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Effect of customized vibratory device on orthodontic tooth movement: A prospective randomized control trial

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Abstract

AIMS: The primary purpose of the present trial was to evaluate the effect of low-frequency (30Hz) vibrations on the rate of canine retraction.

SETTING AND DESIGN: Single-center, split mouth prospective randomized controlled clinical trial

METHODS AND MATERIAL: 100 screened subjects (aged18–25 years) were selected; out of which 30 subjects having Class I bimaxillary protrusion or Class II div 1 malocclusion, requiring upper 1st premolar therapeutic extractions, were selected for the study. A split-mouth study design was prepared for the maxillary arch of each selected individual and was randomly allocated into vibration and nonvibration side (control) groups. A customized vibratory device was fabricated for each subject to deliver low-frequency vibrations (30 Hz). Scanned 3D models were prepared sequentially to assess the amount of tooth movement from baseline (T0),(T1), (T2), (T3), and (T4)-4th month of canine retraction.

STATISTICAL ANALYSIS USED: Independent "t" test.

RESULTS: There was no statistically significant differencein the rate of individual canine retraction among the experimental and control groups when the intergroup comparison was done using independent "t" test at T1-T0, ($P = 0.954$), T2-T1 ($P = 0.244$), T3-T2 ($P = 0.357$), and T4-T3 ($P = 0.189$).

CONCLUSION: The low-frequency vibratory stimulation of 30 Hz using a customized vibratory device did not significantly accelerate the rate of orthodontic tooth movement.

TRIAL REGISTRATION: Registered at ctri.nic.in (CTRI/2019/05/019043).

Keywords:

3D models, accelerating, canine retraction, customized, randomization, vibrations

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Introduction

Comprehensive orthodontic treatment usually takes a long duration of time, which sometimes discourages patients from undergoing orthodontic treatment.[1] Therefore, attempts to accelerate orthodontic tooth movement have been made in the recent past. They have been a subject of debates as well.[2] The methods can be broadly classified into Invasive and Noninvasive. The invasive methods include corticotomy, dentoalveolar distraction, periodontal distraction, and microosteoperforations. Noninvasive methods constitute injections of prostaglandin E and vitamin D, drug injections of parathyroid hormone, electric and magnetic stimulation, low-energy laser, and vibration.

Vibration has been a relatively new field of interest to researchers. Initial studies to evaluate the effect of vibration on orthodontic tooth movement, which were conducted on animals, have shown promising results. Nishimura *et al.*[3] had

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conducted a study in rats and concluded that vibration increases the rate of orthodontic tooth movement by enhancing the expression of RANKL in PDL. Evidence from such animal studies had suggested that cells respond more rapidly to oscillation force as compared to a constant force when they have been subjected to multiple cyclic (vibration) forces. The accelerated bone remodeling and increase in the rate of tooth movement, in other words, were analogous to the reduction in overall treatment time.

Various commercial vibratory devices have been designed to provide a cyclic vibrational force of both low and high frequency, which can be directly used by patients.Tooth Masseuse (111 Hz), AcceleDent (30 Hz), and Vpro5 appliances (120 Hz) have been commonly used but most of the studies have been done on AcceleDent Aura device.Many researchers have also used powered toothbrushes[4,5] to accelerate tooth movement. The different vibratory devices produce varying vibrational frequencies from 30Hz to 120Hz and a force ranging from 0.2N to 0.06N. In the recent literature, many systemic reviews have been conducted but the findings have been controversial. Systematic reviews by Lyu *et al*.[6] and Jing *et al*.[7] stated that vibratory devices could not change the rate of orthodontic tooth movement. On the other hand, a systematic review by Keerthana *et al*.[8] had stated that vibratory devices using 30Hz frequency (AcceleDent, Powered toothbrush with 30Hz) have been efficient in accelerating orthodontic tooth movement.The above systematic reviews have also pointed out the requirement of concrete evidence: high quality randomized clinical trials in the future.

