Evaluation of the rate of anterior segment retraction using friction versus frictionless mechanics: A randomized clinical trial.

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

Faculty of Oral and Dental Medicine, Future University

Submitted by

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Principle investigator:

Monica G. Tawfik, BDS, masters' student and will be the main operator in carrying out all the procedures for patients and is responsible for sample recruitment, clinical procedures, data collection, writing of thesis and result interpretation and analysis.

Main supervisor:

Yehia Mostafa, BDS, MSc, PhD – Principle investigator and Chairman of the Department of Orthodontics and Dento-facial Orthopedics, Future University in Egypt. Has created the idea of the research and will aid in the data analysis and the deduction of conclusions.

Co-supervisor:

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Committees:

- Orthodontics Department Council.
- College Board Committee.
- Ethics Committee.

Introduction

In this day and age, facial and dental aesthetics play key roles in promoting a healthier self-esteem, perceived attractiveness and gaining better career opportunities. This has, in turn, motivated patients to seek orthodontic treatment. Thus far, there has been a continuous pursuit by researchers for methods that provide the best possible aesthetics and function, in the shortest duration, with the least amount of drawbacks.

Despite, the various advantages of orthodontic treatment, its main disadvantage is the prolonged duration [1,2].

In many cases presented to the orthodontic clinic, four first premolar extractions are required. In bimaxillary dentoalveolar protrusion, four premolar extractions will provide space in both arches to align and/or retract anterior teeth.

Individuals having bimaxillary dentoalveolar protrusion are characterized by proclined upper and lower incisors and increased procumbency of the lips thus suffering from poor facial esthetics [3].

Extraction space closure may be done by two different methods; the en masse retraction method which involves retraction of all six anterior teeth in one step. While the two-step retraction method involves the full retraction of the canine followed by the four incisors.

The two-step technique is considered more advantageous over en masse retraction in the sense that retraction of the canine and then the retraction of the four incisors will induce less load on the anchorage units and ensure full retraction on the anterior teeth. This will be achieved via increasing the number of teeth in the anchorage unit via including the canine while retracting the four incisors [4]. Although the two-step technique may seem to be more time consuming than en masse retraction, it is thought to be well worth the wait to decrease the amount of anchorage loss and to maximize the amount of anterior segment retraction.

Various methods of anterior segment retraction have been implemented, the major two methods are friction and frictionless mechanics. Friction mechanics; which is also termed as “sliding mechanics”; involves the sliding of the teeth along the arch wire. While frictionless mechanics also termed as “segmental mechanics” involves the movement of the teeth due to the action of the loop or spring. Frictionless mechanics doesn’t involve the sliding of the teeth along the arch wire i.e. there isn’t any friction between the wire and the bracket during tooth movement.[4]

Friction “sliding” mechanics involves the use of elastomeric power chains and coil springs and space closure occurs by the sliding of the brackets on the wire [5]. It is more convenient and more frequently used for its simplicity for the patient and clinician. However, it provides compromised results due the unaccounted loss of force due to friction.[6] Friction is mainly the result of; bracket slot width, bracket composition, wire dimensions and composition, ligation method used, interbracket distance and the interface between the bracket and archwire[7].

On the other hand, in frictionless “segmental” mechanics, there is no guiding wire; hence there is no loss of applied force due to friction. This is due to the fact that the spring provides both the force and the moment. Therefore, this renders frictionless mechanics with a properly shaped loop more predictable and versatile than sliding mechanics [7]. Therefore, in frictionless mechanics a meticulously designed appliance has a greater activation range and a more constant force level and moment to force ratio.

Thus far, there has been a void in the literature regarding the optimum method to be utilized for anterior segment retraction in patients with bimaxillary protrusion. Hence, there is a need for a randomized clinical trial to gain some evidence as to which method should be implemented in the day-to-day clinical practice.

Literature Review.

