INVESTIGATING THE EFFECT OF VIBRATIONAL DEVICES TO ASSESS THE RATE OF ORTHODONTIC TOOTH MOVEMENT - A SYSTEMATIC REVIEW AND META-ANALYSIS

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Abstract

Objective: To critically evaluate the existing evidence with respect to the effect of vibrational devices on the rate of tooth movement during orthodontic treatment.

Materials and methods: Unrestricted electronic search in PubMed/ MEDLINE, DOAJ, Cochrane Central as well as manual searches was conducted upto June 2020. Only randomized controlled trials (RCTs) were included. Study selection, data extraction, and bias assessment were done by two independent reviewers. The Cochrane risk-of-bias tool was used, and the quality of evidence was graded using the GRADE approach. A fixed-effects meta-analysis of continuous data, with its 95% confidence intervals (CIs), was used.

Results: The initial electronic database search resulted in 3528 titles. 37 articles were cited as duplicates. After screening the abstracts, 326 relevant titles were selected by two independent reviewers and were excluded for not being related to the topic. Following examination and discussion by the reviewers 14 articles were selected for full text evaluation. Hand searching of the reference lists of the selected studies did not deliver additional papers. After pre-screening, application of the inclusion and exclusion criteria and handling of the PICO questions, nine studies remained (two studies with no post intervention data, four studies were inappropriate for outcome of interest and two studies did not have the measures of effect as per the protocol). Seven studies were finally included in the qualitative synthesis which used for data extraction and statistical analysis. Out of the seven, four studies were included in the quantitative synthesis. Results also showed a statistically non-significant difference regarding the effect of vibrational devices on rate of tooth movement when compared with non-vibratory stimulus and sham devices.

Conclusion: There is weak evidence of the effect and use of vibrational devices in increasing the rate of tooth movement in orthodontic treatment. The meta-analysis aided us to conclude that there is no significant difference in the rate of tooth movement outcome after use of vibrational devices as compared to control group in patients undergoing orthodontic treatment.

Keywords: Meta-Analysis, Orthodontic Tooth Movement, Sham Device, Vibrational Devices, Little's Irregularity Index.

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1. INTRODUCTION

With the advent of modern Orthodontics along with more and more demand for facial aesthetics, Orthodontic treatment is the need of the hour for many individuals today. Patients are looking for quicker modalities of treatment and reduced treatment duration. Not surprisingly, there is a demand by the public for shorter treatment times, with parents wanting treatment completed in 12 to 18 months, although adolescent patients would like it completed in 6 months or less.[1] Traditionally, orthodontic treatment involved 2 or more years in fixed appliances[2]; more recently, it has been reported to have shortened to less than 2 years.[3] Considering the risks associated with orthodontic treatment such as root resorption and demineralization, it is certain that Orthodontists are looking for modalities and ways to decrease treatment times to reduce these risks for their patients[4]. Thus, the prospect of accelerating the biologic response of the periodontal ligament and alveolar remodeling is alluring, as it could concede speedy tooth movement and shorter treatment duration[5]. Orthodontic treatments vary widely, approximately 2 or more years in fixed appliance therapy.[6,1] If it were possible to accelerate the rate of orthodontic tooth movement, this would obviously be a desirable outcome, especially if it could be accomplished in a noninvasive manner. Microvibration has been reported in a retrospective, unblinded study to result in a 30% increase in the rates of leveling and alignment with the AcceleDent appliance (30 Hz, 0.2 N or about 20 g).[7] With patients desiring significantly shorter treatments of only 6 to 12 months, this places tremendous pressure on orthodontic clinicians to find ways to accelerate treatment[1]. There is little evidence to support nonsurgical adjunctive interventions to increase the rate of tooth movement, as suggested by a recent Cochrane review which advocates that a well-designed randomized clinical trial is needed[8]. A popular noninvasive method to accelerate tooth movement is the application of intermittent vibrational forces to the dentition.[9-11] To achieve the desired tooth movement, certain forces are applied to the dentition and alveolar bone resulting in ischemia or inflammation to

