AcceleDent™ System

THE FAST TRACK TO STRAIGHT TEETH
The Science

Force characteristics traditionally studied in orthodontics:

1. Magnitude
2. Duration
3. Point of Application
4. Direction

Only recently considered:

5. Frequency
Pulsatile forces have been proven to alter physiological responses in long bones

- Increased rate of fracture healing
- Increased cellular signaling to enhance bone density
Juvent Dynamic Motion Therapy

• Biomechanical stimulation system, that transmits gentle, dynamic, specific and repetitive vibrations applied to the soles of the feet
• The vibration system gently stimulates the bones and muscles
• Patients stand on it for 20 minutes a day to achieve maximum benefit for muscle mass & strength
EXOGEN® Ultrasound Bone Healing System

- Low-intensity pulsed ultrasound
- Chronic non-unions & acute fractures
  - Heals fresh fractures 38% faster
  - Heals 86% of non-unions
  - 20 minutes per day
- Applied directly to skin at the fracture site
- Used at home, at work, or while traveling
Dr. Jeremy Mao

- Interdisciplinary PhD in musculoskeletal engineering goes on to become an orthodontist
- *Iwao Yasuda Award* – highest honor given in physical regulation of medical biology
- Professor and Director of the Tissue Engineering and Regenerative Medicine Laboratory at Columbia University
- Associate Dean of Research at Columbia Medical School
- 50 patents on the regeneration of facial and dental tissues
The Hypothesis

would similar pulsatile (cyclic) forces have an effect on alveolar bone and therefore speed tooth movement versus traditional Tx?
## Scientific Literature Well Established

<table>
<thead>
<tr>
<th>Authors</th>
<th>Year</th>
<th>Journal</th>
<th>Frequency (Hertz)</th>
<th>Amplitude</th>
<th>Model</th>
<th>Key Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mao, et. al.</td>
<td>2005</td>
<td>Frontiers Biosc.</td>
<td>0.2</td>
<td>2 N</td>
<td>Rabbit</td>
<td>Bone Remodeling <strong>increase</strong></td>
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<tr>
<td>Mao and Kopher</td>
<td>2003</td>
<td>J. Bone Mineral Res.</td>
<td>1.0</td>
<td>5 N</td>
<td>Rabbit</td>
<td>Bone Remodeling <strong>increase</strong></td>
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<td>Mao and Tang</td>
<td>2006</td>
<td>Cell &amp; Tiss. Res.</td>
<td>4.0</td>
<td>500 mN</td>
<td>Rat</td>
<td>Gene Expression <strong>increase</strong></td>
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<td>Mao and Vij</td>
<td>2006</td>
<td>Bone</td>
<td>4.0</td>
<td>300 mN</td>
<td>Rat</td>
<td>Bone Remodeling <strong>increase</strong>; Osteoblast <strong>increase</strong>; Osteoclast <strong>increase</strong></td>
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<td>Mao and Peptan</td>
<td>2008</td>
<td>Bone</td>
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<td>Bone Remodeling <strong>increase</strong>; Osteoblast <strong>increase</strong></td>
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<td>Shapiro, et. al.</td>
<td>1979</td>
<td>AJO-DO</td>
<td>0.7</td>
<td>89 ounces</td>
<td>Human (n = 1)</td>
<td>Tooth movement rate <strong>increase</strong></td>
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<tr>
<td>Collins, et. al.</td>
<td>2005</td>
<td>J. Biomech.</td>
<td>4.0</td>
<td>1 N</td>
<td>Rat</td>
<td>Gene Expression <strong>increase</strong></td>
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<tr>
<td>Almubarak, et. al.</td>
<td>2006</td>
<td>Cell &amp; Tiss. Res.</td>
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<td>Rat</td>
<td>Gene Expression <strong>increase</strong></td>
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<tr>
<td>Darendeliler, et. al.</td>
<td>2007</td>
<td>Aus. Dent. J.</td>
<td>30.0</td>
<td>25 grams (0.25 N; spring)</td>
<td>Rat</td>
<td>PEMF induced <strong>increase</strong> rates of tooth movement</td>
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<tr>
<td>Nishimura et. al.</td>
<td>2008</td>
<td>AJO-DO</td>
<td>60.0</td>
<td>12.8 grams (0.128 N)</td>
<td>Rat</td>
<td>Tooth movement rate <strong>increase</strong>; Osteoclast <strong>increase</strong></td>
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<tr>
<td>Shimizu</td>
<td>1986</td>
<td>J. Japan. Ortho. Society</td>
<td>115 - 140</td>
<td>40 grams (0.4 N; average)</td>
<td>Monkey</td>
<td>Tooth movement <strong>increase</strong></td>
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<tr>
<td>Liu</td>
<td>2010</td>
<td>AADR/CADR; pre-publication</td>
<td>4.0</td>
<td>20 grams (0.2 N)</td>
<td>Rat</td>
<td>Accelerated tooth movement</td>
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<tr>
<td>Liu</td>
<td>2011</td>
<td>IADR/AADR/CADR; pre-pub.</td>
<td>4.0</td>
<td>20 μm</td>
<td>Rat</td>
<td>Accelerated tooth movement</td>
</tr>
</tbody>
</table>

Consistent results of increased bone remodeling & tooth movement
Rabbit Cranial Suture Model

*mimics the forces to which the periodontal and other sutural articulations* of the craniofacial skeleton are exposed during orthodontic treatment since the remodeling mechanisms of all fibrous joints are known to be similar.

Meikle, European Journal of Orthodontics, 2006
Rabbit Cranial Suture Model with Cyclic Force

cyclic force increased sutural width

Vibration increased the quantity of osteoclasts

Nishimura et al, AJODO, 2008
Rat Study using Pulsed Electromagnetic Field (PEMF) vibration on tooth movement

Magnets + PEMF enhanced the effect of conventional mechanical forces

Darendeliler et al, Australian Dental Journal, 2007
Effects of Mechanical Stimuli on Adaptive Remodeling of Condylar Cartilage

The results in mice suggest that low-magnitude, high-frequency (30 Hz) mechanical stimuli enhance adaptive remodeling of condylar cartilage. Evidenced by endochondral bone replacing hypertrophic cartilage

*Therefore, no adverse effect on TMJ expected*

Sriram et al, Journal of Dental Research, 2009
Relevant Findings from Animal Studies

• Factors that increase the rate of bone remodeling also increase the rate of tooth movement
• Dynamic rather than static forces lead to the build up of bone (anabolic effect) ¹⁻⁴
• The application of low magnitude cyclical forces enables the modulation of cell biology within fibrous articulations⁵⁻⁶
• When bone is given a sufficient recovery period (8 hours), it is able to regain its mechano-sensitivity (ability to respond)⁷

1. Turner et al, Bone, 1992
2. Rubin et al, J Bone Miner Res, 1995
4. Leblanc et al, J Bone Miner Res, 1990
Synopsis of Animal Study Findings

The rate of orthodontic tooth movement depends on the speed at which the bone surrounding the teeth remodels.

