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Article

Effects of a 120Hz high-frequency acceleration device on orthodontic discomfort

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Abstract: Evaluation of the effects of a high-frequency acceleration (HFA) device on patient pain response to orthodontic forces. A multi-centered trial investigating pain sensitivity to orthodontic forces on 75 subjects at 4 study centers. Subjects underwent clear aligner treatment, with or without adjunctive HFA and documented their pain intensity using the validated NRS10 numeric rating scale. In-Office and At-Home ratings were measured separately for each subject for immediate and extended effect evaluations. Use of HFA devices in conjunction with clear aligner orthodontic treatment demonstrated significant reduction in subjects' recorded pain ratings vs controls within 5 minutes of aligner exchange, (p = 0.006) and significant reduction in recorded pain ratings vs controls over a 7-day period following aligner exchange (p = 0.018). A 99.6% daily compliance rate with at home use of the HFA device was recorded for all subjects in the study. HFA significantly reduces pain attributed to orthodontic force. HFA delivers clinically significant immediate pain relief, and clinically significant extended pain relief over the 7 days following adjustment.

Keywords: Orthodontics Clear Aligner, Pain; Vibration, High-Frequency, HFA.

1. Introduction

With increasing awareness and acceptance of orthodontic treatment by the general population has come a concomitant reduction in patience with both the discomfort and length of treatment associated with treatment. Specifically, both the fear of pain frequently associated with treatment and the length of time in treatment are the concerns most often cited by potential patients as the barriers to treatment acceptance. A survey of orthodontic patients indicated that 58.3% cited orthodontic pain as their primary complaint, followed by treatment duration [1]. Jones and Chan concluded that compliance with orthodontic treatment may be predicated on the amount of discomfort and pain experienced at the onset of treatment [2]. Burstone reported two types of pain associated with orthodontic force application, immediate and delayed. The immediate response being attributed to compression and the delayed response to hyperalgesia of the periodontal ligament [3,4]. New technologies that address patient concerns and potential barriers to accepting treatment are increasingly in demand. Pulse vibration technology has come to the forefront as an adjunctive technology that may significantly reduce both, patient pain to orthodontic forces and the length of time in treatment.

Pulse vibration has been studied at various force levels and vibrational frequencies with mixed results [5-12]. Previous literature, studies, and clinical trials have demonstrated that vibration at low-frequency (below 45 HZ) was not effective at reducing orthodontic pain associated with fixed braces or removable aligners [5-8]. However, Lobre et al. did report effectiveness in reducing pain in patients in fixed appliances at a low-frequency [9]. In contrast, pain reduction emanating from dental origin has been reported when a high-frequency (above 90 HZ) device was used [10]. Further, research investigating the effect of high-frequency as compared to low-frequency with painful

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temporomandibular disorders demonstrated high-frequency to have a significant reduction in pain, whereas the low-frequency had no significant effect [11].

A possible mechanism for pain reduction with vibration is the "gate control" theory, which suggests that pain can be reduced by simultaneous activation of nerve fibers that conduct non-noxious stimuli [13]. Another possibility is that the pain-relieving effects of vibration may be effected by increasing vascularity and reducing areas of ischemia, and through the simultaneous activation of large diameter sensory nerve fibers [14,15]. Use of NSAIDs to manage pain in conjunction with orthodontic tooth movement has been shown to decrease prostaglandin synthesis leading to a decrease in the inflammatory cytokines and chemokines that promote the bone resorption process, and thus may negatively impact the rate of tooth movement [16,17].

To date, patient compliance with the use of vibration devices remains a potential issue. A recent vibration study cited compliance at 17 days per month with a device requiring 20 minutes daily use [18], while another vibration study cited patient compliance as an issue despite daily reminder calls throughout the trial period [19]. The investigator suggested that future research could possibly be directed toward shortening the obligatory 20-minute vibration period in order to increase patient compliance.

