

The effects of a vibrational appliance on tooth movement and patient discomfort: a prospective randomised clinical trial

Peter Miles,^{*,†} Heath Smith,[†] Robert Weyant⁺ and Daniel J. Rinchuse[†]

Private Practice, Caloundra and University of Queensland Department of Orthodontics, Australia,^{*} Seton Hill University Graduate Program in Orthodontics, Greensburg, Pennsylvania, USA[†] and Department of Dental Public Health and Information Management, School of Dental Medicine, University of Pittsburgh, Pittsburgh, Pennsylvania, USA⁺

Introduction: The aim of this study was to assess the rate of tooth movement and discomfort experienced by orthodontic patients using a vibrational appliance (Tooth Masseur).

Methods: In this randomised controlled trial (RCT), 66 consecutive patients were assigned to a control or experimental group. The experimental group was instructed to use a vibrational appliance for a minimum of 20 minutes per day. All of the patients had the same fixed appliance and a 0.014 inch thermal NiTi wire during the 10 week study period. Impressions of the mandibular six anterior teeth were taken at 4 time points: at the start of treatment, 5 weeks, 8 weeks, and at 10 weeks after commencement. Little's Irregularity Index was used to record alignment and assess the rate of tooth movement. A discomfort score chart was used to evaluate patient pain levels at 5 time points.

Results: 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 in irregularity or pain levels were observed at any of the time points between the groups.

Conclusions: 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. (Aust Orthod J 2012; 28: 213–218)

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Peter Miles: pmiles@beautifulsmiles.com.au; Daniel J. Rinchuse: drinchuse@setonhill.edu

Introduction

Orthodontists and patients would prefer the shortest treatment time possible. Treatment time is inherently dependent upon an individual's rate of tooth movement and so the possibility of accelerating the biological response of the PDL¹ and alveolar remodelling has potential beneficial effects.

Although the exact mechanism of alveolar remodelling is not completely understood, there are two main theories: (1) piezoelectricity generated in the alveolar bone, and (2) pressure-tension within the PDL.² Piezoelectricity proposes that orthodontic induced bending of alveolar bone generates an electrical charge, which, in turn, initiates an osteogenic response.³ This

was supported by Zengo et al.,⁴ who demonstrated electronegative and electropositive properties of osteoblasts and osteoclasts, respectively. The pressure-tension theory involves alterations in blood flow through the PDL which activates cellular responses through chemical mediators.²

Based upon the piezoelectricity theory, Davidovitch et al.⁵ suggested that applying exogenous electrical currents could accelerate tooth movement. These electrical potentials could simply be created by applying a force to bend alveolar bone and generate piezoelectric charges.⁶ Shapiro et al.⁶ stated that these forces should not be continuous as the piezoelectricity is only created when stress is applied and released.

Therefore, vibrational appliances could be effective in initiating stress-induced changes by applying intermittent forces at a rapid rate.

Kopher and Mao⁷ found that applying cyclic forces to craniofacial bones in growing rabbits enhances sutural growth. This finding was further supported by an extension and continuation of the sutural study and additional work involving the cyclic loading of craniofacial bones in a postnatal rat model.^{8,9}

A secondary mode of action of vibrational appliances may involve perturbations and the reduction of the stick-slip behaviour between wires and brackets. An *in vitro* study found that 'the reduction of frictional resistance was proportional to the magnitude of the perturbations'.¹⁰ A further *in vitro* study evaluated an applied vibration frequency of 1.35 Hz when brackets were displaced by amounts of 0, 0.25, 0.5, and 1 mm to produce a resistance to sliding.¹¹ It was found that 0.16 mm of mesio-distal crown movement produced up to 85% reduction in sliding resistance. Liew et al.¹² showed a 60-85% reduction in friction was produced by vertical wire displacement as a result of 25-400 grams of applied force. However, recent literature¹³ suggests that *in vitro* studies do not accurately reflect the clinical mode of archwire sliding. Intra-oral forces such as mastication, greatly reduce the frictional resistance between brackets and archwires, which has led to an 'overestimation of the clinical significance of friction'.¹³

Initial research involving vibrational appliances and orthodontic tooth movement was limited to animal models.¹⁴⁻¹⁶ Nishimura et al.¹⁴ has shown in Wistar rats that approximately 15% more tooth movement was achieved in 21 days by utilising resonance vibration for 8 minutes per day (on days 0, 7, and 14), when compared with a control group affected by only static forces. Loading a vibrational force in *Macaca fuscata* monkeys for 1.5 hours per day over three weeks was reported to provide 1.3 to 1.4 times greater tooth movement (~25-30% faster) than loading by a static force.¹⁵ An increase in tooth movement of this magnitude achieved in humans would be considered clinically significant.