the periodontal ligament with successive release of prostaglandins, bradykinin, histamine, serotonin and substance P.[12] These mediators invigorate local nerve endings and send pain signals to the brain.[13] The use of supplemental vibrational force has been advocated as a method of speeding up orthodontic tooth movement. This involves the application of low-level vibration directly to the dentition as it is subjected to orthodontic force. The basic principle underlying orthodontic tooth movement is the ability of alveolar bone to respond with remodeling following the application of external force [14]. Using this principle, vibrational force has been shown to aid in the maintenance of bone mass in post-menopausal women [15] or subjects with reduced mobility and prolonged bedrest [16-18]. At the same time, data from animal models indicates an increased rate of tooth movement, osteoclastic activity and bone remodeling within the periodontium [9,11]. These data have been used to inform the development of commercial vibrational appliances for clinical use, one of which is AcceleDent® (OrthoAccel Technologies, Houston, Texas USA). This is a hands free portable device consisting of an activator unit and removable thermoplastic occlusal wafer, which the patient bites onto. The activator unit vibrates and delivers a force of 0.2 N at a frequency of 30 Hz to the dentition. The manufacturer suggests that it is used for 20 minutes per day in order to increase the speed of tooth movement and thereby reduce treatment time. Clinical benefits from the use of supplemental vibration have been reported from case reports and non-randomized retrospective cohort studies [7,19,20,21] Previous studies have demonstrated that vibration effectively increases the rate of orthodontic tooth movement[22]. A device generating vibrations named AcceleDent was designed in the U.S for faster orthodontic treatment. It was patented as a "vibrating orthodontic remodeling device" by U.S. Department of Commerce's United States Patent and Trademark Office [23]. Several such devices have been used which help in increasing the rate of tooth movement and thus significantly help in reducing the overall treatment time. The purpose of this Systematic Review and Meta-Analysis is to cumulatively analyze the effect of vibrational devices on rate of tooth movement in patients undergoing Orthodontic treatment. This systematic review was planned to critically evaluate the existing evidence with respect to the effect of vibrational devices on rate of tooth movement during orthodontic treatment.

2. MATERIALS AND METHODS

Protocol development and Registration

This review was registered on priori based in the International Prospective Register of Systematic Reviews (PROSPERO; CRD42020186581). It was conducted and reported according to the Cochrane Handbook of Systematic Reviews of Interventions version 5.1.0 [24] and following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)[25].

The following focused question in the Patient, Intervention, Comparison and Outcome (PICO) format was posed "Does use of vibrational devices have any effect on the rate of tooth movement in patients undergoing orthodontic treatment?"

Information Sources and Literature Search

An electronic search was carried out by two review authors (RL and GK) in multiple electronic databases without restriction of language on PubMed/ MEDLINE, DOAJ, Cochrane Central Register Controlled Trials and Google Scholar until June of 2020. In addition, a specific electronic search in the following journals was also conducted: American Journal of Orthodontics and Dentofacial Orthopedics, Angle Orthodontist, APOS trends in Orthodontics, Progress in Orthodontics, European Journal of Orthodontics, Seminars in Orthodontics. Searched in the ClinicalTrials.gov database and in the references of included studies (cross-referencing), were also conducted.

MeSH terms, keywords and other free terms related to PICO question were used with Boolean operators (OR, AND) to combine searches. The same keywords were used for all search platforms followed the syntax rules of each database. The search strategy and PICOS tool are presented in Table 1.

Eligibility Criteria

Population (P): Orthodontic patients without any gender or age predilection

Interventions (I): Patients using vibratory device
Comparison (C): Patients who do not use any vibratory device (control)
Outcome (O): There was no restriction on possible data acquisition sources for the primary outcome for assessment of tooth movement like Little's irregularity index, incisor irregularity index
Study design (S): We evaluated only randomized controlled trials (RCTs) conducted in humans.
Time (T): follow-up period kept at 1 week to 5 months approximately

Exclusion criteria
Cross-sectional studies, animal studies, nonclinical studies, case reports and reviews and non-relevant studies were excluded. In addition, studies reporting only a single intervention were excluded.

Primary Outcome
Assessment of rate of tooth movement with the help of Little's irregularity index.

Secondary Outcomes
None

Study Selection
This review included randomized controlled trials that evaluated the effect of vibratory devices on the rate of tooth movement used by patients undergoing orthodontic treatment. The search and screening process were carried out by two independent reviewing authors (RL and GK), following the previously established protocol, first analyzing titles and abstracts. Relevant articles were read in full text and judged against the inclusion/exclusion criteria for a final judgment. Discrepancies among authors/reviewers were resolved through careful discussion by the third author (JS). The search agreement between the two reviewers was evaluated by the Cohen's Kappa (k=0.81) test. If needed, the authors of the included studies were contacted by e-mail for clarification of any doubts.

