Orthodontic pain with fixed appliances and clear aligners: A 6-month comparison

Victor Chan,[a] Bhavna Shroff,[a] Neal D. Kravitz,[b] Caroline Carrico,[c] Daniel Hawkins,[d] Phuong Tran,[a] and Steven Lindauer[a]
Richmond and South Riding, Va

Introduction: This prospective study compared pain perception, intensity, and analgesic use among patients treated with fixed appliances (FAs) and clear aligners (CAs) over 6 months. **Methods:** Digital surveys were collected from 87 adult patients treated with CA or FA from 2 orthodontic offices. The 7-item survey was sent at 3-time points (preappointment, 2-day postappointment, and 7-day postappointment) for each appointment. Wilcoxon, *t* test, and Fisher exact chi-square tests were performed with significance set at 0.05. **Results:** The FA group had a higher rate and intensity of pain 2 days after the second, third, and fifth appointments ($P < 0.030$). At 7 days postappointment, the FA group had a higher rate and intensity of pain for the first and fifth appointments. Dull pain was reported the most in both groups, with a proportion of FA patients reporting throbbing (31%) or sharp (20%) pain ($P = 0.035$) at 2 days postappointment. The CA group reported the most pain at rest, whereas the FA group reported chewing as the most painful ($P = 0.002$). The FA group had a higher rate of analgesic consumption after the first appointment ($P = 0.037$). **Conclusions:** Both the FA and CA groups experienced similar rates and intensities of pain 2 days after the delivery of appliances at the first appointment. Although CA pain intensity remained minimal, FA pain peaked 2 days postappointment whenever a new orthodontic stimulus was introduced and remained elevated 7 days postappointment when that stimulus was a new archwire material. (Am J Orthod Dentofacial Orthop 2024;■:■-■)

The perception of pain is a common concern among orthodontic patients. Pain can deter patients and parents from seeking orthodontic treatment. Even patients undergoing treatment or nearing treatment completion still perceive pain as a discouraging factor.[1] Therefore, proper consultation with attention to pain management is important at the initiation and during orthodontic treatment.[2]

The physiology of pain and the degree of severity of pain are multifactorial. Age, gender, culture, society, emotional and cognitive factors play a critical role.[3] For example, patients aged >13 years tend to report more frequent incidence of pain with fixed appliances (FA) than younger patients.[4] Studies have also documented that females tend to have an increased perception of pain, analgesic consumption, and discomfort when performing daily functions such as biting and chewing.[4]

Orthodontic pain is mainly reported at placement of separators, initial placement of appliances, and after subsequent adjustments. Longitudinal trends in pain associated with FAs and clear aligners (CAs) are documented across several studies over a minimum of 1-2 weeks and at a maximum of 2-3 months. Over the first 7 days of FA treatment, pain intensity peaks at 24 hours and declines to pretreatment levels by day 7.[4,5] Similarly, over the first 7 days of CA treatment, pain peaks at 24 hours then declines to remain slightly above baseline at approximately day 7.[6] This trend does not seem to

[a]Department of Orthodontics, Virginia Commonwealth University, Richmond, Va.
[b]Private Practice, South Riding, Va.
[c]Department of Dental Public Health and Policy, School of Dentistry, Virginia Commonwealth University, Richmond, Va.
[d]Department of Oral and Maxillofacial Surgery, Virginia Commonwealth University, Richmond, Va.
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Address correspondence to: Bhavna Shroff, Department of Orthodontics, Virginia Commonwealth University, 520 N 12th St, Rm 111, PO Box 980566, Richmond, VA 23298-0566; e-mail, bshroff@vcu.edu.
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continue further into treatment. After the first and second months, White et al[7] found that pain intensity stayed near the baseline for 4 days after adjustments for both the FA and CA groups.

