Accelerated and More Predictable Tooth Movement Using High Frequency Vibration (HFV) 120Hz with Aligner Treatment

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ABSTRACT

Objective: To evaluate the effect of a high frequency vibration (HFV) device on clear aligner exchange intervals and treatment time required to achieve prescribed tooth movements.

Materials and Methods: 16 subjects who presented with Class I skeletal malocclusions characterized by minimal to moderate crowding (3-5 mm) and treated with Invisalign clear aligners were divided into two groups. Group 1 subjects (N=8) underwent aligner treatment in conjunction with the daily use of an HFV device, and exchanged aligners every 5 days. Group 2 subjects (controls; N=8) underwent aligner treatment without use of the HFV device, and exchanged aligners every 14 days according to the manufacturer's recommended aligner exchange interval. All subjects were treated by one investigator, and results were evaluated both by the total number of aligners used and the number of refinements required to complete treatment.

Results: A significant decrease both in treatment time and the number of aligners required to complete treatment was observed between the subjects using the HFV device and the controls. In addition, the subjects who used the HFV device required no refinements to complete treatment, whereas 6 of 8 of the control subjects required refinements.

CONCLUSION

Use of an HFV device in conjunction with Invisalign treatment resulted in more predictable and consistent tooth movement with aligners and a significant decrease in the length of treatment.

BACKGROUND

Clear aligner therapy has become an increasingly popular orthodontic treatment modality elected by adults and teens alike who seek to avoid traditional fixed braces. However, progression of aligner treatment as well as the estimated time in treatment may not occur as originally planned by the clinician. Even under optimal conditions, where aligner design, treatment planning, and patient cooperation is optimal, the progression of treatment may not completely be expressed clinically according to the original sequentially programmed plan for tooth movement. This may be due to individual variations in physiological and biological factors that impact bone remodeling, and/or external mechanical factors such as patient failure to properly seat aligners or to identify their accurate tracking. Previous literature and studies investigating pulse vibration devices have reported mixed results with regard to their effect on orthodontic treatment.[1-4] While some studies have claimed positive effects on tooth movement, others have reported no effects when compared to controls. Research indicates that that both the vibrational frequency of the device as well as the force delivered may play an important role in the capacity for pulse vibration to influence bone remodeling.[5] A recent university based, randomized clinical trial[1], investigating low frequency mechanical vibration found no evidence to support accelerated tooth movement or decreased treatment time. Conversely, a recent university based, randomized clinical trial[4] investigating high frequency mechanical vibration demonstrated both significant accelerated tooth movement and increased cytokine production, a known biological factor in bone remodeling and subsequent orthodontic tooth movement.

Disclaimer: Propel Orthodontics markets the VPro5™ as a high frequency vibration aligner seater. This unpublished draft article may describe uses of high frequency vibration technology in general and/or the VPro5 specifically that are outside of our labeling. Propel Orthodontics provided financial support to the author.

Independent of the biological factors, accurate physical seating of the aligner on all areas of the tooth surface is critical to the accurate and complete transfer of forces to the teeth. Accordingly, a common practice among clinicians has been to recommend the use of treatment adjuncts such as Chewies to facilitate aligner seating. One of the challenges with this practice has been an observed undesirable aligner distortion.[6] Extrinsic impacts of tray distortion may result in modified forces applied to the tooth, while intrinsic consequences of tray distortion were significantly increased pain as noted by Fujiyama.[7] Efforts to improve treatment efficiency delivering faster, more predictable tooth movement is at the forefront of modern orthodontic treatment. Therefore, it has been hypothesized that HFV facilitates simultaneous and complete mandibular and maxillary full arch aligner seating that maximizes optimal, complete, and continuous forces to the teeth. It is this optimal aligner seating effect that supports accelerated tray progression and subsequent accelerated tooth movement when compared to traditional orthodontic aligner exchange and practice without the use of HFV.

METHODS

This retrospective, observational clinical study investigated both the rate of aligner exchange and the time required to complete treatment among subjects that received clear aligner treatment, with and without HFV adjunctive treatment.