Orthodontic force coupled with a cyclical force (microvibrations) **safely accelerates tooth movement.**

Microvibrations stimulate bone metabolism molecules that regulate the quantity and activity of bone cells (osteoclasts & osteoblasts).
"Bone resorption creates the space for teeth to move, while bone formation fills the gap behind the tooth. The concept of AcceleDent is based on the scientific principle that with cyclic forces there is more bone remodeling."

“The goal of all this science”, Mao concludes, “is not just to automate the process but to improve the quality of orthodontics."
University Patient Studies
Dr. Jeryl English
D.D.S, M.S.

- Professor & Chairman Dept of Orthodontics
- Former Professor & Program Director of orthodontic program at Baylor College of Dentistry
- Research interests include surgical orthodontic interdisciplinary & functional treatment

Dr. Chung H Kau

- Relocated to be Chair and Professor at the Department of Orthodontics, University of Alabama at Birmingham
- Active research in 3-D imaging
Clinical Pilot Trial

- N = 17 pts enrolled; data collected on 14 pts
- No active control (historical/published data)
- Inclusion criteria: Class I malocclusion with crowding or spacing of at least 6 mm for mandibular incisors, lower number 1’s through 3’s
- Average age: 20.5 years (12 to 57)
- 6 consecutive months of AcceleDent™ use
- First Generation AcceleDent™ device
  - 25 gram force and 30 HZ frequency
- Measure tooth movement & patient perception and ease of use
- Measure root resorption using Cone Beam CT
Impressive Safety/Efficacy Results

- Extremely high product preference scores
- Excellent safety profile (no root resorption)
Tooth Movement Results

- Total rate of tooth movement:
  - mandible = 0.526 mm/wk or 2.1 mm/month
  - maxilla = 0.759 mm/wk or 3.0 mm/month
  - the rate of movement between mandible and maxilla was statistically significant
  - Orthodontic Products  April 2010

- Published literature results are 1 mm/month
  - UTHSC Houston performed a META analysis of all existing literature
Tooth Movement Results

Alignment Movement


Extraction Space Movement

Root Resorption Results

• The decrease in mean root lengths ranged from 0.127 mm to 0.416 mm in both arches.
  – No clinically relevant root resorption
Patient Perception of Device Components

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
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<td>EASE OF USE</td>
<td>22.10</td>
<td>40.21</td>
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<td>34.96</td>
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<td>43.56</td>
<td>43.11</td>
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<td>HYGIENE</td>
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<td>15.27</td>
<td>13.39</td>
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<td>19.81</td>
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<td>RELIABILITY</td>
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<td>34.13</td>
<td>37.86</td>
<td>38.04</td>
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<td>40.19</td>
<td>40.55</td>
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<td>NOISE</td>
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<td>26.63</td>
<td>17.68</td>
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<td>12.50</td>
<td>10.00</td>
<td>13.80</td>
<td>8.11</td>
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Ease of Use by Patient

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<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
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<td>OVERALL SATISFACTION</td>
<td>7.50</td>
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<td>18.64</td>
<td>18.46</td>
<td>20.30</td>
<td>15.67</td>
<td>24.61</td>
<td>26.31</td>
<td>40.00</td>
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<td>DISCOMFORT</td>
<td>30.20</td>
<td>18.29</td>
<td>23.27</td>
<td>21.43</td>
<td>25.85</td>
<td>22.89</td>
<td>36.65</td>
<td>32.44</td>
<td>39.40</td>
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<td>SCHEDULE DISRUPTION</td>
<td>27.75</td>
<td>24.92</td>
<td>21.36</td>
<td>17.75</td>
<td>20.23</td>
<td>15.31</td>
<td>15.55</td>
<td>20.33</td>
<td>27.90</td>
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<td>CLEANLINESS &amp; MAINTENANCE</td>
<td>39.10</td>
<td>35.29</td>
<td>28.55</td>
<td>36.39</td>
<td>39.46</td>
<td>35.65</td>
<td>34.00</td>
<td>38.61</td>
<td>40.75</td>
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<tr>
<td>DROOLING</td>
<td>-15.10</td>
<td>-0.29</td>
<td>23.64</td>
<td>14.86</td>
<td>27.31</td>
<td>24.27</td>
<td>21.20</td>
<td>24.28</td>
<td>22.20</td>
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Randomized Clinical Trial Results
Dubravko Pavlin - D.M.D., M.S.D., Ph.D.

- Professor of Orthodontics and Director of Orthodontic Residency Program, University of Texas Health Science Center at San Antonio
- D.M.D. and M.S.D - the University of Zagreb, Croatia
- Ph.D. in Biological Sciences - the University of Connecticut
- Laboratory research in regulation of genes in bone during mechanical loading and distraction osteogenesis
- Reviewer for several clinical and basic science journals
- Participated in improvements of the AcceleDent design
- Author of research protocol for AcceleDent RCT and independent reviewer of data
Dr. Peter Gakungka – BDS, MS, PhD.
- Craniofacial biologist & Assistant Professor of orthodontics
- Clinical investigation on accelerated orthodontic tooth movement
- Research of the role of growth factors in normal and abnormal craniofacial growth
- Prevention of enamel white spot lesions

Dr. Ravikumar R Anthony – BDS, MDS, MS
- Clinical Instructor of orthodontics
- Private practice in orthodontics
- Clinical research on accelerated tooth movement
- Research on the role of Sost Gene in bone
- Innovations in clinical orthodontics
Clinical Trial Design

- Single Site – Univ. Texas Health Science Center at San Antonio
- Prospective
- Blinded
- Randomized
- Controlled
  - Treatment Group
  - Sham Control Group
- Complement to fixed MBT appliance & 20 minutes daily use
- 4 weeks between visits
Enrolled (N=45)

AcceleDent (N=23)
- Reportable Data (N=21)
  - Standard End-of-Study Exit (N=16)
    - Including N=2 with Multiple TAD Failures
  - Achieved Maximum Clinical Benefit (N=2)
  - Lost to Follow Up with rate data (N=2)
  - Multiple TAD Failures with rate data (N=1)
- Unreportable Data (N=2)
  - Withdrawn due to poor oral hygiene causing loose TADs (N=2)

Sham Device (N=22)
- Reportable Data (N=18)
  - Standard End of Study Exit (N=16)
    - Including N=3 with Multiple TAD Failures
  - Achieved Maximum Clinical Benefit (N=1)
  - Lost to Follow Up with rate data (N=1)
- Unreportable Data (N=4)
  - Failed to Meet Enrollment Criteria (N=2)
  - Withdrawn due to poor oral hygiene causing loose TADs (N=2)
Gender is an important covariant as males did better than females because teen females were skeletally mature.