Different initial alignment archwire materials minimally impact pain intensity. No difference in pain intensity was reported between the initial placement of superelastic alloy, 0.014-in Japanese nickel-titanium (NiTi) (GAC International Inc, Central Islip, NY) and multistrand stainless steel, 0.015-in Twistflex (3M Unitek Corp, Monrovia, Calif) archwires.[8] Fernandes et al[9] found that 0.014-in Sentalloy, Light (GAC International Inc) was marginally less painful than 0.014-in Nitinol (3M Unitek Corp). This difference was only significant at 4 hours postinitial placement of these wires. No other significant difference in pain intensity was found over the study period (the first 11 hours or first 7 days of alignment). Archwire dimensions (round, square, and rectangular) and manufacturer (3M Unitek Corp; GAC International Inc; and Ormco, Glendora, Calif) have been shown not to influence discomfort.[10]

Some clinicians claim that the use of CA materials, originally polyurethane, reduces the pain and discomfort associated with orthodontic treatment. However, there has been no study directly investigating the influence of the softness and flexibility of different CA trays on pain perception. Fujiyama et al[11] reported that most pain from Invisalign CA arises from prescribed deformation of the aligner (ie, the accentuated curve in the vertical dimension or arch expansion in the transverse dimension) rather than manufacturing defects such as nonsmoothed aligner edges (including aligners missing distal halves of second molars) or deformation of attachments.[11] Out of 12,311 total aligners for 90 patients, there were only 369 painful aligners (3%). Approximately 0.2% were due to nonsmooth edges, 0.2% due to deformation of attachments, and 2.6% due to deformation of the aligner.[11]

Initial pain intensity associated with FA and CA has been compared. During the first week of treatment, CA resulted in lower pain intensity while improving the patient's quality of life and psychosocial well-being.[6] There has been general agreement that CA is less painful in the first week. However, Shalish et al[12] reported relatively high levels of CA pain in the first few days when compared with buccal FA over 2 weeks.[12] When compared with self-ligating brackets, CAs were also less painful during the first week of treatment.[13]

FA and CA pain intensity has not yet been longitudinally investigated beyond the first 2 months of treatment.[7] Interestingly, a cross-sectional study at the conclusion of treatment found that the only differing variable between the modalities was that CA treatment resulted in better satisfaction with eating and chewing, not with pain.[14] Longitudinal data is lacking on whether or not the pattern of orthodontic pain intensity and quality changes over the first 6 months of treatment.

This study aimed to compare pain intensity, perception, and analgesic consumption between subjects treated with buccal FA and CA over the first 6 months of treatment. The most painful time (during a masticatory function or at rest) and pain quality (dull, throbbing, or sharp) were also compared. The goal was to provide data for orthodontists to use in conversation with patients debating between FA and CA treatment.

MATERIAL AND METHODS

This study was approved as exempt by the Institutional Review Board at the Virginia Commonwealth University under protocol no. HM20024066.

A prospective, parallel, 2-arm, longitudinal cohort study was conducted at 2 centers: (1) Virginia Commonwealth University Department of Orthodontics and (2) a private practice in Northern Virginia. Subjects were divided into 2 groups: 1 group treated with Invisalign (Align Technology, Santa Clara, Calif) (CA group) and 1 group treated with buccal fixed edgewise appliances (FA group). Both centers contributed CA and FA subjects. For the FA group, Mini Master 0.018-in brackets and MRX bands (American Orthodontics, Sheboygan, Wisconsin) were used at the first center, and Synergy 0.022-in brackets (Rocky Mountain Orthodontics, Franklin, Ind) were used at the second center. Inclusion criteria were (1) adult patients aged $\geq$18 years, (2) crowding $\leq$5 mm, (3) no more than half cusp Class II or Class III dental malocclusion, (4) overbite $\leq$50%, (5) overjet $\leq$5 mm, (6) nonextraction, and (7) no history of syndromes, cleft lip, and cleft palate. These inclusion criteria were well within the providers' scope of treatment using either FA or CA; therefore, each patient was given the choice of either modality. Only Invisalign patients with at least 24 aligners (including refinements) were included. Moreover, 24 subjects who did not respond to any surveys or habitually rescheduled appointments were excluded to obtain consistent longitudinal data.