Subjects

Per protocol, up to 10 subjects who received clear aligner therapy in conjunction with HFV and an equal number of subjects who received clear aligner therapy without the use of HFV were eligible for this investigation. Subjects were selected consecutively from treatment records. There were 8 HFV cases available for selection and 8 Control cases therefore were selected. Ten cases met the protocol criteria for controls, however 2 had also received manual-osteoperforation (MOP) therapy and were therefore excluded. Subjects treated with HFV initiated treatment between February, 2016 and September, 2016. Subjects treated at the same center prior to the introduction of HFV (controls) initiated treatment between January, 2014 and August, 2015. Subjects were selected based on the following criteria:

Inclusion Criteria

a. Class I Occlusion
b. Mild to moderate crowding (3mm-5mm)
c. Age range 14 -45 years of age (males or females) at initial treatment visit
d. Good oral hygiene, no periodontal inflammation at initial visit
e. Healthy; subjects were free of any systemic diseases
f. Smartrack™ aligner material
g. Completed the clear aligner treatment series
h. Received a post treatment digital retainer scan

Exclusion Criteria

a. Subjects with caries present at time of treatment
b. Chronic NSAID, steroid therapy
c. Bisphosphonate Therapy
d. Pregnancy

Study Center

This study consisted of subjects who were treated by Dr. Thomas Shipley in Peoria AZ, a licensed dental professional who has experience in Invisalign clear aligner therapy, and who has completed clear aligner cases with and without adjunctive HFV treatment.

Procedure

This retrospective analysis of treatment data includes the following: 1. treatment start and finish dates, 2. number of aligners in the initial series, 3. aligner exchange rate in days, 4. number of case refinements, and 5. any additional trays required to complete treatment. In order to ensure comparability of selected cases, the HFV (Experimental) group was compared to the non-HFV(Control) group with the baseline ABO Discrepancy index[8] (DI) measurements obtained using intra-oral digital 3D measurements, and analyzed using OrthoCad™[9] version 4.0.4.403 digital model analyzer for each case. All study measurements were performed by the same clinical research associate. To evaluate intrarater measurement reliability, 5 subjects were randomly selected by drawing from study subjects to perform 4 different calibration measures on. Baseline measurements were recorded for overjet, overbite, #8 incisor width and #27 canine width, and repeated 1 week and 2 weeks later. Excellent repeatability was demonstrated as measured by Pearson Correlation of (0.996 & .991) at week 1 & 2 for composite overjet n = 5, (1.0 & 1.0) at week 1 & 2 for composite overbite n=5, (.959 & .959) at week 1 & 2 for composite #8 incisor width n=5, and (1.0-1.0) at week 1 & 2 for composite #27 canine width n=5. Correlation was significant at 0.01 level for overjet, overbite and canine width (2-tailed). Correlation was significant at 0.05 level for incisor width (2-tailed).

Statistical Analysis

Categorical variables were compared between groups using the Fisher Exact test. Continuous variables were compared between groups using the t-test for independent samples. Where the parametric assumptions may be questioned, these test results were confirmed by the non-parametric Mann-Whitney U tests. Paired comparisons within treatment groups were made using paired t-tests. Multiple linear regression was used to simultaneously evaluate the effects of treatment and sex on the number of aligners required. A significance criterion of $p<0.05$ was applied throughout.

Ethics

This protocol was submitted and approved by an Institutional Review Board (IRB) prior to study initiation. Data gathered from subject charts was coded to maintain subject confidentiality and privacy.

RESULTS

Sample Characteristics

The groups were of similar complexity by the ABO Discrepancy Index (HFV mean=12.25, SD=9.63, Control mean=16.13, SD=14.32, p=0.536 by t-test, p=0.428 confirmed by U test). HFV subjects were older than Controls, but not significantly so (HFV mean=27.6, SD=11.4, Control mean=18.9, SD=7.8, p=0.095 by t-test). All of the HFV subjects were female while the Control group contained 3 females and 5 males (p=0.026 by Fisher Exact test).

Crowding

Means for upper crowding did not differ between groups at baseline (HFV mean=0.74mm, SD=3.47mm, Control mean=-0.95mm, SD=4.45mm, p=0.412 by t-test). Means for lower crowding also did not differ between groups at baseline (HFV mean=1.86mm, SD=2.76mm, Control mean= 0.60mm, SD=2.24mm, p=0.332 by t-test). Both upper and lower crowding were at 0.0mm for all subjects in both groups at post-treatment.

