

# The clinical evaluation of a novel cyclical force generating device in orthodontics

*Chung How Kau, Jennifer T Nguyen, and Jeryl D English report the results of their study*

## Abstract

The purpose of this study was to determine the clinical effects of a cyclical force generating device on tooth movement and overall orthodontic treatment time. In addition, the levels of patient compliance and patient satisfaction were evaluated. Patients who were undergoing active orthodontic treatment with fixed appliances, with no previous history of orthodontic treatment, were invited to participate in this study. The subjects were instructed to use the device for 20 minutes daily for a period of 6 consecutive months. Rates of tooth movement, patient compliance, and patient perception data were evaluated. Fourteen patients completed the study. The total rate of movement for the mandibular arch was 0.526 mm per week or 2.1 mm per 28-day month; the total rate of movement for the maxillary arch was 0.759 mm per week or 3.0 mm per 28-day month. There was a statistically significant difference between the rates of movement in the maxillary arch compared with the mandibular arch ( $p > 0.05$ ). The patient compliance rate as measured by data recorded from the devices by the study engineer indicated a 67% compliance rate. Overall patient satisfaction with the device increased over the course of treatment time for most variables as indicated by the mean scores. Paired t-test value indicated that there was a statistically significant change in overall satisfaction for all variables measured with the exception of drooling and noise. It was concluded that the rates of movement of teeth during orthodontic treatment were increased with the use of the device; patient compliance with use of device was 67%; and patient acceptance of and compliance with the device was clinically significant.

The most common treatment approach to correcting dental malocclusion is through the use of static mechanical forces, which traditionally involves an appliance system of metal arch wires and brackets. Static mechanical forces in orthodontic treatments move teeth within the jaw bone and rely on force-induced remodeling to elicit tooth movement. The traditional fixed-force system is augmented with elastics, metal bands, head gear, expansion appliances, and other ancillary devices as determined by the clinician. These forces are static in that they are, for the most part, applied only at specific treatment intervals by the clinician, but then subsequently stay constant and are not altered between visits.

Bone is a flexible tissue, and application of steady pressure to the teeth (static force) through the use of orthodontic arch wires permits teeth to be systemically moved into the new positions through this compliant medium. When a force is exerted on a tooth in a specific direction, the altered state of the periodontal ligaments (PDLs) behind the tooth results in bone resorption via osteoclastic activity. New bone forms in the area of increased PDL tension due to stimulation of osteoblastic activity. The direction of movement of the tooth is influenced by polarity created by the point of application of the mechanical forces. Mechanical pressure to the tooth induces an electropositive state, whereas the resultant tension to the PDLs induces an electronegative state. When the tooth is under tension and increased in convexity, the area is in an electronegative state. This is associated with osteoblastic activity of bone deposition.<sup>1</sup>

Cells respond to mechanical stress to the tooth and its periodontal tissue, or PDL.<sup>2</sup> The periodontal tissue is a connective tissue attaching the tooth to the alveolar bone. This tissue withstands the compressive forces during

mastication while stabilizing the tooth. In addition, tooth movement invokes an inflammatory process, and cytokines, such as interleukin-1 (IL-1), IL-6, and receptor activator for nuclear factor  $\kappa$  B ligand (RANKL) are inflammatory mediators or pro-inflammatory remodelers of the PDL.<sup>3</sup> RANKL is reportedly essential to the osteoclast formation, function, and survival.<sup>2</sup>

Until recently, all studies relating to the use of vibratory or cyclical forces during orthodontic treatment have been tested on rats. However, many investigators question the validity of extrapolating animal experimental findings to the human condition. For example, the alveolar bone of rats has been shown to be significantly denser than the alveolar bone in humans. In addition, the osteoid tissue along the alveolar bone is less abundant in rats than in humans, demonstrating reduced formation of osteoblasts. Small amounts of acid mucopolysaccharides are found on the extracellular matrix of rat bone, and calcium balance is controlled by intestinal absorption rather than bone tissue. Moreover, studies have also identified structural dissimilarities in the periodontal tissue. Finally, rats develop tissue during root formation during the application of orthodontic forces much faster than humans, although the mechanisms of formation are the same.<sup>4</sup>

This clinical study represents the first attempt to use a cyclical force generating device on human subjects to determine its impact on the rate of tooth movement during traditional orthodontic treatment. The purpose of this study was to measure clinically the effect of the device on orthodontic treatment time, and in addition, to evaluate patient compliance and acceptance of this adjunctive treatment.

