Comprehensive Comparison of Canine Retraction using Nickel-titanium Closed-coil Springs Versus Elastomeric Power Chains during Orthodontic Treatment – A Split-mouth Randomized Controlled

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INTRODUCTION:

Extraction versus non-extraction treatment has always been a debate in orthodontics but with the passage of time extraction treatment due to its greater stability has gained popularity.[1,2] In patients with severe crowding and/or proclination of teeth, extraction of first premolars followed by retraction of canines has been a common and preferred practice.[3] Canine retraction is a time-consuming procedure and acceleration of this process will shorten the treatment time and also help in avoiding the related adverse effects.[4,5]

The most common techniques used for canine retraction are sliding and loop mechanics which have been discussed frequently in literature.[6] Both techniques possess their merits, encompassing advantages, such as minimal friction and precise manipulation of space closure using loops.[7] Whereas, while using sliding mechanics, one can have the benefits of reduced wire bending time, control of arch form and root alignment.[7] However, both of these methods have their limitations. With loop mechanics, the additional chair side time, skills, soft tissue irritation, root resorption, bacterial build up and uncontrolled tipping present a challenge.[8,9] Friction and binding of wire to the bracket slot results in slow tooth movement and anchorage loss with sliding mechanics.[9]

Despite its limitations, sliding mechanics is a common technique used for canine retraction.[10] The two widely used methods for sliding teeth include elastomeric power chains and Nickel-titanium (Ni-Ti) closed-coil springs.[11] Elastomeric power chains are extensively used in orthodontics because of their ease of use, effectiveness and patient comfort by allowing periods of regeneration.[12] Elastomeric power chains exert heavy intermittent forces when they return to their original length after being stretched, with decay of forces as they revert, requiring a greater number of appliance activation.[13]

On the other hand, Ni-Ti closed-coil springs apply light continuous forces and deliver a constant force over a period that lead to more efficient tooth movement and steadier space closure[14], with reduced number of appliance activation.[15] An in vitro study by Barsoum et al.[16] reported a reduction in force with Ni-Ti closed-coil springs after 18 hours and remained constant for about

21 days. Badran et al.[17] also found that Ni-Ti closed-coil springs were less tolerated than elastomeric power chains by patients but produced an average of 0.5 mm more tooth movement than the elastomeric power chain during the 12-week study period. Therefore, consideration of canine retraction with Ni-Ti closed-coil springs and elastomeric power chains is critical for enhancing the overall effectiveness of orthodontic treatment and to achieve desired treatment outcomes.

RATIONALE:

Premolar extraction followed by canine retraction is one of the common practices in orthodontics to treat malocclusion such as severe crowding and proclination of anterior teeth.[18] It is essential to know methods and techniques that result in minimum or no adverse effects on roots of teeth and periodontal health. This will help the clinicians to choose the best method that will result in a faster and more physiological closure of extraction spaces. Moreover, to the best of our knowledge, limited studies have compared the effects of Ni-Ti closed-coil springs and elastomeric power chains on canine root resorption, gingival health and plaque accumulation.[8,17,22] It is necessary to establish a comparison between these methods, as it can help clinicians to provide better care and enhance the overall effectiveness of orthodontic treatment.

OBJECTIVE:

Primary Objective: The objective of this study is to compare the canine retraction rate (in mm with a 100 mm marked scale) using Ni-Ti closed-coil springs versus elastomeric power chains during canine retraction in subjects with first premolar extractions over a period of three months.
Secondary Objective: This study will also include an assessment of canine root resorption (in mm using periapical radiograph), dental plaque accumulation and gingival health (according to indices mentioned below with CPI-TN probe) using Ni-Ti closed-coil springs versus elastomeric power chains during canine retraction in subjects with first premolar extractions over a period of three months.

HYPOTHESIS:

Null Hypothesis: There is no significant difference between Ni-Ti closed-coil spring and elastomeric power chain on the canine root resorption, retraction rate, dental plaque accumulation and gingival health in subjects with first premolar extractions.

Alternate Hypothesis: There is a significant difference between Ni-Ti closed-coil spring and elastomeric power chain on the canine root resorption, retraction rate, dental plaque accumulation and gingival health in subjects with first premolar extractions.