Age is a minimally important covariant.
<table>
<thead>
<tr>
<th>Ethnic Origin</th>
<th>AcceleDent</th>
<th>Sham Control</th>
<th>Total</th>
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<td>Caucasian</td>
<td>6</td>
<td>8</td>
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<td>African American</td>
<td>2</td>
<td>2</td>
<td>4</td>
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<tr>
<td>Asian (Korean)</td>
<td>0</td>
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<td>1</td>
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<tr>
<td>Hispanic</td>
<td>15</td>
<td>11</td>
<td>26</td>
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</tbody>
</table>

Ethnicity did not have an influence on results
AcceleDent™ moves teeth 38% - 50% FASTER
# PRIMARY EFFICACY ENDPOINT
(canine, age & gender as covariants)

## Space Closure Average Rate of Tooth Movement – ITT Group (mm/wk)

<table>
<thead>
<tr>
<th></th>
<th>AcceleDent</th>
<th>Sham Control</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Count</strong></td>
<td>23</td>
<td>22</td>
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<tr>
<td><strong>LS Mean</strong></td>
<td>0.27</td>
<td>0.18</td>
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<tr>
<td><strong>Std Error</strong></td>
<td>0.036</td>
<td>0.035</td>
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<tr>
<td><strong>Range</strong></td>
<td>0.00 – 0.69</td>
<td>0.00 – 0.43</td>
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<tr>
<td><strong>% Improvement</strong></td>
<td>50%</td>
<td></td>
</tr>
<tr>
<td><strong>P-Value</strong></td>
<td>0.0496</td>
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</table>

## Space Closure Average Rate of Tooth Movement – PP Group (mm/wk)

<table>
<thead>
<tr>
<th></th>
<th>AcceleDent</th>
<th>Sham Control</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Count</strong></td>
<td>21</td>
<td>18</td>
</tr>
<tr>
<td><strong>LS Mean</strong></td>
<td>0.29</td>
<td>0.21</td>
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<tr>
<td><strong>Std Error</strong></td>
<td>0.027</td>
<td>0.028</td>
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<tr>
<td><strong>Range</strong></td>
<td>0.13 – 0.69</td>
<td>0.11 – 0.43</td>
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<tr>
<td><strong>% Improvement</strong></td>
<td>38%</td>
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<tr>
<td><strong>P-Value</strong></td>
<td>0.0234</td>
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### PRIMARY EFFICACY ENDPOINT

#### Effect of Age

<table>
<thead>
<tr>
<th>Age</th>
<th>AcceleDent</th>
<th>Sham Control</th>
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<tbody>
<tr>
<td>Count</td>
<td>11</td>
<td>10</td>
</tr>
<tr>
<td>Mean</td>
<td>0.31</td>
<td>0.25</td>
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<tr>
<td>Std Dev</td>
<td>0.141</td>
<td>0.080</td>
</tr>
<tr>
<td>Range</td>
<td>0.16 – 0.69</td>
<td>0.17 – 0.41</td>
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<tr>
<td>% Improvement</td>
<td>25%</td>
<td></td>
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<tr>
<td>P-Value</td>
<td>0.2411</td>
<td></td>
</tr>
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</table>

**12-19 years old**

**20 - 40 years old**

| Count        | 10         | 8            |
| Mean         | 0.30       | 0.23         |
| Std Dev      | 0.139      | 0.096        |
| Range        | 0.13 – 0.59| 0.11 – 0.43  |
| % Improvement| 35%        |              |
| P-Value      | .1896      |              |

Teens & Adults performed equally well
AcceleDent™ patients finished space closure in less time while closing a bigger extraction space
### SECONDARY EFFICACY ENDPOINT

**Time to Space Closure based on Stable TAD Time Using Individual Quadrants [accounting for treatment, canine retraction, growth (age and gender) and distance moved]**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>PP Population</th>
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<tbody>
<tr>
<td>Stable TAD Time (Days) – using growth in the model</td>
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<td></td>
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<tr>
<td>N</td>
<td>40</td>
<td>35</td>
<td></td>
</tr>
<tr>
<td>LSMEAN (Std. Error)</td>
<td>122.65 (13.63)</td>
<td>150.56 (12.56)</td>
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<tr>
<td>p-value*</td>
<td>0.0361</td>
<td></td>
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<tr>
<td>Stable TAD Time (Days) – using age and gender in the model</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>40</td>
<td>35</td>
<td></td>
</tr>
<tr>
<td>LSMEAN (Std. Error)</td>
<td>148.33 (9.83)</td>
<td>176.31 (9.88)</td>
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<tr>
<td>p-value*</td>
<td>0.0332</td>
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</table>

### Summary of Total Distance of Tooth Movement in mm (treating each quadrant independently) during Space Closure – PP Population

<table>
<thead>
<tr>
<th>Parameter</th>
<th>AcceleDent</th>
<th>Sham</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>40</td>
<td>35</td>
<td>0.3642</td>
</tr>
<tr>
<td>Mean</td>
<td>5.30</td>
<td>4.82</td>
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</tr>
<tr>
<td>Std. Dev.</td>
<td>2.20</td>
<td>2.31</td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>5.70</td>
<td>4.61</td>
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</tr>
<tr>
<td>Min-Max</td>
<td>0-10.46</td>
<td>-0.1-8.31</td>
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</table>

**Total Distance (Sum of Q1 and Q2) of Tooth Movement During Space Closure - PP**

Reduced time by 4 weeks during space closure despite bias of larger distance
## SECONDARY EFFICACY ENDPOINT

