



# Effects of supplemental vibrational force on space closure, treatment duration, and occlusal outcome: A multicenter randomized clinical trial

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**Introduction:** A multicenter parallel 3-arm randomized clinical trial was carried out in 3 university hospitals in the United Kingdom to investigate the effect of supplemental vibratory force on space closure and treatment outcome with fixed appliances. **Methods:** Eighty-one subjects less than 20 years of age with mandibular incisor irregularity undergoing extraction-based fixed appliance treatment were randomly allocated to supplementary (20 minutes/day) use of an intraoral vibrational device (AcceleDent; OrthoAccel Technologies, Houston, Tex) ( $n = 29$ ), an identical nonfunctional (sham) device ( $n = 25$ ), or fixed-appliance only ( $n = 27$ ). Space closure in the mandibular arch was measured from dental study casts taken at the start of space closure, at the next appointment, and at completion of space closure. Final records were taken at completion of treatment. Data were analyzed blindly on a per-protocol basis with descriptive statistics, 1-way analysis of variance, and linear regression modeling with 95% confidence intervals. **Results:** Sixty-one subjects remained in the trial at start of space closure, with all 3 groups comparable for baseline characteristics. The overall median rate of initial mandibular arch space closure (primary outcome) was 0.89 mm per month with no difference for either the AcceleDent group (difference,  $-0.09$  mm/month; 95% CI,  $-0.39$  to  $0.22$  mm/month;  $P = 0.57$ ) or the sham group (difference,  $-0.02$  mm/month; 95% CI,  $-0.32$  to  $0.29$  mm/month;  $P = 0.91$ ) compared with the fixed only group. Similarly, no significant differences were identified between groups for secondary outcomes, including overall treatment duration (median, 18.6 months;  $P > 0.05$ ), number of visits (median, 12;  $P > 0.05$ ), and percentage of improvement in the Peer Assessment Rating (median, 90.0%;  $P > 0.05$ ). **Conclusions:** Supplemental vibratory force during orthodontic treatment with fixed appliances does not affect space closure, treatment duration, total number of visits, or final occlusal outcome. **Registration:** NCT02314975. **Protocol:** The protocol was not published before trial commencement. **Funding:** AcceleDent units were donated by OrthoAccel Technologies; no contribution to the conduct or the writing of this study was made by the manufacturer. (Am J Orthod Dentofacial Orthop 2018;153:469-80)

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Despite numerous innovations and advances in orthodontic appliance design and application, the average duration of comprehensive treatment with fixed appliances has remained relatively stable at just under 20 months.<sup>1</sup> Accelerated orthodontic treatment is desirable, not only to limit the social and dental inconvenience of wearing fixed appliances, but also to help reduce the established risks of iatrogenic damage.<sup>2</sup> Over the years, numerous innovations and adjuncts have been described that purport to speed up tooth movement and reduce overall treatment time. There is currently no robust evidence for faster tooth movement and reduced treatment time in association with any particular appliance design,<sup>3,4</sup> bracket prescription,<sup>5</sup> archwire composition,<sup>6</sup> or treatment adjunct.<sup>7</sup> The sole

exceptions are surgical interventions, such as corticotomies or piezocision, that do seem to accelerate tooth movement, albeit on a relatively short-term basis.<sup>8</sup> However, most of these surgical techniques are invasive and may not be readily acceptable to most patients.<sup>9</sup> Therefore, continued efforts are directed toward the search for a safe, predictable, and acceptable method to reduce orthodontic treatment time, without compromising clinical results.

The use of supplemental vibrational force has been advocated as a method of speeding up orthodontic tooth movement. This involves the application of low-level vibration directly to the dentition as it is subjected to orthodontic force. The basic principle underlying orthodontic tooth movement is the ability of alveolar bone to respond with remodeling after the application of external force.<sup>10</sup> With this principle, vibrational force has been shown to aid in the maintenance of bone mass in postmenopausal women<sup>11</sup> and subjects with reduced mobility and prolonged bed rest.<sup>12-14</sup> At the same time, data from animal models indicate increased rates of tooth movement, osteoclastic activity, and bone remodeling within the periodontium.<sup>15,16</sup> These data have been used to inform the development of commercial vibrational appliances for clinical use, one of which is AcceleDent (OrthoAccel Technologies, Houston, Tex). This is a hands-free portable device consisting of an activator unit and a removable thermo-plastic occlusal wafer that the patient bites onto. The activator unit vibrates and delivers a force of 0.2 N at a frequency of 30 Hz to the dentition. The manufacturer suggests that it should be used for 20 minutes per day to increase the speed of tooth movement and thereby reduce treatment time.

Clinical benefits from supplemental vibration have been reported in case reports and nonrandomized retrospective cohort studies.<sup>17-20</sup> These investigations have shown increases in the rate of orthodontic tooth movement and reductions in treatment time, but their nonrandomized and retrospective design exposes them to potential bias and exaggerated treatment effects.<sup>21</sup> There are data from randomized studies demonstrating statistically significant effects of supplemental vibration when delivered using either AcceleDent or a vibrating toothbrush during orthodontic treatment.<sup>22,23</sup> These data are at both the clinical and biochemical levels, but again, the methodologic design of these studies predisposes them to a high risk of bias.<sup>24</sup> These encouraging results have not been confirmed by other randomized clinical trials investigating rates of tooth movement; these trials found no significant benefit from supplemental vibrational force.<sup>25-27</sup> However, these trials have only reported on the initial alignment

phase with fixed appliances, and no robust evidence exists to date in relation to rates of space closure or overall treatment time when using fixed appliances with supplemental vibration.

### Specific objectives and hypothesis

The aim of this study was to investigate the effect of AcceleDent appliance usage on the outcome of fixed appliance orthodontic treatment. The primary outcome measure for this component of the trial was initial rate of mandibular arch space closure, whereas secondary outcomes included overall rate of mandibular space closure, treatment duration, number of visits, appliance breakages and Peer Assessment Rating (PAR) reduction during treatment. The null hypothesis was that the use of supplemental vibrational force does not improve the rate of mandibular arch space closure, overall treatment duration, or outcome in subjects undergoing comprehensive extraction treatment with fixed appliances.

## MATERIAL AND METHODS

### Trial design and any changes after trial commencement

Data for this investigation were gathered from the follow-up of a 3-arm parallel randomized controlled trial comparing the effect of supplemental vibrational force on orthodontic tooth alignment<sup>27</sup> and are reported according to the CONSORT statement.<sup>28</sup> Ethical approval was obtained from the National Research Ethics Service of the United Kingdom (South East London REC 3: 11/LO/0056), and written informed consent was received from all parents, guardians, and subjects. This trial was registered at the European Clinical Trials Database (EudraCT, 2014-004211-37) on September 29, 2014, and [ClinicalTrials.gov](http://ClinicalTrials.gov) (NCT02314975) on November 25, 2014. No changes to the methodology occurred after trial commencement.

### Participants, eligibility criteria, and settings

Participants were recruited from subjects referred to the orthodontic departments at King's College London Dental Institute (Guy's Hospital), the Royal Alexandra Children's Hospital, Brighton, Sussex; and William Harvey Hospital, Ashford, Kent, United Kingdom. The former is based in a dental school, and the latter two are based in regional hospitals. All offer comprehensive orthodontic treatment for children and adults. Eligibility criteria have been previously described<sup>27</sup> and included: (1) age less than 20 years at the start of treatment, (2) medically fit and well, (3) in the permanent dentition, (4) mandibular incisor

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