# Pain Reduction Observed with Orthodontic Forces & Vibration (PROOF V)

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## ABSTRACT

**Objective:** To evaluate the effect of a high frequency vibration device (HFV) on orthodontic pain

**Materials and Methods:** Retrospective, multi-centered, observational study investigating pain reports of 75 subjects at 4 study centers. All subjects were orthodontic patients that underwent aligner treatment, with or without HFV treatment, and submitted pain ratings. In-Office and At-Home ratings were measured separately for immediate and extended effect measures.

**Results:** Use of HFV in conjunction with aligner treatment demonstrated a 67% reduction in recorded pain scores vs control within 5 minutes of aligner exchange for In-Office ratings. Use of HFV demonstrated a 64% reduction in recorded pain scores vs control over a 7-day period following aligner exchange for At-Home ratings. 99.6% Daily Compliance rate with at home use.

## CONCLUSIONS

1. Use of HFV significantly reduces or eliminates orthodontic pain
2. Use of HFV delivers a clinically meaningful, immediate reduction in orthodontic pain
3. Use of HFV delivers a clinically meaningful, extended reduction in orthodontic pain
4. 99.6% patient compliance is high with 5 Minute HFV
5. 86% of responders indicated they recommend or strongly recommend VPro5 HFV

## BACKGROUND

Orthodontic treatment continues to grow in popularity among both teens and adults. While social stigmas associated with orthodontic treatment are in decline, many are still hesitant to consider treatment. Length of treatment time, and fear of pain associated with treatment are the concerns most often cited as the barriers to treatment acceptance. A study has demonstrated that 58.3% of the subjects cited orthodontic pain as their primary complaint, followed closely by treatment duration.[1] As competition for new patients continues to increase, successful practices continue to seek ways to differentiate their practice, while addressing these cited concerns of potential and existing patients. Vibration in conjunction with orthodontic forces has been studied in various frequencies and force levels with mixed results.[2,3] It appears frequency and force correlate with the therapeutic responses associated with vibration therapy.[4] Previous literature and studies have demonstrated that vibration at low frequency was not effective at reducing pain originating from teeth[2,4], whereas vibration at high frequency was.[3,4] A possible mechanism is the "gate control" theory, which suggests that pain can be reduced by simultaneous activation of nerve fibers that conduct non-noxious stimuli.[5] Another possibility is that vibration may help relieve compression of the periodontal ligament (PDL), promoting normalized circulation[6]. 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 bone resorption process and may negatively impact tooth movement.[7] Efforts to find ways to manage pain as it relates to patient treatment satisfaction, compliance and more efficient treatment continue, along with efforts to address perceived pain for patients

**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.

reluctant to accept treatment. 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[8], while another vibration study cited patient compliance as an issue despite daily reminder calls throughout the trial period[9], Accordingly, the investigator suggesting that future research could possibly be directed toward shortening the 20 minute vibration period in order to reduce interference with patients' personal schedules. Therefore it is hypothesized that high frequency vibration in conjunction with a 5 minute treatment time will not interfere with a patients schedule, and will be effective at reducing pain or discomfort, as compared to control subjects not receiving vibration.

# METHODS

This retrospective, multi-centered, observational study investigated the pain reports of patients at 4 independent study centers. All subjects were orthodontic patients that received aligner treatment, with or without HFV treatment, and supplied in-office pain ratings.

### Subjects

Subject charts were selected sequentially from the clinical records of patients that received aligner therapy, with no age restrictions. No racial and ethnic group requirements were considered. Subjects were selected from the clinical records in the period of February 1, 2016 to February 1, 2017, provided that the clinical record includes pain ratings. Per protocol, selection continued from charts until 12 patients treated with HFV and 12 treated without the use of HFV were obtained from each study center or until the potential subject pool of each investigator was exhausted.

### Inclusion Criteria

1. Subjects were eligible if they received aligner treatment during the study period of February 1, 2016 to February 1, 2017, and completed in-office pain ratings are available in the clinical record.
2. Subject has a history of healthy oral hygiene.

### Exclusion Criteria

1. Vulnerable subjects per IRB definitions
2. Subjects with concurrent caries
3. Subjects who were non-compliant with HFV recommended daily usage
4. Periodontal therapy or medication within 6 months before aligner treatment.
5. Concurrent treatment with medications that could affect the level of inflammation, such as chronic antibiotics, phenytoin, cyclosporin, anti-inflammatory drugs, and systemic corticosteroids.