OPERATIONAL DEFINITIONS:

Ni-Ti Closed-coil Spring:[19] (Annexure A)

Ni-Ti closed-coil spring is a passive compressed spring made up of super elastic Nickel-titanium. Two eyelets are attached to each side of the coil to facilitate its application. The eyelets will be engaged in the hooks of the second premolar and canine brackets and will apply a force of 150 gm.

Elastomeric Power Chain:[20] (Annexure B)

Elastomeric power chains are resilient and latex-free orthodontic materials. They are made up of elastic material and consist of many connected rings. Each ring is engaged in a bracket to apply a force of 175-300 gm.

Plaque Index:[17] (Annexure C)

Plaque index is a grading system used to assess the amount of plaque present at the gingival margins and helps in assessing oral health. It consists of four grades including, Grade 0, 1, 2 and 3. The increase in grade indicates the increased amount of plaque along the gingiva.

Gingival Index:[21] (Annexure D)

Gingival index is a grading system that is used to assess the health of the gingiva. It consists of four grades including, Grade 0, 1, 2 and 3. The increase in grade indicates the compromised gingival health of the teeth.

Root Resorption:[22]

Root resorption is a decrease in root length and width due to an inflammatory process. In orthodontics, during tooth movement, areas of necrosis develop called hyalinized areas, which result in root resorption. Periapical radiographs will be taken to assess the amount of root resorption by determining the length of the tooth from the cusp tip to the root apex.

Retraction Rate:[16]

The retraction rate of canine will be the distance travelled divided by the time interval needed for closure of spaces. It will be noted at four-time intervals i.e at the start of the canine retraction (T_0), after first month (T_1), second month (T_2) and third month follow-up (T_3).

Split-mouth Study:

A randomized controlled trial in which intervention and control are randomly allocated to the different quadrants in the oral cavity. In our study, Ni-Ti closed-coil springs and elastomeric power chains will be randomly allocated to the right and left quadrants of maxillary and mandibular arches.

MATERIAL & METHODS:

Study Design: A single center open labelled parallel split-mouth randomized controlled trial
Settings: Dental clinics, Department of Surgery, The Aga Khan University Hospital, Karachi, Pakistan
Study Duration: One year after ethical review committee (ERC) approval
Sampling Technique: Non-probability consecutive sampling

SAMPLE SIZE:

The sample size was calculated using standard estimate where n = 8(CV2) /(PC2) [1+(1-PC)2] where PC is the proportionate change in means (PC = ($\mu 0 - \mu 1$)/$\mu 0$) and CV is the coefficient of variation (CV = $\sigma 0/\mu 0 = \sigma 1/\mu 1$). The study required a minimum sample size of 33 (N) patients in each group. With an inflation of 40% for an estimated loss to follow up/non-response rate, we will be including 46 (N) participants in this study, to achieve 80% power and to detect at least a 39% change in mean canine retraction rate values of 3.88 ± 2.66 mm and 5.45 ± 1.53 mm, with

elastomeric power chains and Ni-Ti closed-coil springs, respectively[8] and 68% or less change in coefficient of variation at two-sided 5% level of significance.

SAMPLE SELECTION:

Inclusion Criteria:

- Patients aged between 13 - 40 years
- Patients undergoing fixed orthodontic treatment
- Patients requiring all first premolars extraction as part of orthodontic treatment
- Patients with all permanent teeth present and erupted (except for second and third molars)
- All patients who will sign the informed consent/assent form

Exclusion Criteria:

- Patients with systemic diseases that can affect tooth movements
- Patients with uncontrolled periodontal disease
- Patients with craniofacial syndromes
- Pregnant or lactating mothers
- Patients with bracket failures greater than three times per bracket during the study
- Patients on medications that can affect tooth movements
- Patients with Nickel allergy

DATA COLLECTION PROCEDURE:

After obtaining an approval from the Ethical Review Committee and taking informed consent and informed assent from the parents and child respectively, **(Annexure E, F and G)**, these patients will be recruited in the study as participants. Patients visiting the orthodontic clinic at the Aga Khan University Hospital Karachi will be included in this study. Detailed information regarding the study will be provided to the participants and they will be given the choice to either accept or refuse their inclusion in the study. After the extraction of all first premolars under local anesthesia, 0.018" stainless steel archwires will be inserted in the maxillary and mandibular arches. For canine retraction, Ni-Ti closed-coil springs and elastomeric power chains will be randomly allocated to the right and left quadrants of both arches. Radiographic measurement (root resorption) and clinical measurements (canine retraction, plaque accumulation and gingival health) will be

recorded at four points in time. First, at the start of the canine retraction (T_0), after first month (T_1), second month (T_2) and third month follow-up (T_3). Canine retraction rate will be recorded by using a 100 mm marked scale.[16] Data will be collected on an organized study proforma **(Annexure H)**.

