AcceleDent™ Increases the Rate of Orthodontic Tooth Movement:
Results of a Randomized Controlled Clinical Trial

Introduction

Previous studies demonstrated that application of cyclic loading (vibration) reverses bone loss and stimulates bone mass and quality in patients with osteoporosis.[1,2] Experiments in rabbits and rats showed that vibrating forces induce cranial growth, stimulate separation of cranial sutures and accelerate tooth movement. [3,4,5]

An earlier study at the University of Texas Health Science Center - Houston was conducted as a non-controlled clinical trial with a prototype version of AcceleDent (OrthoAccel Technologies, Inc., Houston, Texas).[6] Using this vibration-producing appliance twice daily for 10 minutes accelerated tooth movement during the alignment phase by 70% compared to historical rates published in the literature.[7,8] Cone beam tomograms showed root resorption to be less than 0.5 mm, and no serious adverse events were reported, indicating the safety of the AcceleDent appliance.

The University of Texas Health Science Center - San Antonio recently completed a prospective, randomized, blinded, sham-controlled clinical trial to evaluate the effect of AcceleDent on the rate of tooth movement. Forty-five patients, with crowding in the maxillary arch requiring extraction of first bicuspids, were enrolled and randomly assigned to use an active prototype AcceleDent appliance (n=23) or a sham control appliance (n=22) for 20 minutes daily. The end of study was defined as the point when less than 1mm of extraction space remained to be closed. After the initial alignment, maxillary cuspids were retracted by sliding
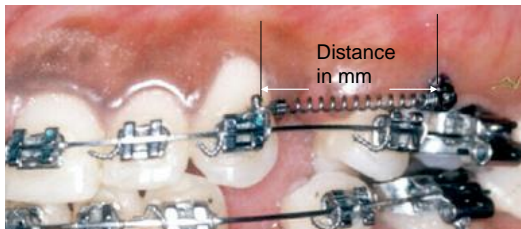

Fig. 1: Measurement of the amount of canine retraction

mechanics along a 0.018 inch stainless steel archwire. A uniform and reproducible force of 180g was applied to the cuspid by a nickel-titanium coil spring attached distally to an osseous mini-implant (Tomas Pin, Dentaurum). At each four-week visit distal movement of the canine was measured with a digital caliper between the mini-implant (Temporary Anchorage Device - TAD) and the distal aspect of the cuspid bracket, parallel to the occlusal plane (Fig. 1).

The technical characteristics of the prototype AcceleDent appliance (Fig. 2) used in both clinical trials were the same as the commercial version currently available. The output force was 25 grams with a frequency of 30 Hz. The current commercial version is ergonomically advanced, comfortable and easy-to-use (Fig. 3).

Fig. 2: AcceleDent prototype

Fig. 3: AcceleDent commercial version

Results

End of study data are available for 39 patients, 21 in the AcceleDent group and 18 in the sham control group (Fig. 4). Enrollment by gender, age and ethnicity is shown in Figures 5-7.
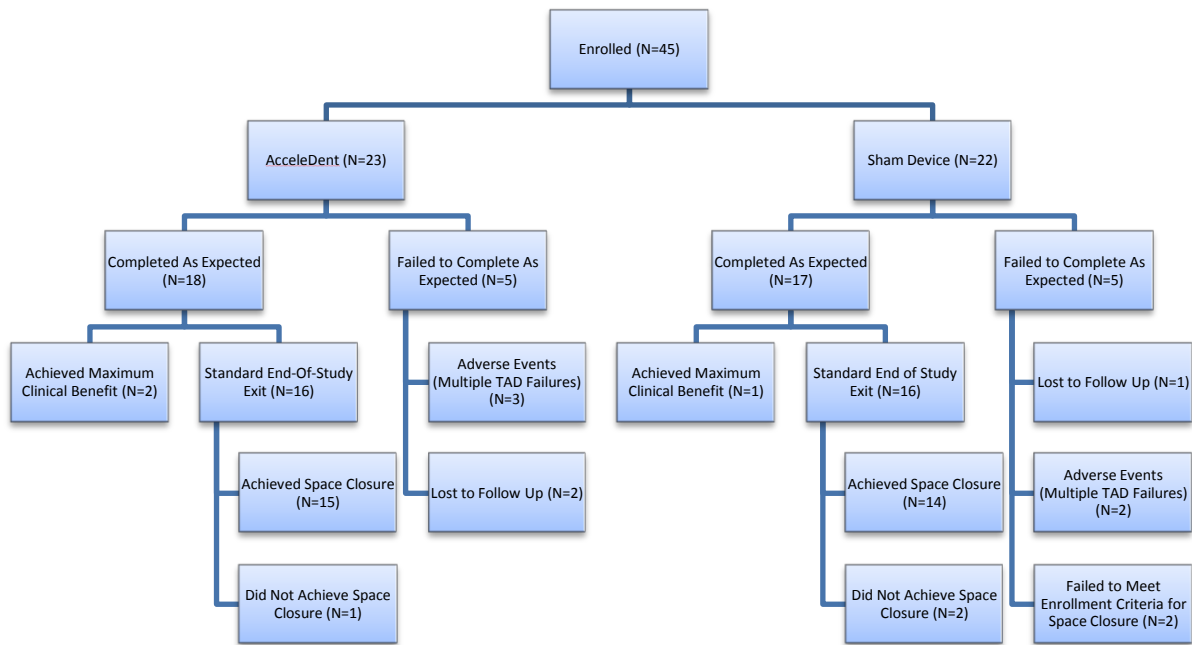
Fig. 4: Patient accountability