A 7-item digital survey was built using Research Electronic Data Capture (REDCap) software (Vanderbilt Univeristy, Nashville, Tenn), which is a secure application for delivering and capturing survey responses for research.[15] The survey was tested for validity and reliability among the faculty, staff, and residents of the Department of Orthodontics and Oral and Maxillofacial Surgery at Virginia Commonwealth University before this study's sample.

The rate of pain experienced was calculated by dividing the number of patients reporting pain by the total number of respondents. If a patient said they were not in pain, they did not receive any additional questions. Pain intensity was measured using a digital visual analog scale (VAS) with a marker that could be toggled on a line between anchors of no discomfort to worst discomfort. The VAS scale also displayed a quantitative value with anchors of 0 for no discomfort and 100 for worst discomfort. Other questions assessed analgesic use, analgesic if taken, pain quality, pain frequency, and most painful time (at rest, chewing, biting on front teeth, or biting on back teeth).

Subjects were surveyed for at least the first 6 months of treatment (corresponding to the first 3-6 appointments). If orthodontic bands were to be placed on the first molars, separators were placed a week before the first appointment. At the first appointment, orthodontic appliances (CA attachments or brackets and bands) were bonded. Adjustment intervals were every 4-8 weeks for FA and every 2-3 months for CA. Typically, adjustments involved switching to larger dimension archwires for FA and delivering new aligners for CA. For the CA group, patients were instructed to change aligner trays every 7 days and wear them 22 h/d at both centers.

For each appointment, patients were asked to complete the same survey at 3 different time points. The first survey was conducted 24 hours before the appointment (preappointment), and it corresponds to a baseline pain intensity. The second survey was 48 hours after the appointment (2 days postappointment), corresponding to the peak pain intensity. The third survey was 7 days after the appointment (7 days postappointment), corresponding to a decreased pain intensity. Automatic reminders to complete the survey were sent to each subject via SMS text messaging through Twilio, a company associated with REDCap.[15] Each participant who responded to at least 1 survey was offered a $25 check as compensation.

A 2:1 ratio of CA to FA recruitment was expected, with a goal of at least 50 CA and 25 FA patients. The 2:1 ratio was selected as more variability was anticipated in the CA group because of potential aligner noncompliance. In addition, this ratio is reflective of the distribution of patients treated in the target population in the 2 centers; most adult patients prefer CA treatment. Because FAs are bonded to the teeth, lower variability was anticipated, and a lower sample size was required to achieve appropriate precision in the estimates. On the basis of the results from the Almasoud study, the sample size goal would have >99% power to detect the observed difference in proportions of 75% compared with 25% experiencing pain at 24 hours and would be able to detect an effect size of 0.7 for differences in pain on the VAS with a significance level of 0.05. The Almasoud study demonstrated an effect size of 1.5 between the 2 groups, a difference that would have >99% power with the target sample size of 75. The actual sample size was increased to account for noncompliance and dropouts.

Statistical analysis

The investigator who collated and analyzed the data was blinded from the treatment modality (FA or CA) within REDCap and worked independently from the other investigators. SAS software (version 8.2; SAS Institute, Cary, NC) was used for all analyses. The significance level was set at 0.05. Demographics were compared between the 2 treatment groups using a *t* test for age and a Fisher exact chi-square test for sex. Percent of patients reporting pain at each appointment (rate of pain experience) was compared between the 2 treatment groups using the Fisher exact chi-square test. Pain intensity based on a VAS was compared between the 2 groups at 2 days postappointment and 7 days postappointment using nonparametric Wilcoxon tests. Because pain intensity was not normally distributed, it was reported as a median value rather than a mean to be more descriptive of the characteristics of the sample. Analgesic use was compared between the 2 groups using the Fisher exact chi-square test. Pain quality and frequency were compared between groups using chi-square tests. Responses regarding the use of analgesics were sparse at the preappointment and 7 days postappointment but sufficient at 2 days postappointment. Therefore, analgesic use data were pooled according to appointment number rather than time point.

