AcceleDent Aura does not influence treatment duration or number of visits

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Background: Many techniques and appliances claim to reduce orthodontic treatment time, one of which is micro-vibration applied by the AcceleDent Aura appliance.
Objectives: The purpose of this study was to report compliance with AcceleDent Aura and to assess any effect on treatment duration, number of visits and bond failures.
Methods: Forty Class II adolescent subjects were randomly assigned to use the AcceleDent Aura appliance or no AcceleDent Aura device during orthodontic treatment with fixed appliances involving maxillary premolar extractions. Compliance was recorded by the AcceleDent Aura appliance and reported for the first 13 months. Overall treatment duration, the number of visits and number of bond failures were also recorded.
Results: AcceleDent compliance reduced over time from a mean 77.8% usage at the start to a mean of 39.5% by the thirteenth month. There was no difference in the number of bond failures between groups ($p = 0.54$) and there was no evidence that the use of the Acceledent Aura appliance influenced treatment duration ($p = 0.26$) or the number of visits ($p = 0.56$).
Conclusions: The AcceleDent Aura appliance had no significant effect on treatment duration, number of visits or the number of bond failures. Compliance with the appliance waned significantly over time.
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Introduction

There are many appliances and techniques available claiming to accelerate the rate of orthodontic tooth movement and thereby reduce treatment time. However, it has been pointed out that claims of shorter treatment times could open up the possibility of liability for breach of contract.[1] Perhaps more concerning is the propensity for some orthodontists to repeat the claims of accelerated treatment made by companies in their own webpages and marketing. This has led to the observation that, "I have seen a decline in ethics.... It has become slightly and progressively worse over time. There are many ethical conundrums and issues facing practitioners today; one of which is how we market our services."[1]

A technique that has been claimed to decrease the amount of time in fixed appliances by up to 50% is micro-vibration applied by the AcceleDent Aura appliance (OrthoAccel Technologies, TX, USA). Early animal research has suggested that tooth movement could be increased by up to 1.3 to 1.4 times faster.[2-4] In a trial evaluating the AcceleDent appliance during maxillary canine retraction, an accelerated rate of canine retraction was reported in the appliance group.[5] However, there were concerns with the methodology used, as the rate of movement was measured directly in the mouth from a miniscrew/TAD. A miniscrew is a potentially unstable landmark and measuring diagonally from the miniscrew across the extraction site is not a true indicator of space closure as any movement would be exaggerated.

More recently a randomised clinical trial has reported no difference in the time for initial alignment,[6] in extraction space closure and overall treatment

time.[7] Similarly, another prospective RCT found no difference in initial alignment,[8] time taken to reach the working wire,[9] or in extraction space closure.[10] It has been suggested that the use of microvibration may help clear aligners seat better and track more favourably. However, a clinical trial investigating weekly aligner changes reported that there was no evidence in adults that use of the AcceleDent Aura device affected aligner completion or the final alignment achieved.[11]

While many studies have investigated the use of adjunctive appliances, the assumption has been made that the appliance was used as directed and therefore had an influence on the outcome. In most cases compliance was not assessed. One of the original clinical publications evaluating an early model of the AcceleDent appliance did monitor compliance in using the appliance.[12] In the study, 17 participants were recruited but three subjects declined to continue, and of the remaining 14, the participants self-reported using the device 80% of the time. However, the device's recorder indicated only 67% compliance. Ideally any analysis would also include subjects who later declined to continue using the appliance, which would lower the compliance to anywhere between 67% and 55%. The time-frame was also unclear and any change in compliance over time was not demonstrated.

The present paper was an ongoing trial of the AcceleDent Aura appliance and reports overall treatment duration, number of visits and number of bond failures. In addition, compliance with the AcceleDent Aura appliance over the first 12.5 months of treatment was recorded.[8,10]

Materials and methods

Trial design and any changes after trial commencement

This was the third part of an ongoing single-centre, randomised clinical trial with a 1:1 allocation.[8,10] No changes occurred during the trial.