Accordingly, it is hypothesized that an HFA device that requires a significantly reduced 5-minute treatment schedule will meet with greater patient compliance with the device and will subsequently be effective in reducing orthodontic pain or discomfort when compared to control subjects not receiving adjunctive vibration treatment.

2. Materials and Methods

This multi-centered, observational trial investigated the reported pain associated with exchanging aligners of 75 patients at 4 independent study centers. The inclusion and exclusion criteria are summarized in Table 1.

Table 1. Inclusion and exclusion criteria for study participation

Inclusion criteria	Exclusion criteria
a) Male and Female.	a) Subjects who indicated treatment with anti-inflammatory medications, or pain medications on pain diary, were excluded from the study.
b) Received aligner treatment during the study period of February 1, 2016 to February 1, 2017.	b) Caries.
c) Default velocity programmed on aligners.	c) Gingivitis.
d) Effective oral hygiene.	d) Periodontal therapy or treatment with periodontal medication within 6 months prior to initiating aligner treatment.
e) Healthy periodontal tissues.	
f) Completed pain ratings scale.	

All subjects were active orthodontic patients undergoing Invisalign (Align Technology, San Jose, CA) clear aligner orthodontic treatment, with or without adjunctive HFA treatment, and documented their pain/discomfort experiences with the validated Numeric Rating Scale (NRS-10) ranging from 1 (no pain) to 10 (worst pain). The HFA device used was VPro (Propel Orthodontics, Ossining, NY) designed to deliver a cyclical (vibrational) force with a frequency of 120Hz for 5 minutes per day. All Clincheck treatment plans were prescribed at default aligner velocity. Subject charts were consecutively selected from the clinical records of patients that contained pain assessments, with no age restrictions during a treatment period from February 1, 2016 to February 1, 2017. Per trial protocol, the consecutive enrollment by treatment initiation date continued until a total of 12 patients treated with HFA (Experimental Group) and 12 treated without the use of HFA (Control Group) were obtained from each study center or until the potential subject pool of each investigator was exhausted. Neither racial nor ethnic differences were considered in this trial. For

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the In-Office Assessment I, subjects in both groups, were instructed to advance 2 aligners from their current aligner, to ensure all subjects experienced some degree of pressure to record relative change to sudden orthodontic adjustment. (i.e., if patient presented wearing aligner 5, then aligner 7 was inserted). Baseline discomfort/pain was assessed in the office immediately following placement of the new aligner for both groups. Change in discomfort/pain was assessed in the office 3 minutes after insertion, and 5 minutes after insertion. For the At-Home Assessment II, a continued observation from the same sample of subjects whom completed Assessment I was conducted. Subjects in both groups were instructed to record their discomfort beginning with the first day of their next aligner change, immediately after aligner insertion as baseline, then each day for 7 consecutive days. The distribution of subjects enrolled is summarized in Table 2.

Table 2. Distribution of subjects enrolled

Subject groups		In-Office		At-Home	
		Aligner	Aligner + HFA	Aligner	Aligner + HFA
Subject enrollment	Completed assessments	31	44	23	39
Sex	Male	9	22	8	20
	Female	22	22	15	19

2.1 Sample Size

A total sample size of up to 24 subjects from each practice (12 per group), to a total of 96 subjects from four study centers were requested for this trial. The sample size was selected to yield 90% power to detect a difference if the true population difference (effect size) is equal to 2/3 of a standard deviation unit.

2.2 Statistical Analysis

The primary analysis compared change in pain ratings from baseline, to the pooled average across the post-baseline intervals, resulting in a single number per subject for Assessment I, and a second value for Assessment II. These values were then compared between the HFA treated subjects and the controls with t-tests for independent samples. Supplemental testing included between-group t-tests at each time point for illustrative purposes. Tests for sex differences were made by inspecting the treatment by sex interactions in 2-way ANOVAs. A significance criterion of $p<0.05$ was applied throughout.