RESULTS

A total of 87 patients responded to at least 1 survey and were included in the study. Four subjects responded to 100% of their possible surveys (range, 6-18 surveys). The number of completed surveys ranged 1-18, and 7%-100% of the survey subjects were sent (based on number of appointments). The response rate did not differ significantly between the 2 groups ($P = 0.972$), with an overall average of 51% for both groups. The response rate was defined as the percentage of possible surveys that subjects responded to account for the variable number of appointments among subjects. Despite the inequality in adjustment intervals between the treatment modalities, the number of FA and CA responses did not differ. The average number of responses from subjects in the FA group was 8.5 and 6.7 for CA ($P = 0.096$). There were 28 patients in the FA group (32%) and 59 patients in the CA

Table I. Characteristics of study participants

Characteristics	*Overall*	*FA*	*CA*	P *value*[†]
Total participants	87 (100)	28 (32)	59 (68)	
Age, y	36.7 ± 13.2	32.7 ± 14.2	38.4 ± 12.5	0.064
Sex				0.854
Male	26 (30)	8 (29)	18 (31)	
Female	61 (70)	20 (71)	41 (69)	

Note. Data are reported as n (%) and mean ± standard deviation.
[†]*P* value from *t* test (age) and Fisher exact test.

Table II. Response rate by appointment, time, and treatment group

	CA			*FA*		
App no.	*Pre*	*2 d*	*7 d*	*Pre*	*2 d*	*7 d*
1	25 (42)	36 (61)	34 (58)	14 (50)	17 (61)	13 (46)
2	39 (68)	36 (63)	36 (63)	15 (54)	18 (64)	16 (57)
3	31 (56)	27 (49)	30 (55)	13 (48)	18 (67)	15 (56)
4	16 (35)	18 (39)	18 (39)	16 (64)	15 (60)	16 (64)
5	11 (61)	11 (61)	12 (67)	13 (54)	10 (42)	13 (54)
6	5 (71)	5 (71)	3 (43)	4 (25)	3 (19)	5 (31)

Note. Data are reported as n (%).
App, appointment; *Pre*, preappointment.

group (68%). The Department of Orthodontics from Virginia Commonwealth University contributed 16 FA and 17 CA patients, and the private practice contributed 12 FA and 42 CA patients. On average, subjects were aged 36.7 years. Approximately 70% of patients were female and 30% were male. The age, gender, and malocclusion distributions did not differ between the groups. The demographic and response rate data are presented in Tables I and II, respectively.

For the preappointment time point, there was no difference in the rate of pain experienced between the FA and CA groups before every appointment except the first appointment. Here, the FA group had more patients who reported experiencing pain (27% vs 0%; $P = 0.014$).

For the 2 days postappointment, there were equally high rates of patients experiencing pain within the FA group (75%) and the CA group (78%) after the first appointment. In contrast, the FA group had a significantly higher rate of patients experiencing pain than the CA group after the second appointment (61% vs 21%; $P = 0.006$), third appointment (83% vs 27%; $P = 0.001$), and fifth appointment (80% vs 18%; $P = 0.009$).

For the 7 days postappointment, the FA group had a significantly higher rate of patients experiencing pain than the CA group after the first (62% vs 24%; $P = 0.020$) and fifth (62% vs 17%; $P = 0.041$) appointment. A complete summary of the percentage of patients who reported pain at each time point relative to each appointment is provided in Table III.

For the preappointment time point, median pain intensity did not differ between the FA and CA groups except before the first appointment, when the FA group had a greater third-quartile pain intensity (13) than the CA group ($P = 0.007$).

For the 2 days postappointment time point, the median pain intensity did not differ between the FA and CA groups after the first appointment (17 vs 20; $P = 0.992$), but that of the FA group was significantly higher after the second ($P = 0.001$), third ($P = 0.0002$), fifth ($P = 0.020$), and sixth appointments ($P = 0.026$).

For the 7 days postappointment time point, the median pain intensity for the FA group was significantly greater than the CA group after the first ($P = 0.024$), fourth ($P = 0.043$), and fifth ($P = 0.029$) appointments. There was no difference after the second, third, and sixth appointments. Median, first-quartile, and third-quartile pain intensities are provided in Table IV.

