

**The effect of supplemental vibration on orthodontic treatment with aligners  
– A Randomized Clinical Trial**

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**ABSTRACT**

**The effect of supplemental vibration on orthodontic treatment with aligners  
– A Randomized Clinical Trial**

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**Background:** Supplemental vibration has been introduced to orthodontics to accelerate the rate of tooth movement and to reduce patient discomfort. **Purpose:** This study investigated the impact of the AcceleDent® device on Invisalign® treatment. Specifically, we wished to determine if using the AcceleDent® device allowed aligners to be changed with a one-week, rather than the usual two-week, regimen. **Study Design:** This 2-armed, randomized, triple-blinded, active-controlled clinical trial was carried out in 2 orthodontic practices in Seattle, WA and Vancouver, BC with a 1:1 allocation ratio. 26 adult subjects (12 male and 14 female, mean age=33) were randomly allocated to either an active or control AcceleDent® device. The control devices were exactly like the active devices, but the coupler that transmitted the force to the mouthpiece was removed. All patients were placed on a one-week regimen for changing aligners and were evaluated by their orthodontist every three weeks. If the fit was adequate, the patients would continue with treatment. If there was a lack of fit, based on pre-established guidelines, the patient would be considered a non-completer. The primary outcome compared the percentage of completers in the active and control groups. A secondary outcome measured the final incisor irregularity and the change in incisor irregularity for those who completed their regimen of aligners. **Results:** Fisher's exact test showed no significant difference in completion rates between the two groups (Active = 77% completion, Control = 85% completion,  $p=.99$ ). Independent-sample t-tests showed no significant difference between final incisor irregularity ( $p=0.75$ ) or the change in incisor irregularity ( $p=0.74$ ) between the two groups. Compliance with aligners and the AcceleDent® device were similar in both groups. **Conclusions:** This study found no evidence that AcceleDent® impacts the ability to complete a series of aligners with a one-week change regimen or the final alignment achieved in this adult patient population. **REGISTRATION:** [ClinicalTrials.gov](https://clinicaltrials.gov) Identifier: NCT02438280. This study was approved by the University of Washington Institutional Review Board (ID: 49073-D). **FUNDING:** This study was funded by OrthoAccel® Technologies.

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## Table of Contents

<b>INTRODUCTION.....</b>	<b>6</b>
<b>METHODS.....</b>	<b>9</b>
<b>RESULTS.....</b>	<b>15</b>
<b>DISCUSSIONS.....</b>	<b>20</b>
<b>OTHER INFORMATION.....</b>	<b>22</b>
<b>CONCLUSIONS.....</b>	<b>23</b>
<b>REFERENCES.....</b>	<b>24</b>

## INTRODUCTION

### Background:

Orthodontic treatment is routinely completed over a period of 1 to 2 years. This length of time can sometimes deter patients, especially adults, from undergoing treatment. The incidence of caries, periodontal disease and root resorption also increases when treatment is prolonged.<sup>1,2</sup> Treatment time is dependent upon several factors, including the plan chosen, the appliances and mechanics used, and an individual's inherent biologic response to orthodontic forces. The possibility of accelerating the biological response of the PDL and alveolar remodeling is attractive, as it could result in faster tooth movement overall.<sup>3</sup> Several techniques, including invasive and non-invasive methods, have been proposed to accelerate the rate of tooth movement. A recent Cochrane review suggested there is very little evidence that non-surgical adjunctive interventions are effective.<sup>4</sup> They also stated that well-designed randomized clinical trials are required to investigate whether these interventions result in a clinically significant reduction in the duration of orthodontic treatment. One of the non-invasive methods is the application of intermittent vibrational force to dentition.<sup>5-7</sup>

The effects of vibration on increasing bone mass in astronauts, postmenopausal women, and individuals susceptible to bone loss have been investigated in medicine, and researchers have found positive effects.<sup>8-10</sup> Studies have shown increased sutural growth in animals by applying cyclic mechanical strain in the tensed and compressed sutures.<sup>11-14</sup>

There are more recent studies looking at vibrational effects on bone metabolism at the cellular level. These studies showed that osteocytes can sense low magnitude, high frequency vibration and respond by producing soluble factors that inhibit osteoclast formation.<sup>15,16</sup>

The rationale for the effects of vibration on accelerating orthodontic tooth movement is stimulation of cell differentiation and maturation, so that the bone remodeling that is necessary for tooth movement occurs more quickly.<sup>17</sup> From that perspective, the effect appears to be analogous to local injury (i.e., creation of microfractures in the alveolar bone), just with a less invasive mechanism to produce the injury effect than corticotomy or bone perforation.<sup>17</sup>