2.3 Ethical Considerations

This protocol was submitted and approved by an Institutional Review Board (IRB) prior to trial initiation. Data gathered from each of the subjects were coded to ensure subject confidentiality and privacy.

3. Results

3.1 Assessment I: In-Office 5-Minute Immediate Effect NRS-10 Pain Rating

Data were obtained from 75 subjects (31 male/44 female). The experimental group was comprised of 44 subjects (22 male/22 female) and underwent aligner treatment with HFA. The control group was comprised of 31 subjects (9 male/22 female) and underwent aligner treatment alone. Complete in-office ratings were available for all subjects recorded as baseline after advancing aligners, at 3 minutes, and 5 minutes following aligner placement. The HFA group declined 1.82 points (SD=1.47) while the Control group declined 0.94 points (SD=1.05) a difference that was

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statistically significant (p=0.006). The mean in-office pain ratings at each time point are graphically illustrated in Figure 1, and in Table 3.

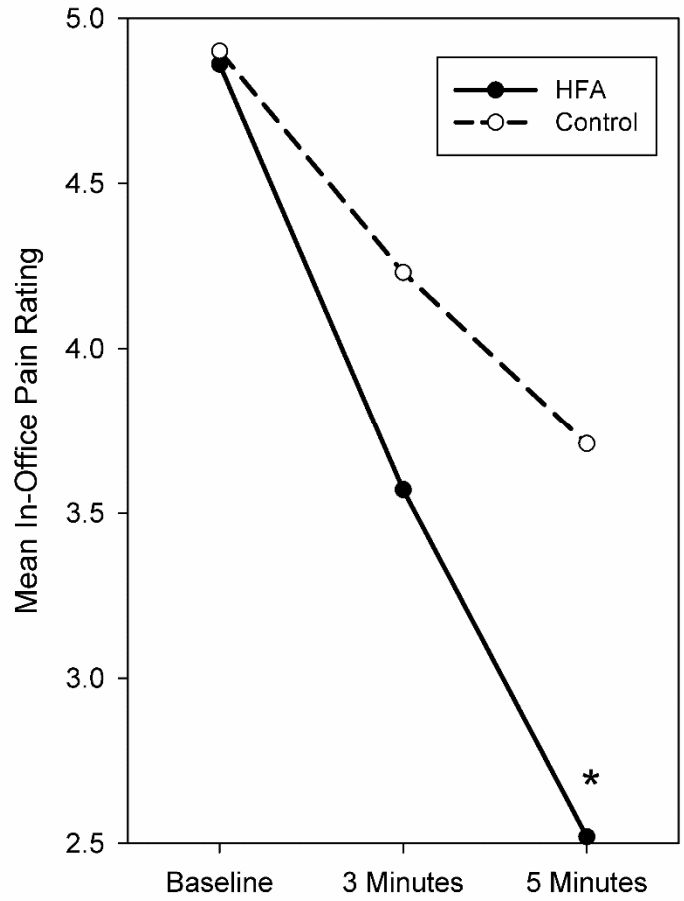

Figure 1. In-Office 5-Minute Immediate Effect NRS-10 Pain Ratings.
* = Statistically significant P<0.05

Table 3. Pooled average reduction from baseline in Assessment I Immediate Effect NRS-10 Pain.

Group	In-Office	
	Aligner	**Aligner + HFA**
Pain Reduction	0.94	1.82
SD	1.05	1.47
P	0.006*	

* = Statistically significant P<0.05

3.2 Assessment II: At-Home 7-Day Extended Effect NRS-10 Pain Rating

Data were obtained from the same pool of candidates whom completed Assessment I. 39 subjects (20 male/19 female) who underwent HFA treatment, and 23 (8 male/15 female) controls returned at-home daily NRS-10 pain surveys. There were 542 data points recorded of the 544 expected (99.6% complete) for these pain ratings. The two missing data points were imputed by

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linear interpolation for the adjacent days in each case. The HFA-treated group declined 2.86 points (SD=1.78) while those with the control treatment declined 1.73 points (SD=1.72), a difference that was statistically significant (p=0.018). The mean at-home pain ratings at each time point are graphically illustrated in Figure 2, and in Table 4. One investigator did not obtain at-home pain ratings for his control subjects. If the HFA-treated subjects for that investigator were excluded from the trial data, the HFA group decline was 2.80 points (SD=2.03) which remained a significantly greater decline than that of the controls (p=0.049). Neither adverse events nor unexpected adverse reactions associated with the use of the investigational vibrational device were reported.