Qualitatively, the median pain intensity of the FA group elevated to a peak at 2 days postappointment and then declined at 7 days postappointment for the second through sixth appointments. For the first appointment, the pain intensity of the FA group elevated from preappointment to 2 days postappointment and remained elevated at the 7 days postappointment.

The median pain intensity remained at 0 for the CA group at the preappointment, 2 days postappointment, and 7 days postappointment time points from the second through the sixth appointment. The only elevated median pain intensity (20) was at 2 days postappointment time point after the first appointment. The CA group median pain intensity trend for the first appointment closely matched the pattern for the FA group median pain intensity trend for the second through sixth appointment. These trends are illustrated in Figure 1.

For the 2 days postappointment time point, the FA group had a higher rate of analgesic use than the CA group after the first appointment (67% vs 29%; $P = 0.037$). For the remaining appointments, the rate of analgesic use remained higher in the FA group (range, 33%-67%) than in the CA group (range, 0%-43%) but did not reach statistical significance. The number of patients who took analgesics in the FA group remained fairly constant, whereas the number of patients who took analgesics in the CA group decreased from 8 subjects at the first appointment eventually to 0 subjects by the fourth appointment. Analgesic use data are summarized in Table V.

Table III. Rate of pain reported by appointment and treatment group

	Preappointment			*2 d Postappointment*			*7 d Postappointment*		
App no.	*FA*	*CA*	P *value*[†]	*FA*	*CA*	P *value*[†]	*FA*	*CA*	P *value*[†]
1	4 (27)	0 (0)	0.014	12 (75)	28 (78)	0.826	8 (62)	8 (24)	0.020
2	1 (7)	4 (11)	>0.999	11 (61)	7 (21)	0.006	3 (19)	7 (19)	>0.999
3	1 (8)	4 (13)	>0.999	15 (83)	7 (27)	0.001	3 (20)	9 (30)	0.722
4	2 (13)	4 (25)	0.654	9 (60)	4 (24)	0.070	7 (44)	2 (12)	0.057
5	3 (23)	1 (9)	0.596	8 (80)	2 (18)	0.009	8 (62)	2 (17)	0.041
6	0 (0)	0 (0)		3 (100)	1 (20)	0.143	3 (60)	0 (0)	0.196

Note. Data are reported as n (%).
App, appointment.
[†]*P* value from Fisher exact test and χ^2 tests.

Table IV. VAS pain intensity by appointment and treatment group

	Preappointment			*2 d Postappointment*			*7 d Postappointment*		
App no.	*FA*	*CA*	P *value*[†]	*FA*	*CA*	P *value*[†]	*FA*	*CA*	P *value*[†]
1	0 (0-13)	0 (0-0)	0.007	17 (0-60)	20 (8-50)	0.992	20 (0-25)	0 (0-0)	0.024
2	0 (0-0)	0 (0-0)	0.204	24.5 (0-50)	0 (0-0)	0.001	0 (0-0)	0 (0-0)	0.927
3	0 (0-0)	0 (0-0)	0.641	33 (7.5-62)	0 (0-5)	0.0002	0 (0-0)	0 (0-9)	0.654
4	0 (0-0)	0 (0-0)	0.261	20 (0-56)	0 (0-0)	0.066	0 (0-20)	0 (0-0)	0.043
5	0 (0-0)	0 (0-0)	0.475	32 (4-50)	0 (0-0)	0.020	15 (0-35)	0 (0-0)	0.029
6	0 (0-0)	0 (0-0)	>0.999	58 (15-60)	0 (0-0)	0.026	8.5 (0-23.5)	0 (0-0)	0.270

Note. Data are reported as median (interquartile range).
App, appointment.
[†]*P* value from Wilcoxon rank sum test.

Pain quality, pain frequency, and most painful time responses across all appointments were combined to increase sample size and statistical power for the preappointment, 2-day postappointment, and 7-day postappointment time points.

At preappointment, pain quality did not differ between the treatment groups ($P = 0.258$). Interestingly, most of the FA (90%) and CA (62%) groups reported dull pain.

