Cover paper

Research title: (The effect of two and four activations daily of the periodontal distractor on pain intensity and pulp vitality of maxillary canine: Randomized Clinical Trial)

Study Start: February 1, 2021 [Actual]

Primary Completion: August 1, 2022 [Actual]

Study Completion: October 15, 2022 [Actual]

Objectives:

Since the periodontal distractor may cause some degree of suffering for the patients and may affect pulp vitality, Therefore the aim of the present study was to evaluate the effect of twice and four activations day of periodontal distractor on pain intensity and pulp vitality of maxillary canine.

Methodology:

PICO:

- Problem: orthodontic patients that have
  (1)Class I malocclusion severe crowding or bi maxillary protrusion
  (2)Class II div 1 malocclusion.
- Intervention: performing bilateral maxillary 1st premolar extraction, inter septal bone cuts then placing periodontal distractor and activate it till complete canine retraction.
- Comparison: two versus four activation per day.
- Outcomes:
  Pain intensity.
  Pulp vitality.

Study design

The study was randomized control study. It was conducted in a sample of 32 canines on 16 female patients attending the Faculty of Dental Medicine for Girls, Al Azhar University, seeking for orthodontic treatment. Their age was ranged from 16 to 22 years. This prospective study was approved by Research Ethic Committee (REC), Faculty of Dental Medicine for Girls, Al Azhar University with this code (REC-OR-21-01) Fig. (8) Showing CONSROT 2010 flow diagram of this study.

All study participants have signed on written informed consent prior to enrollment. The steps of the study, the aim, the potential benefits, and hazards, all were discussed with the patients.

Sample size calculation:

To Compare the effects of two different orthodontic treatment modalities on pain; independent t test was used for comparison between groups. According to a previous study by Raza et al (2021), Mean VAS scores were 16 ± 3.94 (24 hours) at control side, in comparison to 46.50 ± 6.69 (24 hours) A minimum total sample size of 6 samples on each group are sufficient to detect the effect, by increasing 2 patients on each group to overcome dropping out of patients, the number were 8 on each group and 16 on both groups (fig 1).

Patient Records

Inclusion criteria were: 1-Orthodontic Patients need extraction of first permanent premolar for orthodontic reasons (dentoalveolar maxillary protrusion, Class II div 1 malocclusion), 2-No history of previous orthodontic treatment, 3-Absence of any systemic disease, 4- Good oral hygiene and healthy gums look, with no signs of redness, edema, or bleeding during brushing (periodontal inflammation), 5- Highly motivation and cooperation

Exclusion criteria were: 1- Medically compromised patients, -2-Use of medication that may affect tooth movement during the period of the study.

After patient selection, routine records of all the patients such as a detailed case history, pretreatment study model, extraoral and intraoral photographs, panorama and lateral cephalometric radiographs were acquired. Pain intensity and discomfort was evaluated at different times by Visual Analogue scale (1st 48 hour after intervention, during each activation of the distractor, and on the Interval between activation) as research related records. Electric pulp testing of canine was done before and after retraction to evaluate pulp vitality.

All the patients in the study required bilateral first premolar extraction. They were divided into two groups (Group I): Canine retraction was done by periodontal distractor with twice activations per day. (Group II): Canine retraction was done by periodontal distractor with four activations per day.

Randomization Allocation concealment:

Randomization was accomplished using online research randomizer. Numbers were from 1 to 16 and each group contained 8 numbers. Set 1 of numbers was assigned to periodontal distractor with two activations per day. Set 2 of numbers was assigned to periodontal distractor with four activations per day. The randomized numbers for the participant were written in opaque white papers which were folded, codes for randomization were kept with another investigator. Allocation of each patient to either group was done by picking up by a colleague with allocation ratio 1:1.

Study phases: This study included four phases:
Phase I: Posterior segment leveling and alignment:

For patients of both groups the orthodontic treatment was started with direct bonding of Roth brackets (Dynaflex,USA) to the maxillary canine, second premolars first molar only. Sectional nickel titanium (NiTi) arch wires were used starting from

0.014" up to stainless steel arch wire 0.016"×0.022". This was undertaken to align the posterior segment before premolar extraction to allow proper placement of distractor without canting. Fig. (1).

Figure (1) After leveling and alignment of posterior segment with sectional wire.

Phase II : Extraction and inter septal bone corticotomy phase.

Patients were referred to the clinic of Oral and Maxillofacial Department, Faculty of Dental Medicine for Girls, Al Azhar University to extract first maxillary premolars with written referral note. The post extraction instructions were firm and clear not to use NSAIDs drugs for analgesia, paracetamol drugs were prescribed[1].