Initial research involving vibrational appliances and orthodontic movement was limited to animal models.<sup>3</sup>

15-30% faster tooth movement was reported by loading a vibrational force in *Macaca fuscata* monkeys and rats.<sup>7,18</sup> This accelerated movement was explained by enhanced RANKL expression in the periodontal ligament without damage to periodontal tissues, such as root resorption.<sup>6</sup> However, the results of two other studies on rats and mice showed that cyclical forces inhibited orthodontic tooth movement.<sup>19,20</sup> Therefore, the effects of cyclical forces on orthodontic tooth movement remains unclear and may cause opposite effects depending on force magnitude, frequency or point of application.

The AcceleDent® device has been introduced to the specialty of orthodontics to reduce treatment time. The theory behind AcceleDent® is that high frequency vibratory forces (30Hz) will stimulate cell differentiation and maturation so that the bone remodeling that is necessary for tooth movement will occur more quickly.<sup>3</sup> Promising rates of tooth movement during fixed orthodontic treatment were described in articles involving vibrational forces applied to human subjects.<sup>21-25</sup> However, these studies had a high risk of bias.<sup>3</sup> A prospective randomized clinical trial investigated the rate of tooth movement using a vibrational appliance (Tooth Masseur) for 20 minutes per day. The results demonstrated no clinical advantage in using the vibrational appliance for the early resolution of crowding.<sup>3</sup> More recently, two randomized clinical trials investigated the use of AcceleDent® in conjunction with orthodontic fixed appliances. These studies have found no evidence that the use of vibration can increase the rate of initial tooth movement, reduce the amount of time required to achieve final alignment, increase anterior arch perimeter, or reduction of Irregularity Index.<sup>26,27</sup> Conversely, one published RCT does report that vibration is associated with a significant increase in the rate of tooth movement.<sup>23</sup>

#### **Significance of this study:**

There have been published case reports from orthodontic practices that claim using the AcceleDent® device with clear aligners may enable patients to change aligners with a 5-7 day regimen (instead of the usual two-week regimen).<sup>28</sup> It has been theorized by clinicians that in addition to increasing cell turnover rates, use of the AcceleDent® device may help to improve the fit of clear aligners by placing a seating force on the occlusal surface of the aligners. However, there are currently no prospective trials reporting on the use of the AcceleDent® device with clear aligners, and it is unknown whether the use of the AcceleDent® device in conjunction with aligners can shorten treatment time.

Thus, we designed this study to investigate the potential benefit of the AcceleDent® device when used in conjunction with clear aligners.

**Specific objectives:**

The purpose of this study was to evaluate whether the AcceleDent® device enables faster orthodontic treatment by allowing patients to change aligners every week, instead of every two weeks. Additionally, for all patients who completed their series of aligners with the one-week change regimen, we assessed the degree to which the anterior teeth were aligned by measuring the initial and end of treatment Irregularity Index.

## METHODS

### **Trial design and changes after trial commencement:**

This study was a multicenter, 2-arm, parallel, randomized, triple-blinded, active-controlled clinical trial with a 1:1 allocation ratio. Institutional Review Board approval was obtained from the University of Washington Human Subjects Division prior to initiating the study procedures on May 15, 2015. (Unique Protocol ID: 49073-D). This study was registered at clinicaltrials.gov with the original release on May 04, 2015 (NCT02438280).

This study was originally designed to be conducted at a single center in Seattle WA. In December 2015, with the approval of the University of Washington Human Subjects Division, an additional subject recruitment site in Vancouver BC was added. This change was immediately reflected on Clinicaltrials.gov. No other changes or modifications were made to the original study protocol and methodology of the research.

The study was designed to evaluate the effects of supplemental vibrational device when it was used in conjunction with clear aligners in adult subjects.

### **Participants, eligibility criteria, and setting:**

Orthodontic patients who were beginning their Invisalign® treatment in one of the two IRB approved private practices in Seattle, WA or Vancouver, BC were invited to participate in this study. Adult orthodontic subjects (18 years or older) with malocclusions whose treatment involved  $\leq 25$  sets of aligners were invited to participate in this study. Also, no significant antero-posterior or transverse movements were planned. Subjects with systematic diseases or syndromes, history or current use of bisphosphonates, current use of prostaglandin inhibitors, generalized moderate to severe periodontitis, or active oral hard or soft tissue lesions were excluded from the study.