### Treatment

Experimental and Control groups were administered an in-office, and at-home assessment. For the in-office assessment experimental subjects received HFV and control subjects did not. Subjects in both groups were instructed to advance 2 aligners from current to ensure all subjects experienced some degree of pressure to measure relative change for a 5 minute period only. (ie: patient is on day 13 of tray 5 today, insert tray 7.) Subject responses were documented on the NRS Numerical Rating Scale.

### Assessment I

Pain was regularly assessed in the office at baseline, 3 minutes, and 5 minutes after placement. The outcome measures were subject reports of pain or discomfort on the NRS Numerical Rating Scale from 1 (no pain) to 10 (worst pain).

### Assessment II

For the at-home assessment, experimental subjects received HFV and control subjects did not. Subjects in both groups were instructed to document their responses on the NRS Numerical Rating Scale beginning with the first day of their next aligner change at baseline, then each day for 7 consecutive days. The outcome measures were subject reports of pain or discomfort on the NRS Numerical Rating Scale from 1 (no pain) to 10 (worst pain).

### Sample Size

A total sample size of up to 24 charts in each practice (12 per group) to a total of 96 subjects for four study centers was requested for this study. 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.

### Statistical Analysis

The primary analysis compared change in pain ratings from baseline, pooled across the post-baseline intervals, resulting in a single number per subject for the in-office data and a second value for the at-home data. These values were then compared between HFV treated subjects and controls with t-tests for independent samples. Supplemental testing included between-groups 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.

### Ethics

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

## RESULTS

Data were available and extracted from 75 subject charts (31 male/44 female). The experimental group comprised of 44 subjects (22 male/22 female) treated with HFV. The control group comprised of 31 subjects (9 male/22 female) treated with the traditional control treatment. There were no adverse events or unexpected adverse reactions associated with the use of the investigational device reported.

### In-Office Ratings

Complete in-office ratings were available for all subjects at baseline, 3 minutes, and 5 minutes after aligner placement. The mean in-office pain ratings are illustrated in Figure 1. The HFV group declined 1.82 points (SD=1.47) while the Control group declined 0.94 points (SD=1.05) and this difference was statistically significant (p=0.006). As illustrated in Figure 1, the maximal difference was noted at the 5-minute time-point.

### At-Home Ratings

At-home ratings were available for 39 subjects with HFV treatment and 23 with the control treatment. 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 linear interpolation for the adjacent days in each case. The mean at-home pain ratings are illustrated in Figure 2. The HFV-treated group declined 2.86 points (SD=1.78) while those with the control treatment declined 1.73 points (SD=1.72). This difference was statistically significant (p=0.018). As illustrated in the Figure, differences from day 2 on were statistically significant.