The second step consisted of performing corticotomies (grooves) in the interseptal bone distal to the canine with bur. Initially, two vertical grooves were done inside the extraction socket, along the buccal and lingual sides then, another groove that was extended obliquely toward the base of the interseptal bone to weaken its resistance Fig. (2). The depth of the undermining grooves was dependent on the thickness of the interseptal bone, as revealed on the Periapical films that was done immediately after extraction . Corticotomy was done by surgical bur on straight hand piece (Apple dental, china) using normal saline for irrigation to prevent adverse thermal changes in the periodontium.

Fig. (2) Inter septal bone Coricotomy with surgical bur on straight hand piece

Phase III: Periodontal distractor construction and placement:

A Hyrax screw(Dentauram, Germany) was modified to form a distractor. Bands on molar and canine were placed with a lingual button welded for the attachment of the elastomeric chain, to counteract any rotation force that was encountered by the canine during the distraction process.

The screw was opened slightly more than the width of premolar to be extracted and extended arms were bent to desirable shape to be soldered on molar and canine bands. The distractor was placed and cemented by glass ionmer cement Fig. (3).

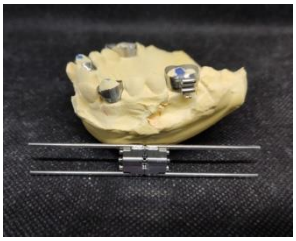
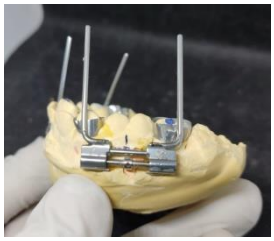

Fig. (3) Steps of periodontal distractor appliance construction from hyrax screw.

Phase IV: Activation of periodontal Distraction Fig. (4) :

Group I : The canine was distracted two per day for a total about 0.4 mm per day.

Group II: four activations of 0.2 mm each for a total about 0.8 mm per day.

The distractor was activated till the distal surface of canine became in contact with the mesial surface of second premolar Fig. (5).

The patients were instructed to apply orthodontic wax on the superior edges of distractor immediately after its placement to minimize discomfort of the oral mucosa as a result of trauma and friction between mucosal tissue and the distractor.

Fig. (4) Activation of periodontal distractor with key



Fig. (5) Before and after complete canine retraction by periodontal distractor

Measurement of pain: Pain intensity and discomfort was evaluated at different times by Visual Analogue scale (1st 48 hour after intervention, during each activation of the distractor, and on the Interval between activation) Fig. (6) **.**

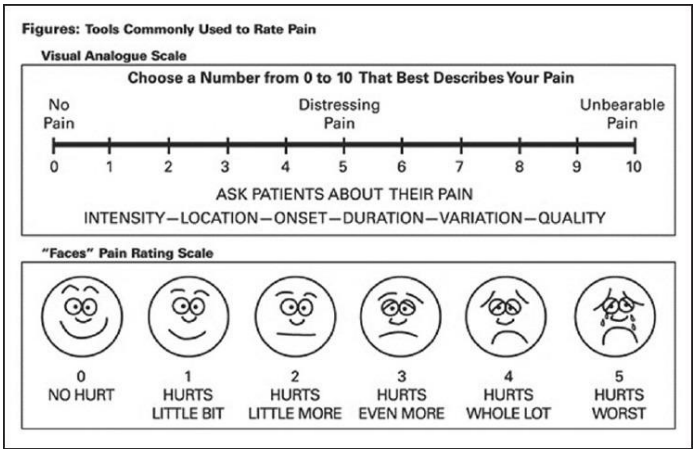

Fig. (6)Visual Analogue scale of pain.

Measurements of Pulp vitality:

The distracted canine's pulp was recorded with noninvasive, simple and clinically popular device. It was electric pulp tester.

The tip of the probe of EPT (Denjoy, china)was applied on sound enamel on the midpoint of each tooth. This area is the most effective site for EPT because of its close proximity to the highly innervated area of canine crown and because it provides a readily reproducible position. An interface medium as tooth paste was placed on tooth after its dryness with air spray to conduct electrical impulses to the tooth. The device has a numeric scale, and these numbers have been used to register changes in test responses Fig. (7).

