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Effectiveness of piezocision versus low-level laser therapy during orthodontic canine retraction: A comparative controlled clinical study

Protocol submitted in partial fulfillment of the requirements for Master Degree of Dental Science in Orthodontics

by

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Introduction

While orthodontic treatment offers substantial benefits, its prolonged duration carries significant risks. Orthodontic appliances, particularly fixed ones, complicate oral hygiene, predisposing patients to dental caries.[1] In addition to hygiene concerns, orthodontic forces can increase the likelihood of iatrogenic effects such as periodontal disease and root resorption.[2–4]

Consequently, a primary goal in contemporary orthodontics is to reduce overall treatment time and mitigate these potential complications. To achieve this, numerous techniques have been developed to accelerate orthodontic tooth movement (OTM). These approaches are broadly classified into two categories: surgical and non-surgical interventions. Surgical methods range from invasive procedures like corticotomy to minimally invasive ones such as micro-osteoperforations.[5] Non-surgical approaches, on the other hand, utilize physical stimuli like low-level laser therapy (LLLT)[6] or locally delivered pharmacological agents to modulate the biological response.[7–11]

Among the minimally invasive surgical techniques, piezocision, first introduced by Dibart et al.,[12] became widely adopted. It accelerates OTM by employing a piezoelectric knife to create precise micro-incisions and localized alveolar decortications.[13–15] This procedure induces the regional acceleratory phenomenon (RAP), a temporary burst of localized bone remodeling that decreases bone density and resistance, facilitating more rapid OTM.[16] Numerous clinical studies have demonstrated the efficacy of piezocision in significantly reducing treatment time.[17–28]

In contrast, LLLT, also known as photobiomodulation, has emerged as a

prominent non-surgical alternative. This technique applies low-intensity light to target tissues, aiming to stimulate cellular metabolism, increase vascularity, and modulate inflammatory mediators.[29–31] Its non-invasive nature makes it an attractive option for both patients and clinicians.[32,33]

Piezocision and LLLT represent distinct philosophies for accelerating OTM: one relying on surgically induced RAP and the other on non-invasive photobiomodulation. While previous studies have attempted to compare these interventions, their findings remain contradictory. Türker et al.[22] reported that LLLT was more effective only during the initial month, with no significant difference overall compared to piezocision. In contrast, Moradinejad et al.[20] found that a combination of both methods was superior, but piezocision alone was more effective than LLLT.

Notably, these studies utilized a split-mouth design,[20,22] which may introduce a carry-over effect where systemic factors or cross-arch biostimulation influence the contralateral side, potentially masking true differences.[34–36] Therefore, a parallel-group randomized controlled trial with a separate control group is necessary to eliminate these confounding variables and provide a clearer evaluation of their efficacy.[37]

This study, therefore, will be directed to compare the clinical efficacy of piezocision and LLLT against a control group during orthodontic canine retraction. The null hypothesis posits that there is no statistically significant difference in the rate of OTM among the three groups.

Aim of the study

The present comparative controlled clinical study will be directed to compare the effectiveness of piezocision and LLLT during orthodontic canine retraction.

Materials and methods

1 Study design

A prospective, single-center, three-arm, parallel-group, randomized controlled clinical trial.

2 PICO(T) Question

Population (P): Orthodontic patients requiring bilateral maxillary first premolar extraction and subsequent canine retraction.

Intervention 1 (I1): Piezocision-assisted canine retraction.

Intervention 2 (I2): LLLT-assisted canine retraction.

Comparison (C): Conventional canine retraction without any acceleration method (Control group).

Outcome (O): Rate of canine retraction.

Time (T): A four-month period from the beginning of the active canine retraction phase.[25,38]

PICO(T) Question: In orthodontic patients requiring bilateral maxillary first premolar extraction followed by canine retraction, is there a difference in the rate of canine retraction among patients treated with piezocision-assisted retraction, LLLT-assisted retraction, and conventional retraction over a four-month period?

3 Study setting and population

This study will be carried out on patients eligible for orthodontic treatment from the Outpatient Clinics of the Department of Orthodontics, Faculty of Dental Medicine, Boys, Cairo, Al-Azhar University.