Ethical Considerations:

This study will be carried out as per the guidelines of the World Medical Association's Declaration of Helsinki.[23] and the principles of Good Clinical Practice (GCP). Any modifications in the protocol will be re-submitted to the ERC. The study will be conducted in compliance with regulations and a copy of the final study protocol will be submitted to ERC. All the recorded data of patients will remain confidential. Access will be provided to no one except the investigators. Participants' names and identities will remain undisclosed; however, data may be seen by ERC or any local regulatory body. Data will be saved for 7 years as per GCP and institutional guidelines.

Randomization:

Randomization will be used in the study to allot one of the two treatment methods used for canine retraction to each side of the mouth to minimize bias and to account for individual variability. By randomly assigning different retraction methods to each side of the mouth any individual-specific factors that may affect the treatment outcomes (oral hygiene habits, masticatory habits) are likely to be equally distributed across the treatment group. Block randomization will be performed to code the type of retraction method in this trial and to determine the sequence of its administration to each participant. This will be controlled by a research faculty member of the Section of Dentistry at AKUH.

Sequence Generation:

In this two-armed study, four-blocks, each with a block size of six-possible allocation sequences for treatment arms will be generated.

(1) AABB, (2) BBAA, (3) ABAB, (4) BABA, (5) ABBA, (6) BAAB

The blocks to be utilized and their order will be determined by the research faculty member using sealed envelope™ online software.[24]

Allocation Sequence Concealment:

After fulfilling the inclusion criteria and obtaining consent, the patient will be recruited in the study. During the recruitment of the participants in the trial, the sealed envelope for a participant will be opened by the enrolling team member and will be allotted an intervention according to the ascending order sequence already generated by the principal investigator who is also a biostatistician.

Enrollment:

After obtaining approval from the ERC (AKUH), each participant fulfilling the inclusion criteria for the study and consenting to participate in the trial will be assigned a participant ID.

Blinding:

The study investigators, patients recruited, and assessors will not be blinded during the trial. All the measurements will be recorded by the co-investigator on the study proforma **(Annexure H)**.

POSSIBLE RISKS OR BENEFITS:

Nickel is a known allergen, though people with nickel allergy tolerate stainless steel brackets and wires quite satisfactorily.[25] However, in case of any adverse events such as allergic reaction to Ni-Ti closed-coil spring such as contact dermatitis, rash, bumps, redness or irritation of the skin or mucosa, its use will be stopped, and patient will be excluded from the study.

Adverse events will be reported to ERC within a week and any serious adverse event will be reported to the Department of surgery, sponsors, CTU, DRC, and ERC within 24 hours. All emergency side effects will be managed in the emergency department and the Department of Surgery will bear the charges.

STUDY GROUPS:

The patients will be screened using the inclusion and exclusion criteria by the co-investigator. Measurements for the canine root resorption, retraction rate, plaque accumulation and gingival health will be taken at T_0, T_1, T_2 and T_3.

Intervention: Ni-Ti closed-coil springs
Control: Elastomeric power chains

The participants will receive routine instructions for oral hygiene maintenance and care of the appliance verbally.

MATERIAL STORAGE:

Ni-ti closed-coil springs and Elastomeric power chains will be stored at room temperature at the Department of Surgery, Dental inventory.

DATA ANALYSIS:

Data will be entered and analyzed in SPSS for Windows (version 23.0, SPSS Inc. Chicago). Frequencies and proportions will be reported for categorical variables, such as gender. Shapiro-Wilk test will be used to check the normality of the data. Descriptive statistics, such as means and standard deviations for normally distributed or median and interquartile range (IQR) for non-normally distributed data will be reported for all baseline clinical factors. Paired t-test will be used for the pairwise comparison. For the two groups the mean/median scores for retraction rate, root resorption, gingival health and plague accumulation between the two groups will be assessed using Independent t-test for normally distributed data and Man-Whitney U test for non-normally distributed data. A p-value ≤ 0.05 at 95% confidence interval will be considered as statistically significant.

