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Supplemental Vibrational Force During Orthodontic Alignment: A Randomized Trial

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Abstract

This prospective 3-arm parallel-group randomized clinical trial investigated the effect of supplemental vibrational force on rate of orthodontic tooth alignment with fixed appliances. Eighty-one subjects (40 males, 41 females; mean age, 14.1 y) undergoing first premolar extraction-based fixed appliance treatment were randomly allocated to treatment supplemented with daily use (20 min) of a removable intraoral vibrational device (AcceleDent; OrthoAccel Technologies Inc.; n = 29), an identical nonfunctional (sham) device (n = 25), or fixed appliances only (n = 27). Mandibular study casts were taken at baseline (treatment start: placement of 0.014-in. nickel-titanium arch wire), initial alignment (0.018-in. nickel-titanium arch wire), and final alignment (0.019 x 0.025–in. stainless steel arch wire). Overall mean irregularity index in the mandibular arch at baseline was 8.5 ± 3.8 mm (95% CI, 7.6 to 9.3) with no significant difference between groups (P = 0.73). For the total sample, mean irregularity index at initial alignment was 2.7 ± 2.8 mm (95% CI, 2.2 to 3.4) with no significant difference between groups (P = 0.40). Mean time from baseline to initial alignment was 59 ± 25 d (95% CI, 54.5 to 65.6); from initial to final alignment, 150 ± 62.5 d (95% CI, 136 to 165); and baseline to final alignment, 209 ± 65 d (95% CI, 195 to 224). Kaplan-Meier analysis demonstrated that patterns of alignment were not significantly different among the 3 groups (P = 0.66). Multivariate linear regression for initial and overall alignment rates using initial irregularity index as the covariate showed no significant differences among groups. The most important influence on both initial and overall rates of alignment was initial irregularity ($P = 0.1 \times 10^{-4}$). 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 (ClinicalTrials.gov NCT02314975).

Keywords: orthodontic appliances, AcceleDent, corrective orthodontics, prospective investigation, tooth movement, vibration

Introduction

Successful orthodontic tooth movement relies on appropriate tissue remodeling within the periodontium following the application of external force (Krishnan and Davidovitch 2006, 2009; Meikle 2006). Although this response is almost instantaneous at the cellular level, orthodontic tooth movement is relatively slow, and treatment times are often in the order of 2 y for comprehensive fixed appliance therapy (DiBiase et al. 2011; Songra et al. 2014). Given the potential negative consequences of prolonged fixed appliance treatment, orthodontists have sought adjuncts to reduce treatment time.

One technique that has been proposed to increase the rate of orthodontic tooth movement is the application of intermittent vibrational force to the dentition (Darendeliler et al. 2007; Nishimura et al. 2008; Kau et al. 2010). It has been recognized for over a century that bone mineral density can be influenced by the environment—particularly peripheral loading, which is exemplified by the significant bone loss observed in astronauts exposed to extended periods of microgravity (LeBlanc et al. 2000). High-frequency, low-magnitude mechanical stimulation can be effective in increasing bone and muscle mass following prolonged loss of functional weight bearing (Holguin et al. 2009; Wang et al. 2012). Moreover, supplemental vibrational therapy can also increase bone density in other groups prone to bone loss, such as postmenopausal women and disabled ambulant children (Rubin et al. 2004; Ward et al. 2004). This principle has also been applied to the craniofacial region

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where cyclic loading can promote suture growth and remodeling (Mao et al. 2003; Peptan et al. 2008). Significantly, vibrational stimulation in rat models of orthodontic tooth movement can increase rates of expansion and space closure (Darendeliler et al. 2007; Nishimura et al. 2008). It has also been suggested that vibrational force application can enhance tooth movement with fixed appliances by reducing frictional resistance to sliding (stick-slip phenomenon) between bracket and arch wire (Olson et al. 2012; Seo et al. 2014). This secondary effect may accelerate both alignment and space closure phases of fixed appliance treatment. Collectively, these findings have prompted the development of vibrational devices for use in human subjects during orthodontic treatment as a method of increasing periodontal remodeling and, therefore, rate of tooth movement.