In every orthodontic treatment involving space closure following extractions of the first premolars, the question of the optimum method of retraction comes to mind. The two methods frequently employed are either friction or frictionless mechanics. Consequently, the time taken for anterior segment retraction has been under constant assessment by various researchers. Moreover, achievement of superior aesthetics, determined by optimum tip, torque and vertical position, must be accomplished. Nevertheless, side effects like anchorage loss, root resorption and pain must be evaluated and minimized. Previous studies and/or reviews that were conducted in relation to this study are discussed under the following titles:

1) **Frictionless mechanics for anterior segment retraction.**
2) **Friction mechanics for anterior segment retraction.**
3) **Comparison of the rate of retraction in Friction vs. Frictionless mechanics.**
4) **Anchorage Requirements and Efficiency of Mini-screws**
5) **Pain and Satisfaction associated with Orthodontic Therapy.**
6) **3D model scanning and its reliability.**

1) Frictionless mechanics for Anterior Segment Retraction.

Kuhlberg and Burstone, (1997)[8] assessed the outcome of off-center positioning on the force system produced by segmented 0.017 x 0.025-inch TMA T-loops. The spring was placed in seven positions, centered, 1mm, 2mm and 3mm toward the anterior attachment, and 1mm, 2mm and 3mm toward the posterior attachments. The horizontal and vertical forces were measured as well as the alpha and beta moments were measured over 6mm of spring activation. The results portrayed that alpha/beta moment ratio was dependent only on the spring position and independent of spring activation. Eccentric positioning of the T-loop springs effectively produces a consistent moment differential through the range of spring activation.

Chen at al, (2000)[9] evaluated the moments and forces generated by various orthodontic T-loop spring designs. The impact of dimensional changes (within clinically used ranges) and the addition of gable bends with the heat treatment were measured. Increasing the vertical or horizontal dimension reduced the spring's load deflection rate and its moment/force ratio.

Thiesen et al, (2005)[10] performed a study to necessitate the incorporation of helices in the design of the T-loops. Evaluating the mechanical characteristics of the beta-titanium T-loops with and without helices, with 0- and 180-degree gable bends, constructed from 0.017x0.025″ and 0.019x0.025″ wire using forty beta-titanium T-loops that were centrally positioned in a universal testing machine. The horizontal force and the moment/force ratios during activation were recorded at 1mm intervals, up to 7mm maximum. The study demonstrated that the transverse section of the wire had the greatest effect on the horizontal force produced by the loops. It was found that loops made with the smaller 0.017x0.025 wire produced significantly lower levels of horizontal force. Lower moment/force ratios were obtained with loops with gable bends. As a rule of thumb, T- loops with helices produced lower magnitudes of horizontal force and moment/force ratios than plain T-loops but the plain T-loops with 180-degree gable bends yielded more adequate force systems.

Keng et al, (2011)[11] conducted a randomized controlled trial on Twelve patients (six males and six females) aged between 13 and 20 years who had upper premolar extractions were included, and each acted as their own control, with a NiTi T-loop allocated to one quadrant and TMA to the other using a split mouth block randomization design. The loops were activated 3 mm at each visit to deliver a load of approximately 150g to the upper canine teeth. They found that the mean rate of canine retraction using preactivated NiTi and TMA T-loops was 0.91 mm/month (±0.46) and 0.87 mm/month (±0.34), respectively. The canine tipping rates were 0.71 degrees/month (±2.34) for NiTi and 1.15 degrees/month (±2.86) for TMA. Both the rate of space closure and the tipping were not significantly different between the two wire types. In conclusion they found that there was no difference in the rate of space closure or tooth angulation between preactivated TMA or NiTi T-loops when used to retract upper canines.

Almeida et al, (2016) [12] compared between thirty compound T-loop springs that 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. Conclusively, the larger wires tested produced higher forces with slight increase on the moments, but the Moment to Force Ratio (M/F) produced by the 0.016” × 0.022” wire was the highest found.

2) Friction mechanics for anterior segment retraction.

Bokas and Woods, (2006) [13] compared the rates of maxillary canine retraction and molar anchorage loss when using either NiTi springs or elastomeric chains delivering a known force with sliding edgewise mechanics. Twelve patients who required maxillary canine retraction into first premolar extraction sites as part of their orthodontic treatment were selected. In a split-mouth design, these patients received pre-calibrated NiTi springs (112 quadrants) and pre-measured elastomeric chains (12 quadrants), all delivering disinitial forces of approximately 200 g and being reactivated at 28 day intervals. The results found indicated that the rates of space closure and molar anchorage loss using either NiTi springs or elastomeric chains, if reactivated every 28 days, are likely to be similar.

