Evaluation of Incisors' Position Following Anterior Segment Retraction Using Friction versus Frictionless Mechanics: A Randomized Clinical trial

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

Faculty of Oral and Dental Medicine, Future University

Submitted by

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Roles and responsibilities:

Principal investigator:

Dorra Bakhit, 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.

Main supervisor:

Prof. **Yehya Mostafa,** BDS, MSc, PhD – Chairman of the 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:

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All authors contributed to refinement of the study protocol.

Co-supervisor:

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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:

Anterior segment retraction is a major step encountered in cases with upper incisors protrusion comprising both bimaxillary protrusion and class II Div-1. Extraction is the treatment of choice for these cases; space closure can be achieved by separately retracting the canine followed by the four incisors. It's still debatable which technique used for anterior segment retraction is more superior than the other friction versus frictionless.

Rationale for carrying out the trial:

The art and science of facial aesthetics has intrigued mankind since the time of Egyptian culture. Upper incisors retraction is needed in cases like protrusion with/without skeletal discrepancy and plays a remarkable role on the appearance of the face as well as on the function of masticatory system[1].

Extraction of 1st premolars is the treatment of choice for these cases with maximum anchorage control to retract the anterior teeth to their greatest extent and to increase the chances of correcting the profile. The mail goal of treatment in such condition is decreasing soft tissue convexity after the retraction of anterior teeth[2].

Space closure is the main stage of orthodontic treatment when extractions are undertaken as part of the treatment plan. It can be achieved either by separately retracting the canine followed by the four incisors (two-step) or by en-masse retraction of the whole anterior segment simultaneously. A debate was raised between the two methods. It has been recommended[3] that separate canine

retraction followed by incisors retraction would provide less load on the posterior teeth, yet no significant differences were found between the two methods.

For years, orthodontists have been looking for an efficient force system that can close extraction spaces quickly, aesthetically, accurately, and effectively. Space closure can be accomplished by adopting friction based mechanics often called “sliding mechanics” or without friction, also known as “Segmental mechanics”[4]. In Friction mechanics; the space site is closed by means of coil springs or elastics allowing the brackets to slide on the orthodontic archwire. On the other hand, frictionless mechanics uses loop and bends to generate force to close the space site which allow differential moments in both active and reactive units[5].

One of the major challenges faced by the orthodontists is to understand and predict the complexities involved in the response of teeth to the forces and the moments. Sliding mechanics is widely used due to its simplicity but it shows lack of force control due to friction between archwire and brackets, and a lack of vertical and horizontal control over anterior teeth thus making the system indeterminant[6]–[8]. Moreover, Previous experiments have demonstrated that the sliding mechanics might lead to uncontrolled tipping or extrusion of the anterior segment.[9][10].

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[9].

It is well known that the amount of tip, torque, extrusion/intrusion in anterior teeth is very critical as it affects the final aesthetic outcome. Accordingly,

anterior segment vertical and horizontal control is considered a primary concern to all orthodontists. Despite the large number of studies dealing with mechanics of space closure, little evidence has been found in the orthodontic literature regarding the best guidelines for anterior teeth position after anterior teeth retraction. Therefore, a recent systematic review has recommended additional studies to determine the best way for anterior segment retraction.[11]

There's scarcity in literature concerning the issue of anterior segment retraction technique and its effect on anterior teeth position. Therefore, a randomized clinical trial has been chosen to investigate this issue, aiming to support clinicians with the best guidelines for anterior segment retraction.

Review of Literature

It's widely accepted that one of the main goals seeking orthodontic treatment is aesthetic[12]. Aesthetics are mainly determined by controlling the position of the anterior teeth. Accordingly, three-dimensional control of anterior teeth during orthodontic treatment is important to avoid any side effects on the dentition which might happen due to the applied orthodontic mechanics. Several approaches have been implemented to control both the anteroposterior and the vertical positions of the incisors with multiple studies conducted to evaluate their effectiveness.

