with mini screws used as anchorage.

Outcome measure:

	Outcome Name	Measuring Tool	Measuring Unit

Primary Outcome	Duration of space closure	Dental digital Model
		Records of visits
			- Scanned digital models in (mm)
			  o Models taken every month
			  o Analysed using 3 Shape Software
			- computerized record system of the recruited patient (months, days, years)

Secondary Outcomes	Anchorage loss	Digital models	- Linear measurement in mm
	Pain	Pain scoring sheets given to patients	- VAS scoring from 1-10(Fig 1)

B-Research question:

Will en-masse retraction offer shorter treatment duration compared to two steps retraction, in patients having maxillary protrusion?

Objectives of the study

Research hypothesis:

The null hypothesis (H_0) of this research is that there's no difference between both en-masse and two steps techniques on duration of retraction during en-masse and two steps retraction following 1st premolar extraction.

Primary objective:

Evaluating the duration of En-masse and two steps retraction using friction mechanics.

Secondary objectives:

Assessing the amount of anchorage loss, pain and discomfort during retraction. In addition to this, of anterior teeth will be measured following en-masse and two steps retraction using friction mechanics.

Study design:

This is a randomized clinical trial with two arms parallel group, and 1:1 allocation ratio. In one group, will receive frictional mechanics during En masse retraction, while the other group will receive frictional mechanics during two steps retraction. The duration 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 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. Age range (14-24)
2. Adolescent & Adult patients (both genders)
3. Patients with maxillary protrusion requiring first premolars extraction (Bimaxillary Protrusion or Class II division 1 cases) as confirmed from lateral cephalometric, pre-treatment records & from clinical examination.
4. Patients with fully erupted permanent teeth (not necessarily including the third molar).
5. Cases requiring maximum anchorage during retraction.
6. 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 Orthodontic Department, Future University in Egypt.

- **Clinical Procedure:**

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

  - Miniscrews will then be placed in the upper arch between the second premolar and first molar.
  - The patient will be referred for extraction of first premolars.

*American Orthodontics

* Jeil Miniscrews

- 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.
- 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)*.
- After leveling and aligning is completed (right before retraction), the patient will be referred for the uptake of pre-intervention records for en masse group (Impression for models, photos extra oral and intra oral and pain questionnaire).
- For two step group canine retraction will take place on a 0.017×0.025 StSt arch wire, once canine retraction stage is completed, the patient will be referred for the uptake of pre-intervention records.

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

- Alginate impressions will be taken before retraction (without the arch wire in place) followed by digital scanning of produced models.
- Photos (Extra and intra oral).
- Pain questionnaire distributed with explanatory session on it.

➢ **Begin of Retraction:**

- 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) (24) extending between the crimpable hooks and the molar hooks.
- 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 of miniscrews stability.
- Replacement of the power chain to maintain a force of 200 gm per side for en masse group and 160 gm per side for two step group.
- Impression taking to asseses amount of space closure.
- Recording the pain scoring sheet.

➢ **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 total resolution of the inflammation.

In case of non compliant patients.

- **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.

- **Retraction records**

Following en-masse and two steps retaction, 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.

- **Criteria of ending the retraction**

  - Class I canine relation
  - Normal overjet
  - Balanced facial profile
  - Closing extraction space

- **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 x 1.6mm diameter TAD (Jeil).
- American Orthodontics Arch wires.
- American Orthodontics Molar bands/tubes.