Participants, eligibility criteria, and settings

A special research grant was provided by the Australian Society of Orthodontists Foundation for Research and Education (ASOFRE) to purchase the AcceleDent® Aura appliances. All patients and parents provided written informed consent with ethical approval obtained from the University of Queensland Dental Sciences Research Ethics Committee (project number 1315). Patients were prospectively recruited from the private orthodontic clinic of the author (P.M.) and met the following selection criteria: 1) children up to age of 16; 2) a fully erupted dentition from first molar forward; 3) erupted or erupting second molars; 4) no missing or previously extracted permanent teeth; 5) undergoing comprehensive orthodontic treatment with full fixed appliances; and 6) a Class II malocclusion requiring the extraction of two upper bicuspids but no lower arch extractions.

Sample size calculation

A previously applied[8] power analysis was performed and 40 subjects were enrolled and randomly divided into two groups. One group of 20 patients was provided with the AcceleDent Aura appliance and the other group of 20 served as a control.

Randomisation (random number generation, allocation concealment, implementation)

The subjects were randomly assigned in sealed, opaque envelopes and shuffled by a staff member. The envelopes were opened by a clinical assistant remote from the operator who was therefore blinded to the subject group assignment.

Blinding

The patients were aware of their treatment group, whereas the operator (P.M.) was blinded to the treatment groups.

Interventions

All patients were indirectly bonded with conventional 0.018" slot, MBT prescription brackets (Victory Series, 3M Unitek, CA, USA) on all lower teeth and the upper bicuspids and 0.022" slot brackets on the molars, while the upper incisors and canines were bonded with MBT equivalent prescription self-ligating In-Ovation C ceramic brackets (GAC International, NY, USA). The wire progression and extraction mechanics have been described previously.[8,10] The AcceleDent Aura appliance records the usage time, the data of which can be downloaded