There are now a number of commercial devices designed to provide cyclic force directly to the dentition as an adjunct to orthodontic treatment. Among these are the Tooth Masseuse and AcceleDent appliances. Tooth Masseuse is a 1-component device that provides a vibrational frequency of 111 Hz and a force of 0.06 N, while AcceleDent is a hands-free device consisting of an activator unit and removable mouthpiece, which provides a vibrational frequency of 30 Hz and a force of 0.2 N. Both devices require the patient to gently bite onto a vibrating thermoplastic wafer, which is in contact with the occlusal surface of the maxillary and mandibular dentitions. It is recommended that subjects use them for around 20 min/d as a supplement to their fixed appliance treatment. There is currently only limited evidence with regard to the clinical efficiency of these devices. A preliminary investigation using AcceleDent demonstrated rates of tooth movement higher than published norms (Kau et al. 2010), while a contemporary AcceleDent device was more recently shown to increase rates of leveling and alignment in class II nonextraction cases (Bowman 2014). However, the retrospective design of these investigations means that these data should be treated with some caution. A prospective study found no significant difference in initial alignment rates between groups of subjects treated with fixed appliances alone or supplemented with the Tooth Masseuse (Miles et al. 2012).

The null hypothesis is that supplemental vibrational force does not increase rate of tooth movement with fixed appliances. This randomized clinical trial therefore investigated the effect of a 20-min daily regime of supplemental vibrational force with the AcceleDent appliance on rate of orthodontic tooth movement during alignment with fixed appliances.

Materials and Methods

Trial Design

Data reported in this investigation were gathered from a 3-arm parallel-group randomized controlled trial comparing the effects of supplemental vibrational force on rate of orthodontic tooth movement. Ethical approval was obtained from the UK National Research Ethics Service (South East London REC 3: 11/LO/0056) and written informed consent received from all parents, guardians, and children. This trial is registered at ClinicalTrials.gov (NCT02314975).

Participants

Participants were recruited from King's College London Dental Institute (Guy's Hospital); the Royal Alexander Children's Hospital, Brighton, Sussex; and William Harvey Hospital, Ashford, Kent. Eligibility for inclusion consisted of the following criteria: (1) <20 y old at start of treatment, (2) no medical contraindications, (3) in the permanent dentition, (4) mandibular arch incisor irregularity, and (5) extraction of mandibular first premolars included in the orthodontic treatment plan.

Interventions

Participants were randomly assigned to 1 of 3 treatment groups:

Accel: preadjusted edgewise fixed appliance treatment with adjunctive daily use of a fully functional AcceleDent vibrational device (OrthoAccel Technologies, Bellaire, TX, USA; Appendix Fig. 1)

Accel sham: preadjusted edgewise fixed appliance treatment with adjunctive daily use of a nonfunctional (sham) AcceleDent device

Fixed only: preadjusted edgewise fixed appliance treatment alone

Subjects allocated to functional or sham devices were given direct verbal and written instruction on operation and usage, were instructed to use their device for 20 min/d, and were informed that a timer was part of the device, allowing the investigator to monitor compliance. The sham device was identical to the active in all respects, except that it did not vibrate.

All first premolar extractions were completed prior to fixed appliance placement. The bonding method and appliances were standardized among groups (precoated 3M Victory series brackets; MBT prescription). After bracket bonding, a predetermined sequence of 0.014-in., 0.018-in., and 0.017 × 0.025–in. nickel titanium (ni-ti) followed by 0.019 × 0.025–in. stainless-steel arch wires were inserted and ligated from first molar to first molar using conventional elastomerics. Arch wire progression occurred only if full bracket engagement was achievable, which required the relevant arch wire to be fully tied into the base of the bracket slot adjacent to each tie wing using elastomeric ligation. All arch wires were cut distal to the first molars with no cinching. No bite planes, auxiliary arches, intermaxillary elastics, or headgears were used during the period of investigation. All subjects were reviewed at approximately 6 weekly intervals and treated by consultant orthodontists (A.T.D., N.J., C.S., J.G., M.T.C.) or specialist registrars (N.R.W., M.A.) under their direct supervision. The primary outcome measure for this investigation was initial rate of tooth alignment in the mandibular arch, while the secondary outcome was time to achieve complete alignment. Mandibular dental study casts were obtained at baseline (placement of upper and lower appliances with 0.014-in. ni-ti arch wires), initial alignment (placement of 0.018-in. ni-ti arch wire), and final alignment (complete engagement of 0.019 × 0.025–in. stainless-steel arch wire). No records were taken on placement of the 0.017 × 0.025–in. ni-ti arch wire. Tooth alignment was measured using Little's (1975) irregularity index, which represents the horizontal linear contact point displacement of each mandibular incisor from the adjacent tooth and is therefore the sum of the 5 individual displacements (Appendix Fig. 2). Rate of initial alignment was calculated as the difference in irregularity index of casts taken at baseline and initial alignment divided by the number of days between measurements. Overall alignment was the number of days from baseline to final alignment. By definition, at final alignment the irregularity index is zero. Dental casts were coded so that measurements were undertaken blind. All measurements were carried out by a single investigator (N.R.W.) using 150-mm digital calipers (ISO 9001; Tesa Technology, Switzerland).