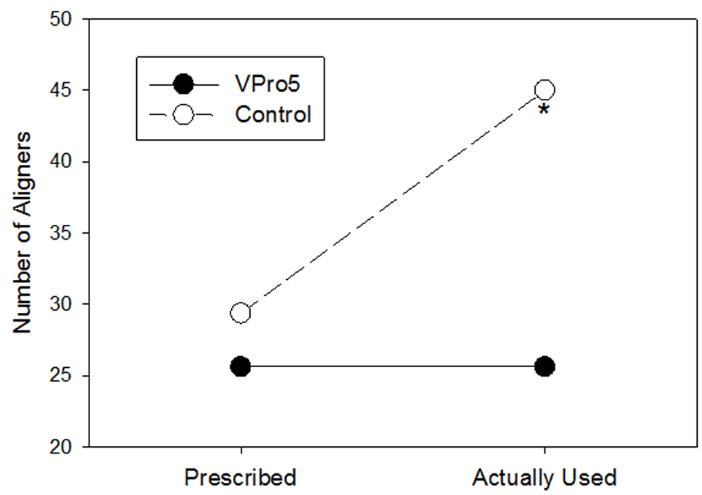

figure 1
Mean number of aligners prescribed and actually used. * p<0.001

Aligner Counts

The mean number of aligners prescribed and actually used are illustrated in Figure 1. The number prescribed was not significantly different between groups (HFV mean=25.63, SD=5.78, Control mean=29.38, SD=6.00, p=0.224 by t-test) while the number actually used was lower in the HFV group than among Controls (HFV mean=25.63, SD=5.78, Control mean=45.00, SD=10.18, p<0.001 by t-test).

Aligner Change Interval and Treatment Duration

The prescribed aligner change interval was 14 days for all subjects in both groups. The actual frequency was 14 days for all control subjects. The actual frequency was 5 days for 7 of the HFV subjects and 3 days for 1 HFV subject (p<0.001 by U test).

The estimated and actual treatment durations are illustrated in Figure 2. The estimated treatment durations did not differ significantly between groups (HFV mean=51.25, SD=11.56, Control means=58.75, SD=12.00, p=0.224 by t-test). As a result of the aligner counts and change intervals, the duration for HFV was significantly lower than Control (HFV mean=19.25, SD=3.88, Control mean=96.75, SD=18.76, p<0.001 by t-test and p<0.001 confirmed by U test). The HFV group duration was significantly lower than estimated (p<0.001 by paired t-test) while the Control group duration was significantly higher than estimated (p=0.005 by paired t-test).

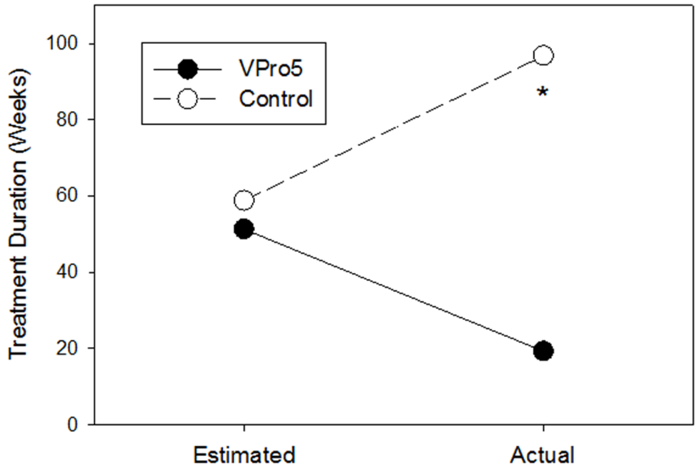

figure 2
Estimated and actual treatment durations. *p<0.001

Case Refinement

The incidence and number of subjects requiring refinement is illustrated in Figure 3 & Table 1. There were no refinements to the treatment schedule in the HFV group. Six of the 8 Control subjects required refinement (5 had 1 refinement, 1 had 2 refinements), adding from 10 to 51 aligner changes.