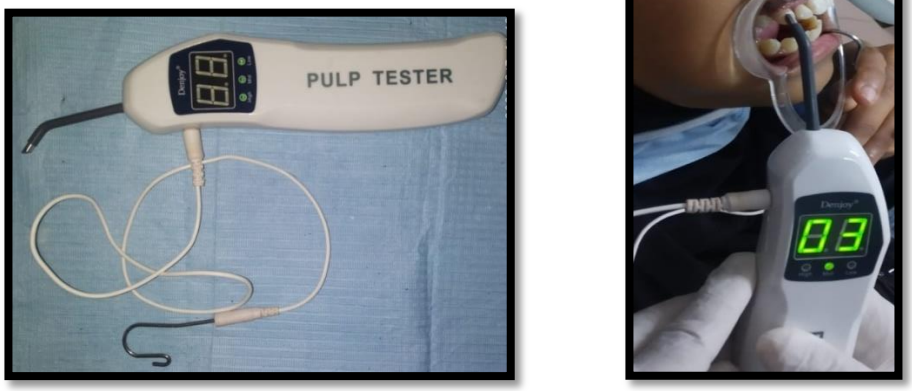

Fig.7 : Measurement of pulp vitality with electric pulp tester.

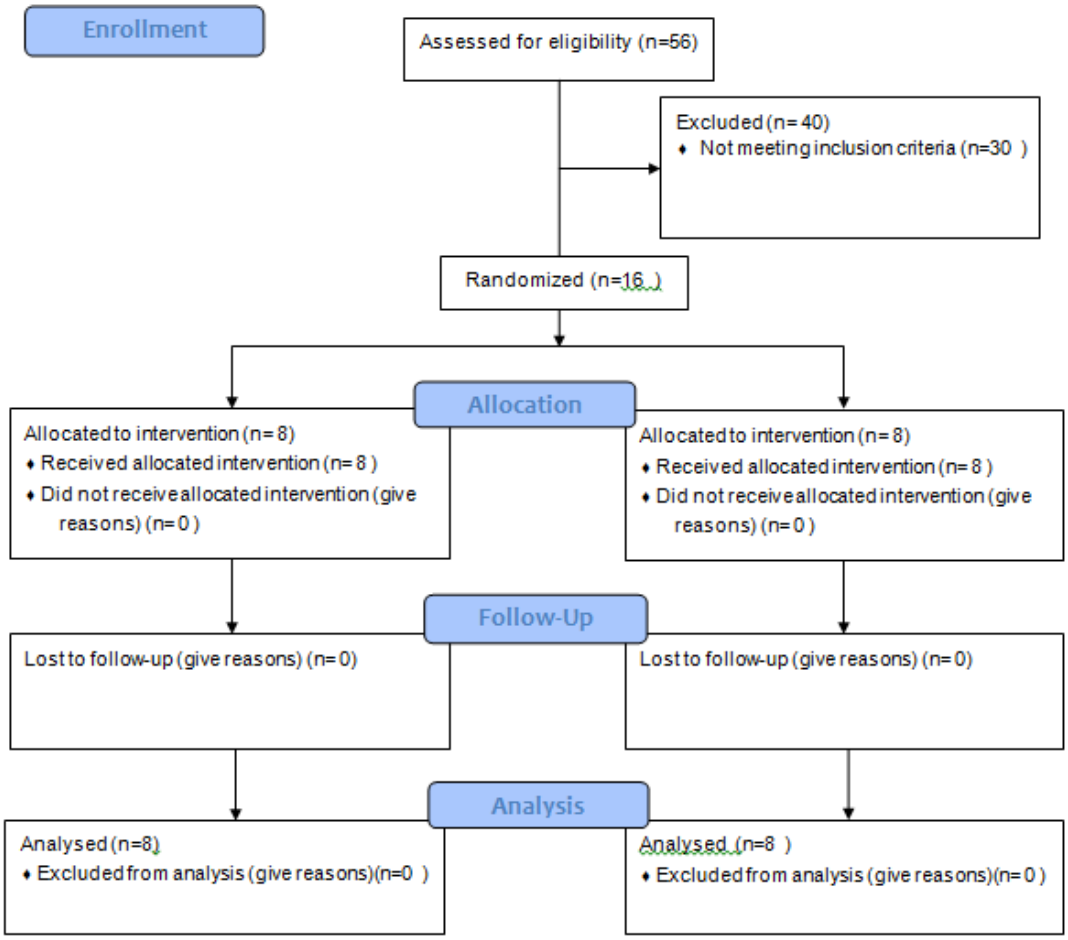

Fig. (8) CONSROT 2010 flow diagram of patients' recruitment and follow-up

Statistical analysis:

Comparison between different intervals was performed by using Friedman`s test (non-parametric data). Comparison between both groups was performed by using Mann Whitney`s test (non-parametric).