Sample Size Calculation

Sample size calculation was based on previous data relating to initial rate of orthodontic tooth movement using a Titanol aligning arch wire (O'Brien et al. 1990). Mean contact point change within the labial segment in a group with initial irregularity index of 3.12 mm was reported as 1.7 mm over 34 d, corresponding to a mean alignment rate of 0.05 mm/d. We considered a 30% increase in initial rate of tooth movement to be clinically relevant (to 0.071/d) with an assumed standard deviation (SD) of 0.025 and 80% power at the 5% significance level, which gave a required sample size of 23 per group (Scott et al. 2008).

Randomization

The randomization sequence was generated using GraphPad online software (http://www.graphpad.com/quickcalcs/index.cfm) with participant allocation undertaken centrally at King's College London, independently from the clinical operators, following recruitment (allocation concealment; Schulz and Grimes 2002).

Statistical Methods

Outcomes were measured in terms of initial and overall alignment. Descriptive statistics are presented in terms of range, mean, and 95% confidence interval (CI). Linear regression was used to assess treatment effect for rates of alignment, as these outcomes were normally distributed. Kaplan-Meier analysis was used to assess treatment effect in terms of time to reach alignment. Corresponding multivariate models and analysis of covariance were used to adjust for initial irregularity and any age or sex effects. Data management and analysis were performed using Stata 12 (Statacorp, College Station, TX, USA).

Classification of missing data was undertaken by examining factors that influenced the likelihood of missingness in the study. If the number of missing values was substantial or if missingness was not at random, their effect was examined and any bias quantified. In addition, Kaplan-Meier analysis took into account incomplete observations produced by subjects that left the study before achieving complete alignment.

To examine measurement reliability, 10 sets of baseline models were selected and remeasured after 2 wk. Analysis of variance with random effects demonstrated high consistency in replications ($F = 40.6$; $P < 0.0001$). Intraclass correlation was 95% (CI, 91% to 99%), which is in the range of excellent measurement agreement.

Results

A CONSORT diagram demonstrating subject flow through the trial is shown in Figure 1. Eighty-one subjects were recruited between July 2011 and May 2014, with 29 allocated to Accel, 25 to Accel sham, and 27 to fixed only. The total sample (40 males and 41 females) had a mean age of 14.06 ± 1.7 y. Mean age of participants allocated to the Accel group was 13.9 ± 1.6 y; Accel sham, 14.1 ± 1.9 y; and fixed only, 14.4 ± 1.8 y. Subject distribution with respect to sex, intervention, and trial site is shown in Appendix Table 1.

Table 1 shows mean irregularity index for each experimental group at baseline and initial alignment. For the total sample, mean baseline irregularity index was 8.5 ± 3.8 mm (95% CI, 7.6 to 9.3), with no significant difference among groups (P = 0.73). At initial alignment, a full data set was obtained except for 1 case allocated to fixed only, where the mandibular cast was lost (see Fig. 1). For the total sample, mean irregularity index at initial alignment was 2.7 ± 2.8 mm (95% CI, 2.2 to 3.4), with no significant difference among groups ($P = 0.40$). Changes in irregularity index over the 3 time points are shown in Table 1; there were no significant differences among groups for any of these variables (P = 0.39, 0.47, 0.60, respectively). Mean alignment rate per day for the samples is shown in Appendix Table 2.