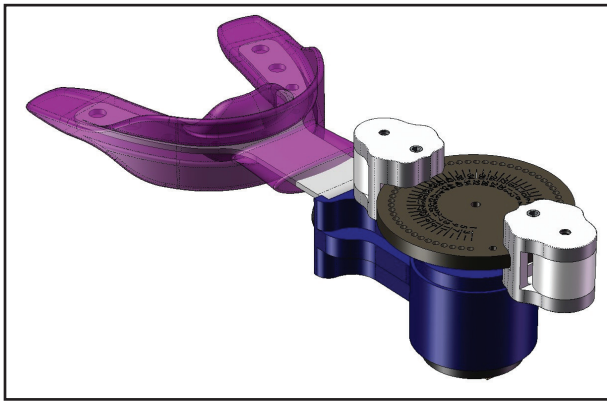


Figure 1: Diagrammatic representation of the AcceleDent device

## Materials and methods

### Subjects

Subjects were selected from patients who presented for orthodontic treatment at the Department of Orthodontics, University of Texas Health Science Center at Houston. Study oversight and approval was given by the relevant Institutional Review Board at the University. Subjects were selected based on the following inclusion criteria:

1. Complete permanent dentition
2. Subjects that in the opinion of the investigator would be compliant with device use
3. Class I malocclusion with crowding or spacing of  $> = 6$  mm for mandibular incisors, lower number 1s through 3s
4. All subjects were candidates for canine retraction with bicuspid extraction
5. All subjects demonstrated clinically acceptable oral hygiene, as determined by the investigator orthodontist

Subjects were excluded from the study if the following conditions existed:

1. Any medical or dental condition that in the opinion of the investigator could impact study results during the expected length of the study
2. Subject was currently using any investigational drug or any other investigational device
3. Subject had plans to relocate or move within 6 months of enrollment
4. Subjects could not comply with the ban on using aspirin or nonsteroidal anti-inflammatory drugs during the course of the study
5. Subjects had a history of use of bisphosphonates (osteoporosis drugs)
6. Subjects were pregnant females.

Patients were instructed to use the experimental device for 20 minutes daily for the 6-month study period.

### Novel device

The device used in this study was the AcceleDent Type 1 (Figure 1). This device applies cyclic forces to move teeth in bone faster through accelerated bone remodeling.<sup>7</sup> The device is a removable orthodontic device, similar to a retainer, that delivers vibratory forces to the dentition.

**GLOBAL EVALUATIONS**

Place an "X" on the line at the point you believe indicated your overall Satisfaction with using the device.

|-----o-----|  
Extremely Unsatisfied      No Change      Extremely Satisfied

In general, how was the

1) DISCOMFORT |-----o-----|  
Considerable Discomfort      Some Discomfort      No Discomfort

2) EASE OF USE |-----o-----|  
Difficult      Fairly Easy      Very Easy

3) SCHEDULE DISRUPTION |-----o-----|  
Significant Disruption      Some Disruption      No Disruption

4) HYGIENE (brushing & flossing habits) |-----o-----|  
Worsened      No Impact      Improved

5) CLEANLINESS & MAINTENANCE (how was it to clean) |-----o-----|  
Difficult      same as other orthodontic materials      Easy

6) DROOLING (the device caused) |-----o-----|  
Significant Drooling      Some Drooling      No Drooling

7) RELIABILITY (how did device work according to instructions) |-----o-----|  
Many Difficulties      Some Difficulties      No Difficulties

8) NOISE |-----o-----|  
Very Annoying Sound      Somewhat Annoying Sound      No Annoying Sound

Figure 2: Sample copy of the evaluation sheet filled in by the patient

The primary components of the device are the activator and mouthpiece. When in use, the patient bites on the mouthpiece after activating the device and the activator, positioned just outside of the mouth, generates and transfers the vibration to the teeth. The mouthpiece is made of polyurethane over-molded onto a metal base. The study activator (7.5 oz vibrating device) consists of a molded hard plastic covering that houses a lithium ion battery, motor, microprocessor, and weights. The two weights are rotated by the motor, which generates vibration at settings of 30 Hz, 20 g (0.2 N) for 20 minutes. The commercial system available internationally is smaller (2.5 oz), but will provide the same amount of vibration. Importantly, AcceleDent Type 1 was designed to work with all existing bracket technologies, and is therefore intended as a complement to, rather than a replacement of, existing bracket technologies (braces).

## Parameters measured

### Rates of tooth movement

The outcome measures were recorded directly at each clinical visit. Crowding was determined as a linear function between the mesio-distal widths of the adjacent teeth (recorded in millimeters) according to the Irregularity Index first described by Little.<sup>5</sup> All linear measurements were recorded manually with a digital vernier calipers. The rate of tooth movement was measured as the change in the displacement of teeth such that as alignment improved over time, there was also a quantitative reduction in the Little's Index score.