### **Intervention:**

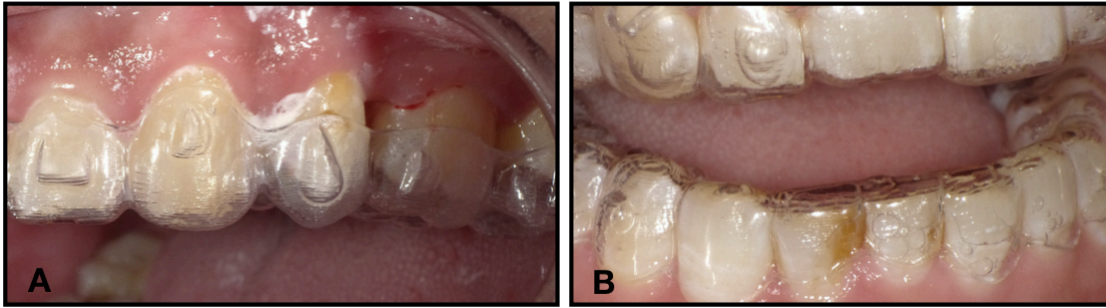
After the initial evaluation of the ClinCheck® treatment simulation by the treating orthodontist, subjects were invited to participate in the study. Subjects were told that the study was investigating the efficiency of a new vibrational device designed to accelerate tooth movement, and that they would be randomly assigned to one of two experimental devices, designated as A or B, which differed in the magnitude

and/or the frequency of vibration. As compensation for enrolling in the study, they received an experimental AcceleDent® device during the study, and after the study ended, they would receive a commercially available device at no charge to be used with any refinement sets of aligners. Subjects in both arms were instructed to use the device daily as recommended by the company (20 minutes per day) during their orthodontic treatment with aligners. The “A” device was the same as the commercially available device. The “B” device was also the same as the commercially available device, but the coupler that transmitted the vibration to the mouthpiece was missing. Thus, the motors on the “B” devices could be turned on and heard, but no vibrational force was delivered to the patient’s teeth.

The aligners were fabricated using the usual approach and prescription of the treating orthodontist, with respect to sequencing of treatment, use of attachments or other treatment features, use of interproximal reduction, etc. Tooth movement was limited to no more than 0.25 mm per aligner. If the treatment in one arch was projected to be completed before completion of the opposing arch, Invisalign® was instructed to stretch out the tooth movement in the arch with fewer aligners so that it matched the number of aligners in the other arch. Thus, the rate of programmed tooth movement in the “stretched” arch was decreased. All subjects were placed on a one-week regimen for changing aligners. Subjects were given three aligners initially, and then seen at three-week intervals to check the fit of the aligners and to receive 3 more aligners.

At each visit, if the last aligner worn did not display an adequate fit as described below, the subject was exited from the study, and was asked to change to a conventional two-week regimen for the remainder of their treatment.

The criteria for lack of adequate fit were 1) spacing greater than 1.5 mm between the aligner and the occlusal or incisal surface of two or more teeth 2) bubbles capturing less than 50% of two or more attachments 3) flexed or stretched aligner which was not fitting tightly over gingival area of two or more teeth 4) any other gross aligner lack of fit which was not due to distortion or damage to the aligner. An intraoral photograph was taken to document the lack of fit at the evaluation appointment (Fig 1).



**Fig 1.** Bubbles capturing less than 50% of attachments and spacing greater than 1.5 mm between the aligners and teeth : **A**, #12, 14, 15,. **B**, #5, 7, 25, 26, 28.

At the end of the first series of aligners, some subjects had to undergo refinement sets of aligners as deemed necessary by the treating orthodontist. These stages of treatment were not included as part of the trial. They were given the option to use a commercially available AcceleDent® device during additional sets of aligners. To ensure blinding throughout the entire study and prevent the subjects from comparing devices, the commercial devices were not dispensed to these subjects until the experimental devices were returned to the study coordinator.

To document the clinical outcome, digital scans prior to the start of the treatment and immediately after finishing the treatment were taken using a second generation of iTero (Align Technology, Inc. San Jose, CA) intraoral digital scanner.

For those subjects who exited the study and were asked to switch to two-week intervals, an additional scan was obtained prior to switching to the two-week interval regimen. A scan of both arches was obtained when both arches completed the full series of aligners.