At 2 days postappointment, the FA group was significantly more likely to experience throbbing pain (31% vs 14%), or sharp pain (20% vs 12%), and the CA group was more likely to experience dull pain (73% vs 49%) ($P = 0.035$).

At 7 days postappointment ($P = 0.088$), the trend was similar to 2 days postappointment but did not reach statistical significance. These data are depicted in Figure 2.

The frequency of pain in both groups did not differ significantly for any of the time points (Fig 3).

The most painful time was assessed by asking subjects to choose when they were most in pain (while resting, chewing, biting on front teeth, and biting on back teeth). For the preappointment ($P = 0.678$) and 7 days postappointment ($P = 0.097$) time points, the most painful function did not differ between the treatment groups. For 2 days postappointment, the FA group was more likely to report the most pain while chewing (66%); the CA group was more likely to be in the most pain either while resting (37%) or while biting with front teeth (20%) ($P = 0.002$). These data are depicted in Figure 4.

DISCUSSION

Most orthodontic pain literature is focused on the first couple of weeks of FA treatment. Our study's objective was to report and compare pain perception between patients treated with FA and CA over 6 months.

The first appointment data are consistent with prior research indicating that separator placement pain intensity peaks after 24 hours and decreases to pretreatment levels after 7 days.[5] Six patients had separators placed 5-7 days before the first appointment, and of these 6 patients, 4 were in pain at the preappointment time point. Because 5-7 days had passed, the FA third-quartile median VAS pain intensity was relatively low (13) and trending toward baseline (0).

Regardless of treatment modality, the first few days of orthodontic treatment are similar. Whether it be brackets and a NiTi wire or attachments and the first