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

1. Friction mechanics for anterior segment retraction.
2. Frictionless mechanics for anterior segment retraction.
3. Friction vs. frictionless.
4. CBCT for evaluation and its reliability.

1) Friction mechanics for anterior segment retraction

Chaudhari and Tarvade (2015)[13] compared the rate of retraction and anchorage loss using nickel titanium closed coil springs and elastomeric chain during en-masse retraction. Forty patients with first premolar extraction were divided into two groups for space closure. The amount of anterior retraction, anchor loss and rate of space closure was measured before start of retraction and at the end of 4 months clinically and radiographically. The results of this study demonstrated faster space closure with anterior retraction along with significant anchorage loss was achieved by using NiTi closed coil spring when compared to elastomeric chain.

Barlow and Kula (2008)[14] reviewed the literature to determine strength of clinical evidence concerning the influence of various factors on the efficiency (rate of tooth movement) of closing extraction spaces using sliding mechanics. Ten prospective clinical trails comparing rates of closure under different variables and only focusing on sliding mechanics were selected to be reviewed. They concluded that arch wire properties, type, size, diameter, along with bracket design, material, and force delivery system all affected friction and hence tooth movement. Then added that Elastomeric power chain produced similar rates of retractions as 150 and 200 g nickel-titanium springs which were equally effective in space closure. Moreover, arch wire size might had no effect on rate of closure but larger size control tipping better, and frictional differences of arch wire type might not be the major factor in rate of closure.

2) Frictionless mechanics for anterior segment retraction

Almeida et al. (2016)[15] compared the force system produced by nickel-titanium T-loop springs made with wires of different dimensions. Thirty compound T-loop springs were divided into three groups according to the dimensions of the nickel-titanium wire used for its design: 0.016" × 0.022", 0.017" × 0.025", and 0.018" × 0.025". The loops were tested on the Orthodontic Force Tester machine at an interbracket distance of 23 mm and activated 9 mm. The larger wires tested produced higher forces with slight increase on the moments, but the M/F produced by the 0.016" × 0.022" wire was the highest found.

Chen et al. (2000)[16] measured the moments and forces produced by various orthodontic T-loop spring designs. 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.

Kuhlberg and Burstone (1997)[17] 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 seven 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 the alpha/beta moment ratio was dependent only on the spring position, and independent of spring activation. Eccentric positioning of T-loop springs effectively produces a consistent moment differential through the range of spring activation.

3) Friction vs. Frictionless

Dincer et al (2000)[1] evaluated the effect of application of 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.

Ziegler and Ingervall (1989)[18] 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 AlastiK chain was compared with that using the canine retraction spring designed by Gjessing. Results revealed that canine was retracted faster and with less distal tipping with the spring than with the sliding mechanics. The canine retraction spring was not superior to the sliding mechanics in controlling canine rotation during the retraction.

4) CBCT for evaluation and its reliability

Gribel et al. (2011)[19] compared the accuracy of craniometric measurements made on lateral cephalograms and on cone beam computed tomography (CBCT) images. Ten fiducial markers were placed on known craniometric landmarks of 25 dry skulls with stable occlusions. CBCT scans and conventional lateral headfilms subsequently were taken of each skull. Direct craniometric measurements were compared with CBCT measurements and with cephalometric measurements using repeated measures analysis of variance (ANOVA). They concluded thatCBCT craniometric measurements are accurate to a subvoxel size and potentially can be used as a quantitative orthodontic diagnostic tool. Two-dimensional cephalometric norms cannot be readily used for three-dimensional measurements because of differences in measurement accuracy between the two exams.