Compliance was tracked three ways. First, subjects were asked to report on three weeks of device usage and aligner wear on questionnaires at three different time points: baseline, midpoint (determined by the orthodontists based on total number of aligners) and completion of their treatment. Second, Invisalign® aligners were embedded with monitors used in Invisalign Teen®, to track usage. Although this monitor does not record the usage precisely, it provided us with the estimate of wear time.<sup>29</sup> Third, the AcceleDent® device was used to track the amount of use each day. This information was downloaded and evaluated from each device at each visit and at the end of treatment.

### **Outcomes:**

As the main outcome, we compared the percentage of subjects who successfully completed their initial series of aligners as planned, using a one-week change interval. Subjects were given three aligners at a time, and were seen at three-week intervals. At each visit, an assessment was made to determine whether the current aligner displayed an adequate fit.

The secondary outcome was the alignment of anterior teeth at the end of treatment for those subjects who were able to complete their series of aligners with the one-week change regimen. This was done by measuring the maxillary and mandibular Incisor Irregularity (II) scores at the beginning and end of treatment.<sup>30</sup> The end of treatment Irregularity Index and the reduction in the Irregularity Index were compared in “A” vs. “B” groups. In order to measure the incisor Irregularity Index, digital models were viewed in OrthoCAD® (Cadent. Inc. Carlstadt NJ), oriented in the occlusal view with a 1 mm grid overlaid, and magnified with the zoom function of OrthoCAD® about 10 times. The exact magnification was measured for each model. The absolute horizontal distances between each of the anatomical contact points were measured, and then the distance was scaled appropriately by using the overlaid 1 mm grid. In patients with missing anterior teeth, the average Irregularity Index was calculated by adjusting for the number of contacts.

Compliance in the active and control arms was monitored using three different methods: 1) Self-report data from questionnaires, 2) Objective wear time of the aligners by the blue dot indicators, 3) AcceleDent® use time obtained from the device.

### **Sample size calculation:**

In order to justify the use of the vibration device, we felt that a much larger percentage of patients should complete treatment on a one-week regimen when an active device was used. The ratio we decided would be a convincing difference was about 50%. Thus, our sample size calculation estimated 99% of patients would complete their aligners with an active device, compared to 50% with a control device. This calculation indicated that 12 subjects were required in each arm. Additionally, we estimated that a 1.5 mm difference in the incisor irregularity would be clinically meaningful between the patients in the active and control arm. With an estimated sample of 12 subjects in each arm and a standard deviation of 1, our power was calculated to be 0.91.

**Randomization:**

A block stratified randomization scheme was used in this study. Stratification was achieved by generating a separate block for each combination of age (older >45 vs. younger  $\leq$  45) and gender covariates. Subjects were assigned to the appropriate block of covariates using a random number sequence in separate blocks of 2 to ensure that equal numbers of subjects would receive the active and control devices.

**Sequence generation:**

The study statistician created the randomization list by using R software (version 3.1.1, R Foundation for Statistical Computing, Vienna, Austria).

**Allocation concealment:**

A randomization chart was kept at the University of Washington, remote from the clinical sites, at all times. At the time of enrollment, the orthodontist contacted the study coordinator by phone or text to receive the assignment based on age and gender.

**Blinding:**

The devices were designated as device "A" or device "B" when they were shipped from the factory. Thus, this was a triple-blinded study, in which the subjects, investigators, and assessors were all blinded to the treatment arms.

The subjects were told that the study was investigating the efficiency of a new vibrational device designed to accelerate tooth movement. They were told they would be randomized to receive devices that differed in frequency and/or amplitude. In reality, the difference was the control devices had amplitude of zero. We employed this deception to guard against poor compliance if a patient suspected they received an inactive device. The IRB was consulted regarding this issue prior to the initiation of the study, and approved of the wording that was used.

A blinded examiner assessed all digital casts and abstracted data from the questionnaires. Likewise, our statistician was blinded to study arms throughout the performance of the statistical analyses.

### **Statistical analysis:**

Descriptive statistics, including means and standard deviation, were used to compare the demographic characteristics of the subjects in each arm.

Investigation of the percentage of subjects who successfully completed the initial 1-week treatment regimen between the 2 arms was carried out using Fisher's exact test, and associated 95% confidence intervals were calculated using exact binomial confidence intervals.

For the differences between the groups' initial Irregularity Index, number of aligners, final Irregularity Index, and changes in Irregularity Index, p-values and 95% confidence intervals were calculated using Independent-samples t-test.