Table 2 shows mean times to reach each time point for the experimental groups. For the total sample, mean time to initial alignment was 59 ± 25 d (95% CI, 54.5 to 65.6). There were no significant differences among groups in time to reach initial alignment ($P = 0.80$). Overall, mean time from initial to final alignment was 150 ± 62.5 d (95% CI, 136 to 165) and from baseline to final alignment, 209 ± 65 d (95% CI, 195 to 224); there were no significant differences among groups for either period (P = 0.41, 0.49, respectively).

Figure 2 shows Kaplan-Meier curves comparing patterns of alignment for the 3 experimental groups. The curves are essentially indistinguishable, reflecting group alignment patterns not significantly different from one another, log-rank $\chi^2(2)$ = 0.94 ($P = 0.63$). In addition, a Cox proportional hazards model demonstrated no differences among groups in terms of time

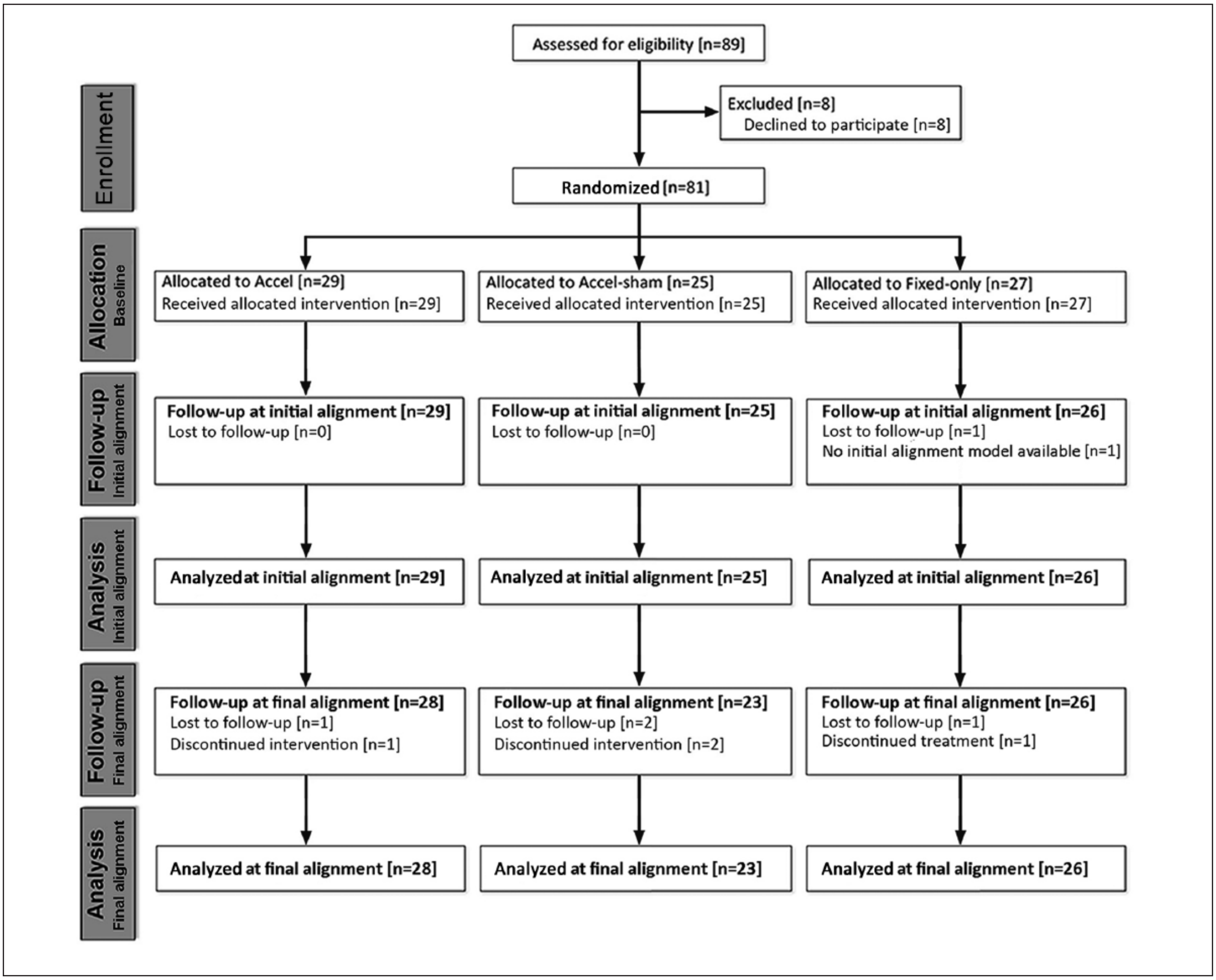

Figure 1. CONSORT diagram showing the flow of subjects in the study. Note that data were lost at initial alignment for 1 subject, but this person remained in the trial and final alignment data were obtained.

patterns to final alignment (P = 0.34), after adjusting for age and sex.

We undertook multivariate linear regression for initial and overall rates of alignment using baseline irregularity index as the covariate. There were no significant differences among groups (Table 3). The most important influence on initial and overall alignment was initial irregularity index. For each millimeter of irregularity, initial rate of alignment increased by 0.01 mm/d (95% CI, 0.005 to 0.01; $P < 0.0001$), while overall rate of alignment increased by 0.004 mm/d (95% CI, 0.003 to 0.01; $P < 0.0001$).