To date, studies have involved and advocated the use of either commercially available vibration devices or powered toothbrushes to accelerate orthodontic tooth movement. However, the vibrational frequencies of these toothbrushes were not fixed and were not designed to provide vibrations efficiently. All commercially available vibration devices have employed some or the other generic tray(s). Such trays could not effectively deliver the desired amount of intensity of vibrational force to the teeth because the occlusal levels of all teeth are not uniform naturally.Thus, these generic trays do not perfectly adapt to individual patient's occlusal plane. The tooth to be moved might not contact the tray, and thus might fall short of receiving the vibration forces effectively. This has been a major confounding factor to cause inconsistency in the results of various studies. Also, the generic tray of commercially available devices would cover the whole of the arch and thus deliver vibrations to all the teeth. To study the effect of vibrations, two different groups (parallel study design) have been required where inter-individual variability has been another confounding factor. To remove these two main confounding factors, the use of a customized vibratory device along with a split-mouth design would be deemed necessary and beneficial.

A split-mouth randomized controlled trial was designed to evaluate the rate of canine retraction using a customized low-frequency vibratory device in subjects with fixed conventional orthodontic therapy.

Specific objectives or hypothesis

The primary purpose of the present study was to evaluate the effect of low-frequency (30Hz) vibrations on the rate of canine retraction. The null hypothesis was that a customized low-frequency vibratory device does not increase the rate of individual canine retraction in maxillary premolar extraction cases.

Material and Methods

Trial design and changes after trial

The study was a single-centered split-mouth randomized controlled trial with a block size of 6 in a 1:1 ratio of allocation. The methods were not changed after trial initiation.

Participants, eligibility criteria, and settings

Ethical approval was obtained from the ethical committee of the University and written informed consent was taken from all the patients. The trial was registered at www.ctri.nic.in (CTRI/2019/05/0XXXX).

Participants in the age group of 18–25 years fulfilling the inclusion criteria having Class I bimaxillary protrusion or Class II div 1 malocclusion, requiring maxillary 1st premolars extraction, with no evidence of bone loss or history of periodontal disease, were selected from the out-patient sectionat the Department of Orthodontics and Dentofacial Orthopaedics. A total of100 subjects were screened initially; out of which 30 subjects were further selected to meet the inclusion and exclusion criteria and were ready to participate in the study.

Sample size calculation

The sample was calculated to a minimum power of 95% (1-β err prob = 0.95) and an α error of 0.05. The sample size estimation was calculated using G Power 3.0.10 software online. The calculations yielded a required sample of 14 per group; however, a sample of 30 per group was taken to further increase the power of the study.

Randomization

To remove the selection bias between the right and left maxillary quadrants (split-mouth study), a random allocation was done by block randomization method with a block size of 6 in 1:1 ratio of allocation. The concealment of the treatment modality to be performed was done in

sequentially numbered sealed opaque envelopes, which were shuffled by the first researcher. To ensure the co-researcher being blinded, the envelopes were opened by assistant operators in aclosed consultation room.

Blinding

In the study, subjects and first researchers were aware of their treatment groups, whereas the co-researcher was blinded toward the treatment groups. All study models were coded and transferred to the co-researcher for measurements.

Intervention

The subjects were treated with preadjusted edgewise appliance with 0.018″ slot MBT prescription (Ormco corporation, orange, CA). After the strap-up, a predetermined wire sequence of 0.014″ NiTi, 0.016″ NiTi, 0.016 X 0.022″ NiTi followed by 0.016X0.022″ SS was used to achieve leveling and alignment. The canine retraction was initiated at least 4 months after the extraction of maxillary 1st premolars to remove any bias due to the regional acceleratory phenomenon post-extraction. Before the commencement of canine retraction, the root was evaluated clinically for its prominence. If the canine root was found to be in the labial cortical bone then either the subject was removed from the study or the root was torqued into the cancellous bone. To reinforce the anchorage value, banding of second molars and placement of transpalatal arch was done. A split-mouth study design was employed in the maxillary arch of each selected individual which was then randomly allocated into vibration and nonvibration sides.