Compliance data downloaded from the devices were analyzed. The difference between the two arms of the study, as well as the difference between completers and non-completers of the one-week aligner regimen, were measured using Wilcoxon rank-sum test.

## RESULTS

### Participant flow:

Fig. 2 is a CONSORT flow chart showing participant flow during this trial. A total of 27 adult subjects (mean age= 33, 12 male , 15 female) were randomized in a 1:1 ratio to one of the active vs. control arms of the study. One female patient from arm B was withdrawn from the study because she reported her device malfunctioned, and the defective B device was accidentally replaced by an A device. Once this error was discovered, the patient was removed from the study, as it was not possible to place her in either group for analysis.

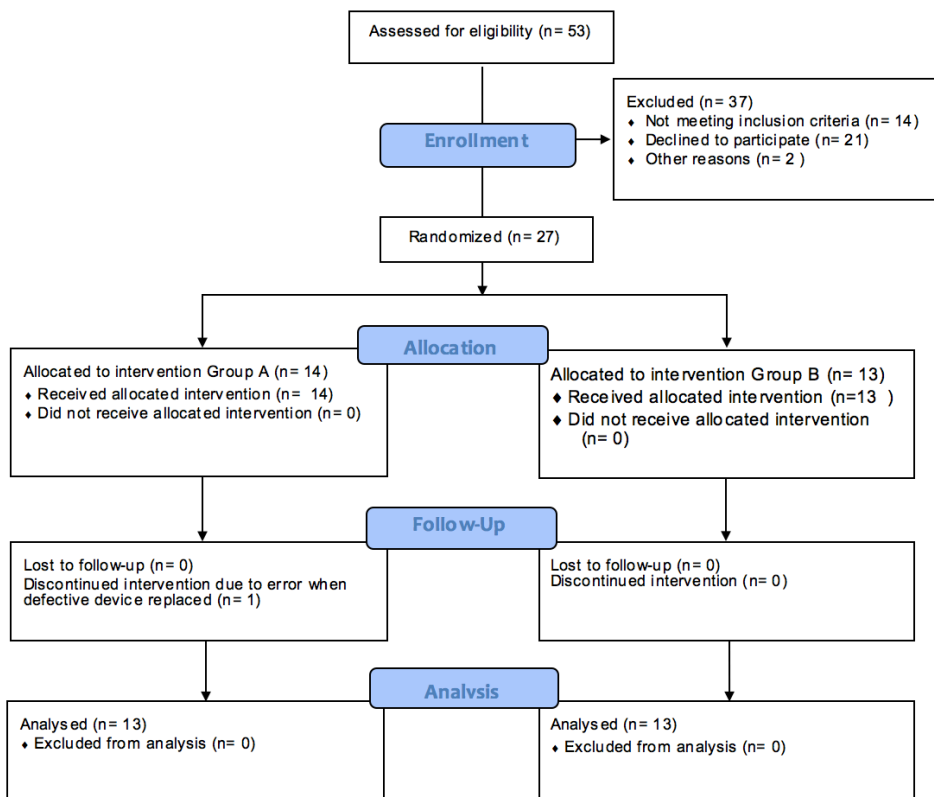


Fig 2: CONSORT diagram showing the flow of subjects

### Recruitment:

Study recruitment started in June 2015 and finished in July 2016.

### Baseline data:

Table 1 shows baseline demographic and clinical characteristics for each group and across the participants of the study. The groups were similar in age, gender, initial Irregularity Index (II) and average number of aligners.

<b>Table 1: Baseline characteristics by treatment group</b>						
	<b>Group A</b>		<b>Group B</b>		<b>Total</b>	
	<b>N</b>	<b>%</b>	<b>N</b>	<b>%</b>	<b>N</b>	<b>%</b>
<b>Gender</b>						
Male	6	46%	6	46%	12	46%
Female	7	54%	7	54%	14	54%
<b>Age group</b>						
≤ 45	11	85%	10	77%	21	81%
> 45	2	15%	3	23%	5	19%
<b>Trial site</b>						
Seattle, WA	5	38%	10	77%	15	58%
Vancouver, BC	8	62%	3	23%	11	42%
	<b>Mean</b>	<b>SD</b>	<b>Mean</b>	<b>SD</b>	<b>Mean</b>	<b>SD</b>
<b>Age (yrs.)</b>	31.4	11.2	34.6	12.6	33.0	11.8
<b>Initial maxillary II</b>	6.2	1.6	5.7	1.9	6.0	1.7
<b>Initial mandibular II</b>	5.6	2.5	5.6	1.9	5.6	2.2
<b>Number of aligners</b>	18.6	3.8	20.1	3.5	19.5	3.7

### Numbers analyzed:

No subject lost follow-up during this study and only 1 subject discontinued intervention due to being given a replacement device that was from the other arm of the study. The orthodontists were able to obtain digital intraoral scans of these subjects prior to the start of treatment as well as at the completion of treatment. These scans were used to measure incisor Irregularity. Compliance data was obtained and downloaded from the devices for further analysis.