Halimi et al, (2012) [14] they searched an electronic database for the records taken between 1970 and 2011 and a few manual reviews for relevant publications. They conveyed that rapid force decay of elastomeric chains occurred after some time and therefore affects its clinical and mechanical properties.

Furthermore, ***Barlow and Kula, (2008)***[15], also conducted a systematic review to evaluate the strength of literature on the various factors that affect the efficiency i.e. the rate of tooth movements using sliding mechanics for extraction space closure. They deduced that arch wire properties, type, size, diameter as well as bracket design, material and force delivery systems affected the amount of friction generated and hence, affected tooth movement. But it was found that the arch wire size, controlled tipping better but had no effect on the rate of closure. On the other hand, they concluded that elastomeric chains produced similar retraction rate when compared to 150g and 200g nickel-titanium springs.

This was further backed by ***Chaudhari and Tarvade, (2015)*** [16], as they compared nickel titanium closed coil springs and elastomeric chains in terms of rate of en-masse retraction and anchorage loss. Clinically and radiographically, they found that elastomeric chains produced faster rate of retraction but higher anchorage loss.

3) Comparison of the rate of retraction in Friction vs. Frictionless mechanics.

In his article, ***Burstone, 1962***[17] introduced the segmented arch technique also called the frictionless approach for closure of extraction spaces. He claimed that the frictionless technique possessed superior mechanics and greater tooth control in contrast to sliding mechanics also called friction mechanics. He based this on the concept of delivering constant light forces that would provide more desirable tooth movements. Moreover, he added that the frictionless technique provided the operator with the ability to add a heavy cross-sectional wire for control of the anchor units and low deflection wire for force delivery on the active units.

Ziegler and Ingervall, (1989)[18] performed a clinical study of maxillary canine retraction with a retraction spring and with sliding mechanics. 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. The rate of canine retraction and degree of tipping, and rotation of the canines were studied in 21 subjects by one of these two methods on either side of the dental arch. Measurements were made in the mouth and on photographs of dental casts. It was found that the 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.

Dinçer et al, (2000) [19] conducted this study aiming to evaluate the effect on the dentoalveolar structures of the application of Poul Gjessing (PG) springs (Frictionless mechanics) for retraction of upper incisors and to compare the outcome with the effect of a closed coil spring (Friction mechanics) retraction system. Thirty-six subjects with Angle Class I or Class II malocclusions were selected for the study, the PG group with 17 subjects and the closed coil group with 19 patients. In the frictionless group the rate of retraction was higher by 1.07mm/ 3 weeks than the friction mechanics. In both groups the incisor retraction was accompanied by mesial movement of the buccal segments. Distal movement of the root apex of the incisors was observed in both groups, although more pronounced in the PG group ($P < 0.01$). A significant incisor intrusion resulting in a decrease in overbite was found in the PG group, whereas the deep bite increased significantly in the coil spring group. The PG spring produced a three-dimensional control in the movement of the upper incisors, so that application of additional intrusive mechanics after completion of the incisor retraction became unnecessary.

Ren et al (2003) [20] carried out a systematic review to find the optimum force magnitude for orthodontic tooth movement. Search was carried out on Medline and manually from the main orthodontic and dental journals, 400 articles were found. Mainly, animal studies were found evaluating different force magnitudes on different kinds of animals. Although, the relation between force magnitude and rate of tooth movements was not evaluated. Hence, this study found that there is a void in literature regarding the relation of optimum force magnitudes and the rate of tooth movement.

Makhlouf et al, (2018) [21], compared canine retraction techniques by NiTi closed coil spring delivering friction mechanics and T-loop delivering frictionless mechanics using a Cone Beam Computed Tomography (CBCT). They evaluated the amount of tooth movement as well as root resorption on ten patients in a split mouth study design. The right maxillary canines were retracted using T-loops made on 0.017 x 0.025 TMA wires and the left maxillary canine using NiTi coil springs with a retraction force of 150g. The NiTi coil spring side showed a higher distal movement than the T-loop side, however, both methods did not cause root resorption with controlled retraction force.

4) Anchorage Requirements and Efficiency of Miniscrews.

Upadhyay et al, (2008)[22], conducted a study to determine the efficiency of mini-implants as intraoral anchorage units for en-masse retraction compared with conventional methods of anchorage reinforcement. It was found that mini-implants were efficient for intraoral anchorage reinforcement for en-masse retraction and intrusion of maxillary anterior teeth. No anchorage loss was seen in either the horizontal or the vertical direction in the miniscrew group when compared with the conventional method.