### The Impact of AcceleDent on Treatment Time Required for the Alignment Stage

<table>
<thead>
<tr>
<th>Change in Arch Perimeter (length units)</th>
<th>Weeks Required with AcceleDent (arch perimeter movement rate of 2.707 length units/week)</th>
<th>Weeks Required without AcceleDent (arch perimeter movement rate of 1.316 length units/week)</th>
<th>Number of Weeks Saved</th>
<th>% Time Increase without AcceleDent</th>
</tr>
</thead>
<tbody>
<tr>
<td>15</td>
<td>5.5</td>
<td>11.4</td>
<td>5.9</td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>7.4</td>
<td>15.2</td>
<td>7.8</td>
<td></td>
</tr>
<tr>
<td>25</td>
<td>9.2</td>
<td>19.0</td>
<td>9.8</td>
<td>106%</td>
</tr>
<tr>
<td>30</td>
<td>11.1</td>
<td>22.8</td>
<td>11.7</td>
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</tbody>
</table>
# SECONDARY EFFICACY ENDPOINT

## The Impact of AcceleDent on Treatment Time Required for Extraction Space Closure (PP Population)

<table>
<thead>
<tr>
<th>Extraction Space Distance to Close (mm)</th>
<th>Weeks Required with AcceleDent (tooth movement rate of 0.29 mm/week)</th>
<th>Weeks Required without AcceleDent (tooth movement of 0.21 mm/week)</th>
<th>Number of Weeks Saved</th>
<th>% Time Increase without AcceleDent</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>10.3</td>
<td>14.3</td>
<td>3.9</td>
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<td>4</td>
<td>13.8</td>
<td>19.0</td>
<td>5.3</td>
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<td>17.2</td>
<td>23.8</td>
<td>6.6</td>
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<td><strong>20.7</strong></td>
<td><strong>28.6</strong></td>
<td><strong>7.9</strong></td>
<td><strong>38%</strong></td>
</tr>
<tr>
<td>7</td>
<td>24.1</td>
<td>33.3</td>
<td>9.2</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>27.6</td>
<td>38.1</td>
<td>10.5</td>
<td></td>
</tr>
</tbody>
</table>
AcceleDent™ safely moves teeth faster without increased root resorption
<table>
<thead>
<tr>
<th>PRIMARY SAFETY ENDPOINT</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th># Patients with any Tooth with Greater than 2 mm Root Resorption</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td>AcceleDent (n=18)</td>
</tr>
<tr>
<td>Total</td>
</tr>
<tr>
<td>8 (47.1%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th># Individual Teeth with Greater than 2 mm Root Resorption</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td>AcceleDent (n=293)</td>
</tr>
<tr>
<td>Total</td>
</tr>
<tr>
<td>13 (4.8%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Average Amount of Root Resorption (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td>AcceleDent (n=18)</td>
</tr>
<tr>
<td>Mean</td>
</tr>
<tr>
<td>Std Dev</td>
</tr>
<tr>
<td>Median</td>
</tr>
<tr>
<td>Range</td>
</tr>
<tr>
<td>P-Value</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>positive sign indicates root resorption</td>
</tr>
</tbody>
</table>
**PRIMARY SAFETY ENDPOINT**

**Posterior Anchorage**

<table>
<thead>
<tr>
<th>Patients with Loose TADs</th>
<th>AcceleDent</th>
<th>Sham Control</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Count</strong></td>
<td>5 (21.7%)</td>
<td>5 (22.7%)</td>
</tr>
</tbody>
</table>

**No Difference in loss of posterior anchorage**

<table>
<thead>
<tr>
<th>Loose TADs</th>
<th>AcceleDent</th>
<th>Sham Control</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Count</strong></td>
<td>16 (30.2%)</td>
<td>11 (22.9%)</td>
</tr>
<tr>
<td></td>
<td>13 from 3 pts</td>
<td>9 from 3 pts</td>
</tr>
</tbody>
</table>
## PRIMARY SAFETY ENDPOINT

### Adverse Events

<table>
<thead>
<tr>
<th>Summary of Adverse Events Assessed as Possibly Related to Treatment</th>
<th>AcceleDent (N=23)</th>
<th>Sham (N=22)</th>
<th>Total (N=45)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>System Organ Class</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Preferred Term</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of subjects with at least one possibly related AE</td>
<td>5 (21.7%)</td>
<td>5 (22.7%)</td>
<td>10 (22.2%)</td>
</tr>
<tr>
<td><strong>Gastrointestinal disorders</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypoaesthesia oral</td>
<td>0</td>
<td>1 (4.6%)</td>
<td>1 (2.2%)</td>
</tr>
<tr>
<td>Nausea</td>
<td>1 (4.4%)</td>
<td>0</td>
<td>1 (2.2%)</td>
</tr>
<tr>
<td>Retching</td>
<td>0</td>
<td>1 (4.6%)</td>
<td>1 (2.2%)</td>
</tr>
<tr>
<td>Toothache</td>
<td>2 (8.7%)</td>
<td>0</td>
<td>2 (4.4%)</td>
</tr>
<tr>
<td><strong>General Disorders and administration site conditions</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Malaise</td>
<td>1 (4.4%)</td>
<td>0</td>
<td>1 (2.2%)</td>
</tr>
<tr>
<td>Sensation of pressure</td>
<td>1 (4.4%)</td>
<td>0</td>
<td>1 (2.2%)</td>
</tr>
<tr>
<td><strong>Injury, poisoning and procedural complications</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical device discomfort</td>
<td>0</td>
<td>1 (4.6%)</td>
<td>1 (2.2%)</td>
</tr>
<tr>
<td>Medical device pain</td>
<td>2 (8.7%)</td>
<td>1 (4.6%)</td>
<td>3 (6.7%)</td>
</tr>
<tr>
<td>Orthodontic appliance complication</td>
<td>1 (4.4%)</td>
<td>1 (4.6%)</td>
<td>2 (4.4%)</td>
</tr>
<tr>
<td>TAD Failure</td>
<td>1 (4.4%)</td>
<td>1 (4.6%)</td>
<td>2 (4.4%)</td>
</tr>
<tr>
<td>Loose Spring</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Musculoskeletal and connective tissue disorders</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain in jaw</td>
<td>0</td>
<td>1 (4.6%)</td>
<td>1 (2.2%)</td>
</tr>
<tr>
<td><strong>Nervous system disorders</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td>1 (4.4%)</td>
<td>2 (9.1%)</td>
<td>3 (6.7%)</td>
</tr>
<tr>
<td>Hypoaesthesia</td>
<td>1 (4.4%)</td>
<td>0</td>
<td>1 (2.2%)</td>
</tr>
<tr>
<td><strong>Respiratory, thoracic and mediastinal disorders</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sneezing</td>
<td>1 (4.4%)</td>
<td>0</td>
<td>1 (2.2%)</td>
</tr>
</tbody>
</table>