On achieving 50% of the sample size, an interim analysis will be run, if the results show that the given intervention is successful in significantly improving the rate of canine retraction in patients then further trial will be stopped and all the participants will be given the intervention.

FINANCE:

Departmental funds from the Department of Surgery and intramural grants will be applied for.

PUBLISHING POLICY/PLAN:

For publication the data will be utilized, and it could be presented in either national or worldwide forums.

DATA CONFIDENTIALITY:

All the recorded data of patients will remain confidential. Access will be provided to no one except the investigators. Participants' names and identities will remain undisclosed; however, data may be seen by ERC or any local regulatory body. Data will be saved for 7 years as per GCP and institutional guidelines.

REFERENCES:

1. Vaden JL, Williams RA, Goforth RL. Class II correction: extraction or nonextraction?. Am J Orthod Dentofacial Orthop. 2018;154:860-76.
2. Benson PE, Alshawy E, Fenton GD, Frawley T, Misra S, Ng T, et al. Extraction vs nonextraction of premolars for orthodontic treatment: a scoping review examining the extent, range, and characteristics of the literature. Am J Orthod Dentofacial Orthop. 2023;161:1-9.
3. Wazwaz F, Seehra J, Carpenter GH, Papageorgiou SN, Cobourne MT. Duration of canine retraction with fixed appliances: a systematic review and meta-analysis. Am J Orthod Dentofacial Orthop. 2023;163:154-72.
4. Jaber ST, Al-Sabbagh R, Hajeer MY. Evaluation of the efficacy of laser-assisted flapless corticotomy in accelerating canine retraction: a split-mouth randomized controlled clinical trial. Oral Maxillofac Surg. 2022;26:81-9.
5. Kulshrestha RS, Tandon R, Chandra P. Canine retraction: a systematic review of different methods used. J Orthod Sci. 2015;4:1-8.
6. Makhlouf M, Aboul-Ezz A, Fayed MS, Hafez H. Evaluating the amount of tooth movement and root resorption during canine retraction with friction versus frictionless mechanics using cone beam computed tomography. J Med Sci. 2018;6:384-8.
7. Prashant PS, Hemant N, Meera G. Friction in orthodontics. J Pharm Bioallied Sci. 2015;2:334-8.
8. Hashemzadeh H, Soleimani M, Golbar M, Soltani AD, Mirmalek SP. Canine and molar movement, rotation, and tipping by Ni-Ti coils versus elastomeric chains in first maxillary premolar extraction orthodontic adolescents: a randomized split-mouth study. Int Orthod. 2022;20:1-7.
9. Sebastian B, Bhuvaraghan A, Thiruvenkatachari B. Orthodontic space closure in sliding mechanics: a systematic review and meta-analysis. Eur J Orthod. 2022;44:210-25.
10. Taha K, Conley RS, Arany P, Warunek S, Al-Jewair T. Effects of mechanical vibrations on maxillary canine retraction and perceived pain: a pilot, single-center, randomized-controlled clinical trial. Odontology. 2020;108:321-30.