Vibratory device and its application

The study was self-funded and to reduce the financial burden, an appropriate customized substitute to the AcceleDent Aura device (OrthoAccel Technologies, Inc., Bellaire, TX) was designed and fabricated to suit the split-mouth design. The customized vibratory device covered only one side of the maxillary arch. A frequency of 30Hz and a force of 0.25N (25g) was determined, calibrated, and standardized at the Mechanical Engineering Department of the University. The device has been registered for patency according to The Patent Act, 1970(Patent no. 307111).

The modified device consisted of four main components [Figure 1]:
a. Sectional metal tray
b. Coin flat microvibrator (13000–15000 rpm)
c. Two Duracell AAA size batteries (1.5V)
d. Plastic body

The side to which the vibration therapy would be given was attributed to randomization. Vibrations were applied on both the buccal and palatal aspects of the experimental side. The vibratory device was customized for every patient by making an impression of the experimental side of the maxillary arch using acrylic temporary relining material (Coe-soft, GC) on the sectional tray using a wax spacer on the incisors, the canine bracket along with the 1st premolar extraction site so that the tray could fit on both buccal and palatal sides [Figure 2]. To prevent the hindrance to the distal movement of the canine, a wide groove was created in the relining material in the direction of the intended tooth movement parallel to the occlusal plane. Written and verbal instructions about the allocated side of vibration (Right or Left maxillary arch) and usage of the device were given to all the subjects. All subjects were trained for self-application of the vibratory device by the first researcher. The subjects were instructed to use their device(s) for 20 min/day [Figure 3]. To enhance the compliance of subjects, they were instructed to feed a daily reminder alarm in their mobile phones and also maintain a diary for everyday records forthe ensuing 4 months of canine retraction. The canine retraction was instituted using a 9mm NiTi closed coil spring (GAC International, Bohemia, NY) from the canine bracket hook to the first molar tube, which delivered a relatively constant force of 150g [Figure 4]. At eachappointment, a Dontrix gauge (American Orthodontics, Sheboygan, Wisconsin) was used to check the retraction force. The bite was raised in those subjects where occlusal interferences were present.

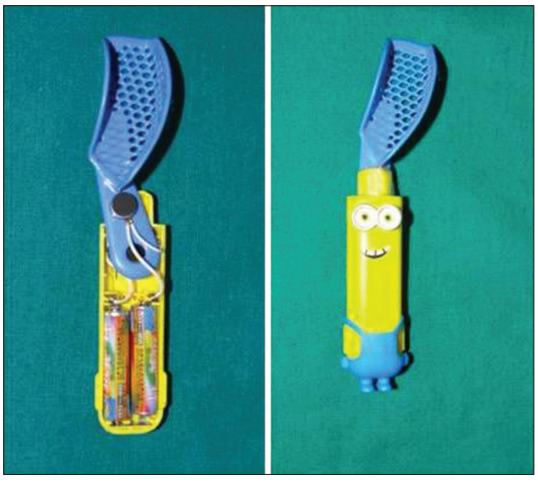


Figure 1: Customized vibratory device

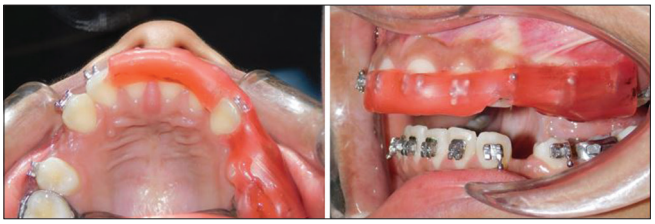


Figure 2: Wax spacer made before making an impression so that the tray could fit on both buccal and palatal side without restricting canine movement

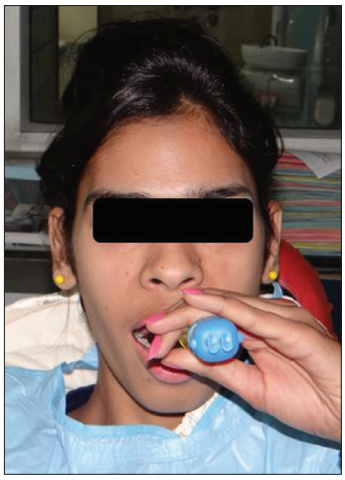


Figure 3: Patient using a vibratory device

Records (impressions, models, and photographs) were taken at the beginning of the study and immediately before canine retraction (T0) and after every 1 month to monitor tooth movement and were repeated in the follow-up, till the 4thmonth of canine retraction.