El-Beialy et al. (2011)[20] evaluated the accuracy and reliability of measurements obtained from 3-dimensional (3D) cone-beam computed tomography (CBCT) for different head orientations. They used Stainless steel wires fixed to a dry skull at different places. The skull was scanned by using CBCT in the centered and 5 other positions. Intraobserver and interobserver reliability tests were performed by using 6 landmarks identified on the virtual 3D skulls by 2 operators. They reported that CBCT measurement is a reliable technique that can be utilized for assessment of both linear and angular measurements.

Database search:

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

Aim of the study

A-PICO format:

Population:

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

Intervention:

Anterior segment retraction using segmental mechanics (frictionless) with miniscrews used as anchorage.

Comparator:

Anterior segment retraction using sliding mechanics (friction) with miniscrews used as anchorage.

Outcome measure:

	Outcome Name	Measuring Tool	Measuring Unit
Primary Outcome	Torque of anterior teeth	CBCT	Degrees
	Tip of anterior teeth	CBCT	Mm
	Vertical position	CBCT	Mm

	Root resorption	CBCT	Scoring system of Levander and Malmgren[21](5 grades classification)

B-Research question:

In Orthodontics adolescent patients requiring 1st premolars extraction followed by anterior segment retraction, can frictionless mechanics offer a better control over the anterior segment 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 anterior teeth position during anterior segment retraction following 1st premolar extraction

Primary objective (s):

Measuring changes in extrusion/ intrusion, tip and torque of anterior teeth following anterior segment retraction using frictionless vs friction mechanics.

Secondary objective:

Measuring the root resorption during anterior segment 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 anterior segment retraction while the other will receive frictional mechanics during retraction to compare the changes in anterior teeth position.

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 is from the Egyptian urban and rural population.

B] Eligibility criteria:

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

1. Female patients, Age range (13-25)
2. Bimaxillary protrusion requiring extraction of four first premolars and maximum anchorage.
3. Patients with fully erupted permanent teeth (not necessarily including the 3rd molar).
4. Good general and oral health.
5. Class I molar relation (Angle's classification)

- **Exclusion Criteria:** for the involved subjects include:

1. Patients suffering from any systemic diseases or syndromes or on anti-inflammatory medication 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.
5. History of previous orthodontics 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**

  Potential patients will be checked for fulfillment of the previously mentioned inclusion criteria. Every participant will be asked to sign an informed consent about the study. Full set of records (study models, 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 at The Future University of Egypt.

- **Clinical Procedure:**

  After taking pre-treatment records:

  - 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 slot).

- Leveling and alignment for the bonded and banded teeth will be initiated following the wire sequence: 0.014 NiTi, 0.016×0.022 NiTi and 0.017×0.025 StSt.
- Then miniscrews will be placed in upper and lower arches between 2nd premolar and 1st molar.
- The patient will be referred for extraction of 1st premolars then canine retraction on a 0.017×0.025 StSt arch wire.
- After canine retraction, the patient will be referred for the pre-intervention records.

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

- The patient will be referred for CBCT which is considered to be the T0 record.

➢ **<u>Start of Retraction:</u>**

Frictionless group:

- A ligature wire will be extended between the canines and miniscrews 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 remaining extraction space after canine retraction. [17], [22].
- A gable angle of 45˚ will be added.
- Distal activation of 4 mm will be done which produced around 160 g of force per side with cinching back the wire distal to molars bilaterally.[23].
- Reactivation will be only done when the two arms of the t-loop approximate 2-3 mm.

Friction group:

- Miniscrews will be checked for stability. In case of any dislodgment or instability, they will be removed and replaced.
- A crimpable hook of 8mm length will be added to the archwire (0.017”x0.025” Stainless steel) distal to the lateral incisors passing through the center of resistance of the anterior segment.
- A ligature tie will be tightly wounded from an undercut in the miniscrew head to canine bracket to stabilize the posterior segment.
- Retraction will start on a 0.017”x0.025” Stainless steel archwire using elastomeric power chain (force applied will be 160 g per side) extending between the crimpable hook and the miniscrew head.
- 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 mini-screws stability.
- Replacement of the power chain to maintain a force of 160 gm per side.
- Reactivation of the T-loop by further distal activation and cinch back if needed.