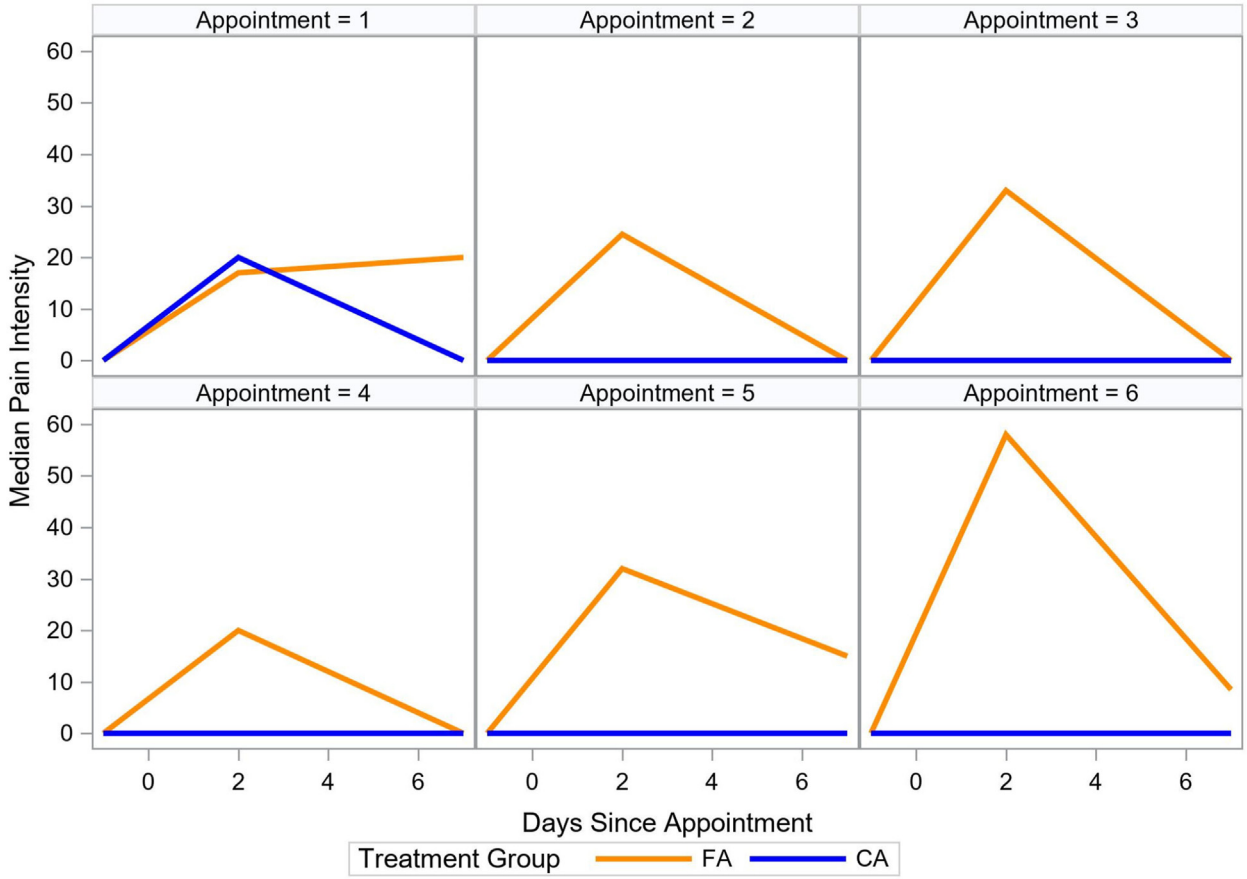

Fig 1. Median VAS pain intensity by appointment and treatment group.

Table V. Rate of analgesic use at 2 day postappointment by treatment group

	2 d Postappointment		
Appointment	*FA*	*CA*	P *value**
1	8 (67)	8 (29)	0.037
2	6 (55)	1 (14)	0.151
3	8 (53)	3 (43)	>0.999
4	6 (67)	0 (0)	0.070
5	5 (63)	0 (0)	0.444
6	1 (33)	0 (0)	>0.999

Note. Data are reported as n (%).
**P* value from Fisher exact test and χ^2 tests.

CA introduced at the first appointment, the same rate (75% vs 78%) and intensity (17 vs 20) of pain at 2 days postappointment occurred for FA and CA patients. The orthodontic force was applied for the first time in both groups, and all patients were forced to adapt to new orthodontic stimuli.

In addition to the first few days, CA patients have low rates of pain (0%-30%) and very low median pain intensities (0). The ability to prescribe elastics at the first appointment may contribute to the comfortability of CA treatment. Because CA patients were typically instructed to wear elastics at the initial appointment, elastics were not new orthodontic stimuli at the second appointment and beyond. The only nonzero pain intensities were the third-quartile pain intensities for the third appointment, which were still relatively low (5 for 2 days postappointment and 9 for 7 days postappointment). Interproximal reduction (IPR) was typically staged after initial alignment was achieved, which means, if necessary, it occurred sometime between the second and sixth appointments as new orthodontic stimuli. Although IPR may explain the nonzero third-quartile pain intensities for the third appointment, it does not appear to produce pain nearly as intense as the first time they receive attachments and aligners. If possible, orthodontists might consider staging all auxiliaries and IPR at the initial appointment to provide a more comfortable experience.