Data Collection and Data Items
The following data items were extracted from the included studies (when available) by two independent reviewing authors (RL and GK): study identification, setting, authors, study design, follow-up, number of subjects, age, gender, type of vibratory device, pain therapy in control group, measurement methods and outcomes (Table 2) Disagreements were resolved through discussion with other reviewers (JS, KN, UD, VV).

Risk of Bias in Individual Trials
Risk-of-bias assessment was performed independently by two review authors (RL and GK) and any disagreement was resolved through a discussion with other review authors (JS, KN, UD, VV). Quality assessment of the selected studies was executed by using the Cochrane Collaboration Tool [24] for randomized controlled trials (RCTs) including random sequence generation, allocation concealment, blinding of participants, incomplete outcome data, selective reporting, and other bias. A bias judgment of low, high or unclear bias based upon the details mentioned in the individual studies.

Summary Measures and Approach to Data Synthesis
It was considered appropriate to pool the studies if similar interventions and outcomes were presented. Prioritizing the qualitative interpretation of all the studies was undertaken. For continuous data, the mean change scores and their standard deviations were pooled, was chosen as a summary effect measure along with its 95% confidence interval (CI). Differences in means and effect size were used as principal summary measures. Forest plots and funnel plots were created to visualize the differences between groups. The publication bias was not predicted as the number of studies were less than 5. The overall estimated effect was categorized as significant where $p < 0.05$. Both absolute and relative between-study heterogeneity was quantified using the Tau^2 and I^2 statistics. Clinical heterogeneity was inspected by looking into the populations, the different interventions, and outcomes. In all cases, the unit of analysis was the individual patient. Review Manager v5.3 was used for statistical analysis as well as for the risk of bias.

We performed sensitivity analyses to gauge the effects of individual studies on the overall effect estimate and to isolate the effects of studies judged with an overall low risk bias (Table 3). The evidence was thus determined

by using GRADE (Grading of Recommendations Assessment, Development and Evaluation) [26]

3. RESULTS

Study Selection

The initial electronic database search resulted in 3528 titles. 37 articles were cited as duplicates. After screening the abstracts, 326 relevant titles were selected by two independent reviewers and were excluded for not being related to the topic. Following examination and discussion by the reviewers 14 articles were selected for full text evaluation. Hand searching of the reference lists of the selected studies did not deliver additional papers. After pre-screening, application of the inclusion and exclusion criteria and handling of the PICO questions, nine studies remained (two studies with no post intervention data, four studies were inappropriate for outcome of interest and two studies did not have the measures of effect as per the protocol). Seven studies were finally included in the qualitative synthesis which used for data extraction and statistical analysis. Out of the seven, four studies were included in the quantitative synthesis. Figure 1 illustrates the PRISMA flowchart.

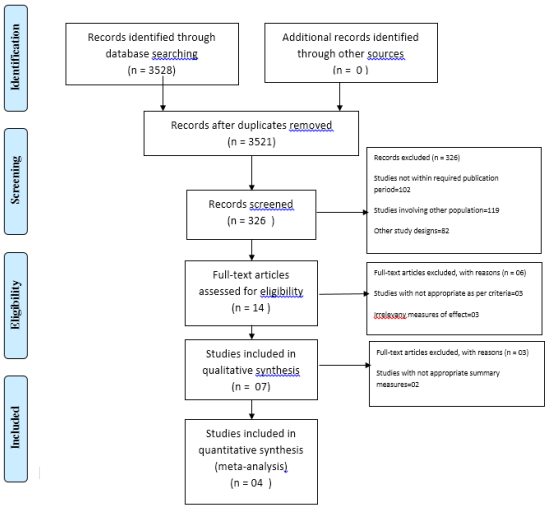

Figure 1: Prisma flow diagram showing the studies exclusion and final inclusion with reason

Study Characteristics

The publication year of studies varied from 2012 to 2020. There are 07 studies [4,5,27-31] included in this review, the general characteristics of which are presented in Table 2. 03 studies were multi-centric, 01 of which was conducted in Canada, Vancouver, and Columbia[5] and the other 02 were conducted at 3 centers in the United Kingdom[29,31]. 02 studies were conducted in Australia[4,28], 01 in Pakistan[27] and 01 in the United States[30]. The study design of all the studies was randomized controlled trial. The age of participants ranged from children to 20 years of age and above throughout the interventions' conducting period, a total of 340 participants were part of the studies' analyses, with 195 in intervention group and 194 in control (positive and passive) groups. Methodological variability was found among the interventions performed in the included studies. Thus, the interventions described by the studies were categorized as follows:

