Effectiveness of low frequency vibration on the rate of canine retraction:A randomized controlled clinical trial

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Competing interest Statement

The authors have no competing interests as defined by Nature Research, or other interests that might be perceived to influence the results and/or discussion reported in this paper.

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ABSTRACT

Objectives: To investigate the effectiveness of AcceleDent Aura vibrating device on rate of canine retraction. **Materials and Methods:** Thirty-two patients requiring extraction of upper first premolars and canine retraction were randomly allocated with a 1:1 ratio into either no-appliance group or the AcceleDent Aura appliance group. Canine retraction was done applying 150gm of retraction force using NiTi coil springs on 16*22 stainless steel archwires. The duration of the study was 4 months. Digital models were obtained directly after extraction of upper first premolars and at monthly intervals during canine retraction for recording the monthly as well as the total distance moved by the canine. Digitized models were superimposed on the initial model and data were statistically analyzed. Anchorage loss, rotation, tipping, torque and root condition were evaluated using cone beam computed tomography imaging. Pain was evaluated by visual analog scale. **Results:** No patients were dropped-out during this study. There was no statistically significant difference between both groups regarding the total distance travelled by the canine (P=0.436), as well as the rate of canine retraction per month (P=0.17). Regarding the pain level, there was no statistically significant difference between the two groups at day 0 (P=0.721), after 24 hrs.(P=0.882), after 72 hrs. (P=0.378) and after 7 days(P=0.964). **Conclusion:** AcceleDent Aura was not able to accelerate orthodontic tooth movement. Pain level couldn't be reduced by vibrational force

with an AcceleDent device during orthodontic treatment. Root condition was not affected by the vibrational forces.

KEY WORDS: AcceleDent; Acceleration of tooth movement; Vibrating devices; Canine retraction; Digital models

INTRODUCTION

Shortening of the treatment time via accelerating orthodontic tooth movement (OTM) continues to be a relentless challenge and demand in the mainstream orthodontics. To date, several modalities have been investigated to accelerate OTM through mechanical, pharmacological, surgical and physical approaches.

Vibrating devices are another example of physical acceleration of OTM. AcceleDent vibrating device (OrthoAccel Technologies, Houston, Texas) has been introduced to the market in 2009. It was intended to be used by the patients in conjunction with fixed orthodontic appliances or aligners, for 20 minutes per day. It vibrates at a frequency of 30Hz and has a force amplitude of 20 grams. The mechanism of action is hypothesized to be via enhancing bone remodelling through increased RANKL expression together with elevation in IL-1 beta levels[1] with a result in rise of the rate of tooth movement after application of vibration in humans

and mice, respectively. The results reported in the literature concerning the efficiency of these devices in acceleration of tooth movement are controversial.[2,3,4,5,6]

The aim of this study was to investigate the effectiveness of AcceleDent Aura vibrating device on the rate of canine retraction. The null hypothesis was that the there is no difference in the rate of canine retraction between AcceleDent Aura appliance group and no appliance group. Other side effects including pain and root resorption were also considered.

MATERIALS AND METHODS

Trial Design

This study was a parallel group two arm randomized controlled clinical trial with 1:1 allocation ratio that was reported following the CONSORT statement.[7] The study was approved by the Evidence Based Center, and the Research Ethics Committee and performed at the Faculty of Dentistry, Cairo University, Egypt . All patients were acquainted with the study procedures, and signed informed consents. No changes or modifications were done to the original methodology of the research

after trial commencement. All methods were performed in accordance with the CONSORT guidelines and regulations.

Sample Size Calculation

The sample size for the current study was calculated based on the results of Kau et al.[8] A total sample size of 52 canines was calculated to detect a large effect size (d=0.8) with 80% power and 5% significance level. This number has been increased to a total sample size of 64 canines to count for the expected sample attrition. The outcome variable is normally distributed. The sample size was calculated using G-Power program (University of Düsseldorf, Düsseldorf, Germany).

Participants, Eligibility Criteria, and Settings

Subjects were selected according to pre-set eligibility criteria (Table 1) and randomly assigned to intervention (AcceleDent Aura) or no-appliance groups using computer randomization sequence generation (https://www.random.org/) with 1:1 allocation ratio. It was not possible to mask the patients or the orthodontist providing the treatment, however, the outcome assessor was masked to the intervention.

All subjects received pre-adjusted MBT 0.022x0.028-inch slot brackets (3M Gemini metal brackets, 3M Unitek Corporation, Monrovia, A, USA) on their upper and lower arches excluding the upper first premolars. The upper arch wire sequence

in the initial levelling and alignment phase was tailored according to the severity of crowding from 0.014-inch NiTi archwire, until reaching 0.016x0.022-inch stainless steel arch wire. Self-drilling miniscrews (TADs-Hubit, Korea), 1.8x8 mm were placed buccally perpendicular to the labial plate of bone at the mucogingival junction between the upper second premolar and first molar bilaterally. Indirect anchorage was prepared bilaterally by inserting a L-shaped 0.019x0.025-inch stainless-steel wire in the auxiliary tube of the upper first molar bands and fixed to the mini-screws with flowable composite.