No Serious Adverse Events
TERTIARY EFFICACY ENDPOINT

Rate of Tooth Movement – Alignment Phase

AcceleDent™ moves teeth 2.06 times (106%) faster
## TERTIARY EFFICACY ENDPOINT

### Alignment Phase Average Rate of Tooth Movement – Little’s Index (mm/wk)

<table>
<thead>
<tr>
<th></th>
<th>AcceleDent</th>
<th>Sham Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Count</td>
<td>8</td>
<td>10</td>
</tr>
<tr>
<td>Mean</td>
<td>0.45</td>
<td>0.51</td>
</tr>
<tr>
<td>Std Dev</td>
<td>0.238</td>
<td>0.282</td>
</tr>
<tr>
<td>Range</td>
<td>0.11 – 0.91</td>
<td>0.10 – 0.90</td>
</tr>
<tr>
<td>P-Value</td>
<td>0.6409</td>
<td></td>
</tr>
</tbody>
</table>

### Alignment Phase Average Rate of Tooth Movement – Change in Perimeter (length units/wk)

#### Excluding pts without extractions

<table>
<thead>
<tr>
<th></th>
<th>AcceleDent</th>
<th>Sham Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Count</td>
<td>5</td>
<td>9</td>
</tr>
<tr>
<td>Mean</td>
<td>2.707</td>
<td>1.316</td>
</tr>
<tr>
<td>Std Dev</td>
<td>1.415</td>
<td>0.997</td>
</tr>
<tr>
<td>Range</td>
<td>1.592 – 4.291</td>
<td>0.171 – 3.488</td>
</tr>
<tr>
<td>P-Value</td>
<td><strong>0.051</strong></td>
<td></td>
</tr>
</tbody>
</table>
AcceleDent patients were:
• Extremely satisfied with treatment
• Thought device was easy to use
• Able to accommodate activities of daily living
TERTIARY EFFICACY ENDPOINT

Ease of Use by Patient- Overall Satisfaction

<table>
<thead>
<tr>
<th>Alignment Phase Visit</th>
<th>Treatments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Treatment Given AcceleDent</td>
</tr>
<tr>
<td>1</td>
<td>(n=15/13) (p=0.885)</td>
</tr>
<tr>
<td>1.1</td>
<td>(n=10/11) (p=0.976)</td>
</tr>
<tr>
<td>1.2</td>
<td>(n=9/10) (p=0.068)</td>
</tr>
<tr>
<td>1.3</td>
<td>(n=3/7) (p=0.756)</td>
</tr>
<tr>
<td>1.4</td>
<td>(n=1/4) (p=NEV)</td>
</tr>
<tr>
<td>1.5</td>
<td>(n=1/2) (p=NEV)</td>
</tr>
<tr>
<td>1.6</td>
<td>(n=1/1) (p=NEV)</td>
</tr>
</tbody>
</table>

Ease of Use by Patient - Overall Satisfaction

<table>
<thead>
<tr>
<th>Space Closure Phase Visit</th>
<th>Treatments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Treatment Given AcceleDent</td>
</tr>
<tr>
<td>2</td>
<td>(n=16/13) (p=0.655)</td>
</tr>
<tr>
<td>3</td>
<td>(n=15/18) (p=0.345)</td>
</tr>
<tr>
<td>4</td>
<td>(n=14/13) (p=0.984)</td>
</tr>
<tr>
<td>5</td>
<td>(n=14/12) (p=0.593)</td>
</tr>
<tr>
<td>6</td>
<td>(n=10/10) (p=0.049)</td>
</tr>
<tr>
<td>7</td>
<td>(n=9/8) (p=0.032)</td>
</tr>
<tr>
<td>8</td>
<td>(n=8/6) (p=0.190)</td>
</tr>
<tr>
<td>9</td>
<td>(n=3/6) (p=0.230)</td>
</tr>
<tr>
<td>10</td>
<td>(n=1/5) (p=NEV)</td>
</tr>
<tr>
<td>11</td>
<td>(n=0/4) (p=NEV)</td>
</tr>
</tbody>
</table>
TERTIARY EFFICACY ENDPOINT

Ease of Use by Patient - Discomfort

Alignment Phase Visit

<table>
<thead>
<tr>
<th>Visit</th>
<th>n/A</th>
<th>p/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>18/14</td>
<td>0.456</td>
</tr>
<tr>
<td>1.2</td>
<td>12/14</td>
<td>0.298</td>
</tr>
<tr>
<td>1.3</td>
<td>5/8</td>
<td>NEV</td>
</tr>
<tr>
<td>1.4</td>
<td>1/5</td>
<td>NEV</td>
</tr>
<tr>
<td>1.5</td>
<td>1/3</td>
<td>NEV</td>
</tr>
<tr>
<td>1.6</td>
<td>1/1</td>
<td>NEV</td>
</tr>
<tr>
<td>1.7</td>
<td>1/0</td>
<td>NEV</td>
</tr>
</tbody>
</table>

Space Closure Phase Visit

<table>
<thead>
<tr>
<th>Visit</th>
<th>n/A</th>
<th>p/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>19/14</td>
<td>0.592</td>
</tr>
<tr>
<td>3</td>
<td>18/15</td>
<td>0.206</td>
</tr>
<tr>
<td>4</td>
<td>17/14</td>
<td>0.350</td>
</tr>
<tr>
<td>5</td>
<td>16/13</td>
<td>0.578</td>
</tr>
<tr>
<td>6</td>
<td>14/11</td>
<td>0.203</td>
</tr>
<tr>
<td>7</td>
<td>11/9</td>
<td>0.943</td>
</tr>
<tr>
<td>8</td>
<td>9/6</td>
<td>0.681</td>
</tr>
<tr>
<td>9</td>
<td>4/6</td>
<td>0.630</td>
</tr>
<tr>
<td>10</td>
<td>2/6</td>
<td>NEV</td>
</tr>
<tr>
<td>11</td>
<td>1/5</td>
<td>NEV</td>
</tr>
<tr>
<td>12</td>
<td>0/1</td>
<td>NEV</td>
</tr>
</tbody>
</table>
**TERTIARY EFFICACY ENDPOINT**

**Patient Perception of Device Components - Ease of Use**

Alignment Phase Visit

- 1 (n=32) (p=0.677)
- 1.1 (n=28) (p=0.819)
- 1.2 (n=26) (p=0.791)
- 1.3 (n=13) (p=0.226)
- 1.4 (n=6) (p=0.435)
- 1.5 (n=4) (p=0.291)
- 1.6 (n=2) (p=0.224)
- 1.7 (n=1) (p=0.001)