(i) All studies used similar vibratory devices as intervention namely - AcceleDent Aura, Tooth Masseuse and Oral B Triumph powered toothbrush appliances for daily usage
(ii) Additional delivery of information was directed for the daily usage of the appliances for specific time period
(iii) The control group was subjected to -: sham device or no vibration device
(iv) The intervention study period ranged from 1 week to 5 months

Therefore, all intervention selected for this review are vibratory devices from AccleDent Aura[1,5,6,8,9], Oral B Triumph[4] and Tooth Masseus[2] and compared with no vibration device and sham device[1,5,9] as the control group. All the articles were published in English. The follow-up loss ranged from 0% to 10.5%. Details on the different forms of interventions were given in all studies at baseline with different periods of reinforcement depending on the duration of study. (Table 2)

Risk of Bias Within Individual Studies

All studies included were judged to have an overall low risk of bias (Figure 2). Quality assessment of the eleven Randomized Controlled Trials was executed according Cochrane Risk of Bias Tool. Several shortcomings were observed because of the lack of blinding of the participants as well as the investigators. One study had high potential of risk of bias, others showed a low potential risk of bias (Figure 2,3)

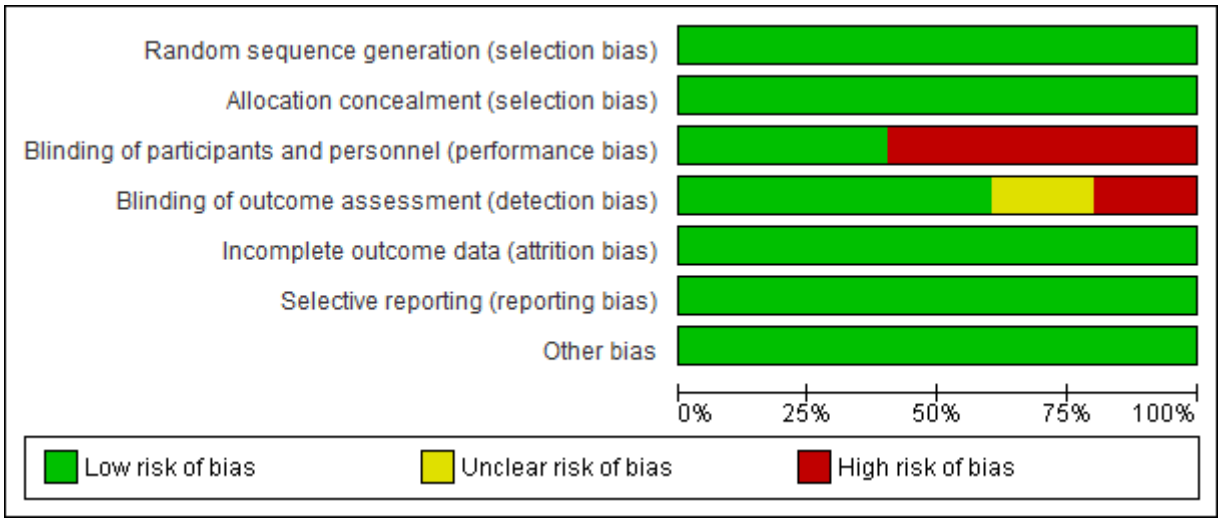

Figure 2- Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies

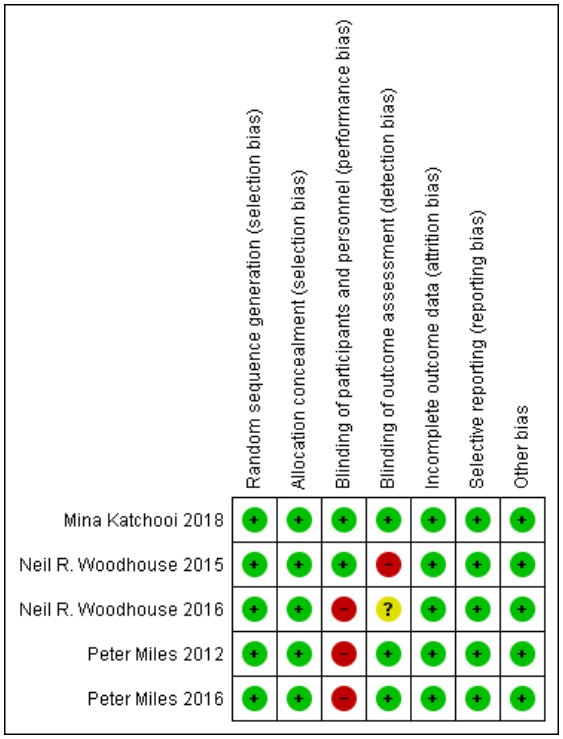

Figure 3- Risk of bias summary: review authors' judgements about each risk of bias item for each included study