A complete case analysis approach was used—by which, cases with missing outcome data were omitted from a particular analysis. Missing data in the study were not substantial: of those that were recruited, only 4 were lost at final alignment (1 Accel, 2 sham, 1 fixed only). An additional fixed-only subject had missing data at initial alignment but did complete the study. Missingness was therefore classified as *missing at random*, as it was not dependent on baseline or initial irregularity or any covariate.

Discussion

In recent years, orthodontists and patients have become increasingly receptive to techniques that might accelerate tooth movement and therefore reduce treatment duration (Uribe et al. 2014). Although numerous innovations in the design and construction of fixed appliances have been advocated, there is little high-quality evidence to suggest that bracket design or arch wire sequence can significantly influence how quickly teeth move (Jian et al. 2013; Papageorgiou et al. 2014a, 2014b). More recently, a number of more invasive surgical and nonsurgical adjuncts to orthodontic treatment have been described, all designed to reduce treatment time. Surgical techniques include alveolar corticotomy (with or without local augmentation) and different forms of distraction (Uzuner and Darendeliler 2013),

Table 1. Irregularity by Randomized Group.

Group	*n*	Min, mm	Max, mm	Mean, mm	95% Confidence Interval	
Irregularity Index						
Baseline						
Accel	29	2.4	23.3	8.3	6.7	9.9
Sham	25	4.2	18.4	8.1	6.8	9.5
Fixed only	27	0.4	16.6	8.9	7.4	10.5
Initial alignment						
Accel	29	0.00	11.0	2.8	1.8	3.8
Sham	25	0.00	9.7	2.2	1.4	3.0
Fixed only	26	0.00	11.2	3.3	1.9	4.7
Change in Irregularity Index						
Baseline to initial alignment						
Accel	29	1.7	14.6	5.5	4.4	6.6
Sham	25	1.7	11.8	5.9	4.8	7.0
Fixed only	26	0.4	13.9	5.7	4.5	6.8
Initial to final alignment						
Accel	28	0	11.0	2.8	1.8	3.8
Sham	23	0	9.7	2.2	1.4	3.0
Fixed only	25	0	10.2	3.0	1.7	4.3
Baseline to final alignment						
Accel	28	2.4	23.3	8.4	6.7	19.0
Sham	23	4.2	13	7.6	6.5	8.7
Fixed only	26	0.4	16.6	8.6	7.2	10.1

Table 2. Alignment Time by Randomized Group.