'Promising rates of tooth movement' were described in initial articles involving vibrational forces applied to human subjects for 20 minutes per day.^{17,18} Approximately 2-3 mm of tooth movement per month in both arches was reported by measuring the

reduction in Little's Irregularity Index;¹⁹ however, these studies may be questioned because of inadequate sample sizes and controls.

In addition to faster orthodontic tooth movement, it has been proposed that vibratory stimulation can decrease pain following orthodontic adjustments. Ottoson et al.²⁰ found that applying vibration at 100 Hz to various points in the skull and facial region reduced pain in 30 of 33 patients suffering from dental pain of various types. Other research demonstrated a reduction in musculoskeletal pain in 69% of patients by using vibratory stimulation²¹ while vibro-tactile stimulation was shown to reduce musculoskeletal pain by as much as 40 per cent.²²

Currently there has not been a published randomised clinical trial (RCT) conducted on human subjects. Therefore, the purpose of the present RCT was to assess the rate of tooth movement and discomfort experienced following the use of a vibrational appliance on orthodontic patients.

Material and methods

Ninety-four consecutive orthodontic patients from the private practice of one author (PM) were invited to participate in the study. Subjects were selected based on the following inclusion criteria: children aged between 11-15, a non-extraction treatment plan in the lower arch, no impactions/unerupted teeth, fixed appliances bonded from first molar to first molar in both arches, and living locally to allow for additional appointments for impressions. Of the 94 patients, 28 did not meet the inclusion criteria or declined to participate, leaving a study cohort of 66. The CONSORT 2010 Statement²³ was used as a guide for the clinical trial. All patients and families were informed of the purpose and methodology of the study and consented to participate. Ethical approval was also obtained prior to the start of data collection from the Institutional Review Board at Seton Hill University, Greensburg, Pennsylvania, USA.

Patients who met the inclusion criteria (Figure 1) were randomly assigned in blocks of six to ensure even numbers in the control and experimental groups. The experimental group was instructed to use a vibrational appliance (Tooth Masseur, Figure 2) which applied a vibrational frequency of 111 Hz and 0.06 N (~6.1 g) for 20 minutes per day, or more if desired. The first