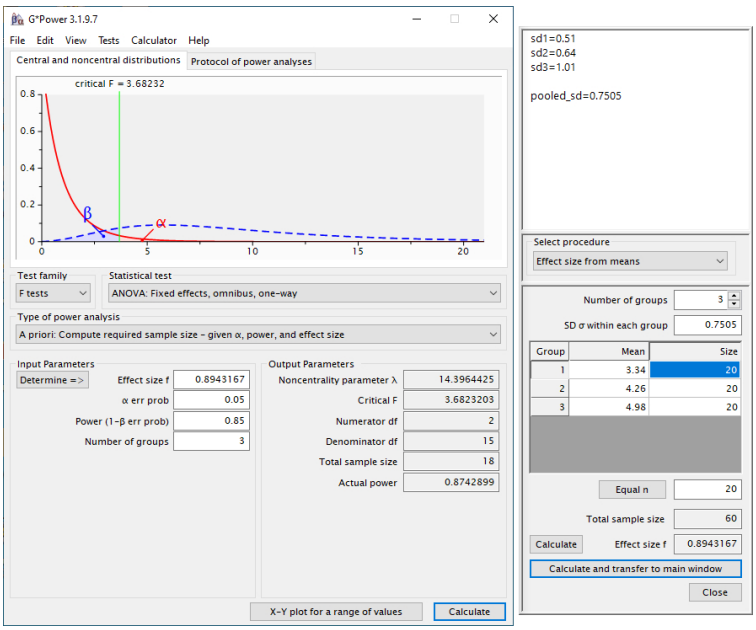

Figure 1: G*Power output for sample size estimation.

4 Sample Size Calculation

An *a priori* power analysis was conducted using G*Power software (version 3.1.9.7; Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany) to determine the appropriate sample size for a one-way analysis of variance (ANOVA).

The calculation was based on parameters derived from a comparable randomized controlled trial,[38] which reported a clinically significant difference of > 1.6 mm in canine retraction over a 4-month period between intervention and control groups. Based on this substantial effect size ($f \approx 0.88$), an alpha level of 0.05, and a power of 85%, a minimum total sample size of 18 participants (6 per group) was determined to be sufficient to detect significant differences (Figure 1).

To account for potential attrition or withdrawal during the follow-up period, the sample size was increased by approximately 15%. Therefore, a total of 21 participants will be recruited and randomly allocated into three equal groups ($n = 7$).

5 Eligibility criteria of population[20]

5.1 Inclusion criteria

1. Age range 18-25 years.
2. Patients with crowding or protrusion requiring at least bilateral maxillary first premolar extraction followed by symmetrical canine retraction.
3. Full set of permanent dentition (third molar not considered).
4. Patients with good oral hygiene.

5.2 Exclusion criteria

1. Previous orthodontic treatment.
2. Patients taking medications or suffering from systemic conditions that can affect orthodontic tooth movement.
3. Active periodontal diseases and/or untreated carious lesions.
4. Congenital orofacial deformities.

5.3 Criteria of discontinuation

1. Multiple missing appointments.
2. Poor oral hygiene.
3. Multiple broken appliances to the extent that interferes with obtaining the treatment objectives.

6 Ethical considerations

The research protocol is approved by the ethical committee of the Faculty of Dental Medicine, Al-Azhar University. The aim of the study will be discussed with

each patient, and he/she will sign an informed written consent before commencing the study. Moreover, patients will be given written instructions to follow during the treatment.

7 Orthodontic records

For each patient, the following records will be taken before the onset of the treatment:

1. Standardized extra and intra oral photographs.
2. Orthodontic study model.
3. Panoramic radiograph.
4. Lateral cephalometric radiograph.

8 Interventions[20,28,38,39]

All participants will receive standard fixed orthodontic appliances. Canine retraction will be initiated using a constant force from a NiTi closed coil spring anchored to a maxillary mini-implant. Participants will be randomly assigned to one of three parallel groups.

8.1 Group 1: Piezocision[28]

On both right and left sides, a minimally invasive flapless piezocision procedure will be performed each month from the beginning of the canine retraction for a total four-month period.

8.2 Group 2: LLLT[22,39]

On both right and left sides, LLLT will be performed at the beginning of canine retraction, after 3, 7, 14 days, and then every 14 days for a total four-month period.

8.3 Group 3: Control Group[38]

Participants in this group will receive the same fixed appliance and retraction mechanics as the experimental groups. However, no surgical intervention or laser application will be performed.

9 Outcome measures

9.1 Primary outcome[20,38]

The primary outcome will be the assessment of the amount and rate of maxillary canine distal movement.

9.2 Secondary outcomes[20,38]

The secondary outcomes will be the evaluation of the maxillary canine's rotation and tipping, also evaluation of the maxillary first molar's mesial movement (anchorage loss) and rotation, and finally pain assessment.

10 Observations[20,38]

10.1 Clinical measurements[20,38]

The amount of maxillary canine distal movement and extraction space closure in millimeters will be measured.

10.2 Study model measurements[20,38]

These will be evaluated via three-dimensional (3D) digital study models obtained before the start of canine retraction (T0) and after four months of canine retraction (T4). The degree of maxillary canine retraction, rotation, tipping, and the maxillary first molar's mesial movement (anchorage loss), and rotation will be evaluated.

10.3 Pain assessment[20,38]

Pain intensity will be evaluated by a 10 cm visual analogue scale (VAS).

11 Data management and analysis

The data will be collected, tabulated, computed, and statistically analyzed using a suitable statistical program.

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