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

In cases of prolonged swelling or pain related to the mini-screw the patient will be given strict oral hygiene measures and the beginning of retraction will be postponed for three weeks.

In cases of loose or broken mini-screws, the screw will be removed and replaced.

- **Retraction records**

Following retraction of the anterior segment, patients will be referred to the same radiology center to acquire the final CBCT to assess the movement and inclination of anterior teeth.

- **Materials**

  - American Orthodontics Brackets, Roth prescription, 0.022 slot size.
  - American Orthodontics Elastomeric power chains.
  - American Orthodontics Elastomeric O-ties.
  - American Orthodontics Ligature wire.
  - Mini-screw (1.6- by 8-mm, bracket head design; Dual Top Anchor System, Jeil Medical Corporation, Seoul, Korea).
  - American Orthodontics Arch wires.
  - American Orthodontics Molar bands/tubes.
  - Crimpable hooks (Dentos Inc.)

D] Outcomes

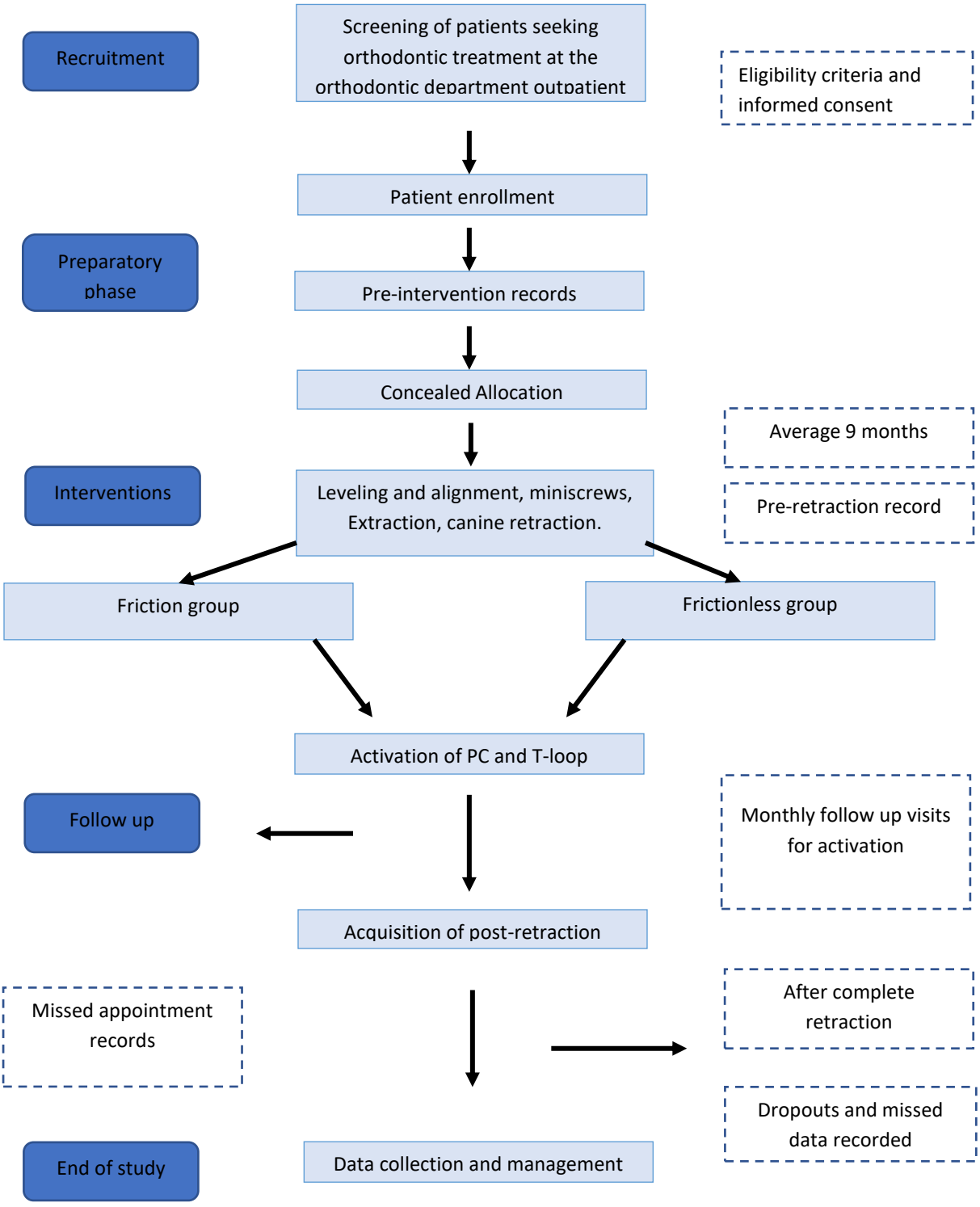
Primary outcome: is to monitor the changes in the anterior teeth position (final anterior teeth tip, torque and vertical position) in association with each technique after retraction