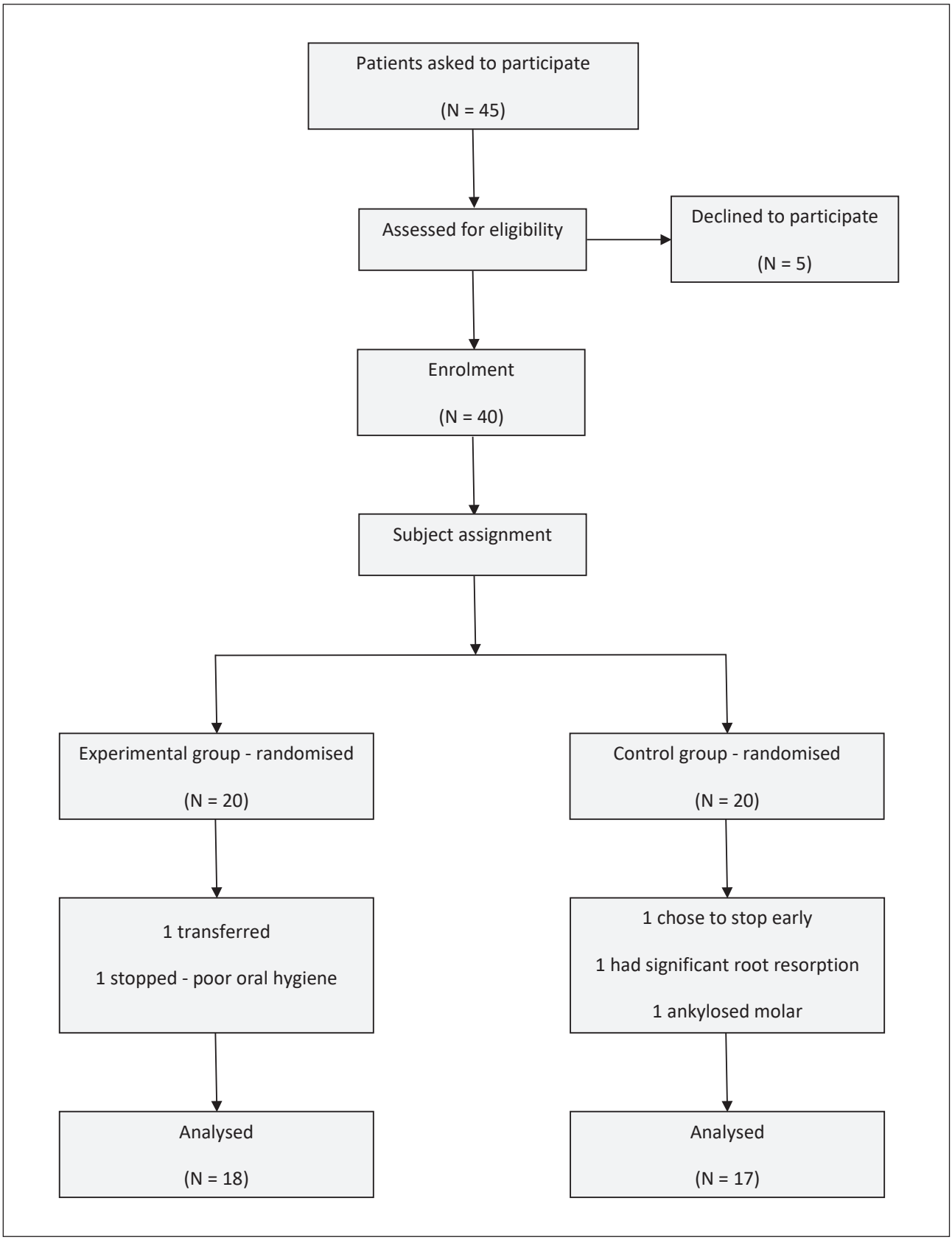

Figure 1. CONSORT diagram showing the flow of subjects through the trial with two dropouts from the AcceleDent group and three from the control.

from the appliance. Participants were asked to use the appliance for 20 minutes daily throughout the study and return their appliances at regular intervals (~three monthly) for recording of the compliance data.

Outcomes and any changes after trial commencement

The primary outcome was total treatment time with secondary outcomes of the number of visits and bond failures. As co-operation with the AcceleDent appliance was tracked throughout the study but treatment time was variable, only the first 12.5 months of compliance data was examined.

Statistical analysis

Descriptive statistics were calculated per treatment arm. Linear regression analysis was implemented in order to assess the effect on duration of treatment alone and adjusted separately for age, gender and initial irregularity. Fisher's exact test was used for the effect of treatment on breakages and Poisson regression for the effect of treatment on the number of visits. Analyses were conducted by the second author (N.P.) using Stata 15 (Statacorp, TX, USA) and SAS 9.4 (SAS Institute Inc., NC, USA) statistical software.

Results

Participation flow

Of the original 40 subjects, 35 completed the trial with three (15%) dropping out of the control group and two (10%) from the AcceleDent group (Figure 1). In the AcceleDent Aura appliance group, one subject transferred and another had treatment paused and discontinued entirely due to poor oral hygiene. In the control group, one subject had significant apical root resorption, another chose to remove appliances early for their birthday, while a third had an ankylosed lower molar that was extending treatment and so was excluded from the analysis.

Baseline data

Table I details the age and gender of the subjects at baseline, which was similar for both groups.

Numbers analysed for each outcome, estimation and precision, subgroup analyses

As the appliance records daily data but also averages over 30 days, it was decided to report data starting at day 15 and every 30 days thereafter to cover approximately 12.5 months of treatment. Table II reports the mean, median, standard deviation and range of the data. Figure 2 illustrates the interquartile range in the coloured bars per 30 days (month), the mean (X), median (horizontal line in the coloured bar) and overall range.

Compliance was found to reduce progressively over the period of investigation from a median of 83.0% (mean = 77.8%) usage at the start to a median 51.0% (mean = 39.5%) by the end of the 12.5 month evaluation period. By the sixth month, one participant had stopped using the appliance altogether while another had stopped for four months, used it once and then stopped altogether. By the eighth month and onwards, the interquartile range had expanded, indicating an even greater variation in the usage and less reliable compliance (Figure 2).

Linear Regression analyses for the unadjusted and adjusted effect of treatment on duration indicated that there was no evidence that the use of the Acceledent Aura appliance influenced treatment duration, as shown in Table III (β = -1.27, 95% CI: -3.36, 0.93, p = 0.26). There was also no difference in treatment duration between the two groups after adjusting for age (β = -0.99, 95% CI: -3.13, 1.15, p = 0.35), gender (β = -1.139, 95% CI: -3.30, 1.02, p = 0.29) and initial irregularity (β = -1.22, 95% CI: -3.30, 0.86, p = 0.24). Although there was more variation in treatment duration in the AcceleDent group compared with the control (Figure 3), there was no significant difference

Table I. Baseline demographics of subjects completing the study.