### Outcomes and estimation:

The percentage of completion rates in each group, and the 95% confidence interval for percentage of completion were calculated (Table 2). There was no significant difference between the two groups in the percentage of subjects who successfully completed their initial series of aligners with a one-week change regimen ( $p=1$ ). To measure the difference in occlusal outcomes between the two groups, the incisor Irregularity Index at the completion of initial treatment, and the reduction in Irregularity Index were compared.

<b>Table 2: Completion rate by treatment group</b>									
	<b>Group A</b>				<b>Group B</b>				<b>p-value</b>
	<b>N</b>	<b>%</b>	<b>95% CI for %</b>		<b>N</b>	<b>%</b>	<b>95% CI for %</b>		
<b>Discontinued</b>	3	23%	5%	54%	2	15%	2%	45%	1
<b>Completed</b>	10	77%	46%	95%	11	85%	55%	98%	

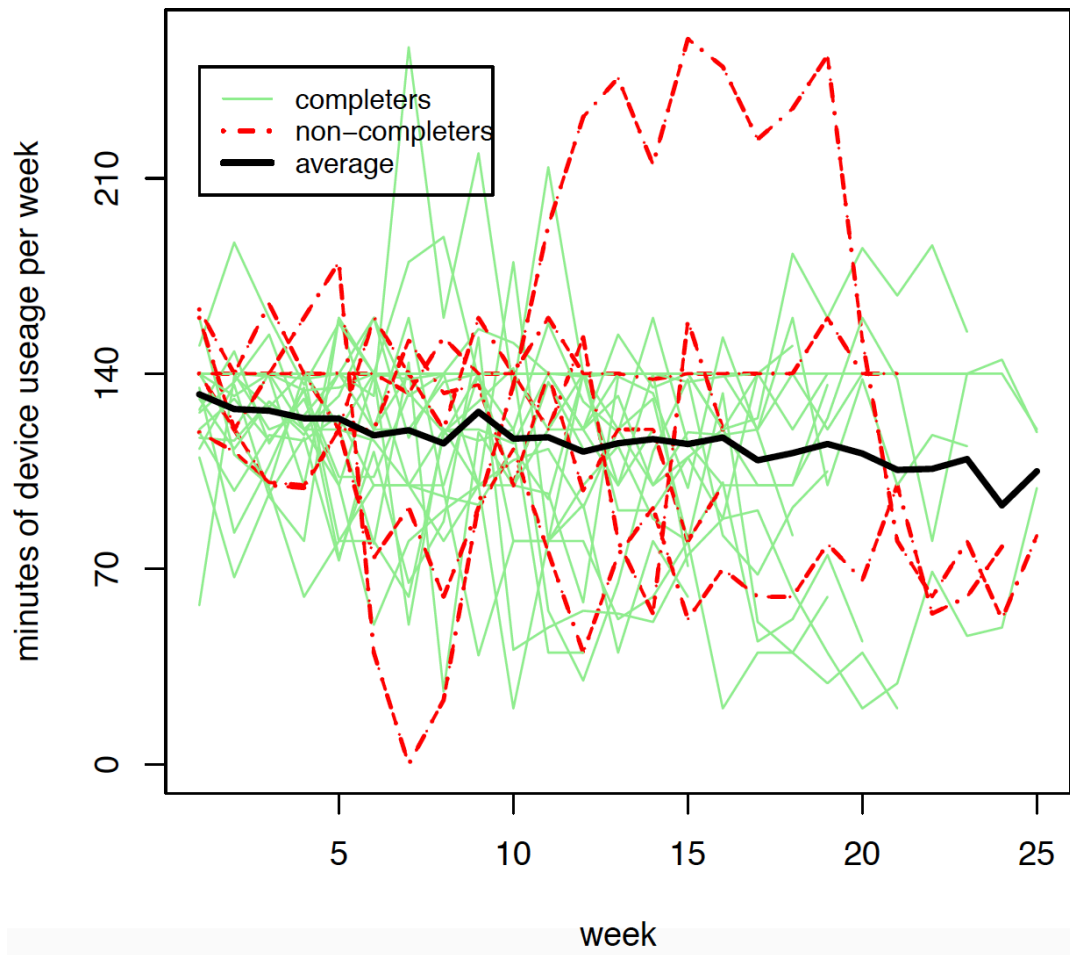
Table 3 shows number of aligners, initial Irregularity Index, final Irregularity Index, changes in Irregularity Index and the 95% confidence interval of difference between the groups. The results show no significant difference between end of treatment incisor Irregularity Index and change in II between the two groups. Because some patients had treatment in one arch “stretched” to match the number of aligners in the opposing arch, we also conducted a sub analysis excluding the arches that were “stretched”. These analyses did not alter the findings compared to those when using the entire sample.