Moreover, skeletal anchorage by mini-implants produced greater anterior tooth retraction (8.17mm vs 6.73 mm) and less maxillary molar mesialization (0.88mm vs 2.07 mm), with a shorter treatment duration (29.81 vs 32.29 months) compared to extraoral headgear anchorage in patients with maxillary dentoalveolar protrusion as reported by ***Yao et al, (2008)***[23].

Chaimanee et al, (2011),[24] investigated the safe zones for mini-screw implant placement. Periapical radiographs of 60 subjects with skeletal Class I, II or III patterns were examined. For each interradicular site, the areas and distances at 3, 5, 7, 9 and 11 mm for the alveolar crest were measured. The study's conclusion was that for all skeletal patterns, the safest zones were the spaces between the second premolars and between the first and second molars in the mandible.

Pithon et al, (2012) [25] investigated whether orthodontic mini implants provide absolute anchorage during the retraction of maxillary anterior teeth after the pre-molar extractions via a systematic review. 550 articles were initially listed, four were found to be potentially eligible, ending with three being selected after applying the inclusion and exclusion criteria. Two of these articles showed absolute anchorage provided by mini-implants and the other demonstrated slight loss of anchorage. There was strong scientific evidence that orthodontic mini-implants provide absolute anchorage during the retraction of maxillary teeth.

Sandler et al, (2014)[26] performed a 3- arm parallel randomized clinical trial to compare the effectiveness of temporary anchorage devices (TADs), Nance button palatal arches, and headgear for anchorage supplementation in cases requiring maximum anchorage. The study comprised of 78 patients with mean age of 14.2 years requiring maximum anchorage and fulfilling all inclusion criteria. Mesial molar movement, duration of anchorage reinforcement, number of treatment visits, number of casual and failed appointments, total treatment time, dento-occlusal change and patients' perceptions of the method of anchorage support was detected. There were more problems with the headgear and Nance buttons than with the TADs. The quality of treatment was better with TADs. As a result, TADs might be the preferred method for reinforcing orthodontic anchorage in patients who need maximum anchorage.

Wahabuddin et al (2015)[27] studied the clinical efficiency of mini-screws in anchorage reinforcement during en-masse retraction of anterior teeth. They concluded that mini-screws were able to resist traction forces up to 200-250g. They also recommended that mini-screws stability required precise surgical technique as well as proper patient cooperation and oral hygiene measures.

Antoszewska-Smith et al (2017)[28] by conducting a systematic review and meta-analysis they compared the efficacy of mini-screws and conventional methods for anchorage reinforcement. They found that the use of mini-screws was more superior in anchorage preservation and, to some extent, enables the reduction of treatment time.

Moreover, ***Chopra et al (2017)***[29] also evaluated amount of anchorage loss between mini-implants and conventional anchorage methods (Nance button and lingual arch). They conducted the study on 50 patients with bimaxillary dentoalveolar protrusion who require four first premolar extractions. They found that anchorage loss was significantly lower using mini-screws (0.2mm in maxillar arch and 0.20mm in the mandibular arch). While, when using conventional methods anchorage loss was (2.0mm in the maxillary arch and 2.1mm in the mandibular arch). They concluded that mini-screws along with proper patient and mini-screw selection, were a viable and better alternative to conventional anchorage reinforcement methods.

Becker et al (2018)[30] conducted a systematic review to find the efficacy of orthodontic mini-implants for en-masse retraction in the maxilla. They reported that mini-implants were associated with significantly lower anchorage loss in the first upper molars compared to conventional anchorage methods for en-masse retraction.

5) Pain associated with Orthodontic Therapy.

Rosier et al, (2002)[31] studied the difference between the Visual Analog Scale (VAS) and the Verbal Descriptor Scale (VDS) in context of the reproducibility of pain measurement and pain perception. Each patient was asked to recall the worst physical pain of their life and rate its intensity and unpleasantness at the beginning of each session. The rating of pain intensity reported via the VAS had significantly smaller session-to-session variation than the VDS. While measuring perceived pain intensity and pain unpleasantness, VAS was significantly more sensitive to small differences and did not portray some of the ordering effects that were present with the VDS.

