Original Article

The Effects of Low-frequency Vibration on Aligner Treatment Duration: A Clinical Trial

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ABSTRACT

Objectives: The aim of this study was to investigate the effectiveness of an orthodontic tooth movement acceleration device (AcceleDent, OrthoAccel Technologies, Houston, Texas) when used during an aligner treatment. **Materials and Methods:** Adult patients who began an aligner treatment (Lineo, Micerium Lab, Avegno, Italy) were allocated to two treatment groups. The first one (Group A), with a 7-day aligner change regimen, used the AcceleDent device for 20 min per day, whereas the second one (Group B) changed the aligners every 14 days and did not use any device. The registered outcomes were the possibility of completing the treatment, the number of aligners needed and treatment duration in the two groups. Moreover, we assessed patients' perception of pain during the first week of treatment. **Results:** Twenty-four patients were allocated to Group A or B depending on the acceptance of AcceleDent use. Patients which used AcceleDent (Group A) completed the treatment using each aligner for fewer days than those belonging to Group B (9.0 ± 1.0 and 15.4 ± 1.2 days, respectively) ($P < 0.001$). As a secondary outcome, a significant difference was found in pain perception during the first week of treatment between the two groups ($P < 0.05$). **Conclusions:** This controlled clinical trial shows that is possible to apply a 7-day change regimen together with AcceleDent use and successfully complete an aligner treatment with a significant saving of time when compared to a standard 14-days change regimen. Finally, the use of this device allowed reduction in pain perception during the orthodontic treatment.

KEYWORDS: *AcceleDent, acceleration, aligner treatment, orthodontic pain measurement, orthodontic tooth movement, vibration/therapeutic use*

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INTRODUCTION

Acceleration of orthodontic tooth movement has recently drawn the attention of an increasing number of researchers and companies, all of them willing to find an effective and safe way to reduce treatment duration. Given that orthodontic treatment has an average duration of approximately 20–24 months,[1,2] the prospect of shortening it is attractive to both orthodontists and patients.

A number of techniques have been proposed in recent years. Among the surgical ones, that is, distraction of the periodontal ligament, distraction of the dento-alveolus, corticotomy, and corticision (minimally invasive surgery), corticotomy appeared to be effective in shortening orthodontic treatment duration,[3-7] albeit with low-grade evidence.[3,8] Among the nonsurgical techniques, that is, medications, phototherapy, pulsed electromagnetic field, and low-frequency vibrations, the number and quality of available publications does not permit a claim of effectiveness nor ineffectiveness

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of these methods, since the current limited evidence is potentially affected by several bias that lower its relevance.[8-12] In this study, we focused on AcceleDent (OrthoAccel Technologies, Houston, Texas), a device that is used 20 min per day, vibrates at a frequency of 30 Hz, and has a force amplitude of 20 g. It has had remarkable commercial success (more than 100,000 patients treated) due to its simplicity, noninvasiveness, and comfort of use. Although several studies have been recently conducted,[13-22] the use of AcceleDent in conjunction with aligner treatment has not been thoroughly investigated until now, and little is known about the efficacy of this combination.

Considering that the actual manufacturer's recommendation is to combine AcceleDent's daily use with a weekly aligner change protocol, we aimed to assess whether this protocol was actually effective in shortening treatment time. In this study, we used AcceleDent in conjunction with Lineo aligners (Micerium S.p.A., Avegno, Italy). Lineo boasts more than 4000 orthodontic cases to date and utilizes Lineo Vision software, which allows clinicians to plan the orthodontic treatment starting with analogic or digital impressions taken during the practice. The requested number of aligners is then produced and sent to the dental office in order to begin the treatment.

Materials and Methods

AcceleDent (OrthoAccel Technologies, Houston, Texas) is an FDA-cleared class II medical device with CE Mark approval, which produces intraoral supplemental vibrational forces. This device is designed to vibrate and deliver a force of 0.25 N at a frequency of 30 Hz to the dentition, with a prescribed usage of 20 min per day. As the motor spins, the offset weight is pre-set to cover 360° so we can look upon it as a homogeneous system of distribution of the same force for every patient.