Time: Group	*n*	Min, d	Max, d	Mean, d	95% Confidence Interval	
Baseline to initial alignment						
Accel	29	28	109	56.3	48.3	71.3
Sham	25	30	132	59.8	49.0	63.4
Fixed only	26	40	136	61.0	51.8	70.6
Initial to final alignment						
Accel	28	49	324	155	128	181
Fixed only	25	70	390	139	113	165
Sham	23	71	309	158	134	182
Baseline to final alignment						
Accel	28	94	378	210.2	185	236
Sham	23	114	393	217.5	191	244
Fixed only	26	125	473	200.7	173	229

while nonsurgical interventions include pharmacologic supplementation (Yamasaki et al. 1984), pulsed electromagnetic fields (Showkatbakhsh et al. 2010), laser therapy (Cruz et al. 2004), low-intensity near infrared light (OrthoPulse), and vibrational force (Kau et al. 2010). Indeed, there is some evidence that surgically facilitated intervention can increase rates of tooth movement, at least in the short term (Gkantidis et al. 2014; Hoogeveen et al. 2014). However, surgery is associated with discomfort, morbidity, and inconvenience for the patient—all of which are less likely without surgical intervention. Among nonsurgical methods, vibrational force can be applied directly by the patient, using removable/portable devices, in the comfort of their homes and at convenient times. Here, we present randomized prospective evidence on the effectiveness of supplemental vibrational force application using an AcceleDent device during fixed appliance orthodontic treatment.

In this investigation, we found that supplemental vibrational force does not significantly increase rates of orthodontic alignment with a fixed appliance; therefore, we were unable to reject the null hypothesis. Rates of alignment in all our allocated groups were similar and comparable with those found in previous investigations of tooth movement with fixed appliances, in terms of both initial and overall alignment (Scott et al. 2008; Fleming et al. 2009). It is fairly consistent that initial rates of alignment are in the order of 0.10 to 0.14 mm/d with fixed appliances, while overall alignment is likely to be achieved in around 200 to 250 d in the presence of moderate crowding. Significantly, initial irregularity index was the only

Table 3. Effect of Initial Irregularity, Age, and Intervention on Reduction of Irregularity.

	Mean Reduction in Irregularity Index	95% Confidence Interval		*P* Value
Initial Rate of Alignment				
Initial irregularity	0.01	0.005	0.01	0.1×10^{-4}
Age	−0.01	−0.01	0.001	0.09
Group				0.41
Accel vs. fixed only	0.01	0.02	0.03	0.66
Accel sham vs. fixed only	0.02	−0.01	0.04	0.20
Accel vs. Accel sham	−0.01	−0.03	0.01	0.36
Overall Rate of Alignment				
Initial irregularity	0.004	0.003	0.005	0.1×10^{-4}
Age	−0.001	−0.003	0.001	0.25
Group				0.47
Accel vs. fixed only	−0.002	−0.01	0.004	0.55
Accel sham vs. fixed only	−0.004	−0.01	0.003	0.22
Accel vs. Accel sham	0.002	−0.004	0.009	0.49

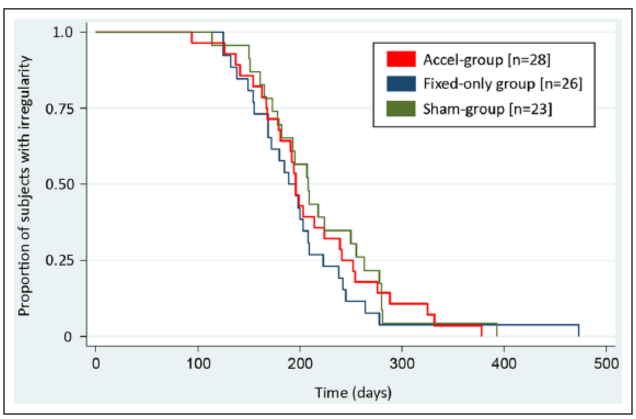

Figure 2. Kaplan-Meier curves comparing patterns of alignment for the 3 experimental groups. The *y*-axis shows the proportion of subjects with irregularity, and the *x*-axis shows the number of days from baseline. There were no significant differences among interventions (Accel-only group, Accel-sham group, and fixed-only group). Numbers represent those subjects in each experimental group analyzed from baseline to final alignment.

thing that influenced rate of tooth movement; the application of supplemental vibrational force did not. This is consistent with studies investigating bracket design and tooth movement (Scott et al. 2008; Fleming et al. 2009).

Our findings are contrary to previous studies investigating vibrational force application and tooth movement. Significant effects have been found over the short term in animal models (Darendeliler et al. 2007; Nishimura et al. 2008), and some clinical data demonstrated that AcceleDent increased rates of tooth movement in subjects undergoing fixed appliance therapy (Kau et al. 2010; Bowman 2014). However, neither study was prospective, and both were poorly reported, which is indicative of potential bias and overestimation of treatment effect (Pandis 2011). Interestingly, a more robust prospective randomized evaluation of another vibrational device (Tooth Masseuse) found no difference in tooth alignment over a 10-wk period (Miles et al. 2012).

