ORIGINAL PAPER

EFFECTS OF TOOTHBRUSH-GENERATED VIBRATION AND ULTRASOUND ON PAIN PERCEPTION FOLLOWING ORTHODONTIC ELASTOMERIC SEPARATION: A RANDOMIZED CONTROLLED CLINICAL TRIAL

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ABSTRACT

Introduction: Vibration and ultrasound have been recently introduced as methods to enhance orthodontic treatment. Beside the limited number of clinical trials evaluating their effectiveness on modulating pain perception, no clinical trial has reported a comparison of these two methods.

Objectives: The aim of the present study was to investigate the effectiveness of vibration and ultrasound on pain perception alleviation, and to compare the efficacy of both interventions given that no previous study has investigated these aspects.

Material and methods: The research sample consisted of 36 patients, who were randomly assigned into three equal groups (vibration group, ultrasound group, and control group). After elastomeric separator placement, two interventional groups were requested to apply vibration and ultrasound for 5 minutes twice-daily on each upper first molar, whilst control group was not subjected to any physical stimulus. In conjunction with this procedure, a pain assessment questionnaire was distributed to all patients, and a daily assessment by visual analogue scale (VAS) was carried out for 5 days since separators placement.

Results: Subjects in vibration group had lower pain scores at all time-points with significant decrease of pain at the first, fourth, and fifth days of application, compared with ultrasound and control groups. No significant differences were noted between ultrasound and control groups among all observational time-points.

Conclusions: Five-minutes, twice-daily application of vibration contributes to the reduction of pain associated with elastomeric separator placement, and could be a suitable method for pain control in the daily orthodontics practice.

Key words: orthodontics, vibration, ultrasound, pain, pain perception.

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INTRODUCTION

Pain and discomfort are considered one of the collateral effects of orthodontic treatment [1, 2]. It has been reported that placement of elastomeric separators, insertion of arch wires, and activation of orthodontic loops trigger a painful process caused by pressure, inflammation, and edema [2-4]. Pain negatively impact orthodontic patients' various life aspects, including oral health-related quality of life [5, 6], compliance [7], and overall satisfaction with treatment results [1]. Nonetheless, pain perception contributes to difficulty in achiev-

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ing oral hygiene procedures, which lead to other complications, such as white spots, caries, and gingivitis [1, 8].

Historically, numerous interventions have been introduced to ease this pain, including non-steroidal anti-inflammatory drugs [9], brain wave music and cognitive behavioral therapy [10], low-energy laser [11], and bite wafers [12]. Recently, high-frequency vibration and low-intensity ultrasound have been introduced as methods that might ease orthodontic pain [13, 14]. The basis of pain relief using vibration relies on the concept of stimulation-induced analgesia, which originates from the gate control theory of pain that was first reported by Melzack and Wall in 1965. This theory states that the stimulation of large nerve fibers (A-β fibers) by non-noxious stimuli prevents the transmission of pain signals by small fibers (A-δ or C fibers) from reaching the central nervous system and, hence, pain suppressed by the non-noxious stimulus [15, 16]. Moreover, the increased vascularity and reduced areas of ischemia by vibration application were also used to interpret the hypothesis of pain relief [13].

Regarding ultrasound, different medical research projects have indicated its' analgesic effects [17, 18]. Schwartz *et al.* revealed a significant reduced pain in 80% of patients with neuro-muscular disease, when low-intensity ultrasound was applied [18]. Medically, different mechanisms were involved in interpreting the effects of ultrasound on pain perception, including the previously-mentioned concept of stimulation-induced analgesia [16] and the thermal effects [19]. The exposure to acoustic wave of ultrasonic energy causes soft tissue molecules to vibrate. Such an increase in molecular motion generates frictional heat that raises tissue temperature. The increased temperature is thought to cause thermal effects, including an increase in enzymatic activity, local blood flow, and pain threshold [20, 21]. However, thermal effect mechanism have be considered with caution while interpreting ultrasound treatment effects, as the currently used intensities are very low [22]. In orthodontics, only one registered completed randomized control trial NCT01828164 investigated the impact of ultrasound on orthodontic pain perception. The reported results in ClinicalTrials.gov indicate that ultrasound was able to significantly reduce orthodontic pain during canine retraction compared with control group.