	Age (SD)	Gender	Irregularity index	Number
Vibration	12.72 (1.23)	12F 6M	4.57 (1.23)	18
Control	13.13 (1.59)	10F 7M	4.56 (2.33)	17
Total				35

Table II. Compliance data reported every 30 days starting from day 15 and over ~13 months. The mean, median, standard deviation, minimum and maximum usage are reported.

Days (Mth)	15 (1)	45 (2)	75 (3)	105 (4)	135 (5)	165 (6)	195 (7)	225 (8)	255 (9)	285 (10)	315 (11)	345 (12)	375 (13)
Mean	77.8	74.1	70.8	70.7	64.8	65.4	56.5	53.1	52.4	49.7	46.8	42.7	39.5
Median	83.0	83.5	76.5	74.5	74.5	70.0	59.0	64.5	62.0	63.5	59.5	60.0	51.0
SD	22.1	26.2	20.5	24.9	30.0	29.2	28.4	34.8	35.4	37.0	39.7	37.2	34.4
Min	28.0	13.0	32.0	7.0	15.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Max	100.0	100.0	100.0	99.0	100.0	100.0	100.0	100.0	100.0	99.0	95.0	87.0	92.0

Table III. Comparison of treatment duration and number of visits per group.

	Accel		Control		*p*-value
	N=18 Mean (%)	sd	N=17 Mean (%)	sd	
Duration	19.49	3.71	20.71	2.33	0.26
Visits	13.39	2.91	14.12	1.58	0.56

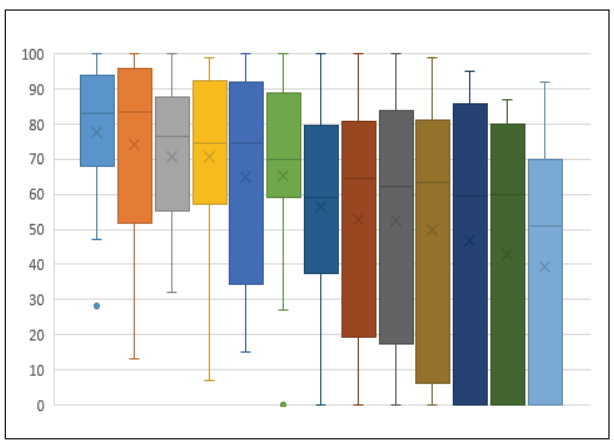

Figure 2. AcceleDent usage data per every 30 days over ~13 months. The range, interquartile range (solid bars), mean (X) and median (horizontal line) are indicated.

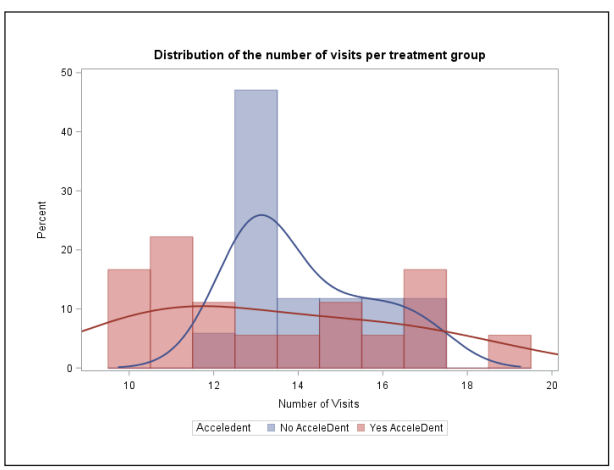

Figure 3. Histogram of the number of visits for the AcceleDent and control groups demonstrating a larger spread in the number of visits for AcceleDent.

Table IV. Number of subjects sorted by the number of bond failures they experienced per group.