Outcomes

Primary outcome: The main objective of the study was to evaluate the effect of low-frequency vibrations (30Hz) on the rate of tooth movement using a customized vibratory device by measuring and comparing the rate of individual canine retraction at the vibration and nonvibration sites.

A series of models from each subject was scanned and 3D model(s) were prepared to assess the amount of canine movement distally, relative to the stable landmark of the ipsilateral median end of the third ruga. All study measurements were performed on digital models. 3D scanning of the plaster models was performed using the inEos X5 scanner (Dentsply Sirona Limited, USA) with a 3D reverse modeling software program. The 3D models were obtained in STL format. Measurements were done using the Blender 2.80 software to the nearest 0.01 mm. The extraction space was measured on a mid-palatine line, which was drawn in the software. Perpendicular lines were drawn from the distal surface of the canine and anteromedial surface of the 3rd palatal rugae toward the mid-palatine line and the distance between them was measured at different time intervals [Figure 5]. Subjects were asked to get their daily diary to analyze and monitor the appliance use. Only those subjects who used the appliance 75% (of the treatment duration) or more were considered in the final data analysis.

Interim analyses and stopping guidelines

Not applicable

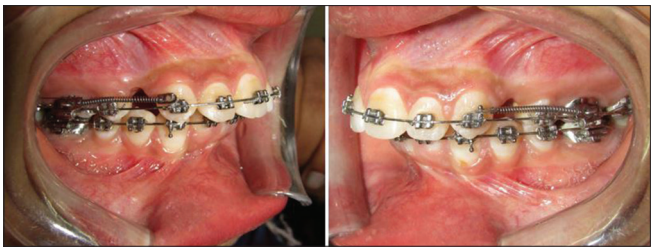


Figure 4: Canine retraction being done using 9mm NiTi closed coil spring from canine bracket hook to the first molar tube which delivered a force of 150g

Statistical analysis

The data were subjected to SPSS software (version 22.0, IBM, Armonk, NY) for analysis. The independent "t" test was applied to find the level of significance in the rate of tooth movement between the control and experimental groups at different time points at 0.05 levels of significance. To check intra-observer reliability, a re-evaluation of fifty percent of the sample was done after 1 week to assess any method error(s) and was calculated using the intraclass coefficient. The reliability coefficient was 0.95, which showed an excellent measurement agreement.

Results

Participant flow

All the 30 participants recruited between January 2019 and October 2019 had completed the study. Five subjects were excluded after the intervention due to their compliance with the vibratory device (compliance less than 75%). Thus, the data of 25 subjects were finally analyzed [Figure 6].

Baseline data

All the baseline information related to the total sample size, number of males and females, the mean, the standard deviation of the age, and mean distance between canine and third rugae was reported, as in Table 1.

Numbers analyzed for each outcome, estimation, and precision, subgroup analyses

A total of 25 subjects per group was analyzed. The results of the study showed a statistically nonsignificant difference in the rate of individual canine retraction among experimental and control groups when the intergroup comparison was done using independent t-test at T1-T0, (P = 0.954), T2-T1 (P = 0.244), T3-T2 (P = 0.357), and T4-T3(P = 0.189 [Table 2, Graph 1].

Additionally, the intragroup comparisons [Table 3] showed no statistically significant difference ($P > 0.05$) in the rate of canine retraction between the control and experimental groups.