<b>Table 3 : Occlusal outcomes by arch (among completers only)</b>												
		<b>Group</b>	<b>N</b>	<b>Mean</b>	<b>SD</b>	<b>SEM</b>	<b>Min</b>	<b>Max</b>	<b>Diff</b>	<b>95% CI of diff.</b>		<b>p-value</b>
<b>Maxilla</b>	Initial II	A	10	5.77	1.4	0.5	3.8	8.2	0.31	-1.25	1.88	0.68
		B	11	5.45	2.0	0.6	3.0	9.0				
	Final II	A	10	2.20	0.92	0.3	1.1	3.9	0.11	-0.60	0.82	0.75
		B	11	2.09	0.54	0.2	1.1	3.0				
	Change in II	A	10	-3.56	0.9	0.3	-5.1	-2.1	-0.20	-1.51	1.10	0.74
		B	11	-3.36	1.8	0.5	-6.5	-1.3				
<b>Mandible</b>	Initial II	A	10	5.23	2.3	0.7	3.1	9.0	0.00	-1.95	1.95	1.00
		B	11	5.23	1.9	0.6	2.9	8.3				
	Final II	A	10	1.67	0.50	0.2	0.9	2.7	0.18	-0.36	0.72	0.49
		B	11	1.49	0.67	0.2	0.3	2.5				
	Change in II	A	10	-3.56	2.2	0.7	-7.5	-1.1	0.18	-1.77	2.12	0.85
		B	11	-3.74	2.1	0.6	-7.2	-0.4				

Compliance data collected from AcceleDent® devices shows both groups were compliant with the device usage (Fig 3) and there was no significant difference between completers and non-completers of the one-week aligner change regimen (Table 4). Data collected from compliance questionnaire indicated that the subjects in both groups reported similar hours of aligner wear per 24 hour (Table 5).

<b>Table 4 : Device compliance-minutes per week</b>						
	<b>N</b>	<b>Mean</b>	<b>SD</b>	<b>Min</b>	<b>Max</b>	<b>p-value</b>
<b>Group A</b>	13	121	24	81	154	0.39
<b>Group B</b>	13	114	19	82	142	
<b>Non-completers</b>	5	124	27	81	147	0.37
<b>Completers</b>	21	115	21	82	154	

<b>Table 5: Self-reported aligner use-hours per day</b>					
		<b>Group A</b>	<b>Group B</b>	<b>Total</b>	<b>p-value</b>
<b>First 3 weeks</b>	<b>N</b>	13	12	25	
	<b>Mean</b>	20.6	21.0	20.8	0.89
	<b>SD</b>	1.8	.9	1.4	
<b>Midpoint 3 weeks</b>	<b>N</b>	12	13	25	
	<b>Mean</b>	20.3	20.6	20.5	0.72
	<b>SD</b>	1.5	1.3	1.4	
<b>Final 3 weeks</b>	<b>N</b>	11	11	22	
	<b>Mean</b>	20.3	20.8	20.6	0.53
	<b>SD</b>	1.8	1.5	1.7	



**Fig 3:** Minutes of device usage per week for all subjects.

**Harms:**

No harm was observed in this study.