***Caraceni et al,* (2002)**[32] evaluated pain measurement tools (PMTs) in palliative care research performed in a multi- lingual multicentre setting. They concluded that Visual analogue scales, numerical rating scales, and verbal rating scales are considered valid to evaluate pain intensity in clinical trials and in other types of studies. The McGill Pain Questionnaire and Brief Pain Inventory are valid in many multilingual versions.

Luppanapornlarp et al, (2010)[33] compared different magnitudes of continuous orthodontic force in order to determine the optimum orthodontic force. They measured Interleukin IL-1b levels in human gingival crevicular fluid (GCF), pain intensity, and the amount of tooth movement. This was carried out in the duration of canine retraction in 16 patients with Class I bimaxillary protrusion. Retraction of maxillary canines was performed using nickel–titanium coil springs on segmented arch-wires with continuous forces of 50g in one group and 150 g in the other group, while the lower canines were used as a control. It was found that IL-1b concentration in the 150 g group displayed the highest level at 24 hours and 2 months with significant differences compared with the control group. At 24 hours, the mean VAS score of pain intensity from the 150 g force was significantly greater than from the 50 g force.

Campos et al, (2013) [34] conducted a study on twenty males to evaluate the relationship between the patient's motivation and the level of informed pain in the two stages of treatment. The questionnaire was divided into five categories including motivation towards treatment. Pain intensity was evaluated daily for fourteen days using a visual analog scale (VAS). The VAS was considered to have good reliability in recording motivation and pain intensity experienced by the patient.

6)3D model scanning and its reliability.

Santoro et al (2003)[35] compared the reliability of measurements carried out on digital models and plaster models. Two independent examiners measured tooth size, overbite and overjet on both models belong to randomly selected pretreatment records of 76 patients. They concluded that, there was a significant difference in measurements tooth size and overbite readings with the measurements on digital casts being smaller. On the other hand, there was no difference in the overjet measurements.

Asquith et al (2007)[36] evaluated the accuracy and reproducibility of measurements made on digital models. They scanned ten study models using Arius3D Foundation System to produce 3D images. To measure reliability and reproducibility, two examiners measured eleven parameters, twice, on both digital models and study models. They concluded that digital models were a reliable mode of measurement and there was no longer a need to produce study models.

Leifert et al, (2009)[37] compared space analysis using digital models and plaster models. 25 impressions were made into plaster models and another 25 impressions were made into 3D digital models using OrthoCAD software. Two examiners measured tooth width and arch lengths on models of patients with Class I crowded permanent dentition. They concluded that the accuracy of the software for space analysis evaluation is clinically acceptable and reproducible when compared to manual measurements on plaster models.

Thiruvenkatachari et al, 2009[38] measured 3D tooth movement with a 3D surface laser scanner aiming to develop a method of measuring 3-dimensional (3D) tooth movement using a 3D surface laser scanner. This study also tested the accuracy of this method, and to compare the measurements with those from cephalometric radiographs. They superimposed pre-treatment and posttreatment models on the palatal rugae then the accuracy and reliability of the laser scanner were evaluated on the experimental model. The results showed the laser scanner was accurate to 0.0235 mm for anteroposterior measurements and 0.0071 mm for buccolingual movements for every 0.5 mm of movement. They concluded that accurate and reliable measurements of tooth displacement were achieved via the 3D laser scanner and it can be considered an alternative to cephalometric radiographs.

Kau et al, (2010) [39] endeavored to determine if measurements obtained from digital models from cone beam computed tomography (CBCT) images were comparable to the traditional method of digital study models by impressions. Digital models of 30 subjects were used. InVivoDental (Anatomage, San Jose, Calif) software was used to analyze CBCT scans taken by a Galileos cone beam scanner (Sirona, Charlotte, NC) and OrthoCAD (Cadent, Fairview, NJ) software was used to analyze impression scans of patients at different stages of orthodontic treatment. Impressions were taken using alginate and were mailed to OrthoCAD for digital conversion. The scans were then electronically returned in digital format for analysis. Finally, they deduced that CBCT digital models were as accurate as OrthoCAD digital models in making linear measurements for overjet, overbite, and crowding measurements.