Table 1: Baseline characteristics of the study

	Experimental	Control	Total
Age (years)	20.17±2.47	20.17±2.47	20.17±2.47 (average)
Sex			
Female	16	16	16
Male	14	14	14
Preretraction extraction space	5.63±1.39 mm	5.43±1.33 mm	5.53 mm (average)
Incisor irregularity index	2.11 mm	2.11 mm	2.11 mm (average)

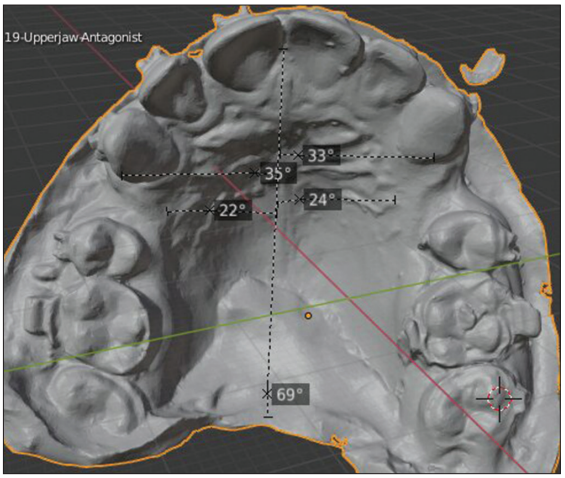


Figure 5: Measurement of the rate of individual canine retraction on 3D models

Harms

No negative outcomes or harms were reported by any of the participant(s) during any time of the study.

Discussion

Main findings in the context of the existing evidence and ensuing interpretation

The present single-centered split-mouth double-blinded randomized clinical controlled trial was designed to evaluate the effects of a customized vibration device that works on low frequency (30 Hz) for accelerating orthodontic tooth movement.Kawasaki *et al*.[9] stated that RANKL: OPG ratio was proportional to age, which affected the rate of bone remodeling and tooth movement. To eliminate the effect of age, adult subjects (age >18 years) were included in the present study. To remove inter-individual variability, a split-mouth design was selected.

All the previously mentioned studies were conducted with commercially available devices; a majority of the studies were supported by research grants from the respective manufacturing companies, which made themprone to a greater potential for bias. The present trial was conducted, using a customized vibratory device (30Hz) using a patient-specific tray. Moreover, customization made the device cost-effective, which made it more affordable to the subjects in comparison to commercially available ones. According

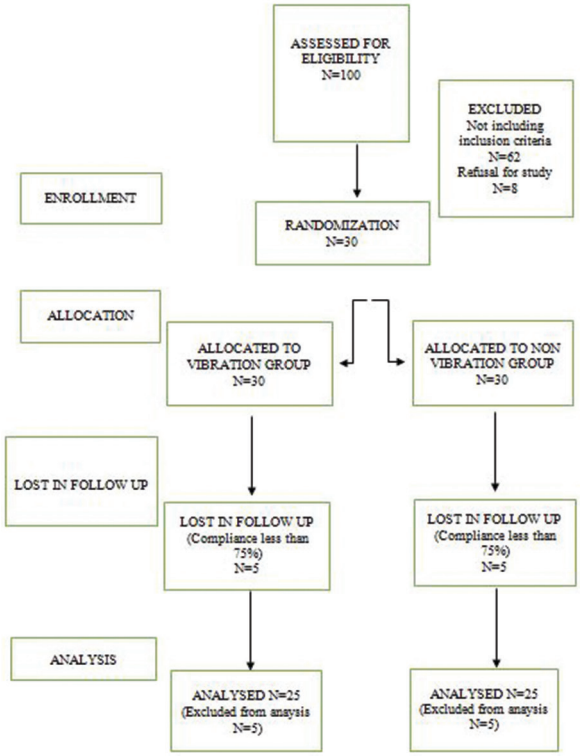


Figure 6: CONSORT flow chart

to Shukla *et al*.,[10] the consistency of the rugae's shape during different orthodontic treatments made it a reliable marker, and the third palatal rugae points remained almost constant with time; therefore, in the present trial, the rate of canine movement was measured on 3D models and anteromedial part of 3rd palatal rugae was used as stable reference landmark.