Number of bond failures	Accel	Control	*p*-value
0	8	10	0.54*
1	6	4	
2	2	1	
3	0	1	
4	2	0	
6	0	1	

in the number of visits as indicated by the Poisson regression analysis (p = 0.56). When examining bond failures, there was no significant difference in the number of breakages between the two groups (p = 0.54, Table IV).

Discussion

Main findings in the context of the existing evidence, interpretation

Compliance is an important component of orthodontic treatment in achieving a successful outcome. However, patients tend to over-report the amount of wear when compared with objective measures of wear time.[13,14] It is also not unusual for compliance to reduce over time.[15,16] For example, when evaluating compliance with retainer wear, good compliance was demonstrated in 69% of participants at 0–3 months but reducing down to 55% at 7–9 months and 45% by 19–24 months.[15] Patients do not adhere to prescribed wear times and an orthodontist's

subjective assessment of patient cooperation can be insufficient for accurate assessment.[16] For these reasons having an objective measure of compliance is considered preferable.

Kau et al.[12] objectively reported 67% compliance using an AcceleDent appliance, although the reporting was unclear as to whether this recording was over the entire six months or at a specific time point. Patients tend to over-report and, if those who ceased using the appliance were also included in the analysis, compliance could drop to as low as 55%. In the current study, the mean compliance had dropped below 67% by month five and the mean usage over the entire first six months was 70.6% and so the results from the current study appear similar or better in comparison. The recommended usage of the appliance is 20 minutes per day but this seldom appears to be achieved. Assuming the appliance is able to deliver accelerated tooth movement, the questions requiring an answer are: i) what is the optimal usage time and, ii) what is the minimal usage time to have a clinically significant effect? For example, the average ~70% compliance found in the present study over the first six months equates to ~14 minutes per day, which may be insufficient for any effect. This compliance time decreased further and so, by 12 months, the mean usage of 42.7% was only ~8.5 minutes. Ideally, compliance data should be reported in future research for any appliance claiming to accelerate orthodontic treatment. This then allows influencing factors of usage time on any detected clinical effect to be examined. Following an assessment of the number of bond failures, there was no significant difference between the two groups. The average bond failure was 5.5%, which is in agreement with that reported subjectively by surveyed practitioners.[17,18]

There were only five dropouts from the study, comprised of three (15%) in the control group and two (10%) in the AcceleDent group (12.5% of the total). This compares well with the reported ~25% dropout in the study by DiBiase et al.[7] As with the previous reports on alignment and space closure, no statistically or clinically significant difference was noted between those using the AcceleDent appliance and the control group.[8,10] The treatment times (19.5, 20.7 months) were similar to the AcceleDent group (20.5 Months) and slightly greater than the sham and control groups (16.7, 17.6 months) reported by DiBiase et al.[7] The results were also similar to those published in a systematic review of average treatment times (19.9 months).[19] In addition, the number of visits (13.7) determined in the present paper was also similar to those reported by DiBiase et al. (12.3).[7] In the present study, the number of visits included both the initial fit of the fixed appliances and the appointment to deband, but it did not include the additional visits for study impressions or any emergency visits during which no adjustments were performed.

Considering the consistent findings throughout this trial, which indicated no discernible difference on initial alignment, time to working wire, space closure and overall treatment duration, it would appear that the AcceleDent Aura appliance offers no benefit to adolescent patients undergoing upper premolar extraction treatment to manage a Class II malocclusion. This is in agreement with previous prospective randomised trials involving the AcceleDent appliance.[6,7]

Limitations

Although compliance reduced throughout the study, in contemporary orthodontic practice, reducing compliance would be expected over time, as seen with the use of other appliances. However, it means that there is a loss of power during the study as only five subjects complied more than 75% of the time by the end of the trial, which would not allow for meaningful statistical analysis.

Conclusions

Compliance varied markedly, with some subjects at six months still complying at a rate of 100% (20 minutes daily) while others had ceased using the appliance altogether.

Compliance with the AcceleDent appliance was found to reduce over time from a mean of 77.8% usage at the start to a mean of 39.5% by the thirteenth month.

There was no difference in the number of bond failures between groups.

When used in a contemporary environment, there was no evidence that the use of the Acceledent Aura appliance influenced treatment duration or the number of visits.

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