Trial design, participants, and settings

This two-arm, controlled study protocol conformed to the ethical guidelines of the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards and was approved by the Institutional Review Board of the University of Palermo General Hospital (A.O.U. Policlinico Paolo Giaccone; approval number 2/2020). The study was registered at the German Registry of Clinical Trials (DRKSID: DRKS00021175). Informed written consent was obtained from all patients.

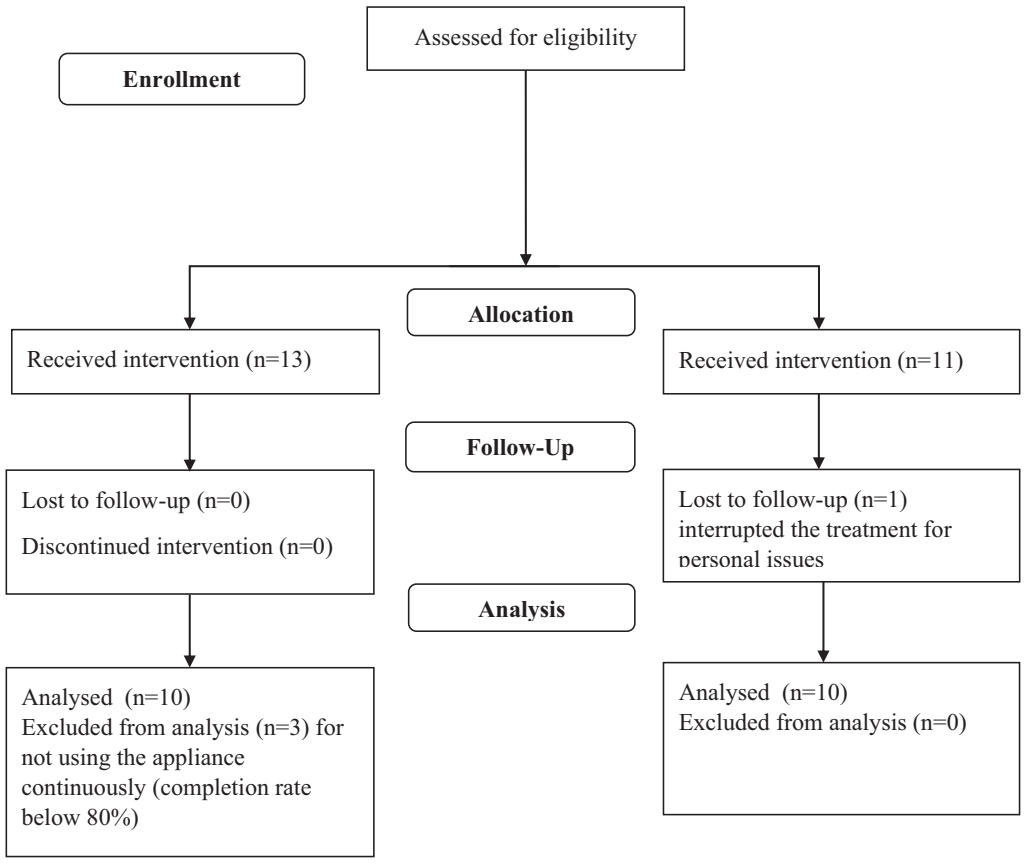

Figure 1: CONSORT diagram showing the flow of subjects through the trial

Healthy adults were recruited who had malocclusions that could be easily treated with aligners without going beyond their main recommendations. Their main cephalometric data are shown in Table 1. The inclusion and exclusion criteria of the study are listed in Tables 2 and 3, respectively.