D] Outcomes

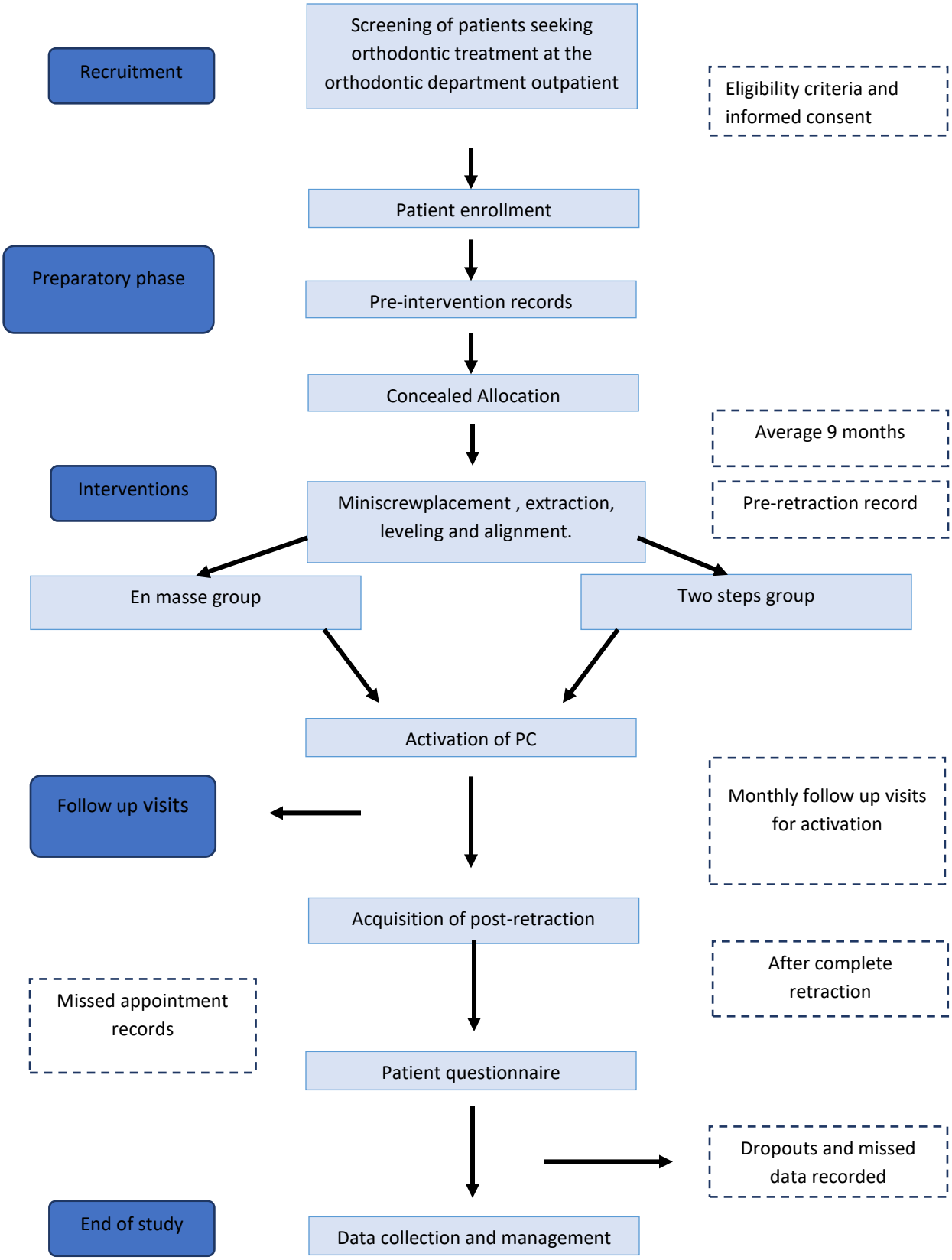
Primary outcome: is to monitor the Duration of space closure during en-masse and two steps retraction. All outcomes will be assessed as the difference between T0 at the start of retraction and T1 after complete space closure.

Secondary outcomes: is to monitor the changes in the anterior teeth position (final anterior teeth tip, torque and vertical position), anchorage loss, 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 orthodontic department, Faculty of Oral and Dental Medicine, Future University in Egypt.
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. Power chain is used for anterior segment retraction.
10. Each patient will come every 4weeks for follow up visit, for appliance activation and uptake of impression for interim records + monitoring of recording the VAS sheet.
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
Miniscrewplacement , extraction, leveling and alignment.
Pre-retraction record
En masse group
Two steps group
Activation of PC
Follow up visits
Monthly follow up visits for activation
Acquisition of post-retraction
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 En masse versus two-steps using 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.

G] Recruitment strategy:

The principal investigator will recruit the patients from the clinic of Orthodontic 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 (En-masse) or B (two steps) 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 Co-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 contact the supervisor to know the order and then the main operator will allocate each patient to assign each participant for the corresponding intervention either (En-masse or two steps 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. Total Retraction Duration: to assess the timing of 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.

Secondary outcome:

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.

2. 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.

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 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, 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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