In some cases, reduction of extraction space was also recorded. This was recorded as a function of space reduced over time in millimeters.

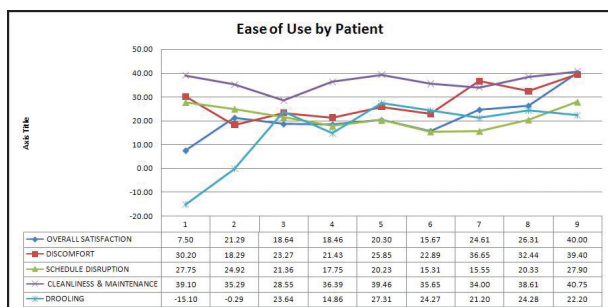


Figure 3: The graphical and quantitative representation of the ease of use of the device by the patient. The parameters presented are: overall satisfaction, discomfort, schedule disruption, cleanliness/maintenance, and drooling. The VAS scores are presented on the vertical axis while the 9 periods are represented on the horizontal axis

### Evaluation of patient compliance with the device

The device includes a microprocessor that stores the date, time, and length of use associated with every device use. This information could be accessed by an engineer during a patient's visit and an overall compliance rate was calculated based on this information. Patients also completed a daily diary where they noted each use of the device.

### Evaluation of patient perception and compliance with the device

Patients were asked at each recall visit to fill in a global evaluation form that discussed the following areas with regard to the device. A visual analog scale (VAS) was used as the assessment tool. An example of this is shown in Figure 2.

VAS readings were hand measured and ranged from -50 to +50, with -50 being the "worst," 0 being neutral, and +50 being "best."

### Statistics

SPSS 16.0.1 was used to determine if the changes were statistically significant.

## Results

The following results were obtained and presented as follows:

### Subjects

Seventeen subjects were recruited to participate in the study. Fourteen completed using the device during the study period. Three subjects declined to continue with the device use for a variety of personal reasons and are not included in this study. The mean age of the subjects was 20.3 years. The oldest patient was 56.6 years and the youngest was 12.1 years.

### Recordings of tooth movement

The total rate of movement for the mandible was 0.526 mm per week or 2.1 mm per 28-day month; the total rate of movement for the maxillary was 0.759 mm per week or 3.0 mm per 28-day month.

There was a statistically significant difference

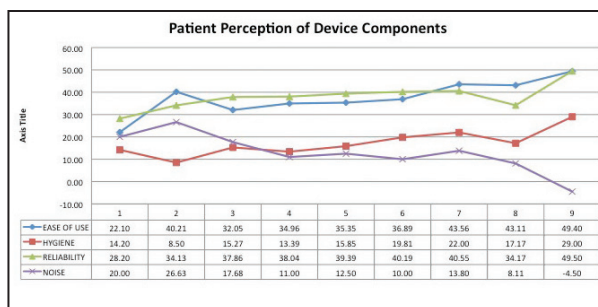


Figure 4: The graphical and quantitative representation of the patient's perception of the device components. The parameters presented are: ease of use, hygiene, reliability, and noise levels. The VAS scores are presented on the vertical axis while the 9 periods are represented on the horizontal axis

between the rates of movement of teeth in the upper arch compared to the lower arch ( $p > 0.05$ ).

### Evaluation of patient compliance

Based on the patient's own self-report, patients reported using the device about 80% of the time that they were instructed to use it. The compliance rate based on the device's use data as recorded by the study engineer indicated a 67% compliance rate. As expected, patients tend to self-report slightly higher rates than those captured by objective methods.

### Evaluation of patient evaluation of the device

Patient evaluation results of these are presented graphically in Figures 3 and 4.

### Ease of use by patient

The overall satisfaction rate of the subjects increased over time for most variables as indicated by the mean scores. The paired t-test value indicated that there was a statistically significant change over the duration of the study period. The parameters that improved over time included overall satisfaction, discomfort, ease of use, schedule disruption, hygiene, cleanliness and maintenance, and reliability. Only drooling and noise did not demonstrate statistically significant improvement and subsequently had the lowest test scores.