Electronic literature searches yielded four recently conducted systematic reviews, reporting an inconclusive potential positive effect of vibration on orthodontic pain perception and thus, raising the need for more studies in this domain [8, 23-25]. Beside the dearth of evidence at present, no clear consensus exists as to the most appropriate protocol of application for both interventions (i.e., vibration and ultrasound), including number and duration of sessions. The application protocol of vibration and ultrasound used in majority of studies assessing pain alleviation, included 20 minutes, single-daily application of stimulation [26-28]. However, a recent recommendation in this field was drawn by Celebi *et al.* proposing that multiple applications of stimulation might be more effective than a single one [29]. Moreover, the used vibration and ultrasound devices have to be applied by patients themselves every day and thus, needs highly compliant patients. Therefore, examining the efficacy of lower durations per session is of major importance to ensure compliance. Additionally, toothbrushes were chosen to generate vibration and ultrasound as they are available and feasible methods for patients to use.

OBJECTIVES

Since introduction, the objectives of this randomized controlled trial were to investigate the effectiveness of 5 minutes, twice-daily application of vibration and ultrasound on pain perception manipulation, and to compare the efficacy of both interventions given that no previous study has investigated these aspects.

MATERIAL AND METHODS

This study was a three-arm parallel randomized controlled clinical trial, in which participants were randomly assigned into three equal groups (vibration, ultrasound, and control groups). The consolidated standards of reporting trials (CONSORT) statement was utilized as a guide for this study [30]. Ethical approval was attained from an ethics committee of the Ministry of Higher Education in (blocked now for peer review). No changes occurred in the methodology after trial commencement.

The study was conducted at the Department of Orthodontics and Dentofacial Orthopedics at the Faculty of Dentistry, (blocked for peer review) University. Participants were recruited from patients referred to or registered in the archives of the department. Eligibility criteria included the following: 1) adult patients (16-30 years old) with full permanent dentition, 2) no history of orthodontic treatment, 3) patients scheduled to undergo orthodontic treatment and required banding, 4) mildly crowded maxillary teeth with tight proximal contacts, where cases can be treated by leveling and alignment without extraction, 5) healthy periodontal tissues and reasonable oral health, 6) absence of treated or untreated apical lesions or tissue ulcers, 7) no consumption of drugs that may interfere with pain perception.

Patients were excluded from the study if 1) the elastomeric separators were removed during observational period, or 2) patients reported consumption of analgesics or anti-inflammatory drugs.

Sample size was calculated using Minitab (Minitab Inc., Pennsylvania, USA) with a power of 0.85, a significance level of 0.05, and assuming that the smallest difference to detect a change in pain level was 9.9 mm on a visual analog scale (VAS), with a variation of 7.7 mm, as reported in a previous study [31]. The result of this