As shown in the CONSORT diagram [Figure 1], a total of 24 patients were treated with the same invisible orthodontics system (Lineo, Micerium Lab, Avegno, Italy). Thirteen patients (Group A) accepted the use of AcceleDent in combination with a weekly aligner change regimen, whereas 11 patients (Group B) were treated without device usage and with a 14-day change regimen (control group). Three patients belonging to Group A were found not to have applied AcceleDent consistently (their completion rate was below 80%); therefore, they have been excluded from the study. Similarly, one patient in group B had to discontinue treatment due to personal issues and therefore was excluded.

All of the remaining 20 patients successfully completed the orthodontic treatment. The sample size seemed to be adequate because previous studies used similar samples.[12,18,19]

All patients were treated in a dental practice in Palermo, Italy.

Intervention

The first visit to the dental office was followed by alginate impressions (which were successively scanned to obtain a digital model) for study model analysis, photographic records, panoramic radiograph, and teleradiogram for cephalometric tracing. After that, if the clinician considered aligner treatment to be viable, participation in the study was proposed to patients and they were allocated to Group A or B depending on whether they were willing to use AcceleDent not. At the same time, the clinician illustrated the Lineo Vision treatment plan (previously reviewed and adjusted if necessary) to every patient.

Standard and usual treatment protocols were applied and included intra-oral elastics, attachments, and IPR according to specific conditions of every clinical case. When a distinct number of aligner was required for the upper and lower arch, patients were instructed to keep the last aligner (which is always thicker, 1 mm) of the arch that ended treatment first, as a form of orthodontic contention, until both arches completed the full set of aligners. Single aligner-inducted displacement was set to 0.25 mm, with the aim of ensuring homogeneity to orthodontic tooth movement rate.

Patients were assigned to one of these two groups:

- Group A: changed aligners every 7 days and placed them between the arches and activated AcceleDent for 20 min per day, from the beginning to the last day of treatment. They were instructed to use it in the evening from 20:00 to 22:00, in a comfortable position, and to use the AcceleDent App to monitor daily use;
- Group B: changed aligners every 14 days, without using any additional device.

Both groups were examined monthly during the treatment period, in order to detect any aligner misfit early and to motivate the patients to keep following the clinician's instructions.

Finally, every participant was administered a VAS (Visual Analogic Scale) questionnaire about pain perception during the first week of treatment.

The decision to focus on the first week was taken because this is typically the most relevant period for orthodontic pain, since for the first time an external force is introduced into dentoalveolar system and this compression induces hypoxia and, therefore, pain. Patients were also asked to avoid taking any painkillers and, if they had to, to tell the clinician which drug they used. No one reported the use of analgesic drugs throughout the treatment.

Statistical analysis

All data were put in a Microsoft Excel 2016 spreadsheet for collection, and StatView software (SAS Institute, Cary, North Carolina) was used to perform statistical analysis. Samples of both demographic and clinical characteristics were compared through descriptive statistics, with means and standard deviations. Pearson's χ^2 test was carried out for the only nominal variable, which is sex.

Student's parametric *t* test and nonparametric Mann–Whitney *U* test were performed to assess whether the two groups of data were significantly different from each other or not. The variables in question are treatment time, total aligners used, average day per aligner, and perceived pain.

Results

Table 4 shows participants' demographic characteristics. The two groups were homogeneous in terms of age and sex, being an average of 35 years old (range: 21 to 58 yrs) and having a female majority (75%). Type and prevalence of malocclusions are shown in Table 5.