**Patient Perception of Device Components - Ease of Use**

Space Closure Phase Visit

- 2 (n=19/14) (p=0.677)
- 3 (n=18/15) (p=0.819)
- 4 (n=17/14) (p=0.791)
- 5 (n=16/13) (p=0.613)
- 6 (n=14/11) (p=0.226)
- 7 (n=11/10) (p=0.435)
- 8 (n=9/6) (p=0.291)
- 9 (n=4/6) (p=0.224)
- 10 (n=2/6) (p=0.001)
- 11 (n=1/5) (p=NEV)
- 12 (n=0/1) (p=NEV)

- Blue: Treatment Given AcceleDent
- Red: Treatment Given Sham Device
TERTIARY EFFICACY ENDPOINT

Ease of Use by Patient - Schedule Disruption

Alignment Phase Visit

TREATMENT GIVEN ACCELEDENT

TREATMENT GIVEN SHAM DEVICE

Space Closure Phase Visit

TREATMENT GIVEN ACCELEDENT

TREATMENT GIVEN SHAM DEVICE
TERTIARY EFFICACY ENDPOINT

**Patient Perception of Device Components - Hygiene**

**Alignment Phase Visit**
- 1: Treatment Given AcceleDent (n=18/14, p=0.721)
- 1.1: Treatment Given AcceleDent (n=14/14, p=0.572)
- 1.2: Treatment Given AcceleDent (n=12/14, p=0.200)
- 1.3: Treatment Given AcceleDent (n=5/8, p=0.885)
- 1.4: Treatment Given AcceleDent (n=1/5, p=NEV)
- 1.5: Treatment Given AcceleDent (n=1/3, p=NEV)
- 1.6: Treatment Given AcceleDent (n=1/1, p=NEV)
- 1.7: Treatment Given AcceleDent (n=0/1, p=NEV)

**Space Closure Phase Visit**
- 2: Treatment Given AcceleDent (n=19/14, p=0.918)
- 3: Treatment Given AcceleDent (n=18/15, p=0.656)
- 4: Treatment Given AcceleDent (n=17/14, p=0.975)
- 5: Treatment Given AcceleDent (n=16/13, p=0.447)
- 6: Treatment Given AcceleDent (n=14/11, p=0.738)
- 7: Treatment Given AcceleDent (n=11/9, p=0.594)
- 8: Treatment Given AcceleDent (n=9/6, p=0.976)
- 9: Treatment Given AcceleDent (n=4/6, p=0.619)
- 10: Treatment Given AcceleDent (n=2/5, p=NEV)
- 11: Treatment Given AcceleDent (n=1/5, p=NEV)
- 12: Treatment Given AcceleDent (n=0/1, p=NEV)

Worsened - Improved
TERTIARY EFFICACY ENDPOINT

Ease of Use by Patient - Cleanliness and Maintenance

Alignment Phase Visit

<table>
<thead>
<tr>
<th>Visit</th>
<th>Treatment Given AcceleDent</th>
<th>Treatment Given Sham Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>100 (n=18/14) p=0.104</td>
<td>80 (n=14/14) p=0.081</td>
</tr>
<tr>
<td>1.1</td>
<td>80 (n=12/14) p=0.381</td>
<td>60 (n=5/8) p=0.255</td>
</tr>
<tr>
<td>1.2</td>
<td>60 (n=1/5) p=NEV</td>
<td>40 (n=1/3) p=NEV</td>
</tr>
<tr>
<td>1.3</td>
<td>40 (n=1/1) p=NEV</td>
<td>20 (n=1/0) p=NEV</td>
</tr>
</tbody>
</table>

Space Closure Phase Visit

<table>
<thead>
<tr>
<th>Visit</th>
<th>Treatment Given AcceleDent</th>
<th>Treatment Given Sham Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>100 (n=19/14) p=0.993</td>
<td>80 (n=18/15) p=0.914</td>
</tr>
<tr>
<td>3</td>
<td>80 (n=17/14) p=0.374</td>
<td>60 (n=16/13) p=0.661</td>
</tr>
<tr>
<td>4</td>
<td>60 (n=14/11) p=0.809</td>
<td>40 (n=11/9) p=0.310</td>
</tr>
<tr>
<td>5</td>
<td>40 (n=15) p=0.398</td>
<td>20 (n=4/6) p=0.196</td>
</tr>
<tr>
<td>6</td>
<td>20 (n=2/6) p=NEV</td>
<td>0 (n=1/5) p=NEV</td>
</tr>
<tr>
<td>7</td>
<td>0 (n=0/1) p=NEV</td>
<td>0 (n=0/1) p=NEV</td>
</tr>
</tbody>
</table>

Difficult - Easy
TERTIARY EFFICACY ENDPOINT

Ease of Use by Patient - Drooling

Alignment Phase Visit

1. (n=18/14) (p=0.576)
2. (n=14/14) (p=0.439)
3. (n=12/14) (p=0.946)
4. (n=5/8) (p=0.964)
5. (n=1/5) (p=NEV)
6. (n=1/3) (p=NEV)
7. (n=1/1) (p=NEV)
8. (n=0/1) (p=NEV)

Space Closure Phase Visit

9. (n=19/14) (p=0.631)
10. (n=18/15) (p=0.159)
11. (n=17/14) (p=0.278)
12. (n=16/13) (p=0.633)
13. (n=14/11) (p=0.474)
14. (n=11/9) (p=0.846)
15. (n=9/6) (p=0.304)
16. (n=4/6) (p=0.550)
17. (n=2/6) (p=0.983)
18. (n=1/5) (p=NEV)
19. (n=0/1) (p=NEV)