Secondary outcomes: are to detect the presence of any root resorption associated with the different methods used for anterior segment. All outcomes

will be assessed as the difference between T0 at the start of anterior segment retraction after full canine retraction and T1 after complete space closure.

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 at The Future University of Egypt.
2. All recruited patients must 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 co-supervisor will randomly allocate the patients to one of the intervention groups.
6. Active intervention will start after proper leveling and alignment of the upper and lower arches and canine retraction.
7. The principle investigator will take pre-retraction records for every participant (T0).
8. In Friction mechanics group, Power chain will be used for anterior segment retraction while in Frictionless group, T-loop will be used for retraction.
9. Each patient will come every 4weeks for the follow up visit, for appliance activation and impressions for interim records.
10. After complete space closure, the principle investigator will take post-retraction records for each participant (Tfinal).
11. 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
Leveling and alignment, miniscrews, Extraction, canine retraction.
Pre-retraction record
Friction group
Frictionless group
Activation of PC and T-loop
Follow up
Monthly follow up visits for activation
Acquisition of post-retraction
Missed appointment records
After complete retraction
Dropouts and missed data recorded
End of study
Data collection and management

E] Sample size calculation:

In a previous study by **Dincer et al.** [1], they compared the effect of frictionless mechanics via PG spring (Poul Gjessing spring) (Group I) and friction mechanics using coil spring (Group II). The mean change in distance between central incisor edge and x-axis was of 0.68mm and SD of 0.73 in Group I, while Group II was -0.32mm and SD of 0.79.

Sample size calculation was done based on that study using PS software output. A continuous response variable from independent Group I and Group II subjects was planned. In the 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 needed to study 10 Group II subjects and 10 Group I subjects to be able to reject the null hypothesis. 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 of 15 per group was planned (**Figure 1**).