The most frequent malocclusions treated were found to be Angle Class I (60%), and deep bite and crowding

Table 1: Main cephalometric values of Group A and Group B patients

Group and no. of the patient	SNA (°)	SNB (°)	ANB (°)	FMA (°)	Max incisor to SN (°)	IMPA (°)
A 1	78.2	76.3	1.9	24.3	111.2	92.8
A 2	80.2	79.1	1.1	27.8	108.2	89.4
A 3	83.4	81.7	1.7	24.6	112.1	94.3
A 4	84	80.1	3.9	25.6	109.3	93.4
A 5	78.5	78.3	0.2	27.3	113.4	94.1
A 6	82	78.9	3.1	26.9	107.6	88.3
A 7	76.3	75.6	0.7	28.2	110.1	94.4
A 8	81.6	80.3	1.3	26.7	115.6	96.2
A 9	85.9	83.5	2.4	24.9	113.5	96.4
A 10	78.4	77	1.4	25.6	114.5	93.7
B 1	79.8	78.6	1.2	25.9	109.3	92.3
B 2	82.7	78.9	3.8	26.8	113.1	96.1
B 3	85.6	82.9	2.7	27.2	115	91.6
B 4	79.3	76.9	2.4	26.1	112.2	90.1
B 5	86.1	82.8	3.3	24.9	106.2	87.3
B 6	82.1	81.9	0.2	25.7	117.3	89.2
B 7	84.4	80.9	3.5	24.5	112.1	97.5
B 8	79.8	76.1	3.7	24.3	108.2	90
B 9	78.6	76	2.6	25.7	111	94.2
B 10	80.2	79.3	0.9	26.9	116.4	91

Table 2: Inclusion criteria

Inclusion criteria
Adult patients
Complete development of every tooth
Complete permanent dentition
Dental-alveolar malocclusion
No tooth rotations > 30°
No sagittal correction > 4 mm
No crowding or diastema > 5 mm
Negative pharmacological anamnesis for medications with any effect over bone metabolism
Negative pathological anamnesis for any illness with effects over oral cavity

Table 3: Exclusion criteria

Exclusion criteria
Skeletal malocclusions
Extraction case
Previous orthodontic treatment
Signs or symptoms of periodontal disease in progress
Signs or symptoms of bruxism
Signs or symptoms of TMJ disorder
Structural abnormalities of the craniofacial or dental-alveolar complex

(75% and 70%, respectively) turned out to be the main orthodontic issues at pretreatment stage.

Table 6 shows comparisons between the two groups concerning age, total number of aligners applied, treatment period, average days per aligner usage to complete the treatment and finally VAS evaluation of pain during the first week.

Age

Mean age (in years) in Group A was 36 ± 10.1, ranging from 21 to 47. Age in Group B was similar and ranged from 23 to 58, with a mean age of 34.3 ± 11.1. The two groups showed no statistically significant difference (P = 0.72), proving themselves to be homogeneous on this parameter.

Total number of aligners

Patients in Group A applied 41.1 ± 22.4 aligners on average, with a minimum of 19 and a maximum of 56. Group B needed an average of 33.1 ± 15.5 aligners, ranging from 17 to 64 aligners. Also in this case, the difference between the two groups was found to be not statistically significant (P = 0.36), which was predictable if we consider that the participants were selected on the basis of malocclusion type and severity.

Treatment duration

Total treatment duration in Group A was 366.6 ± 187.4 days (from a minimum of 146 to a maximum of 502 days), whereas patients in Group B stayed in treatment for an average of 509.3 ± 243.5 days, ranging from 248 to 961 days. No significant difference was found analysing this variable.

Average days per aligner

To complete the treatment, patients from Group A wore each aligner for 9.0 ± 1.0 days on average, from a minimum of 8.1 to a maximum of 10.6 days. In Group B, the average was 15.4 ± 1.2 days, ranging from 12.9 to 16.9 days. The average difference between the

two groups was 6.4 days per aligner, almost a week. The difference is statistically significant ($P < 0.001$).

Pain perception during first week of treatment

Participants from Group A reported a VAS value of 2.4 ± 1.0 on average (ranging from 1 to 4), whereas the mean value in Group B was significantly higher: 4.4 ± 1.4 (minimum 2, maximum 7) ($P < 0.05$).