Significant - None
Many Difficulties - None

Patient Perception of Device Components - Reliability

Alignment Phase Visit

1. Treatment Given AcceleDent
   - Many Difficulties: 18/13
   - None: 13/13
   - p = 0.808

2. Treatment Given Sham Device
   - Many Difficulties: 13/13
   - None: 13/13
   - p = 0.977

3. Treatment Given AcceleDent
   - Many Difficulties: 12/13
   - None: 12/13
   - p = 0.978

4. Treatment Given Sham Device
   - Many Difficulties: 5/7
   - None: 7/5
   - p = 0.336

5. Treatment Given AcceleDent
   - Many Difficulties: 1/4
   - None: 4/1
   - p = NEV

6. Treatment Given Sham Device
   - Many Difficulties: 1/3
   - None: 3/1
   - p = NEV

7. Treatment Given AcceleDent
   - Many Difficulties: 1/1
   - None: 1/1
   - p = NEV

8. Treatment Given Sham Device
   - Many Difficulties: 1/0
   - None: 0/1
   - p = NEV

Many Difficulties - None

Patient Perception of Device Components - Reliability

Space Closure Phase Visit

1. Treatment Given AcceleDent
   - Many Difficulties: 19/14
   - None: 14/19
   - p = 0.158

2. Treatment Given Sham Device
   - Many Difficulties: 18/15
   - None: 15/18
   - p = 0.175

3. Treatment Given AcceleDent
   - Many Difficulties: 17/13
   - None: 13/17
   - p = 0.626

4. Treatment Given Sham Device
   - Many Difficulties: 16/13
   - None: 13/16
   - p = 0.396

5. Treatment Given AcceleDent
   - Many Difficulties: 14/11
   - None: 11/14
   - p = 0.658

6. Treatment Given Sham Device
   - Many Difficulties: 11/9
   - None: 9/11
   - p = 0.812

7. Treatment Given AcceleDent
   - Many Difficulties: 9/6
   - None: 6/9
   - p = 0.684

8. Treatment Given Sham Device
   - Many Difficulties: 4/6
   - None: 6/4
   - p = 0.355

9. Treatment Given AcceleDent
   - Many Difficulties: 2/6
   - None: 6/2
   - p = 0.013

10. Treatment Given Sham Device
    - Many Difficulties: 1/5
    - None: 5/1
    - p = NEV

11. Treatment Given AcceleDent
    - Many Difficulties: 0/1
    - None: 1/0
    - p = NEV

12. Treatment Given Sham Device
    - Many Difficulties: 0/1
    - None: 1/0
    - p = NEV
TERTIARY EFFICACY ENDPOINT

Patient Perception of Device Components - Noise

Alignment Phase Visit

- Treatment Given AcceleDent
- Treatment Given Sham Device

Space Closure Phase Visit

- Treatment Given AcceleDent
- Treatment Given Sham Device
Single Word Frequency to Describe Device

- easy/effortless: 80
- Good: 40
- simple: 30
- ok: 20
- Annoying: 10
- Boring/dull: 10
- strange/weird/different: 10
- effective: 10
- great: 10
Human Studies on Discomfort During Treatment
Vibratory Stimulation as a method of reducing pain after orthodontic appliance adjustment

- 21 males 27 females (teens and adults)
- No patients took analgesics
- **Group A** no pain relief
- **Group B** 15 minutes vibratory device immediately after arch wire placed
- Visual Analogue Scoring for both groups after arch wire placement

Fig. 3  Visual analog scores for control and experimental (vibratory stimulation) groups at various time intervals and archwire placement.
Conclusions

• Discomfort significantly less at every time interval for those who used vibratory apparatus

• Must be used for pain reduction prior to the onset of pain

• Most patients reported not being able to tolerate the vibratory stimulation after discomfort was present

• May be a useful tool in preventing dental pain associated with orthodontic treatment.
Vibratory stimulation for the relief of pain of dental origin

• Studied the effect of vibratory stimulation on pain of dental origin in 36 patients.

• Vibration at 100 Hz applied to various points in the facial region.

• Not pain due to orthodontic appliances.

• Concluded that vibration causes an elevation in subjective threshold for detection of pain.

Ottoson et al, Pain, 1981
Hypothesis on Pain Reduction

- Vibrations are thought to alter the ischemic response by having a vasodilating effect in the periodontal ligament. This may assist to re-establish the blood supply after the application of force on the tooth.
- The increased blood flow may also play a contributory role in accelerating the bone remodeling process.
- The effect of vibration is most likely dependent on the activation of rapidly adapting receptors and is probably due to an interaction between large fibers and small pain-carrying fibers.
- Vibration may activate large fibers more selectively.
Conclusions from Animal and Human Studies

1. The rate of orthodontic tooth movement greatly depends on the speed at which the bone surrounding the teeth remodels.

2. Studies have shown that orthodontic force coupled with microvibrations safely accelerates tooth movement.

3. Microvibrations stimulate bone metabolism molecules that regulate the quantity and activity of bone cells.

4. Microvibrations may assist in pain reduction following placement and activation of arch wires.
Activator

25 gram force
30 Hz frequency
20 minutes daily use
Small & Large Sizes
Open, Deep, Flat Bite Profiles
Individually packaged

Mouthpiece
Charging Port

Week: 6/7 (86%)

Month: 25/30 (83%)

Total: 145 uses
Trial Mouthpiece Set
Trial fit on patient or study model

Sterilization Methods

- Steam **Sterilization** with pre-vacuum:
  - 3-4 minutes at 270°F to 274°F
  - 30 minute dry time

- Steam **Sterilization** with gravity displacement:
  - 15 minutes at 270°F
  - 30 minute dry time
For the Patient – Base Set & Mouthpiece
• Simple and Easy
• 20 minutes daily use
• Incorporate into activities of daily living
  – Watching TV
  – Reading / Homework
  – Listening to music/computer

• Compatible with all types of braces
Case Presentations
MARKET INTRODUCTION

October 2009 to October 2010 in UK & EU (Limited release)

March 2010 thru Dec 2010 in Australia (Limited release)

January 2011 Full Market Introduction in UK and Australia
Case Presentations

Dr. Asif Chatoo

– BSc., BDS, FDS RCS (Eng), MSc., MOrth RCS (Eng)
– Qualified as a dentist from King's College, London.
– Masters Degree in Orthodontics from GKT Dental Institute, London.
– Received specialist training in Lingual Orthodontics
– Interest in the multidisciplinary treatment of adult patients
25 yr old female
Class I incisor relationship on a class I skeletal base
Moderate crowding of upper and lower arches.