11. Mohammed H, Rizk MZ, Wafaie K, Almuzian M. Effectiveness of Nickel-titanium springs vs elastomeric chains in orthodontic space closure: a systematic review and meta-analysis. Orthod Craniofac Res. 2018;21:12-9.
12. Halimi A, Benyahia H, Doukkali A, Azeroual MF, Zaoui F. A systematic review of force decay in orthodontic elastomeric power chains. Int Orthod. 2012;10:223-40.
13. Menon VV, Madhavan S, Chacko T, Gopalakrishnan S, Jacob J, Parayancode A. Comparative assessment of force decay of the elastomeric chain with the use of various mouth rinses in simulated oral environment: an in vitro study. J Pharm Bioallied Sci. 2019;11:269-73.
14. Cox C, Nguyen T, Koroluk L, Ko CC. In-vivo force decay of Nickel-titanium closed-coil springs. Am J Orthod Dentofacial Orthop. 2014;145:505-13.
15. Albelasy NF, Abdelnaby YL. Impact of retraction force magnitudes on mobility of maxillary canines: a split-mouth design. Prog Orthod. 2022;23:1-6.
16. Barsoum HA, ElSayed HS, El Sharaby FA, Palomo JM, Mostafa YA. Comprehensive comparison of canine retraction using Ni-Ti closed-coil springs vs elastomeric chains. Angle Orthod. 2021;91:441-8.
17. Badran SA, Al-Zaben JM, Al-Taie LM, Tbeishi H, Al-Omiri MK. Comparing patient-centered outcomes and efficiency of space closure between Nickel-titanium closed-coil springs and elastomeric power chains during orthodontic treatment. Angle Orthod. 2022;92:471-7.
18. Andhare P, Datana S, Agarwal SS, Chopra SS. Comparison of in vivo and in vitro force decay of elastomeric chains/modules: a systematic review and meta analysis. J World Fed Orthod. 2021;10:155-62.
19. Carvalho DF, Vieira VT, Castro R, Oliveira LB. An in vitro comparison of the forces released by closed Nickel-titanium springs. J Contemp Dent Pract. 2019;20:1380-3.
20. Tawfik MG, Izzat Bakhit DM, El Sharaby FA, Moustafa YA, Dehis HM. Evaluation of the rate of anterior segment retraction in orthodontic patients with bimaxillary protrusion using friction vs frictionless mechanics: a single-center, single-blind randomized clinical trial. Angle Orthod. 2022;92:738-45.

21. Zanatta FB, Ardenghi TM, Antoniazzi RP, Pinto TM, Rösing CK. Association between gingival bleeding and gingival enlargement and oral health-related quality of life (OHRQoL) of subjects under fixed orthodontic treatment: a cross-sectional study. BMC Oral Health. 2012;12:1-10.

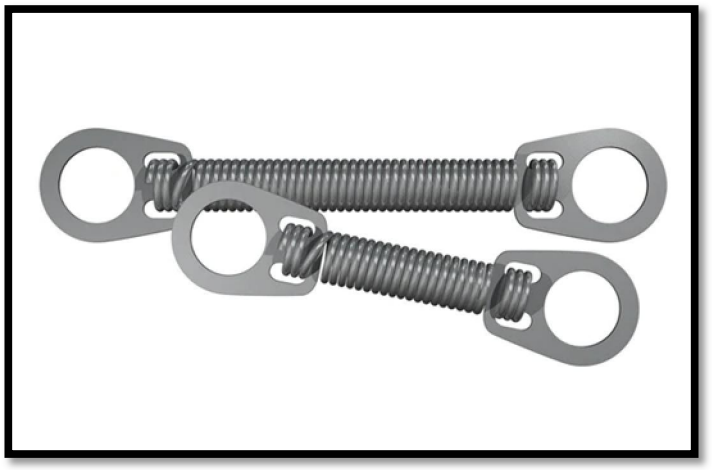
22. Jiang F, Chen J, Kula K, Gu H, Du Y, Eckert G. Root resorptions associated with canine retraction treatment. Am J Orthod Dentofacial Orthop. 2017;152:348-54.

23. Malik AY, Foster C. The revised Declaration of Helsinki: cosmetic or real change? J R Soc Med. 2016;109:184-9.

24. Pocock SJ. Clinical trials: a practical approach. John Wiley & Sons; 2013 Jul 17.

25. Zigante M, Rincic Mlinaric M, Kastelan M, Perkovic V, Trinajstic Zrinski M, Spalj S. Symptoms of Titanium and Nickel allergic sensitization in orthodontic treatment. Prog Orthod. 2020;21:1-7.

Annexure A: Ni-Ti Closed-coil Spring[19]



Annexure B: Elastomeric Power Chain[20]

Annexure C: Plaque Index[17]

0	No plaque
1	Thin plaque layer at the gingival margin, only detectable by scraping with a probe
2	Moderate layer of plaque along the gingival margin; inter-dental spaces. Plaque is visible to the naked eye
3	Abundant plaque along the gingival margin; interdental spaces filled with plaque

Annexure D: Gingival Index[21]

0	Normal gingiva; no inflammation; no discoloration (erythema); no bleeding
1	Mild inflammation; slight erythema; minimal superficial alterations; no bleeding
2	Moderate inflammation; erythema; bleeding on probing
3	Severe inflammation; severe erythema and swelling; tendency to spontaneous bleeding; possible ulceration