Discussion

Orthodontic movement is now known to be triggered by the effect of forces over the periodontal ligament, generating different areas of tension and pressure. The main executors of bone remodeling around the tooth are osteoclasts and osteoblasts, guided by changing concentrations of cytokines like nuclear factor kappa B ligand (RANKL), osteoprotegerin (OPG), transforming growth factor β (TGF- β), prostaglandin E_2 (PGE_2). Experimental studies showed how the application of high-frequency vibrations together with orthodontic forces can significantly increase the concentration of pro-inflammatory cytokines in gingival crevicular fluid, assuming that this can lead to facilitation and acceleration of orthodontic movement.[23] Lau *et al.*[24] observed *in vitro* marked reactivity of the osteocytes to low-magnitude, high-frequency vibration, making it reasonable that this cells' cytoskeleton can act as a mechanoreceptor and regulator of crucial equilibrium between RANKL and OPG. The overall effect seems to be the union of a purely mechanical initiating effect and a more biological one, which results in an increase of pro-inflammatory tissue response.

A first and relevant observation must be made by looking at the study sample. Putting together Table 4 data and a decades-long expertise in invisible orthodontics, we can reflect on the fact that adult females and employed patients are a prominent part of the catchment area in this dentistry field. Much could be told about the reasons of this prevalence, but that is not the focus of this work. However, it is clear that this patient cohort requires and deserves an aesthetic and fast treatment; an adult employee, who is often also a parent, needs to complete his or her treatment in as short a time as possible, as any visit to the dentist represents time deducted from personal or work commitments. Time is therefore seen as an absolute priority, obviously together with the successful completion and comfort of the orthodontic therapy. The majority of adult patients show an interest and willingness to use an orthodontic movement accelerator, but this openness is significantly reduced when a surgical method is proposed.[25]

A comfortable and minimally invasive method such as intra-oral vibrations administration could serve as a benchmark in orthodontic treatment in adults, leading towards a simple, handy and safe way to reduce treatment duration.

Data shown in Table 6 clearly demonstrate that it is possible to complete treatment by combining AcceleDent application and transparent aligners even

Table 4: Participants' demographic characteristics

	Group A (AcceleDent) *N* = 10	Group B (control) *N* = 10	Total *N* = 20
Age (year) ± DS	36.0 ± 10	34.1 ± 11	35.0 ± 10.3
Sex *	M = 2 (20%) F = 8 (80%)	M = 3 (30%) F = 7 (70%)	M = 5 (25%) F = 15 (75%)

*Statistically not significant differences ($P = 0.6$; Pearson's $\chi 2$ test)

Table 5: Malocclusion types and prevalence

	Group A (AcceleDent) *N* = 10	Group B (control) *N* = 10	Total *N* = 20
Deep bite	9 (90%)	6 (60%)	15 (75%)
Open bite	0 (0%)	0 (0%)	0 (0%)
Crowding	6 (60%)	8 (80%)	14 (70%)
Diastemas	1 (10%)	0 (0%)	1 (5%)
Crossbite	2 (20%)	1 (10%)	3 (15%)
Class I malocclusion	5 (50%)	7 (70%)	12 (60%)
Class II malocclusion	4 (40%)	2 (20%)	6 (30%)
Class III malocclusion	1 (10%)	1 (1%)	2 (10%)

Table 6: Means and standard deviation (SD) for every parameter considered in the two groups

	Group A (AcceleDent)	Group B (control)	Average difference	Student's *t*-test	Mann–Whitney *U* test
Age ± SD (years)	36 ± 10.1	34.3 ± 11.1	–1.4	$P = 0.72$	$P = 0.57$
n total aligners ± SD	41.1 ± 22.4	33.1 ± 15.5	8	$P = 0.36$	$P = 0.38$
Treatment period ± SD (days)	366.6 ± 187.4	509.3 ± 243.5	–143.3	$P = 0.16$	$P = 0.15$
Average days per aligner ± SD	9.0 ± 1.0	15.4 ± 1.2	–6.4	$P < 0.0001$*	$P = 0.0002$*
Pain visual analogic scale ± SD	2.4 ± 1.0	4.4 ± 1.4	–2.0	$P < 0.0018$*	$P = 0.003$*