Sousa et al, (2012)[40] assessed the reliability of measurements made on 3D digital models that were scanned using a laser scanner (D-250, 3Shape). Using Geomagic Study 5 software, twenty digital models were analyzed. Eleven linear measurements were done including measurements of arch length and width. Measurements were carried out manually on plaster models as well as using the software on digital models. They found that there was so statistical difference between measurements made on digital models and plaster models. Hence, digital models were, both reproducible and reliable, modes of linear measurements.

Kim and Lagravére, (2016) [41] aimed to compare the accuracy of Bolton analysis obtained from digital models scanned with the Ortho Insight three-dimensional (3D) laser scanner system to those obtained from cone-beam computed tomography (CBCT) images and traditional plaster models. CBCT scans and plaster models were obtained from 50 patients. Plaster models were scanned using the Ortho Insight 3D laser scanner; Bolton ratios were calculated with its software. CBCT scans were imported and analyzed using AVIZO software. Plaster models were measured with a digital caliper.

Data were analyzed with descriptive statistics and the intraclass correlation coefficient (ICC). They finally found that laser scanned digital models are highly accurate compared to physical models and CBCT scans for assessing the spatial relationships of dental arches for orthodontic diagnosis.

Rossini et al, (2016)[42] conducted a systematic review to evaluate the accuracy and sensitivity of measurements carried out on digital models compared to plaster models. Thirty-five relevant articles were selected from the years between January 2000 to November 2014 by using a grading system developed by the Swedish Council on Technology Assessment in Health Care and the Cochrane tool for risk of bias assessment to rate the methodologic quality. They found that there was no significant difference in all measured parameters, in majority of studies. Therefore, they concluded that digital models possessed high levels of accuracy, reliability and reproducibility when compared with conventional study models.

Furthermore, ***Abdi et al, (2017)***[43] carried out a study in order to evaluate the validity of maxillary models by the weighted rugae superimposition method. They randomly selected 24 maxillary plaster models of 12-year-old patients as well as their models at 14 years old. They scanned the models two times using a bench top structured light 3D scanner. Once using the weighted rugae and the other using the unweighted rugae superimposition methods. They concluded that the un-weighted superimposition made no significant differences in terms of total displacements of registration landmarks, while the weighted method recognized the medial points of the 3rd rugae as the most stable landmark. Hence, the weighted rugae superimposition method was found to be a stable method for analysis of tooth movements.

Most recently, ***Pazera and Gkantidis, (2020)***[44] carried out a retrospective study using twenty- four pre- and post- treatment cephalometric radiographs as well as their 3D digital models. They aimed to investigate the anteroposterior and vertical changes of the median rugae which is often used as a reference for superimposition of dental models in reference to the underlying skeletal structures. The incisive papilla and the three rugae points were placed on dental models and then registered on the cephalometric radiographs. The vertical and horizontal movements of the papilla and the rugae points, as well as a central incisor were measured (Viewbox 4 Software). They concluded that, both the second and the third rugae can be used as references for superimposition for assessment of tooth movement. While the use of the incisive papilla and first rugae was not recommended as they were affected by tooth movement.

Aim of the Study

The aim of the current study was to assess the rate of anterior segment retraction using friction or frictionless mechanics. As well as evaluate the tip, torque, vertical position, and root resorption of the incisors. Moreover, anchorage loss and pain experienced was assessed.

A-PICO Question:

Patient/Population:

Female orthodontic patients with bimaxillary protrusion requiring first premolars extractions followed by anterior segment retraction.

Intervention:

Anterior segment retraction using T- loops (Frictionless mechanics) with mini-screws used as anchorage.

Comparator:

Anterior segment retraction using sliding mechanics (Friction mechanics) with mini-screws used as anchorage.

Outcomes:

- **Primary Outcome:** measuring the rate of anterior segment retraction for space closure when frictionless and friction mechanics were used.

Secondary Outcomes: measuring the changes in incisal position with regards to tip, torque and vertical position following

Outcome measure:

Outcome measure		Measure tool	Measure unit
1ry Outcome	Assess the rate of anterior segment retraction	Digital scanned dental models.	mm
2ry Outcomes	1) Assess amount of anchorage loss.	Digital scanned dental models.	mm
	2) Pain	Pain scoring sheets given to patients.	VAS scoring from 1-10

B-Research question:

In orthodontic adolescent patients in need of 1st premolar extractions followed by anterior segment retraction, is there a difference, in terms of rate of anterior segment retraction, between friction and frictionless mechanics?