## Discussion

AcceleDent Type 1 in theory provides a cyclical force in addition to the standard static force provided by standard orthodontic treatment. The application of these cyclical forces induces accelerated remodeling of alveolar bone, thereby enabling accelerated tooth movement. In a series of rabbit experiments (N=24), Mao demonstrated that cyclical forces applied at 2 N and with frequencies of 0.2 and 1 Hz for 20 minutes daily provided in conjunction with typical static orthodontic forces provided 24-hours per day induced increased cranial growth, sutural separation, and proliferation of osteoblast-like cells. Histological evidence indicated wider separation of the premaxillomaxillary suture, frontonasal suture, and maxillopalatine suture associated with cyclic loading.<sup>6,7</sup> In

contrast, sutures associated with control and static loads were less separated. Thus the hypothetical basis for using this device is to decrease overall orthodontic treatment time. Additionally, this type of device idea (cyclic force) has been used and approved for use in other areas of the body (e.g., the Juvent 1000 device for maintaining and/or enhancing muscle strength, function, and postural stability).

### Rates of tooth movement

The rates of tooth movement were encouraging. The conventional wisdom regarding normal rates of tooth movement are about 1 mm of movement per month. In this sample, we saw between 2-3 mm per month, depending on the arch in which the movement was measured. However, the majority of the results were

measured in terms of movements as a reduction of Little's Index scores, and the sample size in this study was small (n=14). Future studies will need to be carried out on a broader clinical spectrum of cases.

### Evaluation of patient compliance

Patients reported their compliance at about 80%; whereas automatic device compliance detection reported compliance at about 67%. Compliance tended to be very good in adult patients while it was lower in some teenage patients, particularly male teenagers. Other mitigating factors that impacted the study included the occurrence of a major hurricane and a small number of device complications (device breakdown leading to device replacement). Some patients were without power for 2 or 3 weeks due to the hurricane, and therefore could not recharge their devices. Three patients were without device use for more than a day due to device malfunction. All patients received new devices within 1 week of any malfunction.

### Evaluation of patient perception and compliance with the device

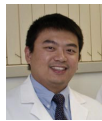
In this study, it was surprising to find that the subjects' overall satisfaction with the device was high. There were very few complaints with adverse side effects such as discomfort, ease of use, and schedule disruption. The primary complaints with the use of the device in terms of perception were drooling and the noise level. These issues have been significantly addressed in the newer versions of the device.

### Conclusions

In general, the first prototype of this novel device demonstrates good promise to the orthodontic profession. The initial safety and efficacy studies conducted in this initial study demonstrated positive results and have the potential of being an alternative to a surgical approach.<sup>8</sup>

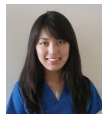
The following conclusions can be made within the limits of the study:

- The rates of movement of teeth during orthodontic treatment was accelerated with the use of the device
- The subject compliance with the use of the device was 67%
- The acceptance of and compliance with the device was high. **Q**



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Dr. English has presented numerous lectures both nationally and internationally in his career. He is board certified by the American Board of Orthodontics. Dr. English has published 82 abstracts, 85 refereed articles, 6 book chapters, and an orthodontic text book published by Elsevier entitled Mosby's Orthodontic Review. In March 2007, he was presented with the University of Missouri, Kansas City, Orthodontic Alumnus of the Year award. Dr. English serves as Director for the SWSO for the American Board of Orthodontics and will serve as the ABO President from 2010-2011.

### References

1. Darendeliler MA, Zea A, Shen G, Zoellner H. Effects of pulsed electromagnetic field vibration on tooth movement induced by magnetic and mechanical forces: a preliminary study. *Aust Dent J* 2007;52(4):282-287.
2. Nishimura M, Chiba M, Ohashi T, Sato M, Shimizu Y, Igarashi K, et al. Periodontal tissue activation by vibration: intermittent stimulation by resonance vibration accelerates experimental tooth movement in rats. *Am J Orthod Dentofacial Orthop* 2008;133(4):572-583.
3. Meikle MC. The tissue, cellular, and molecular regulation of orthodontic tooth movement: 100 years after Carl Sandstedt. *Eur J Orthod* 2006;28(3):221-240.
4. Ren Y, Maltha JC, Kuijpers-Jagtman AM. The rat as a model for orthodontic tooth movement--a critical review and a proposed solution. *Eur J Orthod* 2004;26(5):483-490.
5. Little RM. The irregularity index: a quantitative score of mandibular anterior alignment. *Am J Orthod* 1975;68(5):554-563.
6. Mao JJ. Mechanobiology of craniofacial sutures. *J Dent Res* 2002;81(12):810-816.
7. Mao JJ, Nah HD. Growth and development: hereditary and mechanical modulations. *Am J Orthod Dentofacial Orthop* 2004;125(6):676-689.
8. Wilcko WM, Wilcko T, Bouquot JE, Ferguson DJ. Rapid orthodontics with alveolar reshaping: two case reports of decrowding. *Int J Periodontics Restorative Dent* 2001;21(1):9-19.