Start
12 Weeks

UL4 extracted and replaced with pontic

Courtesy of Dr. Asif Chatoo

THE LONDON LINGUAL ORTHODONTIC CLINIC
24 Weeks

Courtesy of Dr. Asif Chatoo
30 Weeks

Courtesy of Dr. Asif Chatoo
Adult male

Class II division 1 incisor relationship on a Class II skeletal base
Crowding of upper and lower labial segments & deep overbite
12 weeks

Upper lingual & lower labial braces
Compare 12 weeks

significant improvement in alignment with reduction of overjet & overbite

Courtesy of Dr. Asif Chatoo
Start

Adult female
Relapse of previous orthodontic treatment
Class III skeletal discrepancy
Asymmetry in smile between left & right side
Cross bite of upper left lateral incisor
Mild crowding of lower arch
Patient did not want extractions

Courtesy of Dr. Asif Chatoo
8 Weeks

Upper lingual & lower labial appliances
Accept centerline discrepancy of lower arch & mandibular asymmetry

Courtesy of Dr. Asif Chatoo
16 Weeks

Courtesy of Dr. Asif Chatoo
32 Weeks

Courtesy of
Dr. Asif Chatoo
40 Weeks

Courtesy of Dr. Asif Chatoo
46 Weeks

90% compliance with AcceleDent throughout treatment

Original treatment plan estimated at 78 wks

At patient request appliances removed 8 wks early

Courtesy of Dr. Asif Chatoo
Star

46 Weeks

Courtesy of Dr. Asif Chatoo
Case Presentations

Dr. Sharon Orton-Gibbs

- BDS, FDS, D.Orth, M.Orth, MSc
- Qualified in dentistry from Bristol University, with Honors in 1983
- Studied orthodontics at the Eastman Dental Hospital in London
- Practice was established in 1968 by her father Harry Orton who was awarded the Order of the British Empire for services to orthodontics. She joined in 1987 and took over in 1995.
- Member of the British, European and American Societies for the Study of Orthodontics and the World Federation of Orthodontists.
- Until June 2007, was a part-time Consultant at St Helier Hospital, Carshalton as lead clinician and responsible for training post-graduates.
18 year old male

Class III combination ortho & surgical case
Treatment Plan

Orthodontic alignment

L8s extracted

5mm maxillary advancement with 2mm impaction

3mm mandibular reduction & correction of midline

Patient wanted to be complete within 12 months for 1st year of University
Mouthpiece Fitted

Courtesy of Dr. Sharon Orton-Gibbs
Start

9 Weeks

Courtesy of Dr. Sharon Orton-Gibbs
5 days post orthognathic surgery
(9 months into treatment & 2 months of delay with travels and parents away)

Courtesy of Dr. Sharon Orton-Gibbs
6.5 weeks post surgery
46 Weeks Total Treatment Time

Courtesy of
Dr. Sharon Orton-Gibbs
Finish – 46 Weeks

Courtesy of Dr. Sharon Orton-Gibbs
“I found using AcceleDent straightforward and uncomplicated – it was easy to include the 20 minutes routine into my day. It's great to know that I won't need to travel back from the north for more treatment and I am extremely happy with the result.”

Courtesy of Dr. Sharon Orton-Gibbs
Start

46 Weeks

Courtesy of Dr. Sharon Orton-Gibbs
17 year old male
Start

6 Weeks

Courtesy of
Dr. Sharon Orton-Gibbs
5.5 Months

Courtesy of Dr. Sharon Orton-Gibbs
7.5 months treatment - 5 days post-op
Start

9.5 months

Courtesy of Dr. Sharon Orton-Gibbs
Case Presentations

Dr. Stewart Hawthorn

- MSc, BDS, FDS, Morth
- Dental graduation - 1979
  University of Dundee - Scotland
- Orthodontic graduation - 1988
  Guys Hospital – England
36 year old female
Severely crowded Class II Division 1
Over Jet = 8mm
Anterior Open Bite = 3mm & caused by thumb sucking

Courtesy of Dr. Stewart Hawthorn
Remove four x 1\textsuperscript{st} premolars
Upper and lower self-ligating appliances
Bite closing mechanics
Retain with bonded retainers
Estimated treatment time at least 24 months
14 Weeks
LL2 has just been bonded
28 Weeks
85% AcceleDent compliance
Start

28 Weeks
14 year old male

Crowded Class II Division 2; Skeletal Class II

Incompetent lip pattern

Excluded upper canines

Class II molars
Non extraction with upper and lower self-ligating fixed appliances

Open the spaces for the upper canines

Open the bite

Estimated treatment time = 18 months
Enough space has been created to bond the canines
14 Weeks

.020x.020 square arch wire

Bite beginning to open & molars beginning to correct
80% AcceleDent compliance
Good bite opening & molar correction with alignment of upper canines
Revised estimated treatment time < 15 months
39 year old female
Class II Division 1 incisor relationship
13 mm overjet
10 mm overbite
Previous treatment with 4 premolars extracted
& functional appliance
Patient declined surgery
SNA 88
SNB 81
ANB 7
MMA 17
U1/Max 115
L1/Man 95
OJ 13
OB 10

Estimated Treatment time 24 months+
28 weeks
Non extraction
Upper & Lower self-ligating
TADs & Class II elastics
Start

28 Weeks

95% AcceleDent compliance
Arches aligning well
2nd molars bonded to aid with bite opening
Estimated Tx time reduced to 21 months or less
18 year old female
Class III incisor relationship with Skeletal I base
Mild lower crowding
Moderate upper crowding
Poor prognosis for UR6
Bond up

25 weeks

Extracted UR6 to bring UR3 into the arch
Tooth colored self-ligating brackets
UR3 bonded at 25 weeks
Estimated Treatment time 18-21 months
Start

32 Weeks

UR3 seating well
Estimated Treatment time 15-18 months
94% AcceleDent compliance
Good arch form developing
Space closure at UR6 starting
Start

56 weeks

Estimated time to completion 16 months
60% AcceleDent compliance
Estimated time to completion 16 months
60% AcceleDent compliance
Important Closing Thoughts

• Strong supporting science demonstrates cyclical forces can modulate local bone biology

• Clinical trial indicates:
  – **Safely** move teeth 38% - 50% during space closure and 2x faster during alignment phase

• Complements any treatment approach

• Reduced treatment time enables improved practice productivity
Important Closing Thoughts

• Logistical changes
  – Decrease wire change interval
ORTHODONTIST VALUE PROPOSITION: ↑ Profitability

Relax. You don’t have to change a thing.

AcceleDent works with your current approach. Clinically proven to accelerate orthodontic tooth movement by 38% – 50%.

Conventional
Self-ligating
Lingual

IMPROVING PRACTICE EFFICIENCIES & ECONOMICS
- Finish cases faster
- See more patients in less time
  Generate higher profitability VIA:
  (1) Margin per case
  (2) More consults → more new starts
  (3) Eliminating unnecessary visits

EXPANDING ORTHODONTIC APPLICATIONS
- Easy to implement
- Can be used with any orthodontic case
- Practice differentiation to attract new patients
- Appealing to adults
Thank you!