Gender	AcceleDent	Sham Control	Total
Male	6	11	17
Female	17	11	28
Total	23	22	45

Fig. 5: Enrollment by gender

Age (years)	AcceleDent	Sham Control	Total
12 – 19	11	12	23
20 – 40	12	10	22
Total	23	22	45
Mean	21.8	21.4	21.6
Range	12.4 – 38.0	12.4 – 40.6	12.4 – 40.6

Fig. 6: Enrollment by age

Ethnic Origin	AcceleDent	Sham Control	Total
Caucasian	6	8	14
African American	2	2	4
Asian (Korean)	0	1	1
Hispanic	15	11	26

Fig. 7: Enrollment by ethnicity

Alignment Phase Average Rate of Tooth Movement – Change in Perimeter (length units/wk)		
	AcceleDent	Sham Control
Count	5	9
Mean	2.71	1.32
Std Dev	1.42	1.00
Range	1.59 – 4.29	0.17 – 3.49
% Improvement	106%	
P-Value	0.05	

Fig. 8: Rate of tooth movement during alignment

During the alignment stage, tooth movement in the AcceleDent group was over 2 times faster as determined by the rate of change in the mandibular arch perimeter (Fig. 8). The rate in the AcceleDent group was 2.71 length units/wk versus 1.32 length units/wk in the sham control group. The perimeter was defined by tracing the labiolingual centers of each tooth from canine to canine.[9] The difference between groups was statistically significant (p =0.05).

The rate of tooth movement during space closure was 38% faster in the AcceleDent group compared to the sham control group (p=0.02), with rates of 0.29 mm/wk and 0.21 mm/wk, respectively (Fig. 9). The increased rate of tooth movement was greater in adults than in teens (Fig. 10).

To assess the safety of the appliance, the effect of AcceleDent on root resorption was quantitatively evaluated from panoramic radiographs of each patient (Fig. 11). The results demonstrate that patients using the AcceleDent appliance had no serious adverse events and exhibited neither increased root resorption nor an increased risk of TAD loosening compared to the sham control group.

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Space Closure Average Rate of Tooth Movement – (mm/wk)		
	AcceleDent	**Sham Control**
Count	21	18
LS Mean	0.29	0.21
Std Error	0.03	0.03
Range	0.13 – 0.69	0.11 – 0.43
% Improvement	38%	
P-Value	0.02	

Fig. 9: Rate of tooth movement during space closure

In addition, overall satisfaction, discomfort, ease-of-use, schedule disruption, hygiene, cleanliness and maintenance, drooling, reliability and noise were assessed using a Visual Analog Scale and confirmed a high level of patient satisfaction (Fig. 12). The most frequently used words to describe AcceleDent were "easy", "effortless", "good" and "simple". The most common activities reported during use of AcceleDent were watching television, reading, using the computer, listening to music and doing school work.

Space Closure Average Rate of Tooth Movement – (mm/wk)		
12 – 19 years old	**AcceleDent**	**Sham Control**
Count	11	10
Mean	0.31	0.25
Std Dev	0.14	0.08
Range	0.16 – 0.69	0.17 – 0.41
% Improvement	25%	
P-Value	0.24	
20 – 40 years old	**AcceleDent**	**Sham Control**
Count	10	8
Mean	0.30	0.23
Std Dev	0.14	0.10
Range	0.13 – 0.59	0.11 – 0.43
% Improvement	35%	
P-Value	0.19	

Fig. 10: Rates for teens and adults during space closure

# Patients with any Tooth with Greater than 2 mm Root Resorption		
	AcceleDent (n=18)	**Sham Control (n=17)**
Total	8 (44.4%)	8 (47.1%)

# Individual Teeth with Greater than 2 mm Root Resorption		
	AcceleDent (n=293)	**Sham Control (n=270)**
Total	18 (6.1%)	13 (4.8%)