Objectives of the study

Research hypothesis:

The null hypothesis of this research is that there is no difference in rate of anterior segment retraction between friction and frictionless mechanics.

Primary objective:

Measuring the rate of anterior segment retraction using frictionless versus friction mechanics.

Secondary objectives:

Assess amount of anchorage loss and pain experienced.

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 friction mechanics during retraction to compare the results for differences in rate.

Materials 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. Adolescent patients (females only).
  2. Patients requiring 1st premolars extraction followed by anterior segment retraction.
  3. Patients with fully erupted permanent teeth (not necessarily including the 3rd molar).
  4. Cases requiring maximum anchorage during anterior segment retraction.

- **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.

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, 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 undergo:

- Bonding of all teeth except for first premolars, banding/bonding the first and second molars will be done using bidimensional brackets Roth prescription (0.022 slot prescription brackets)
- Levelling and alignment for the bonded and banded teeth will be initiated which will be done by 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 arch between 2nd premolar and 1st molar.
- The patient will be referred for extraction of 1st premolars then 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 taking of pre-intervention records.

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

- Impressions will be taken followed by digital scanning for the produced stone models which are the T_0 record.

➢ **<u>Beginning of Retraction:</u>**

Frictionless group:

- A ligature wire extending between the canines and mini-screws 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 in half the remaining extraction space after canine retraction. [15], [16].
- A gable angle of 45° will be added.
- Distal activation of 4 mm will be done that will produce around 160 g per side of retraction force[17], with cinch back the wire distal to 2nd molars bilaterally.

Friction group:

- Crimpable hooks added to the arch wire (0.017”x0.025” Stainless steel) distal to the lateral incisor passing through the center of resistance of the anterior segment.
- A ligature wire extending between the canines and mini-screws will be used for proper anchorage control.

- Retraction will start on a 0.017”x0.025” Stainless steel wire with an elastomeric power chain (force applied will be 160 g) extending between the crimpable hooks and the mini-screws.
- The force will be measured by a force gauge and reactivated each visit to maintain force of retraction constant all over the retraction phase.

➢ **<u>Follow up visits</u>**

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

- Evaluation of the mini implants stability.
- Replacement of the power chain to maintain a force of 160g.
- Reactivation of the T-loop by further distal activation and cinch back.

➢ **<u>Criteria for discontinuing or modifying the allocated intervention:</u>**

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.

➢ **<u>Post-retraction Questionnaire:</u>**

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

- **Retraction records**

The scanned dental models will assess the rate of retraction and molar anchorage loss achieved throughout the study.

- **Material Used**
    - American Orthodontics Brackets, Roth prescription, Bidimensional slot size.
    - American Orthodontics Elastomeric power chains
    - American Orthodontics Elastomeric O-ties
    - American Orthodontics Ligature wire.
    - Jeil, Mini Screws, 8 mm length.
    - American Orthodontics Arch wires.
    - American Orthodontics Molar bands/tubes.