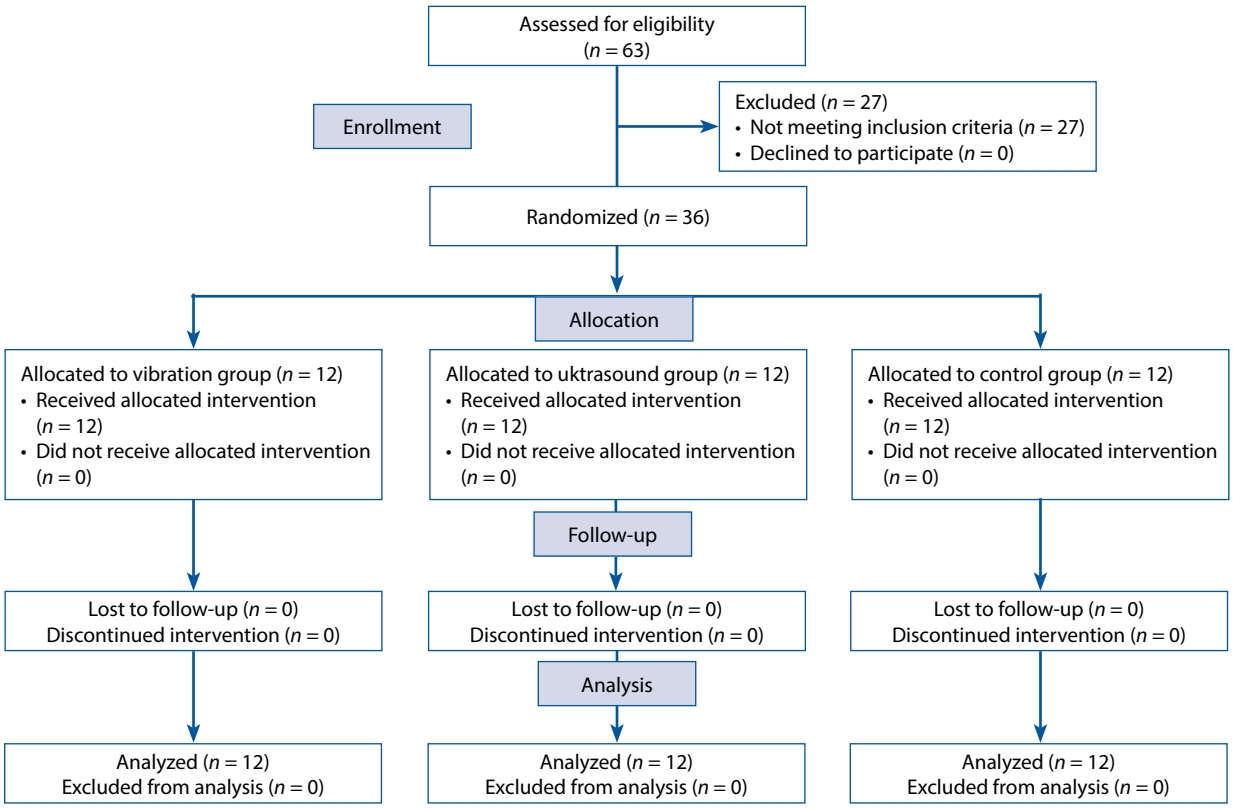

FIGURE 1. CONSORT flow diagram of patients flow throughout the study

calculation showed that a sample of 36 patients was required, i.e., 12 patients in each group.

Informed consent was obtained from all individual participants included in the study. Patients were randomly and equally distributed into three groups (vibration, ultrasound, or control) using a simple, manual random distribution. A shaded sealed envelope was drawn from multiple envelopes indicating the group to which the patient would belong. Envelopes for group assignments were opened after placement of elastomeric separators to ensure allocation concealment.

Subjects and principal investigator blinding to the use of vibration, ultrasound, or neither was not possible; however, pain questionnaires were coded appropriately, so that both outcome assessor and statistician were blinded to the assignment.

A detailed verbally and written explanation of the research objectives and methods were provided to all patients who met the inclusion criteria. Elastomeric separators (0.5 mm, Ortho Classic, Las Vegas, USA) were inserted at the mesial and distal of both maxillary first molars. Then, vibration was applied on the buccal aspects of each maxillary first molar twice a day for 5 minutes at each session, using electrical toothbrushes (Oral B Vitality™ Sonic; Procter & Gamble Company, Ohio, USA). Ultrasound was applied on the buccal aspects of dentoalveolar ridge of each maxillary first molar twice-daily for 5 minutes at each application, using ultrasound emitting toothbrushes (Emmi dent; Emmi Ultrasonic Co., Mörfelden-Walldorf, Germany). Patients assigned to the control group received no physical stimulation. In conjunction with this procedure, a pain assessment questionnaire was distributed to all participants, and a daily assessment was carried out for 5 days since the placement of elastomeric separator.

The main outcome measure was the maximum amount of spontaneous pain scored for the maxillary first molars at each day. Pain was assessed by questionnaires that were formulated using 100 mm visual analogue scale (VAS). It was instructed to place a sign at the number representing the intensity of pain felt, where marking the number '0' indicated 'no pain', while the most severe pain was indicated as '100'.

Statistical Package for Social Science (SPSS for Windows, version 22.0; SPSS, Chicago, USA) was applied to perform statistical analysis. Initially, a test of homogeneity was carried out for variables that can manipulate pain-based results, including age of participants, gender distribution, and crowding severity among the studied groups. Then, Shapiro-Wilk normality test was used. Accordingly, Kruskal-Wallis *H* test was selected to compare the results of the three studied groups. Finally, Mann-Whitney U test was applied, whenever appropriate, to compare VAS scores of each two groups.

TABLE 1. Baseline characteristics of patients

Groups	*n*	Sex		Mean age	SD of mean age	Mean Little's index value	SD of mean Little's index value
		Female	Male				
Vibrations	12	11	1	20.75	3.54	7.95	3.26
Ultrasound	12	10	2	17.91	2.39	7.79	2.06
Control	12	9	3	20.16	3.32	7.48	2.25
Total sample	36	30	6	19.61	3.28	7.74	2.51

RESULTS

Thirty-six patients were recruited to the trial between August 2019 and December 2019, with 12 patients allocated to each group. Figure 1 shows CONSORT flow diagram illustrating patients flow throughout the study. A complete follow-up and analysis were achieved for all patients.