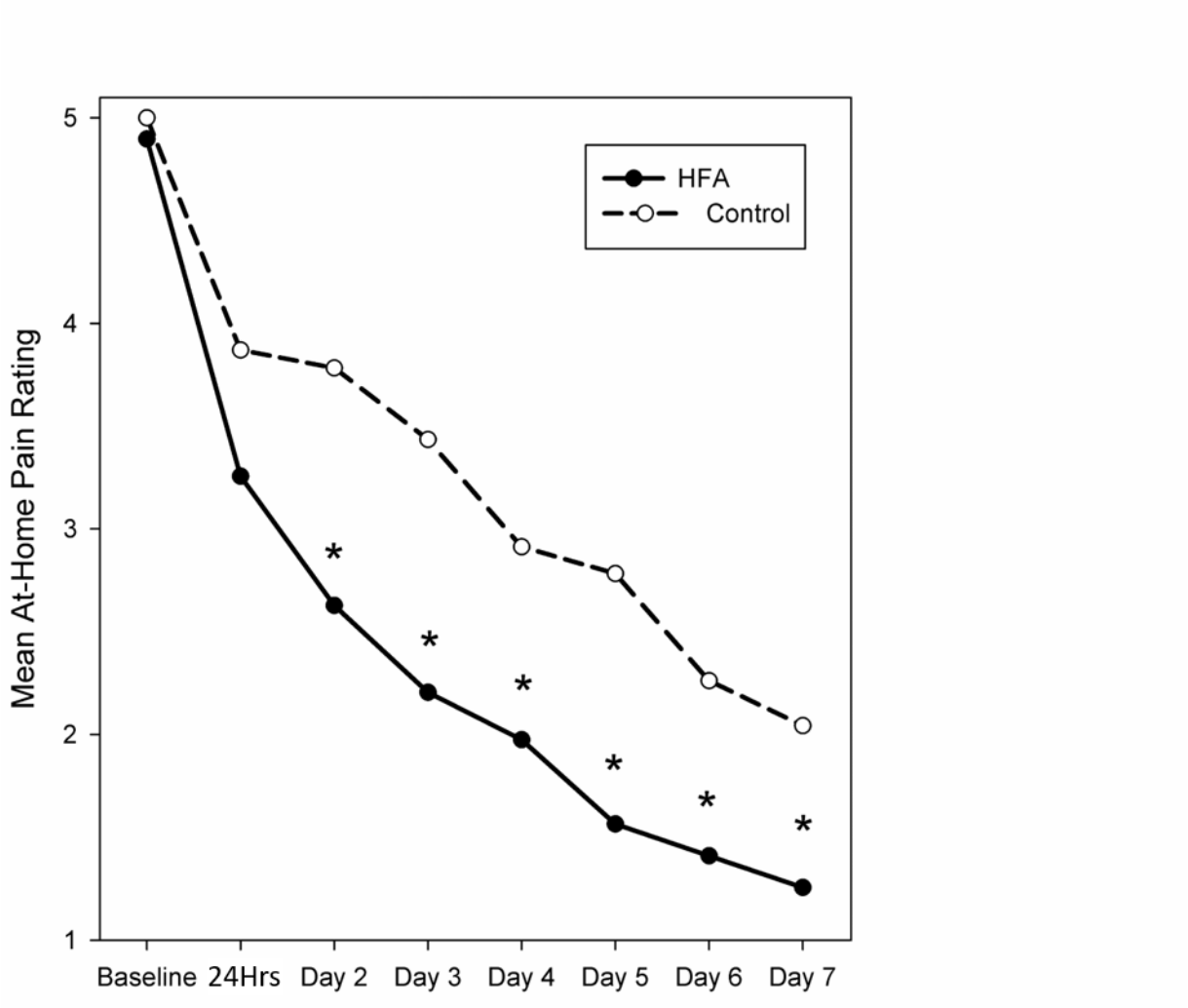

Figure 2. At-Home 7-Day Extended Effect NRS-10 Pain Ratings.
* = Statistically significant P<0.05

Table 4. Pooled average reduction from baseline in Assessment II Extended Effect NRS-10 Pain.

Group	At-Home	
	Aligner	Aligner + HFA
Pain Reduction	1.73	2.86
SD	1.72	1.78
P	0.018*	

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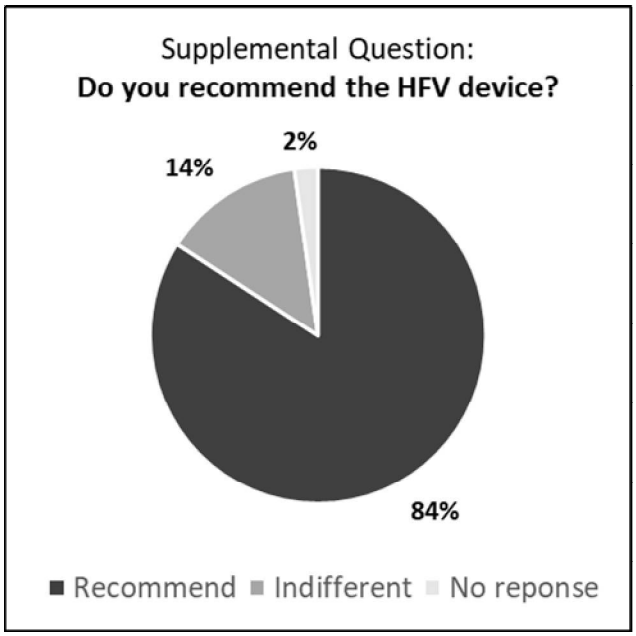
* = Statistically significant P<0.05

3.3 Sex Differences

Two-way ANOVAs were used to test for sex differences in the efficacy of the HFA device as compared to controls. If there was a differential response by sex, it would express as an interaction effect in these ANOVAs. The treatment by sex interaction was not significant for either in-office (p=0.395) or at-home (p=0.143) data. Accordingly, no sex differences in efficacy of the device were detected.

3.4 Supplemental Question to Subjects

Subjects treated with HFA all had experience with aligner treatment prior to initiation of the trial. When asked if they would recommend the HFA device, 37 of 44 subjects (84%) indicated that they would either recommend or strongly recommend its use; 6 (14%) were indifferent, and 1 (2%) did not respond. Figure 3.



4. Discussion

Pain management remains a significant concern in orthodontic treatment with 90% of patients reporting their experience as painful, and nearly 1 in 3 patients considering ceasing treatment due to pain [20]. The literature is replete with evidence of the negative impact that discomfort and pain has on patient compliance with the orthodontic treatment regimen and is a major factor in missed orthodontic appointments [2,21-23]. Importantly, pain associated with orthodontic treatment is often underestimated by clinicians. A study by Krukemeyer [21], investigating immediate in-office orthodontic pain, and at-home pain for 2 days following orthodontic adjustment reported that clinicians significantly underestimated pain immediately following the last appointment by 43%, while 58.5% of patients agreed or agreed strongly with the statement ''I have pain for days after an appointment." With the orthodontic profession significantly increasing its use of removable orthodontic appliances in the form of clear aligner treatment, managing patient discomfort and pain effectively is critical to patient comfort and compliance. Keim [24] reported that 'pain management and, even more important, pain prevention are given short shrift in many orthodontic training programs'. Krishnan [23], further stated that, "Many patients as well as parents consider initial lack of information about possible discomfort during treatment to be a major cause of the poor

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compliance exhibited." Krukemeyer suggested that patients' initial attitude towards orthodontic treatment should be understood during the diagnostic phase itself and should be discussed with the patients in all its reality [21]. Pre-emptively addressing spoken or unspoken concerns of patients as they relate to discomfort with options to manage it at the initial consultation may lead to a better patient experience and improved compliance with treatment.