Results of Individual Studies and Data Synthesis

A quantitative synthesis (Meta-analysis) was done on the selected two studies. The studies with groups that got any sort of intervention vs. controls concerning the rate of tooth movement assessment outcomes were analyzed. On forest plot deduction for the two studies (Katchooi and Miles 2012), the mean difference was 0.23 (-0.17,0.63) with fixed effect model based on the heterogeneity value of I^2 =0% (Figure 4) not favoring the intervention group, resulting that the vibrational devices do not have any change on the tooth movement when used as an adjunct to aligners. We conducted a subgroup analysis for the assessment of rate of tooth movement when comparing the vibration device with a control group having no vibration device exposure. When the intervention of Vibration device was compared with that of control, the cumulative MD (mean diff) was found to be 0.44 (0.04,0.84) with fixed effect model was used due to significant heterogeneity between studies (I^2 = 0%, p = 0.001). In this analysis there was significant inclination of rate of tooth movement seen favoring the control group, indicating that the vibration device may not all together have any effect on the rate of tooth movement ultimately. (Figure 5)

Publication bias:

Publication bias was not assessed for these outcomes because more than five studies are required to detect funnel plot asymmetry.

Patient-Reported Outcomes

Patient-reported outcome is not a specific outcome but a category of all. Under this domain, none of the studies assessed the rate of tooth movement experienced along with its time or duration. Compliance was not assessed in all the studies hence; pain assessment still can be inconclusive.

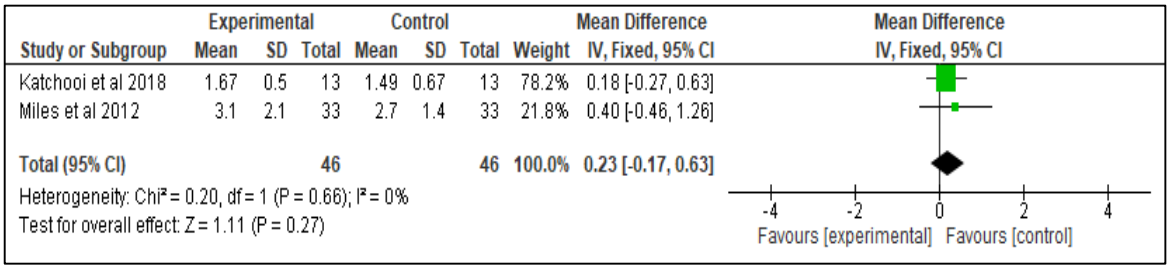

Figure 4 – Forest Plot for tooth movement outcome with Little's irregularity index

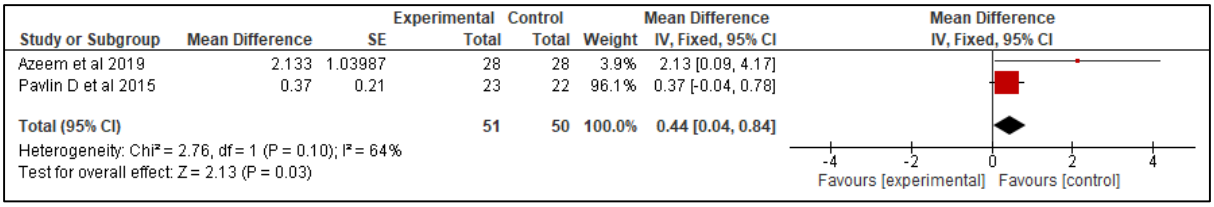

Figure 5- Forest plot for tooth movement with Little's irregularity index

Quality of Evidence

GRADE approach suggested that the quality of evidence was moderate for the explored and intended outcomes. Downgrading was due to shortcomings in the methodological quality of few of included RCTs.