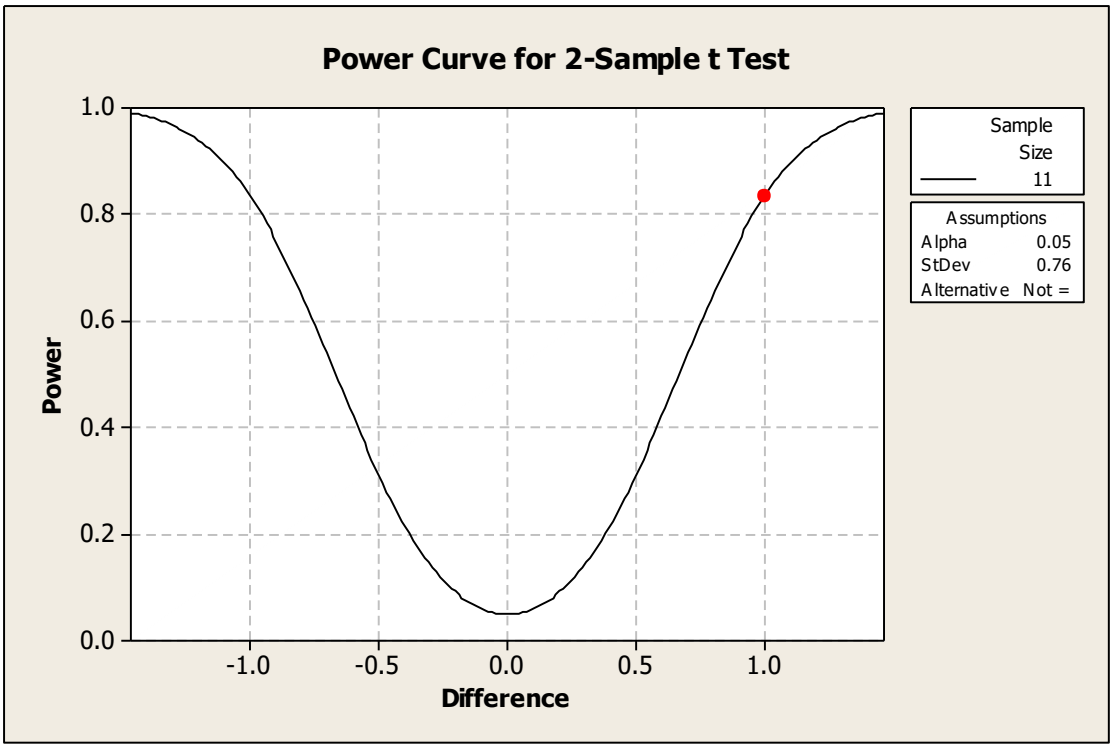


Figure 1: Power curve for 2-sample t-test denoting the power of the study.

Statistical Methods

All statistical calculations will be done using computer program IBM SPSS (Statistical Package for the Social Science; IBM Corp, Armonk, NY, USA) release 22 for Microsoft Windows.

Numerical data will be tested for the normal assumption using Kolmogorov Smirnov and Shapiro Wilk tests. If normal distribution was found; therefore, data will be statistically described in terms of mean ± standard deviation (± SD). Student t test will be used to compare between the study groups for independent samples in comparing normally distributed data. Paired t test will be used within group comparisons in comparing normally distributed data and Two-sided p values less than 0.05 will be considered statistically significant.

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 (Friction) or B (Frictionless) using Microsoft Office Excel 2007 sheet. and will write the patient numbers in the first column, and will select function RAND()to generate the randomization number in the second column. These numbers will be sorted according to the randomization number so the first column numbers will be randomly distributed.

B] Allocation concealment mechanism:

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

C] Implementation:

At time of intervention, the main operator will send the patient to the secretary 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 leveling and alignment stage.

D] Blinding:

Blinding of the operators: Blinding will not be possible for the operators during the application interventions and during the follow up visits. The principal operator is responsible for assigning subjects to interventions according to the concealed allocation, appliance activation at follow up visits.

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

III) Data collection, management and analysis:

A] Data collection methods:

Primary outcome:

1. Anterior teeth torque, extrusion/intrusion: will be assessed by the principle investigator via CBCT taken before and after the completion of retraction. The principal investigator identified the landmarks, reference lines and planes, then interpreted the measurements in degrees and millimeters.

2. Anterior teeth tip: will be assessed by the principle investigator via CBCT taken before and after the completion of retraction.

Secondary outcomes:

1. Root resorption: will be assessed 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[21] 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.

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 and radiographs.

C] Statistical Analysis:

• The principle investigator will be responsible for the extraction of the required data from the CBCT taken before and after retraction 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 used 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 Inter-observer and intra-observer reliability will be assessed using $P \leq 0.05$.

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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