Average Amount of Root Resorption (mm)		
	AcceleDent (n=18)	**Sham Control (n=17)**
Mean	-0.28	0.04
Std Dev	0.82	0.68
Median	-0.18	0.08
Range	-1.96 to 0.91	-1.31 to 1.25
P-Value	0.22	

Positive sign indicates root resorption

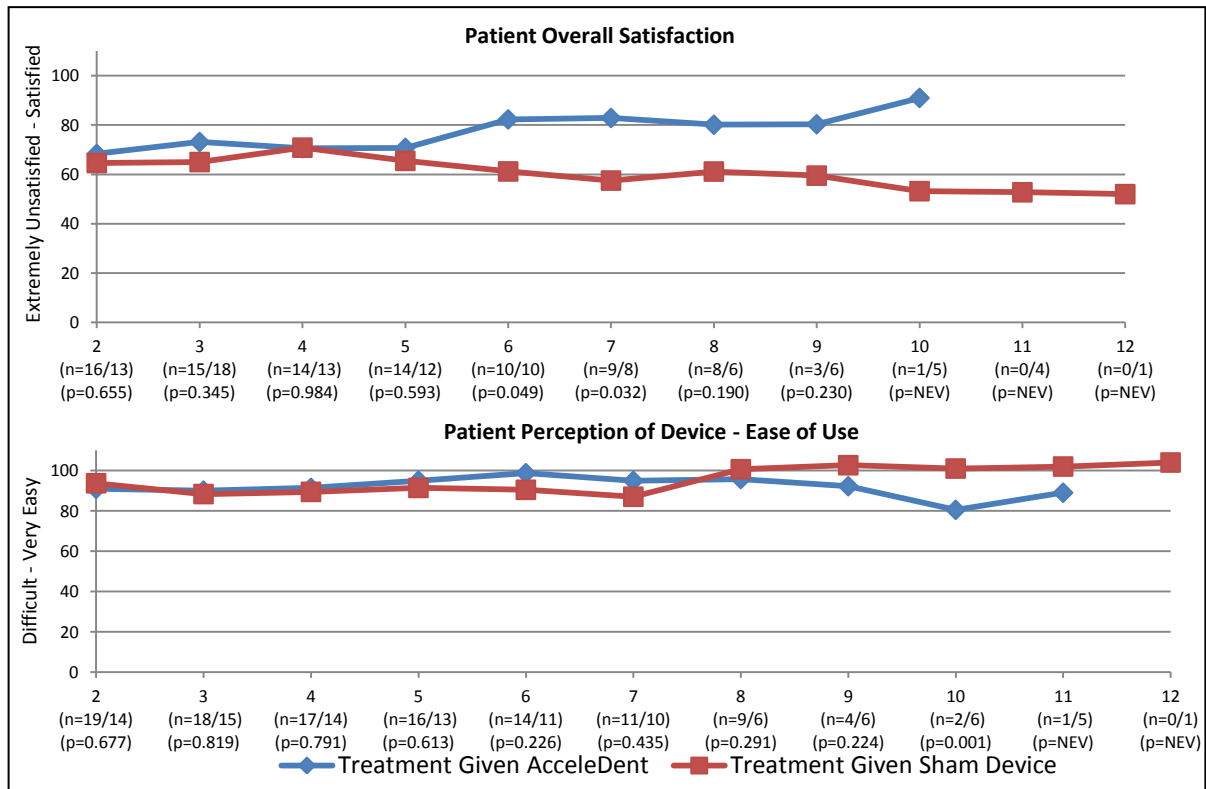Fig. 11: Assessment of root resorption

Fig. 12: VAS Scores – Overall Satisfaction and Ease of Use during space closure

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Conclusion

The results of the randomized controlled clinical trial demonstrate that AcceleDent can increase the rate of tooth movement when used in conjunction with conventional orthodontics. These findings are consistent with the results from orthopedic research,[1,2] animal models[3,4,5] and experience of private practitioners (reported in personal communications, data on file). The results confirm an accelerated tooth movement both during initial alignment (2.06 times or 106% faster) and space closure (1.38 times or 38% faster) phases of orthodontic treatment.

Use of AcceleDent did not increase the risk of either root resorption or TAD loosening. The only potentially device-related events that occurred in more than one case in this clinical trial related to tooth discomfort, soreness, or numbness, all of which are commonly reported with standard orthodontic treatment. In all cases, the events were mild and transient and none required discontinuation or any significant modification of treatment procedures. Overall satisfaction, as well as eight specific assessments, indicates that patients accepted the treatment well and easily incorporated the use of AcceleDent into their daily activities.

The direct clinical benefit from daily use of AcceleDent is shortened treatment time. In a case with an extraction space of 6-8 mm, the AcceleDent device will save the patient approximately 11-15 weeks during the space closure phase of orthodontic treatment. However, considering the acceleration of tooth movement during the alignment phase, the reduction to overall treatment time is likely to be even greater.

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