4. DISCUSSION

The number of adults receiving orthodontic therapy is increasing, and the main concern for them is prolonged treatment duration, which poses high risks for caries, root resorption, and decreased patient compliance and satisfaction.[32,33] Various techniques for accelerated tooth movement are invasive in nature as they involve surgical insult.[32,34-41] Recently, an atraumatic technique of accelerated tooth movement by accelerating periodontal and alveolar bone remodeling using vibratory stimulation was introduced.[30,42] A recent study using the Tooth Masseuse device in orthodontic patients reported no effect on the rate of tooth movement, which is in agreement with the present results.[38] This is perhaps because the electronic toothbrush was never intended or designed to accelerate tooth movement, and have insignificant potential to stimulate molecular mechanisms controlling acceleratory tooth movement. Studies on corticotomy[43] and micro-osteoperforations[44] revealed that these minor oral surgical procedures are effective in accelerating orthodontic tooth movement. Furthermore, a recent systematic review and meta-analysis on methods of accelerating orthodontic tooth movement, not including mechanical vibratory stimuli, found some evidence for the effectiveness of corticotomy surgical procedures.[45] In this systematic review and meta-analysis, we aimed to investigate the different types and regimens of vibratory devices used and assessed their association with the rate of orthodontic tooth movement with an intention to verify if this protocol actually reduces the treatment duration in patients undergoing orthodontic treatment. The aim of the current Systematic review and Meta-Analysis was to explore the effect of vibratory stimuli on the rate of orthodontic tooth movement. To our knowledge, this is the first systematic review addressing and assessing the validity of vibrational stimulus to accelerate orthodontic tooth movement. This review included 7 Randomized controlled clinical trials comprising an overall sample of several patients. The heterogeneity in methodology and non-comparability of outcome measures in retrieved publications prevented a quantitative synthesis from being performed in all the 7 articles. Meta-Analysis could be done in only 4 articles out of 7.Therefore, we collected, appraised and qualitatively synthesized the other articles and the currently available literatures to provide evidence regarding this issue.We selected studies with all the interventions using vibratory devices prescribed by orthodontist compared with a control group. The best evidence on vibration and orthodontic therapy after following the meticulous selection criteria ,we finalized 7

studies which were RCTs for this systematic review.

With the exception of five studies[1,2,28,29,31], none of the other studies had rigorous study design which was because of absence of blinding of participants and outcome assessors. Without a doubt, all the included studies had successfully accomplished their study objectives. Summarizing Azeem et al [27] we judged to have high risk of bias, since there was no allocation concealment and blinding of participants and investigators.There were only two studies assessing the pain outcome by using VAS survey which could be considered for meta-analysis with favourable outcome. The two studies showed that there was a significant difference between the groups, advocating the control group ultimately indicating that vibrational devices had no effect in reducing pain. 5 RCTs reported no difference in pain/discomfort perception but 4 RCTs did indicate that there was reduced pain during the initial alignment. The over bias was well accepted and reported in all the studies. The studies cumulatively suggested that there was a trend in the pain levels which were higher in the experimental groups as compared to control in the initial 24 hours but after 1 week to 10 days the pain reduced to similar levels in both the groups. Thus indicating that vibratory devices do not accomplish the task of reducing pain when compared to analgesics to a superior level in the commencing period of orthodontic treatment. Though two of the studies[14,29] did suggest that vibratory devices were effective in reducing pain but the compliance and type of device is also significant along with the duration of use which was reported to be varying from 10 mins to 20 mins with different intervals in a day and with range of 1week to 4 months' usage. The consistency of these effects can be seem to collaborate with most of studies that reported pain levels were high on 1st and 2nd day after the treatment initiation but reduced after a week. Most of the studies involved used AccelDent Aura[1,2,14,30,31] as the intervention, seconded to Tooth Masseus[27,29].

Although this systematic review was performed carefully following normalized procedures, several limitations which deserved further discussion still existed. First, the shortage of high-quality clinical trials is evident. Though a comprehensive literature search was performed, only seven studies were included in this review. Future well-designed studies are needed to obtain a more reliable conclusion. Second, the methodological heterogeneity and non-comparability of original outcomes could bias the qualitative summarization of this review. Third, the language restriction in literature search could have introduced bias into this review.

Recommendations for Future Research

More and future RCTs should be designed to detect differences between intervention groups through a priori sample size which is larger. Investigators are encouraged to report all possible outcomes, risk of bias and associated side effects with outcome measures which can be analyzed. The ideal time period to use the vibrational devices should also be decided to enhance the rate of orthodontic tooth movement. Prospective RCTs should be designed to determine which device is better in increasing the rate of orthodontic tooth movement in initial alignment and also with appropriate outcomes which can be further assessed for meta-analysis.