The present study represents high-level evidence regarding vibrational force supplementation and fixed appliance treatment. Subjects were allocated prospectively, in a randomized manner, with allocation concealment. There were relatively few subjects lost to follow-up, and the sample retained appropriate power. However, no clinical trial is perfect, and it is important to discuss potential limitations. One potential issue was compliance, particularly for the sham group, where 2 subjects stopped using their device after the first adjustment. Attempts were made to formally monitor compliance, as both functional and sham devices were constructed with in-built timers. Unfortunately, these timers proved to be unreliable, and we were not able to obtain a complete data set. However, a timer is not infallible, and there is nothing to stop an individual from simply turning on the device without placing it in his or her mouth, if one wishes to truly conceal noncompliance. Definitive compliance monitoring would require a device timer combined with an intraoral monitor to determine that the occlusal component was actually in the mouth when the device was on. An alternative strategy might have been to provide subjects with a log book to self-report usage; however, self-reporting is also problematic, being often associated with compliance overestimation (Cureton et al. 1993; Pauls et al. 2013). Here, subjects were told that their devices contained timers and that these data would be collected as part of the trial. Despite the failure of the timers to work reliably, subjects were closely monitored, being asked to bring their devices with them for inspection, demonstrate to the operator a familiarity of use, and operate it for 20 min in the waiting room prior to attendance. However, unidentified noncompliance may have affected tooth movement outcome in experimental groups. Further research is warranted to evaluate patient compliance with these devices and its impact on tooth movement.

In this investigation, crowding was assessed using an irregularity index measuring summed contact point displacement in the labial segment (Little 1975). This index is simple to use and reproducible, and has informed previous clinical studies estimating changes in tooth alignment (O'Brien et al. 1990; Scott et al. 2008; Ong et al. 2010; Miles et al. 2012; Pancherz et al. 2014; Songra et al. 2014). Because of this evidence base, data relating to change in contact point displacement during alignment informed the sample size calculation required for this investigation, based on clinically relevant changes (O'Brien et al. 1990). Other methods are available to measure crowding, but these generally rely on an estimation of arch perimeter, which can introduce inconsistency (Johal and Battagel 1997). One option might have been to measure passive space closure within the first premolar extraction spaces during alignment; however, this represents a secondary movement during this stage of treatment, and it was felt that mandibular incisor alignment was more clinically relevant. The influence of AcceleDent usage during formal space closure will be the subject of a further report.

Finally, tooth alignment was evaluated at normal time points during treatment, based on arch wire progression. This could disadvantage an experimental sample with significantly increased tooth movement because the arch wire might be passive for some time before the next scheduled visit and record collection. However, given that there was still residual irregularity present overall at initial alignment (2.7 mm) with no significant differences among groups, this was unlikely. The initial 0.014-in. ni-ti arch wire would still be active in the presence of existing irregularity. We emphasize that this was a "real world" study that attempted to evaluate the effect of supplemental vibrational force during routine orthodontic treatment with fixed appliances and whether this intervention can positively influence clinical outcome. Although it is impossible to control for every variable, we believe that the methodology was robust and presents high-quality evidence with regard to vibrational force application and its influence on tooth alignment with fixed appliances.

Conclusions

This prospective randomized clinical trial found no evidence that supplemental vibrational force with an AcceleDent device can increase the rate of initial tooth alignment or reduce the time required to achieve complete alignment when used in conjunction with a preadjusted edgewise fixed appliance.

Author Contributions

N.R. Woodhouse, A.T. DiBiase, contributed to design and data acquisition, drafted and critically revised the manuscript; N. Johnson, C. Slipper, J. Grant, M. Alsaleh, contributed to data acquisition, drafted the manuscript; A.N.A. Donaldson, contributed to data analysis and interpretation, drafted and critically revised the manuscript; M.T. Cobourne, contributed to design, data analysis, and interpretation, drafted and critically revised the manuscript. All authors gave final approval and agree to be accountable for all aspects of the work.

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