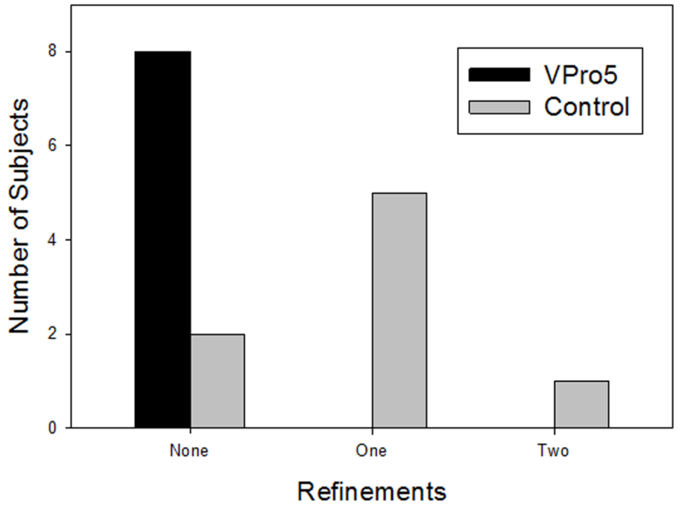

figure 3
Number of subjects requiring case refinement

Group	Initial Aligners[1] Prescribed (Mean)	Total Aligners[2] Required (Mean)	Total Refinements
HFV	26	26	0
Control	29	45	7

table 1
Aligners prescribed vs aligner required & case refinements
[1]No statistical significance, [2]Statistical significance

Potential Sex Bias

The unequal sex distribution cannot be corrected by statistical methods. However, to test for potential sex effects on aligner changes, multiple regression was employed to test for the influence of treatment and sex on the number of aligners utilized. The regression coefficient for treatment was statistically significant (coefficient=18.71, SE=5.81, p=0.007) while the coefficient for sex was not (coefficient=1.07, SE=6.27, p=0.867).

DISCUSSION

The results of this study demonstrate that clear aligner treatment duration can be significantly reduced using an HFV device by reducing both the intervals between aligner exchanges and the total number of aligners required to complete treatment. Subjects in both groups were diagnosed with statistically similar Class I skeletal malocclusions with mild to moderate crowding, as measured by initial ABO Discrepancy Index. Subjects using adjunctive HFV treatment required 43% fewer aligners to complete their case. While the high frequency vibration subjects in this study showed no refinements, despite matching initial complexity to controls, this study does not suggest all refinements can be eliminated through incorporating the use of HFV. Future studies with more complex cases, including individual rate limiting teeth are warranted. It is important to note that tray interval is relative to prescription. Clincheck™ treatment planning software at default prescription level delivers a threshold maximum of 0.25mm movement allowed per tray.[10] Many clinicians have been using accelerated tray interval successfully for years through decreasing the prescribed velocity of tooth movement within their treatment planning software in attempt to improve predictability[11], or reduce pain[12]. However, this practice does not reduce treatment time of initial prescription. For example, a 26 aligner case at default rate is predicted to span 12 months. By decreasing prescribed velocity, the same case may be rendered a 52 aligner case spanning the same 12 months at accelerated aligner interval. It is therefore also important to note, all subjects in both groups were at default prescription level. Therefore the HFV Group showed faster more predictable tooth movements and in this study required no refinements. While office visits were not tabulated in this study, it is assumed that refinement scans, more frequent Clincheck set-ups, and the delivery of additional aligners required to complete treatment resulted in significantly more doctor time and office visits to complete the case for the control group that did not receive HFV treatment. Whether these results may be related to intrinsic biological factors as seen by the increased bone remodeling associated with high frequency vibration in Alikhani's research[2], or extrinsic factors such as optimized force delivery[13] through complete dual arch aligner seating is yet to be fully understood. Future research on these questions is warranted. Consumers and clinicians alike continue to search for more efficient means to straighten teeth. The magnitudes of differences between groups in this study is striking and consistent with expectations given the background reports.

CONCLUSIONS

1. Accelerated and more predictable tooth movement was achieved using adjunctive HFV treatment with aligner therapy.
2. Use of a HFV device allowed 64% faster aligner exchanges than control.
3. HFV subjects required fewer refinements than control subjects.
4. HFV subjects required fewer aligners to complete treatment than controls.

Acknowledgement: The high frequency device discussed herein is the commercially available device manufactured by Propel Orthodontics, LLC USA.

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