5. CONCLUSIONS

The ability of vibrational devices to increase the rate of tooth movement and thus reduce overall treatment time among orthodontic patients has been studied in several RCTs. The results indicated by the meta-analysis show that there is no significant difference in the rate of tooth movement outcome after use of vibrational devices as compared to control group which was correlated with majority of the studies included in qualitative analysis. Thus we concluded that vibrational devices have no effect on increasing the rate of tooth movement in patients undergoing orthodontic treatment. Based on current information, weak evidence suggests that vibrational stimulus is effective for accelerating tooth movement and thus is inconclusive. There is a need for well-designed randomized controlled trials to obtain more reliable results.

Declarations

1. Ethical Approval and Consent to participate

Ethical Approval and Consent to participate is taken from Prospero registry for Systematic

review and Meta- analysis. This topic is registered with prospero, with PROSPERO ID - (PROSPERO; CRD 42020186581)

2. Consent for publication
Consent for publication is also taken from Prospero registry for Systematic review and Meta- analysis.

3. Availability of supporting data – Not applicable

4. Competing interests – The authors declare no conflicts of interest

5. Funding – Nil

6. Authors' contributions – All authors have contributed to the fulfillment ad completion of this Systematic review and Meta- analysis

7. Acknowledgements – I would like to acknowledge my co-authors who have been very resourceful throughout the process of completion of this Systematic review and Meta-Analysis

Abbreviations
CI- Confidence Interval
DOAJ- Directory of Open Access Journal
GRADE- Grading of Recommendations Assessment, Development and Evaluation
NSAIDS- Nonsteroidal anti-inflammatory drugs
PDL-Periodontal Ligament
PICOS- Patient, Intervention, Comparison and Outcome
PRISMA- Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCTs- Randomized Controlled Trials
SMD-Standard mean difference
LII – Little's Irregularity Index

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Figure Legends

Figure 1: PRISMA flow diagram showing the studies exclusion and final inclusion with reasons
Figure 2- Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies
Figure 3- Risk of bias summary: review authors' judgements about each risk of bias item for each included study.
Figure 4 – Forest Plot for assessment of rate of tooth movement with Little’s Irregularity Index
Figure 5- Forest Plot for subgroup analysis

Table 1: The search strategy and PICOS tool

Search strategy	
Focused Question	Does use of vibrational devices have any effect on the rate of tooth movement in patients undergoing orthodontic treatment?
Search strategy	
Population	Rate of tooth movement (Text Word) OR Orthodontic patients (Text Word) OR Adolescents [MeSH] OR Using vibrational devices (Text Word) OR Undergoing Orthodontic Treatment (Text Word)
Intervention	AcceleDent(Text Word) OR Vibratory Device (Text Word) OR Sham Device(Text Word) OR Oral B (Text Word) OR Vibration OR Tooth Masseuse (Text Word) OR Electric Toothbrush (Text Word) OR AcceleDent Aura OR Mechanical Vibration (Text Word)
Comparisons	Patients not using a vibratory device OR Non vibratory device group (Text Word)
Outcomes	Rate of tooth movement [MeSH] Incisor Irregularity index OR Little's Irregularity index [MeSH] OR Plaster model (Text Word) OR General Linear model (Text Word)
Study design	Controlled clinical trial, Clinical trial and randomized controlled trial
Search combination	#1 AND #2 AND #3 AND #4 Vibration in Orthodontics AND Accelerated Orthodontics AND Vibratory devices to accelerate rate of orthodontic tooth movement AND Acceledent Aura randomized control trial AND Rate of tooth movement on using vibratory devices AND Effect of vibratory devices on rate of tooth movement in orthodontics
Database search	
Language	English
Eletronic Databases	PubMed/MEDLINE, Cochrane Central Register of Controlled Trials, Google Scholar
Journals	American Journal of Orthodontics and Dentofacial Orthopedics, Angle Orthodontist, APOS trends in Orthodontics, Progress in Orthodontics, European Journal of Orthodontics, Seminars in Orthodontics