Baseline characteristics of patients in each group are reported in Table 1. The results of homogeneity tests revealed no significant differences between the groups in terms of participants' mean age (p = 0.07), gender distribution (p = 0.54), and crowding severity (p = 0.90). Homogeneity tests results are shown in Table 2.

An intention-to-treat analysis was primarily planned to involve all patients who were randomly assigned to the treatment; however, no dropouts occurred during the study. Table 3 represents Kruskal-Wallis H test results of comparing pain intensities of the three studied groups in the five evaluated time points. A significant difference was observed between the three groups at the following time points: First day (p = 0.04), fourth day (p = 0.03), and fifth day (p = 0.02), whilst no differences were appreciated in the second and third days.

Mann-Whitney U test was performed for the time points, showing intergroup significant differences in comparing each two groups. The results of this test are shown in Table 4. At days 1, 4, and 5, a significant reduction in pain scores was noticed in the vibration group compared with the ultrasound and control groups. No other significant differences were observed. The linear chart was used to express pain level changes across the studied groups at all observational time points, as shown in Figure 2.

TABLE 2. Homogeneity tests

Variables	Test used	*p*-value
Participants' mean age	One-way ANOVA	0.079 (N.S.)
Sex distribution across groups	χ^2	0.549 (N.S.)
Crowding severity across groups	One-way ANOVA	0.908 (N.S.)

TABLE 3. Results of comparing pain intensities of the three groups with five evaluation time points using Kruskal-Wallis H test

Groups/Outcome	Mean rank	χ^2	*p*-value
Pain intensity at day 1			
Vibrations	12.33	6.302	0.043*
Ultrasound	21.54		
Control	21.63		
Pain intensity at day 2			
Vibrations	15.75	1.524	0.467 (N.S.)
Ultrasound	18.75		
Control	21.00		
Pain intensity at day 3			
Vibrations	14.96	2.337	0.311 (N.S.)
Ultrasound	19.17		
Control	21.38		
Pain intensity at day 4			
Vibrations	12.08	6.926	0.031*
Ultrasound	20.96		
Control	22.46		
Pain intensity at day 5			
Vibrations	11.83	7.417	0.025*
Ultrasound	21.13		
Control	22.54		

*NS – non-significant difference (p > 0.05). *Significant difference (p ≤ 0.05)*

DISCUSSION

Pain is an unpleased sensory and emotional experience that involves activating multiple areas responsible for receiving pain in the brain [2]. Despite the fact that orthodontic-induced pain could not be avoided, clinicians should take all possible precautions, which could provide more comfortable treatment, including the use of adjunctive interventions contributing to pain reduction [29].

To our best of knowledge, this was the first randomized controlled trial that assessed and compared the efficacy of vibration and ultrasound in alleviating orthodontic pain perception. The electronic literature search in PubMed and Scopus have yielded several randomized controlled trials, which investigated pain alleviation by vibration [13, 26, 29, 32, 33]. In these studies, a protocol of a single-daily application of stimulation was utilized,

TABLE 4. Results of Mann-Whitney U test of comparing each two groups at time points with significant differences

Groups/Outcome	Mean rank	Sum of ranks	*z*-value	*p*-value
Pain intensity at day 1				
Vibrations vs. control				
Vibrations	9.67	116.00	–1.994	0.046*
Control	15.33	184.00		
Ultrasound vs. control				
Ultrasound	12.29	147.50	–0.147	0.883 (N.S.)
Control	12.71	152.50		
Vibrations vs. ultrasound				
Vibrations	9.17	110.00	–2.332	0.020*
Ultrasound	15.83	190.00		
Pain intensity at day 4				
Vibrations vs. control				
Vibrations	9.13	109.50	–2.373	0.018*
Control	15.88	190.50		
Ultrasound vs. control				
Ultrasound	11.92	143.00	–0.408	0.683 (N.S.)
Control	13.08	157.00		
Vibrations vs. ultrasound				
Vibrations	9.46	113.50	–2.127	0.033*
Ultrasound	15.54	186.50		
Pain intensity at day 5				
Vibrations vs. control				
Vibrations	8.96	107.50	–2.472	0.013*
Control	16.04	192.50		
Ultrasound vs. control				
Ultrasound	12.00	144.00	–0.350	0.726 (N.S.)
Control	13.00	156.00		
Vibrations vs. ultrasound				
Vibrations	9.38	112.50	–2.182	0.029*
Ultrasound	15.63	187.50		

*N.S. – non-significant difference ($p > 0.05$). *Significant difference ($p \leq 0.05$)*

with durations that varied between 15 and 20 minutes per day. Alternatively, a protocol of 5 minutes, twice-daily application of stimulation was applied in the current study.