Interventions and Outcomes

At the end of the levelling and alignment phase, the patients were referred for upper bilateral first premolar extraction and an upper alginate impression was taken. Retraction of the canine was done using NiTi coil spring delivering a force of 150 gm per side calibrated using digital force gauge, attached between the hook of the canine bracket and the first molar tube on a of 16*2 stainless steel basal archwire (Figure 1). The intervention group subjects were given AcceleDent devices which delivered gentle micropulses (0.25 N at 30 Hz) and were instructed to wear them every day for 20 mins according to the manufacturer instructions. The patient compliance to intervention instructions were monitored by asking the patient and writing every day on chart how long she used it and compare this with the data

download from the appliance that recorded their daily usage during the period of space closure.

Follow-up visits were scheduled every four weeks. At each follow up visit, recalibration of the NiTi retraction spring was done using the same force gauge when necessary to maintain 150 gm force delivery. TADs stability and occlusal interferences during canine retraction were also regularly checked. An alginate impression for the upper arch was taken monthly.

The plaster models collected (T0-T4) were digitized using desktop scanner (3Shape R500, 3shape, Copenhagen, Denmark) The canine retraction was assessed using two methods; the incremental rate of canine retraction and the total distance travelled by the canine. Using the 3Shape OrthoAnalyzer software**Error! Bookmark not defined.** the four consecutive models (T1-T4) were superimposed[9] on the base model (T0) using three points registration upon the third rugae area (Figure 2). Colour-mapped superimposition was used to verify the accuracy of the superimposition. The difference in the position of the canine cusp tip was used to calculate the incremental rate of canine retraction (Figure 3). For intra- and inter-rater reliability, measurements of the digital models were done by the same operator (NA) twice, 2 weeks apart and repeated by another operator (MA).

Cone beam Computed Tomography

Pre- and post-retraction CBCT images were obtained for each patient using the same CBCT machine with the following parameters: Resolution (Voxel size): 0.3\0.3 mm, exposure time: 10-20 sec, Anode voltage: 57-90 kV, field of view (FOV): 6×8 cm limited to the maxilla, and anode current: 4-16 mA. A total of 36 CBCT images were obtained at the end of the study (18 pre-retraction and 18 post-retraction) upon which the analysis was done.

The DICOM files obtained from the imaging centre were manipulated using In vivo 5 (Anatomage) version 5.3 software to perform the CBCT measurements as follows: Landmarks (Table 2), reference lines/planes (Table 3) (Figure 4) and measurements (Table 4) were all recorded in their corresponding modules. Then, an analysis was created and saved to be used for all pre- & post-retraction CBCT images.

Measurements used in the CBCT Analysis

Measurements of the total distance of canine retraction, the canine tipping, torque and rotation were analysed by measuring the angles between the long axis lines for the canines and the three reference planes were measured to detect tipping and torque movements. Also, the angle between the horizontal line of the first molar and the sagittal plane to detect canine rotation.

For assessment of root resorption, the axial guided navigation method explained by Castro et al[10] and Schwartz et al[11] was used. Using the software In-vivo 5, version 5.3(Anatomage, Inc., Santa Clara, CA 95054, USA). the pre- & post-retraction CBCTs obtained for each patient were used to evaluate the effect of AcceleDent on root resorption, the linear length between the root apex and cusps tip was measured.

The evaluation was carried by two blinded examiners. In order to fully visualize the root, the CBCT image was re-oriented on each root so that the cross-section would pass through the long axis of each canine (Figure 5).

The degree of pain was measured by Visual Analog Score (VAS), these charts were filled by the patients for the following week after beginning of canine retraction at time intervals (0, 24 hours , 48 hours, 72 hours and 7 days) and were gathered at the end of the week. The pain VAS was in the format of a chart that contained a series of 10-cm horizontal scales on which the patient marked the degree of pain (0 to 10, where 0 refer to no pain and 10 refer to sever pain) at the indicated time periods.

Statistical Analysis

Data management and statistical analysis were done using Statistical Package

for Social Sciences, Version 21.0 (SPSS Inc., Chicago III) for Windows. Shapiro-Wilk tests of normality were used to test normality of all quantitative variable distributions. Canine retraction in millimetres was presented as mean and standard deviation (SD). Kruskal-Wallis test was used to test the difference in the incremental rate of retraction between the two groups. Independent t-test was used to determine the statistical differences in the total distance travelled. *P*-value <0.05 was considered statistically significant. All tests were two-sided. Concordance correlation coefficients (CCCs) were calculated to detect the intra- and inter-examiner reliability of the measurements.