Sr. No	Study Id	Place of the study	Study design	Sample size at baseline	Total sample at follow up= N. (drop out %)	Age group	Gender N(%)	Type of vibratory device Intervention group	Type of device in Control group	Follow up period	Outcome assessment (tooth movement assessment)	Mean	Authors Conclusions
1.	Azeem et al	Pakistan 2019	parallel, double-blind, prospective, randomized, controlled trial	28	28	18 to 24 years	M-18 F-10	Oral-B Triumph	No appliance group	60 days	Plaster models	MD-2.133 SE-1.039	The amount of tooth movement was similar for canines on the vibration side and on the non-vibration side (mean 0.81 ± 0.10 mm and 0.82 ± 0.11 mm, respectively, $p > 0.05$).
2.	Katchooi M[2]	Seattle, Washington and Vancouver, British Columbia, Canada. 2018	Multi-centre, 2-arm, parallel, randomized, triple-blinded, active-controlled clinical trial	27	26	18 years or older	M-12 F-14	Acceledent device with coupler that transmitted the vibration to the mouthpiece	Sham device	every 1 week for 3 weeks	Incisor irregularity index	I-1.67±0.5 C-1.49±0.67	The Fisher exact test showed no significant difference in completion rates between the 2 groups (group A, 77%; group B, 85%; P 5 1). Independent-sample t tests showed no significant difference between the final irregularity index or change in irregularity index between the 2 groups.
3.	Pavlin D et al	United States 2015	prospective, randomized, controlled, double-blind, parallel group clinical trial	45	45	12 to 40 yrs	Not specified	AcceleDent	No appliance group	9 months	general linear model	MD-0.37 SE-0.217	Themeanrateofmovementwassignificantlyhigherfor the AcceleDents groupwith1.16mm/month(95%CI:0.86–1.46) comparedto 0.79 mm/month(95%CI:0.49–1.09) inthecontrolgroup,withthemean differenceof0.37mm/month(95%CI:0.07–0.81, P ¼ 0.05). These results showed that low-levelcyclicloadingof0.25 Nat30Hzincreasestherateof tooth movement when applied as an adjunct to orthodontic treatment.
4.	Miles P[28]	Private Practice, Caloundra and	randomised controlled trial (RCT)	66	60	11 to 15 yrs.	M-26 F-40	Tooth Masseuse vibrational	No appliance group	10 week study	Littles Incisor irregularity index	I-3.1±2.1 C-2.7±1.4	The experimental group showed a 65% reduction in irregularity at 10 weeks, while the control group showed a 69% reduction in irregularity over the same period. No significant differences

		University of Queensland Department of Orthodontics, Australia 2012						appliance group					in irregularity or pain levels were observed at any of the time points between the groups. The results demonstrate that, for 20 minute use per day, there appears to be no clinical advantage in using the vibrational appliance for the early resolution of crowding or the alleviation of pain during initial alignment.
5.	Miles P[1]	University of Queensland in Brisbane, Australia 2016	2-arm parallel trial, single-center, randomized clinical trial with a 1:1 allocation.	40	40	children up to age 16	M-26 F-14	AcceleDent Aura appliance group	Sham device	4hours, 24hours, 3 days and 1 week	irregularity index	I-2.8(CI: 1.8-3.8) C-2.2(CI: 1.4-3.0)	The AcceleDent Aura appliance had no effect compared with no appliance on increasing anterior arch perimeter, or reducing irregularity during initial alignment with fixed appliances,
6.	Woodhouse N	3 centres in United Kingdom, brighton, guys and Canterbury 2015	randomised controlled trial (RCT)	81	81	less than 20 yrs. age.	Not specified	vibrational device AcceleDent	identical nonfunctional (sham) device	10 week study	Littles Incisor irregularity index	I-3.1±2.1 C-2.7±1.4	Tooth movement and alignment was able to proceed normally in subjects using functional and non-functional vibratory devices with no significant differences between randomized groups.
7.	Woodhouse N	3 centres in United Kingdom, brighton, guys and Canterbury 2016	A multicenter parallel 3-arm randomized clinical trial	81	81	less than 20 yrs. age	M-40 F-41	vibrational device AcceleDent	identical nonfunctional (sham) device	150 days	Littles Incisor irregularity index	-	This prospective randomized clinical trial found no evidence that supplemental vibrational force can significantly increase the rate of initial tooth movement or reduce the amount of time required to achieve final alignment when used in conjunction with a preadjusted edgewise fixed appliance

Table 2: Characteristics of the included studies

Certainty Assessment						
No. of participants (studies) and Follow-up	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication Bias	Overall certainty of Evidence
SSI (5 RCTs)	Serious [a]	Not serious	Not serious	Not serious	None	□□□o Moderate

-I=Intervention Group
-C=Control Group
-VAS=Visual Analog Scale

M=Male
F=Female

GRADE Approach: Vibrational device vs Control
a Downgraded two levels for risk of bias within all included RCTs.
b Downgraded one level for low number of included trials.
c SMD values denote only the highest and lowest observations. Detailed results are presented
d Downgraded one level for statistical heterogeneity