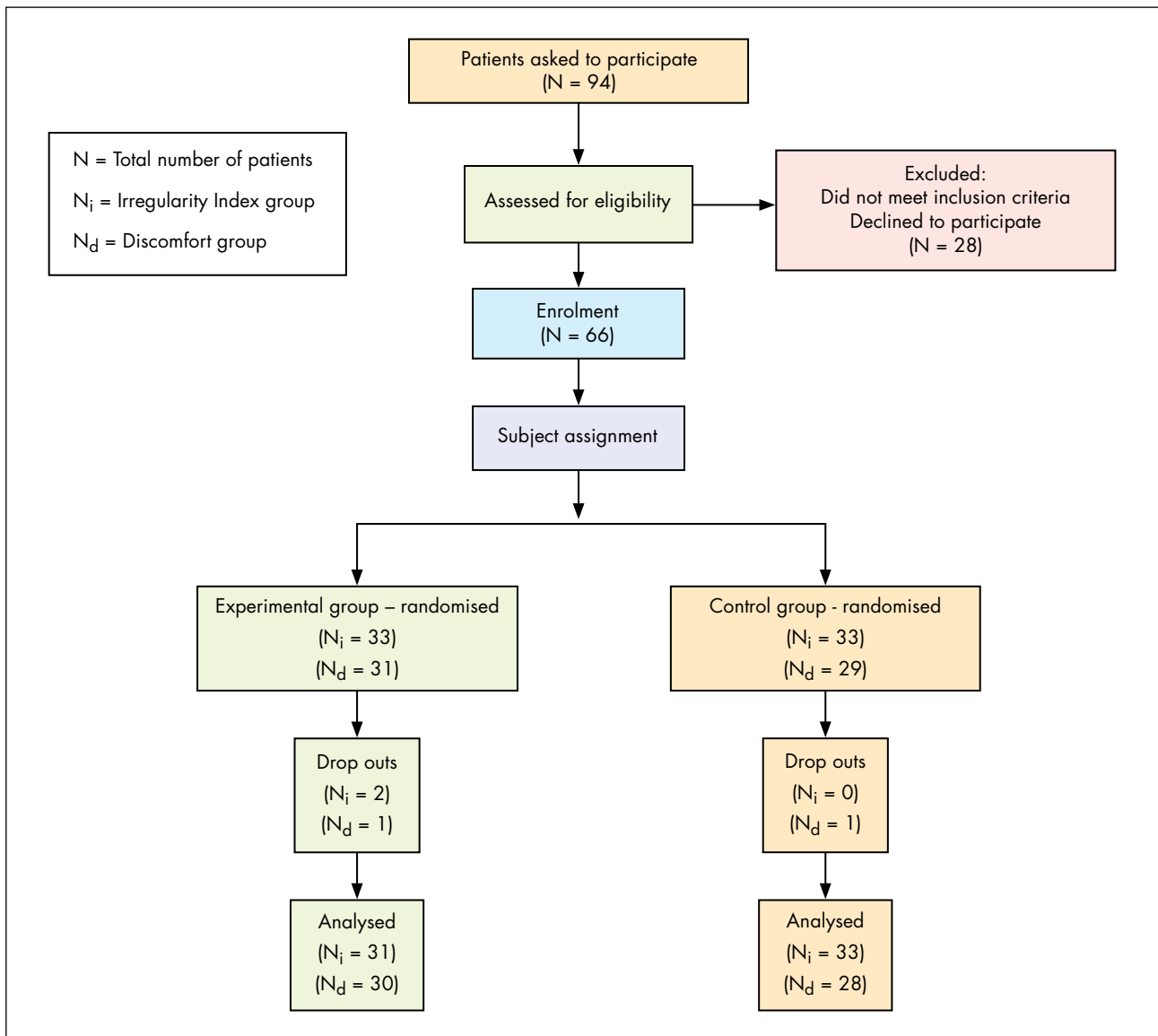


Figure 1. Consort diagram for patient participation.

Flow chart modelled after: Moher et al. Consort 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trials. BMJ 2010; 340:c869.

use was immediately after the initial wire was placed, to alleviate discomfort while patient instructions were being delivered. All patients were treated with conventional 0.018 inch slot, MBT prescription brackets (Victory Series, 3M Unitek, Monrovia, CA, USA). The arch wire in both groups was a 0.014 inch M5 Heaters™ thermal NiTi wire (G&H Wire Co., Franklin, IN, USA) which remained in place during the 10-week experimental time period. Alginate impressions of the lower anterior teeth were taken at 4 time points: at the start of treatment, at 5 weeks, 8 weeks, and at 10 weeks after commencement. The



Figure 2. Tooth Masseur

Table I. Pretreatment demographics.

	Control group	Experimental group
Age, mean (standard error) in years	13.1 (0.18)	13.0 (0.18)
Number of Males	14	12
Number of Females	19	21

impression at 8 weeks was used to assess the possibility that initial alignment may occur 20% faster when using vibration, but no wire adjustment or retying was performed. The starting arch wire was retied at the 5-week appointment but no other adjustment was made during the 10-week study period. The clinician was blinded to the study participants at all appointments. Identification numbers were assigned to the models prior to measurement to ensure blinding. The irregularity index was measured by one of the authors (PM). After data collection was complete, the model numbers were matched back to the corresponding patients.

Little's Irregularity Index²⁴ was used to record irregularity at 4 time points: at the start of treatment, at 5 weeks, 8 weeks, and at 10 weeks. A discomfort score chart was used to evaluate the pain levels experienced by each patient. The patient was instructed to record the level of discomfort at 5 different time points by placing a mark on a 100 mm VAS (Visual Analogue Scale).²⁵ The 5 time points were: immediately after initial bracket and wire placement, 6-8 hours after appliances were placed, 1 day after, 3 days after, and 7 days after appliances were placed. Patients were asked to avoid analgesics containing ibuprofen, as the rate of tooth movement can potentially be affected.^{26,27} A staff member who was blinded to the study groups and trained in the use of a micrometer measured the VAS data.

Statistical analysis

A power analysis based upon data from a previous study²⁸ demonstrated that for a clinically significant difference of 20% faster alignment/reduction in

Table II. Irregularity index values.

Time point	Control group	Experimental group
T0 (initial), mean (SD) in mm	4.9 (2.5)	6.2 (3.7)
T1 (5 weeks), mean (SD) in mm	2.7 (1.4)	3.1 (2.1)
T2 (8 weeks), mean (SD) in mm	1.9 (1.0)	2.4 (1.3)
T3 (10 weeks), mean (SD) in mm	1.6 (0.9)	2.1 (1.1)

irregularity, a sample size of 59 would be required to achieve a 90% power at a significance level of 0.05. To allow for 10% dropout, a final sample of 66 subjects was chosen. The data from the various time points were compiled on a spreadsheet and submitted for statistical analysis using JMP® Version 7 (SAS Institute Inc., Cary, NC, USA 1989-2007). Means were calculated for irregularity and pain scores so that changes between the time points could be compared. A one-way ANOVA was used to determine if there was a statistically significant difference in age between groups and gender was evaluated by using a contingency analysis. A matched pairs *t*-test was used to determine differences in the irregularity indices and pain scores. Paired *t*-tests were used to evaluate the reliability of measures. A significance level of $p \leq 0.05$ was used for all tests.