*Statistically significant differences ($P < 0.05$)

when a 7-day change regimen is applied, obtaining therapeutic success in less time. The reported treatment duration analysis highlights the need to wear each aligner for 15.4 days on average, when a 14-day change regimen is used. The difference compared to the hypothetical 14 days is due to loss of time, that is, delays in making an appointment at the dentist's. This minor variable has however been included in calculations in both groups so that they could reflect true treatment duration.

The key information is the mean number of days that every patient in Group A (with AcceleDent) wore each aligner to get to satisfactory treatment goals, that is 9.0 days. Reviewing the data, they indicate that the experimental group completed the treatment taking an average of 38% less time in comparison to the control Group B. This difference was shown to be statistically significant ($P < 0.001$), as well as clinically relevant since Group A's therapeutic intervention lasted an average of 12 months and 6 days. Calculating a mean 38% saving of time, we can conclude that every patient in Group A completed the orthodontic therapy 7 months and 12 days before the same patient in control Group B.

Given that every patient successfully completed the treatment, the whole of Group A (which was instructed to change the aligners every 7 days) is located significantly below Group B in this chart.

That means that the experimental group homogeneously reached treatment goals wearing every aligner for less time than the control group.

Other relevant results can be seen when interpreting the "Total aligner number" and "Treatment duration" data in Table 6. First, it is crucial to point out that the total aligner number exclusively depended on malocclusion severity and on the extent of planned tooth movement, all factors which vary according to each specific clinical case. Lineo's employees tasked with 3D orthodontic set up were in fact unaware of AcceleDent use or non-use; therefore, they planned orthodontic movements in the same, consistent way in every case object of this study. Having said that, a clinically (even if not statistically) significant result must be discussed. Despite the fact that the mean total aligner number in Group A was higher than that in Group B (41.1 versus 33.1), due to the time saving already discussed, total treatment duration was instead lower in Group A rather than in Group B. A mean treatment time of 366 days in the experimental group was observed, versus the 509 days of the control group. So, in summary, the average patient in the AcceleDent Group completed the treatment wearing more aligners but for less time (1 year on average) as opposed to the control group whose patients wore fewer aligners but for a longer period (1 year, 5 months on average). Although the sample is limited, which leads to possible bias in the investigation of treatment duration that is highly correlated to initial malocclusion, it is reasonable to believe that this trend would also be shown in a larger number of patients.

These data support the initial hypothesis, which was that it is possible to successfully complete an orthodontic treatment by changing the aligners every 7 days instead of every 14, as long as AcceleDent is used daily. Of the just two recent available publications that investigate the correlation between aligners and AcceleDent, our results were similar to one[14] and disagree with the other,[18] even if this study significantly differs from the latter in terms of methodology.

The study by Lombardo *et al*.[14] appears to be particularly relevant since it started from the same assumption of this work, namely that AcceleDent allows completion of aligner orthodontic treatments changing the aligners every 7 days, and came to the same conclusion. This conclusion is that using a 7-day aligner change protocol together with AcceleDent rather than using the common 2-week aligner change protocol does not affect the successful outcome of the treatment, which is completed in both cases as the results show.

Since the beginning of invisible orthodontics, companies have been recommending changing the aligners every 2 weeks, even if this prescription is now being questioned. And if these treatment methods proved themselves to be effective in their 14-day aligner change form, much is yet to be investigated before declaring other protocols safe and efficacious. No peer-reviewed randomized clinical trials (RCTs) has yet shown the equivalence of other protocols to the original one, therefore the choice and responsibility of applying a different aligner change regimen rests on the shoulders of the clinicians.