D] Outcomes

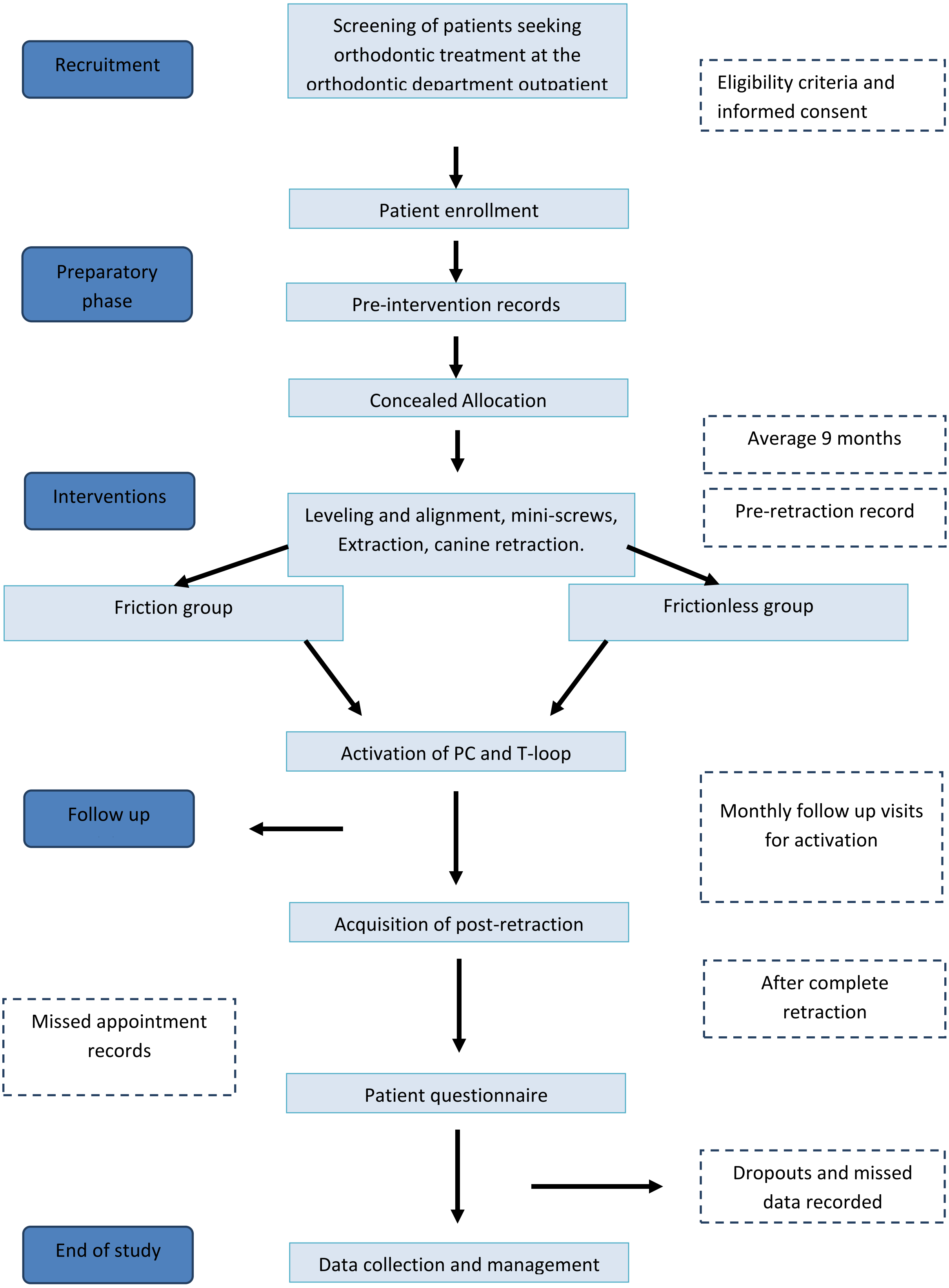
Primary outcome: is to monitor the rate of anterior segment retraction using both frictionless and friction methods.

Secondary outcomes is to monitor anchorage loss and pain, in association with each technique after retraction during anterior segment retraction,. All outcomes will be assessed as the difference between T_0 at the start of anterior segment retraction after full canine retraction and T_{final} 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, 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 supervisor will randomly allocate the patients to one of the intervention groups.
6. Active intervention will begin 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. (T_0)
8. In Friction mechanics group, Power chain is used for anterior segment retraction while in Frictionless group, T-loop is used for retraction.
9. Each patient will come every 4weeks for follow up visit, for appliance activation and uptake of impression for interim records.
10. After complete space closure, the principle investigator will take post-retraction records for each participant. (T_{final})
11. Every patient will fill up a questionnaire regarding his experience during treatment.
12. The principle investigator will continue the normal treatment and achieve proper finishing for every patient after the end of the study.



CONSORT flow chart of the flow of participants in the study.

E] Sample size calculation:

Our sample size calculation is based on a previous study comparing the effect of friction and frictionless mechanics. [14]

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, dental impressions and acquisition of dental casts.

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

III) Data collection, management and analysis:

A] Data collection methods:

Primary 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 will digitize the models and identify the landmarks, reference lines and planes on the pre, interim and post-retraction digital dental models for measurements reading.

Secondary outcomes:

1. Anchorage loss: will be accessed by the principal investigator via scanned study models 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 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 Kolmogorov Smirnov and Shapiro Wilk tests 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 Inter-observer and intra-observer reliability was 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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