Results

Sixty-six patients were enrolled in the study, of whom 64 patients reported for all 4 impression appointments. Pain scores were recorded by 60 patients, with 58 completing all 5 time points. Table I shows the pretreatment demographics of both groups. The age range for the study was 11.1 to 15.7 years with an average age of 13.1 years for the control group and 13.0 years for the experimental group. Table II shows the mean irregularity indices for both groups at the 4 time points. The initial irregularity means for the control and experimental groups were 4.9 mm and 6.2 mm, respectively. After 10 weeks of treatment, the control group had a mean irregularity index value of

Table III. Mean irregularity differences.

Time point	Control group	Experimental group
T0-T2, mean (SD) in mm	3.1 (2.4)	3.4 (2.7)
T0-T3, mean (SD) in mm	3.4 (2.4)	4.0 (3.3)

1.6 mm, while the experimental group had a mean irregularity index value of 2.1 mm. Table III shows the mean irregularity difference for both groups at the 8 and 10 week time points. The irregularity difference between T0-T3 (10 weeks of treatment) was 3.4 mm for the control group and 4.0 mm for the experimental group. Table IV shows the mean VAS score for both groups at the 5 time points following appliance placement.

Discussion

The scheduled appointment for placement of the second archwire in PM's practice is routinely at 10 weeks.²⁹ If a vibrational device can cause a 20% increase in the rate of tooth movement, then hypothetically, the second wire could be placed at 8 weeks which relates to the extra appointment in the study protocol. At the 8-week time point, the appliance group irregularity reduced 3.4 mm while the control group irregularity reduced by 3.4 mm at the 10-week time point. This would imply that the appliance would achieve a 20% faster reduction in irregularity. However, despite the randomisation process, there were five outliers with an irregularity index greater than 10 mm which were all assigned to the experimental group and resulted in a higher initial irregularity in this group. Therefore, a comparison of the two groups required an account of the difference in baseline irregularity. The experimental group demonstrated a 55% (3.4/6.2) reduction in irregularity at 8 weeks, while the control group demonstrated a 63% (3.1/4.9) reduction in irregularity at 8 weeks. By 10 weeks the experimental group demonstrated a 65% (4.0/6.2) reduction in irregularity while the control group demonstrated a 69% (3.4/4.9) reduction in irregularity. Therefore, the results indicated no advantage in using the Tooth Masseur for the early resolution of crowding. In addition, the results also indicated no significant benefit in using the appliance to reduce pain.

Table IV. VAS scores.

Time point	Control group	Experimental group
T0, mean (SD) in mm	8.1 (12.3)	12.4 (13.3)
T1, mean (SD) in mm	39.6 (25.8)	40.4 (20.8)
T2, mean (SD) in mm	47.6 (24.5)	41.5 (27.2)
T3, mean (SD) in mm	19.9 (15.5)	18.8 (18.5)
T4, mean (SD) in mm	5.5 (7.8)	4.0 (6.3)

It is imperative that when clinicians evaluate the effectiveness of new appliances, there is an awareness of the potential for observational bias. For example, an enthusiastic clinician may decide to change to the next archwire at 8 weeks instead of 10 weeks; however, because of normal biological variation, some patients could have changed to the next wire at 8 weeks anyway. Therefore, positive results can be easily misconstrued by observational bias and the lack of controls can result in false conclusions.

Obviously the results of this study may not be generalised to other vibratory devices since we used a specific vibratory device (Tooth Masseur), a particular vibratory frequency (111Hz), and force (0.06 N ~6.1 g). In addition, Rinchuse et al.³⁰ have argued that a protocol of consecutively treated patients may not provide a homogeneous sample that can be randomised into treatment and control groups. It would have been preferable to have the same baseline irregularities for both groups so that a stratification or minimisation strategy could have been employed.

Conclusions

The present results demonstrate no advantage in using the Tooth Masseur for 20 minutes per day for the early resolution of crowding or the alleviation of pain.

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Corresponding author

Dr Peter Miles
10 Mayes Avenue
Caloundra, Queensland, 4551
Australia
Email: pmiles@beautifulsmiles.com.au

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