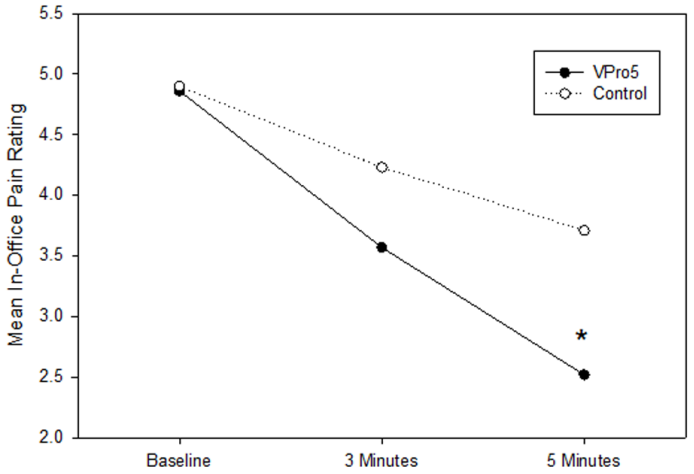


figure 1
Mean in-office pain ratings. * p<0.05

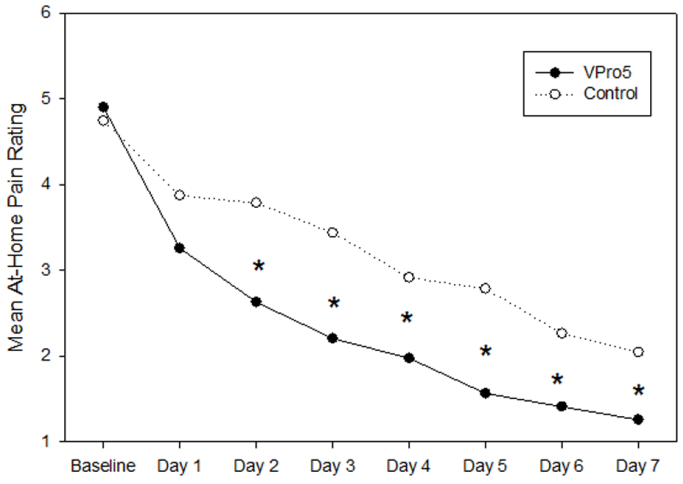


figure 2
Mean at-home pain ratings. * p<0.05

### Sex Differences

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

### Supplemental Question

Subjects treated with HFV had all experienced the traditional treatment on prior aligner changes. When asked if they would recommend VPro5 HFV, 37 of 44 subjects indicated that they would recommend, or strongly recommend use of VPro5 HFV. Six were indifferent. One non-responder.

## DISCUSSION

Pain management is a concern in orthodontic treatment. The literature is replete with evidence of the negative impact discomfort has on compliance with the orthodontic treatment regimen.[10] Further, pain associated with orthodontic treatment is often underestimated by clinicians. A study by Krukemeyer[11] reports that practitioners underestimated pain immediately following the last appointment by 43%, and 58.5% of patients agreed or agreed strongly with the statement "I have pain for days after an appointment." With the nature of removable orthodontic appliances such as clear aligner therapy, managing it effectively is paramount. As reported by Keim[12], 'pain management and even more important, pain prevention are given short shrift in many orthodontic training programs'. Krishnan[10] states 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 compliance exhibited. The literature suggests that the patients' initial attitude towards orthodontics should be understood during the diagnostic phase itself and should be discussed with the patients in all its reality.[11] 'Setting the table' at consult by preemptively addressing spoken, or unspoken concerns, as they relate to discomfort with options to manage it, may lead to a better patient experience, and improved compliance with therapy. In this study HFV subjects demonstrated a rapid reduction in pain within 3 minutes, (Figure 1) and a continuous decline in pain scores to levels approaching no detectable pain, whereas control subjects pain scores demonstrate moderate pain with little relief. Thirty percent of HFV patients reported zero detectable discomfort within 5 minutes of use. The extended effects of pain following orthodontic adjustment, such as changing aligners in this study, were evident as well. HFV subjects composite at home pain score at day 7 was 1.3, with 1 being no detectable pain, In fact 77% of HFV patients, (30 of 39), had total elimination of pain while patients in the control group reported ongoing pain statistically significantly higher from HFV patients. (Figure 2) The topic of orthodontic pain has ramifications that extend beyond patient comfort, and ripple through practice efficiency and profitability. Direct impacts of reported pain may be cross referenced through reports on compliance with appointments, compliance with regimen and referral rate of siblings, family and friends. However, indirect impacts of patient comfort as it relates to treatment compliance often go undetected. They may present through increased administration overhead on scheduling, impacts on treatment acceptance related to fear of pain, loss of revenue due to open chair time, and/or additional treatment visits required. A growing intangible is the patient sharing of experiences through social media. This retrospective study shows improvement in mean pain scores after aligner change when traditional treatment is combined with HFV treatment. The magnitude of improvement was 67% of a pooled standard deviation unit for in-office ratings and 64% of a pooled standard deviation unit for at-home ratings. This difference falls between the criteria for moderate and large effects which indicates that these are clinically meaningful effects. Pain and discomfort were reduced equally independent of gender. 542 of 544 data points returned from at-home survey demonstrate a remarkable daily compliance rate of 99.6%. This study demonstrates HFV as an effective treatment to reduce orthodontic pain and discomfort without supplemental pharmacological analgesia. Near perfect compliance shows 5 minutes was not an interference to their daily schedule, which may directly and indirectly contribute to improved patient experience, and increased practice efficiency and overall profitability.

## CONCLUSIONS

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

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