As regards pain perception during first week of treatment, the data showed some relevant results. Significant differences in the values ($P < 0.018$) show that Group A perceived less pain in comparison to Group B, whose participants did not use AcceleDent. Lobre *et al*.[26] attribute this effect to the decrease of periodontal ligament compression and to the gate control theory of pain. The measurements is certainly partial (relating the first week of treatment), therefore turns out to be difficult to compare to the few RCTs available in literature. Among these ones, Lobre *et al*.[26]

found the same pain reduction we observed, whereas Woodhouse *et al*.[27] found that the use of AcceleDent had no significant effect over pain perception. On the contrary, in the study by Miles *et al*.,[13] a lower need of painkillers was observed in the group that used AcceleDent, which supports the device's efficacy in pain control.

In this study, as an unexpected result, patients from the experimental Group A reported that using the device immediately after the weekly aligner change significantly reduced the pain that is usually related to this moment. In fact, the newly introduced forces of every aligner can be annoying and are usually the main patient complaint. This accidental observation could pave the way to a new recommendation for the patients, that is to apply AcceleDent right after changing the aligner in order to minimize the discomfort that this act involves.

Some authors and clinicians claim that AcceleDent can improve the accuracy of dental movements, but this effect could not be investigated in this paper because of the huge amount of variables to be excluded before confirming this advantage. Nonetheless, it would be desirable to investigate this claim in a further study, because if AcceleDent was proved to facilitate most complex teeth movements, it would open up new ways of dealing with difficult clinical cases (i.e. rotations, translations, severe crowding).

In conclusion, the present data suggest that it is possible to complete an invisible orthodontic treatment changing the aligners every 7 days, using AcceleDent at the same time, thus saving a significant amount of time and reducing patients' discomfort. This duration shortening is of primary concern when adults are treated: these patients, now more than ever, look at therapy duration as an obstacle to their personal and working commitments. Furthermore, it must be noted that the device cost can be compensated by the reduced need to attend periodical appointments, which are fewer since the treatment time is shorter. Finally, a reduction in perceived pain was observed during the first week of treatment, which is usually the most uncomfortable. The discomfort caused by the aligner change is known to negatively impact patients' satisfaction with treatment, so this finding is also significant.

The study's main limitations are the small sample size and the study design. In fact, the actual study design is not capable of revealing if the reduction in treatment time is due to the use of the new device, or if the aligners alone are already able to induce the registered rate of tooth movement. Lack of randomization and blindness to group allocation are other minor limitations.

Conclusion

The results of this study showed that associating AcceleDent with invisible orthodontics led to a successful, comfortable and fast treatment. Further research is needed to assess if the acceleration of treatment time is to be attributed to the use of AcceleDent or to the new aligner change regimen. It is unclear, in fact, if the gain of time in the experimental Group A is due to the use of the new device or if the aligners alone are already able to induce the observed rate of tooth movement. One significant improvement could be brought by a RCT with a larger sample size, comparing aligner treatments with and without AcceleDent use, keeping the aligner change regimen at the same number of days so that the full effect of vibrations could be clearly seen.

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Conflict of interest

The authors declare no conflict of interest.

Authors contributions

Study conception and design: GB, MF, GP. Data collection and acquisition: MF. Data analysis: GP. Data interpretation: GB, GC, MF, GAS. Manuscript writing: GB, MF, GP. Funding: GB, GC, MF, GP, GAS. All the authors approved the final version of the manuscript for publication.

Ethical policy and institutional review board statement

The study was conducted according to the guidelines of the 1964 Declaration of Helsinki and its later amendments. The study protocol was approved by the Institutional Review Board of the University of Palermo General Hospital (A.O.U. Policlinico Paolo Giaccone; approval number 2/2020). The study was registered at the German Registry of Clinical Trials (DRKSID: DRKS00021175).

Patient declaration of consent

Informed consent was obtained from all subjects involved in the study.

Data availability statement

The data set used in the current study is available on request from MF (massimo.fazio94@hotmail.it).

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