Numeric rating scales (NRS-10) as a method of measuring pain intensity in clinical research are an accepted research protocol and have proven to be sensitive to measurement of both acute and chronic pain [25]. Burstone has delineated two categories of orthodontic pain as being 1) Immediate and 2) Delayed onset [3,4]. Burstone further describes immediate pain being derived from sudden heavy forces on the tooth, e.g. hard figure of eight tie between the central incisors to close a midline diastema. The delayed pain attributed to a variety of force values from light to heavy and representing hyperalgaesia of the periodontal membrane peaking at 24 hours. The results of this research show HFA to provide significant relief of immediate 'compressive' pain compared to control which may be related to the gate theory previously described by Melzack [13]. Patients that underwent adjunctive HFA treatment demonstrated a rapid reduction in pain within 5 minutes of use to levels approaching no detectable pain, whereas control subjects' pain ratings demonstrated moderate pain with minimal relief. Within 5 minutes of advancing 2 aligners, 60% of the HFA treated patients reported complete, or near complete elimination of detectable discomfort which was twice that of the control group. The HFA effects on delayed pain following aligner exchange were also evident. HFA treated subjects in this trial reported significantly less pain than controls in the days following adjustment which may be related to HFA reducing areas of ischemia as reported by Long [14]. The HFA treated subjects composite at-home pain rating at day 7 was 1.3, with 1 being no detectable pain. In fact, 77% of the HFA treated patients (30 of 39), experienced a total elimination of pain and 97% (38 of 39) reported complete or near complete elimination of pain, whereas patients in the control group reported higher ongoing pain that was statistically significant from the HFA patients.

Orthodontic pain associated with tooth movement has additional ramifications that extend beyond patient comfort and compliance, as it can directly impact practice efficiency and profitability. Patient orthodontic pain can adversely affect referral rates of siblings, parents/spouses, and friends. Moreover, unmanaged orthodontic pain often presents as increased administration overhead due to extending scheduling changes, loss of revenue due to open chair time, and/or additional treatment visits due to unnecessarily extended treatment.

This trial demonstrated significant immediate improvement, and significant extended improvements in pain scores after aligner change when clear aligner orthodontic treatment is combined with adjunctive high-frequency vibration. The difference between groups falls between the criteria for moderate and large effects which indicates that these are clinically meaningful effects [26].

Importantly, data from the at-home survey demonstrated a daily compliance rate with the HFA device of 99.6%, which suggest that a 5-minute treatment interval is manageable and readily accepted by patients. Finally, this trial demonstrated that HFA devices are effective in reducing pain and discomfort attributed to orthodontic forces without the need for supplemental pharmacological analgesia.

5. Conclusions

1. HFA significantly reduced or eliminated pain attributed to orthodontic force.
2. HFA delivered clinically significant immediate pain relief following adjustment.
3. HFA delivered clinically significant extended pain relief following adjustment.
4. A 99.6% patient compliance rate is significant and indicates that a 5-minute use of the HFA device is manageable for patients of all ages.
5. As a result of their experience with reduced pain and discomfort, 84% of the test subjects indicated that they would recommend or strongly recommend HFA treatment.

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Conflicts of Interest: The authors J.N., G.B., and T.S., have worked as a consultant for Propel Orthodontics and delivered lectures on its products in the past. Propel Orthodontics was permitted to review this manuscript. The right to a final decision on the content and publishing was retained by all authors without requiring approval from a third party.

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