Visual analog scale (VAS) was used to assess pain levels in this study. Despite being affected by personal differences between individuals, VAS is considered the most available used method in studies on pain evaluation [34]. It has been reported that the intensity of orthodontic pain caused by elastomeric separation was greatest at 12-24 hours following separator placement, and then decreased gradually [35, 36]. Therefore, the present study targeted the first five days of application.

Since pain is a complex phenomenon that is influenced by multiple factors, such as age, gender, and the amount of force applied [2, 37], having a uniform distribution of subjects among groups based on these factors is crucial when assessing levels of pain. Krishnan indicated that the severity of pain perception can depend on patient's age and gender [2]. Petrini *et al.* found differences in pain tolerance and assessment among patients of different ages [37]. In the current study, these variables were accordant among the groups.

Our results found a general decrease in pain perception at all five observational time points, when vibrations were applied for 5 minutes, twice-daily, with a significant reduction in three time points. Taking into account that the intensity of pain is greatest at the first day following separators placement [35, 36], the signif-

icant decrease in pain at day 1 is clinically beneficial. Our findings are in disagreement with previous studies. Woodhouse *et al.* [27] Taha *et al.* [28], and Miles *et al.* [26] found that vibration application had no impact on orthodontic pain perception. This could be attributed to the protocol used in the present study, which involved a twice-daily application of stimulation. With the understanding of stimulation-induced analgesia to indicate pain suppression, multiple vibration applications per day could induce multiple activations of large diameter sensory nerve fibers, which might be needed to obtain a long-term pain relief. Of note, our results showed that lower durations of vibration (10 minutes/site) could be enough to stimulate the analgesic effect.

Although pain perception was reduced in the ultrasound group compared with the control group, this reduction was not statistically significant at all time points. The present findings disagree with results of the registered completed randomized control trial NCT01828164, which indicated a significant reduction of pain perception when using ultrasound. Considering that the registered study applied ultrasound for 20 minutes per day, this might indicate the need of more than 10 minutes of ultrasound application at each molar per day to achieve the desired analgesic effect.

The inability to blind patients is considered one of the limitations of this study. Additionally, so far, there is little to no reliable method to determine whether patients are using their devices as instructed. Although some vibrational devices contain indicators that track usage time, these indicators cannot confirm the intraoral use of a device with possible errors in data synchronization, as indicated in a previous study [27]. Finally, the application of paper-based questionnaires does not allow the researcher to know precisely when the patients entered their responses, which might increase the potential of retrospective documentation. Therefore, it is recommended to record pain scores of future studies using internet-based questionnaires, in which date and time of documentation are recorded accurately.

Finally, the potential problems related to a patient's compliance with instructions could be encountered in everyday clinical practice, and any study that might repeat the design of the present research could face these issues. However, we believe that our results reflect the real use of the two devices and thus can be generalized to other subjects of the same age and with the same malocclusion.

CONCLUSIONS

The present study evaluated the efficacy of 5 minutes, twice-daily application of vibration and ultrasound on pain perception following elastomeric separation, and assumed that five minutes, twice-daily application of vibration contributes to the reduction of pain associated with elastomeric separation. However, the application of ultrasound within the same duration did not cause any significant alleviation in the perception of pain.

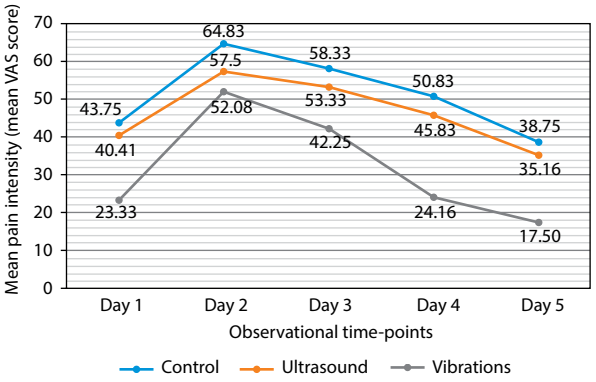

FIGURE 2. Pain level changes across the studied groups at all observational time points

CONFLICT OF INTEREST

The authors declare no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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