Currently, there have been various devices that work on either high or low frequencies but with varying and debatable results.AcceleDent device (OrthoAccel Technologies, Bellaire, Texas, USA) was the first commercially available appliance that produced vibration at low frequencies (30Hz) and maximum number ofstudies have been conducted using thesame even though they have shown contradictory results.

Result of this trial showed that low-frequency vibration therapy does not significantly increase the rate of canine retraction (P = 0.189), somewhat similar to the study done by Taha *et al*.,[11] a randomized controlled

Table 2: Intergroup comparison of the rate of canine retraction between experimental and control groups

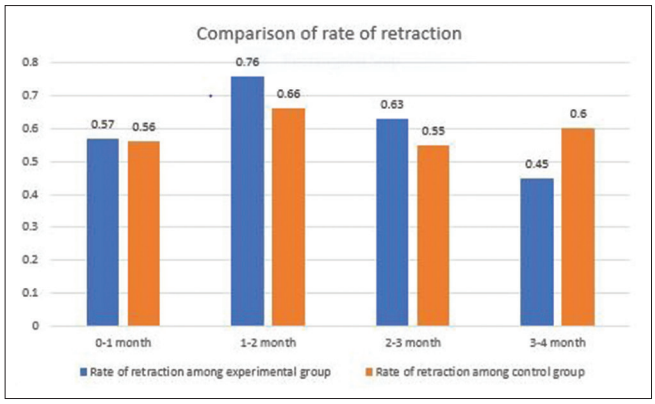
I Intervals Dif	Control	Experimental	Mean Difference	Standard error	95% Confidence interval		
					Lower	Upper	*P*
1st Month (T1-T0)	0.56±0.23	0.57±0.23	0.01	0.031	0.19	0.33	0.954**
2nd Month (T2-T1)	0.66±0.19	0.76±0.25	0.10	0.017	0.23	0.53	0.244**
3rd Month (T3-T2)	0.55±0.26	0.63±0.34	0.08	0.032	0.33	0.47	0.357**
4th Month (T4-T3)	0.60±0.37	0.45±0.22	- 0.15	0.019	0.28	0.46	0.189**

* Significant at $P \leq 0.05$; **Nonsignificant at $P \geq 0.05$

Table 3: Intragroup comparisons for the rate of canine retraction between different time intervals

Groups	Time Frame	Mean Difference	Standard Error	Degree of Freedom	*P*	95% CI interval	
						Lower	Upper
Control	T1 vs T2	0.020	0.18	1	0.413**	0.05	0.09
	T1 vs T3	0.036	0.29	1	0.324**	0.03	0.07
	T1 vs T4	0.039	0.34	1	0.232**	0.02	0.04
	T2 vs T3	0.025	0.16	1	0.156**	0.01	0.03
	T2 vs T4	–0.031	0.15	1	0.415**	0.02	0.05
	T3 vs T4	–0.037	0.16	1	0.633**	0.01	0.04
Experimental	T1 vs T2	0.114	0.12	1	0.422**	0.14	0.39
	T1 vs T3	0.118	0.14	1	0.512**	0.19	0.50
	T1 vs T4	0.213	0.43	1	0.321**	0.26	0.47
	T2 vs T3	0.006	0.35	1	0.753**	0.01	0.07
	T2 vs T4	0.003	0.21	1	0.424**	0.02	0.06
	T3 vs T4	0.002	0.16	1	0.556**	0.01	0.09

Post hoc bonferroni test; * Significant at $P \leq 0.05$; **Nonsignificant at $P \geq 0.05$



Graph 1: Bar diagram showing the comparison of the rate of individual canine retraction among the experimental and control groups

clinical trial that used AcceleDent device (30Hz) and it was observed that there was no statistically significant difference between the experimental and control groups related to the rate of canine retraction. Miles *et al*.[12] and DiBiase *et al*.[13] conducted randomized clinical trials to evaluate the effect of low-frequency vibrations by the AcceleDent Aura appliance (30Hz) on the rate of en-masse maxillary retraction and found that there was no significant difference in the rate of space closure. Woodhouse *et al*.[14] conducted a randomized clinical trial to evaluate the effect of vibrational force on timing for alignment and leveling with the use of the AcceleDent appliance. They also found no effect of vibration on the reduction in the amount of time required to achieve final alignment.