## DISCUSSIONS

It has been shown that both orthodontists and patients are interested in utilizing techniques to shorten orthodontic treatment duration. Most orthodontists feel that techniques reducing treatment times by 20% to 40% attractive, and would be willing to pay up to 20% of their treatment fee to companies to use an alternative technology to reduce treatment time.<sup>31</sup>

Previous trials and case reports have investigated the effects of supplemental vibrational devices in conjunction with fixed orthodontic treatment. The results from three controlled randomized clinical trials have shown no clinical significant difference similar to this study.<sup>3,26,27</sup>

When this trial was designed, orthodontists routinely instructed subjects to change aligners every 2 weeks. Some orthodontists reported that the use of AcceleDent® in conjunction with Invisalign® might shorten the treatment time by improving the aligners placement and engagement to dentition and instruct the subjects to change aligners every week instead of two weeks.<sup>28</sup> The current data on the impact of AcceleDent® on orthodontic treatment with aligners is limited and there has not been any published data to investigate the claims of the company and practitioners who prescribe AcceleDent® in conjunction with clear aligners. A recent trial by Alfonso et al. at University of Florida found no accelerated rate of tooth movement with AcceleDent® Aura device when used in conjunction with Zendura® plastic aligners.<sup>32</sup>

In October 2016, Align Technology® made an announcement to recommend weekly aligner changes to shorten treatment time without compromising the outcomes. 85% of our subjects with minor malocclusions were able to successfully finish their aligner treatment regardless of AcceleDent® use. Therefore, the result of our study is not surprising with this new announcement.

The compliance rate was high with no significant difference in the groups. Therefore, compliance did not affect the results of this study. However, all subjects did bite 20 minutes a day on AcceleDent® mouth piece wafer. Since vibration did not have any impact on the rate of tooth movement, the ability to change the aligners every week could be the result of a better seating of aligners similar to chewies, which is a significantly cheaper alternative.

### **Limitations:**

1. The sample size was chosen based on what we considered a significant difference in completion rates. The rationale was that to justify the use of this device, which may cost around \$1000, it must have a large impact on the ability to complete a series of aligners with a one week change regiment. This study found completion rates of 77% (A group, which was active) and 85% (B group, which was control), which was much lower than we expected. These rates suggest that the vibration device does not have a large impact on the ability to complete a series of aligners when patients have mild malocclusions. Post hoc analysis indicates that to achieve 80% power to detect a difference of 8% in the completion rates, each group would need to have 376 patients.

2. We ordered Invisalign® trays with the blue dot indicator to objectively track aligner wear compliance. These dots are designed to fade over a period of two weeks, which is the routine aligner wear regimen. However, we instructed our subjects to change their aligners every week. We noticed one week of compliant aligner wear was not sufficient to fade the indicator. Therefore, we were not able to rely on the outcome of this measurement and we had to rely on the self-report data from the questionnaires to measure aligner wear compliance.

3. In the majority of our subjects, the treatment in one arch was “stretched” at least a few aligners in order to have equal numbers of active aligners in both arches. The stretched arches would have fared better with the 1 week change, as they had less movement. In order to eliminate the bias introduced by slowing down the movements in the arches with shorter treatment time, we separately analyzed all the outcomes of the study for the arches with greater number of aligners. The differences between the groups were not significant in those arches.

### **Interpretation:**

This study found no difference in using supplemental vibration in conjunction with aligners. Subjects in both groups were able to complete the aligner series with one week change regime. This results could be due to several common characteristics of the subjects of this study; 1) good cooperation, 2) mild malocclusions, 3) biting on mouth piece wafer for 20 minutes per day during treatment. 7 day aligner change regimen is recently suggested by Invisalign® as a routine procedure. In the near future, Invisalign® users are going to push the envelope even further to 3-5 day aligner change regimen, and the

question is whether this could be achieved by supplemental vibration. These regimens are unlikely to be applicable to more severe malocclusions that require more difficult movements.

**Generalizability:**

This study was carried out in two different private practices in Vancouver BC and Seattle WA. Both practitioners were considered experienced Invisalign® orthodontists (When joining the study, both doctors had 15 years of experience with Invisalign® treatment, and treated more than 50% of their patients with Invisalign®). The subjects in this study were adult patients with minor malocclusions seen in orthodontic private practice. Therefore, the outcomes could be generalized to adult subjects with minor malocclusions who are being treated by Invisalign® in a private practice setting.

## **OTHER INFORMATION**

**Registration:**

This study was registered at [clinicaltrials.gov](https://clinicaltrials.gov) with the original release on May 04, 2015 (NCT02438280).

**Protocol:**

The protocol was not published before trial commencement.

**Funding:**

This study was funded by OrthoAccel® Technologies.

## **CONCLUSIONS**

1. This study found no evidence that AcceleDent® impacts the ability to complete a series of aligners with a one-week change regimen or the final alignment achieved.
2. AcceleDent® had no effect on end of treatment alignment achieved when used in conjunction with Invisalign®.

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