On the contrary, few authors did find an increase in the rate of tooth movement using low-frequency vibrations. Kau *et al*.[15] presented a clinical study on 14 subjects who were given an Acceledent device (30 Hz) along with conventional orthodontic treatment. In their study, an increased rate of space closure was observed. Pavlin *et al*.[16] conducted a randomized controlled trial and found that the application of vibration significantly increased the rate of canine retraction. However, in their study, the rate of canine movement was compared between two different groups and the measurements were done intra-orally with no predecided stable landmarks. Thus, inter-individual variability could be a factor that might have possibly induced a bias.

Results of studies conducted on high-frequency vibration devices such as Tooth Masseuse (111 Hz), Vpro5 appliances (120 Hz), and Powered toothbrushes (60–120Hz) have also been quite contradictory. Liao *et al*.[17] andLeethanakul *et al*.[18] used Powered toothbrushes during canine retraction and found that high-frequency vibratory stimulus increased the rate of orthodontic tooth movement. Contrary to that, Jain *et al*.[4] and Azeem *et al*.[5] observed that vibratory stimulus from power toothbrushes did not accelerate the rate of tooth movement.

Recently, according to the animal study conductedby Alikhani *et al*.,[19] it was shown that vibrational forces intensified the existing inflammation only under preexisting inflammatory conditions like orthodontic tooth movement, which increased catabolic activities,

while under physiological conditions it did not stimulate inflammation and had shown anabolic effects. Various other studies had also proposed the fact that vibrational loading stimulated the cellular response by initiating the signaling pathway in the bone that leads to faster tooth movement. Miles *et al*.[20] also hypothesized that a secondary mode of action of vibrational appliances may involve increasing the number of perturbations and the reduction of the "stick-slip behavior" between wires and brackets. Siriphan *et al*.[21] conducted a randomized clinical trial and stated that the clinical application of 30 Hz or 60 Hz vibration stimulus did not increase the secretion of RANKL and OPG. Shipley *et al*.[22] stated that acceleration of tooth movement was dependent upon the frequency, and also acceleration g-force from the vibratory device that enhanced the cytokines and osteoclast proliferation.

Thus, the findings from different studies may help in understanding the conflicting results. The results of the present clinical trial have stood in unequivocal support of the null hypotheses, i.e., the use of low-frequency vibrational force with a customized vibration device did not increase the rate of an individual canine retraction. The possible explanation for no increase in the rate of canine retraction could have been that 30Hz frequency was inadequate to stimulate the adequate release of inflammatory cytokines and chemokines from PDL and alveolar bone in comparison to that from the orthodontic force.

Limitations

The following may be listed as limitations of the present study:

(1) The study did not measure the inflammatory markers.
(2) The study was evaluated for 4 months only.
(3) Pain perception or discomfort and root resorption(s), if any, were not evaluated.
(4) Comparative effects of low frequency with high frequency were not compared.

Future studies would still be needed to determine the exact frequency of vibration and adequate duration of clinical application that could provide maximum cellular response.

Generalizability

The results could not be generalized because the trial was done by the use of a customized design of a vibratory device and data from a 4-month trial could not be applied to the entire duration of orthodontic treatment.

Conclusion

Following conclusions could be drawn from the trial:

1. The low-frequency vibratory stimulation of 30 Hz applied for 20 minutes per day using a customized vibratory device with fixed orthodontic treatment did not significantly accelerate the rate of canine retraction.
2. The adjunct use of the vibratory device to accelerate tooth movement was not supported by this randomized controlled trial.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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