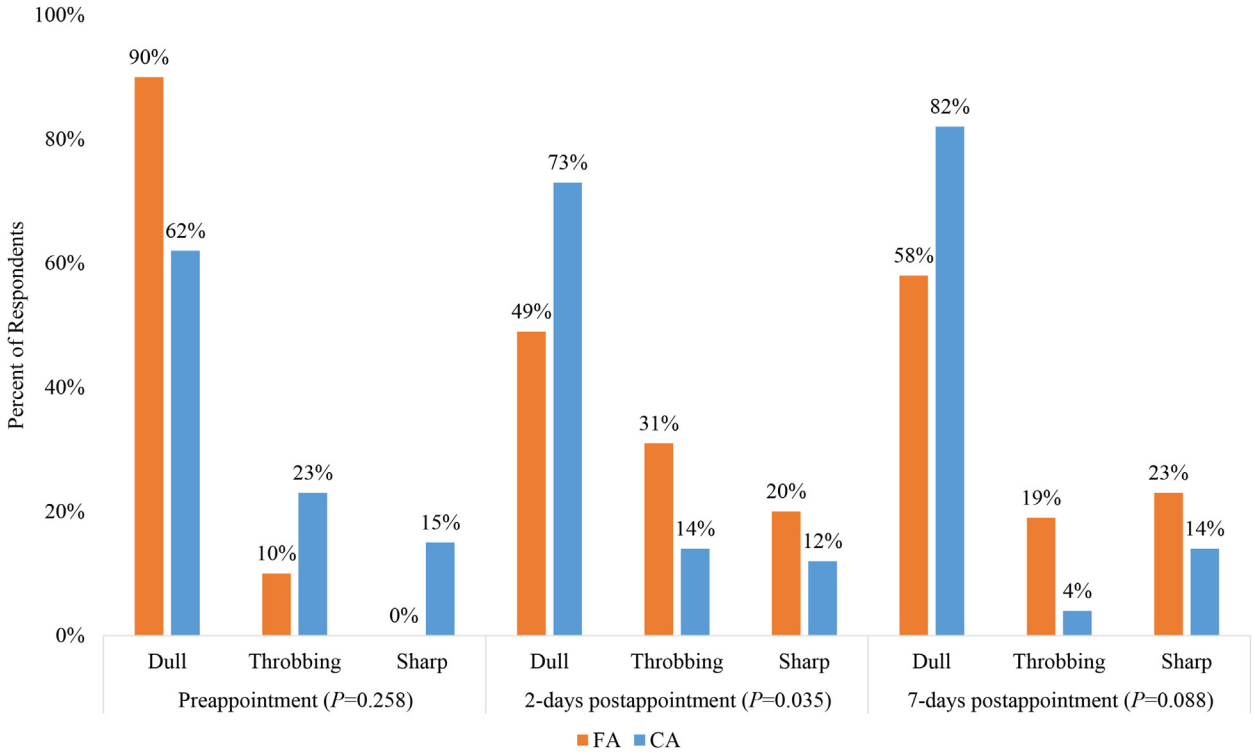

Fig 2. Pain quality by treatment group. Sample sizes are as follows: FA: n = 10, 59, and 31 for preappointment, 2 days postappointment, and 7 days postappointment, respectively; CA: n = 13, 49, and 28 for preappointment, 2 days postappointment, and 7 days postappointment.

Progressing to the next aligner or receiving additional aligners at appointments does not increase the rate or intensity of pain at 2 days and 7 days postappointment. By the second appointment, CA patients have psychologically grown accustomed to switching trays. Although FA and archwires can be fully activated when tying the appliances, CA forces are divided incrementally over a set of individual aligners.[16] The difference in temporal force activation of these 2 treatment modalities might explain why, for every adjustment (second through sixth appointments), the 2 days postappointment median pain intensity in the FA group ranged 17-58, whereas it was 0 in the CA group.

Removing and reactivating the same archwire at an adjustment may not produce a significantly greater rate of pain for FA patients than for CA patients. At the fourth and sixth appointments, the 2-day postappointment rate of pain did not differ between the treatment modalities. This is consistent with our theory of requiring new orthodontic stimuli to produce higher rates of pain because a new archwire was typically not inserted at these appointments. To fully align the dentition, the fourth appointment typically involved the removal and reactivation of a full-dimension, rectangular NiTi wire initially placed at the third appointment. The sixth appointment typically involved the removal and reactivation of the stainless steel wire initially placed at the fifth appointment. Although archwire sequence over a set number of appointments could not be controlled because of variability in patient malocclusion, the providers generally followed the sequence described in this discussion.

FA pain lingered longer than CA pain whenever a new wire material (NiTi at the first appointment and stainless steel at the fourth or fifth appointment) or elastics (fifth appointment) were introduced. After these appointments, FA pain was significantly more prevalent and intense than CA pain at 7 days postappointment. When NiTi and stainless steel wires are first introduced, they both exert forces that patients have never experienced before. Because these wire materials are new orthodontic stimuli, FA patients may take longer than 7 days for the rate and intensity of pain to decline back to baseline, as opposed to the second and third appointments when the wire material typically was not changed. When rigid stainless steel wires are introduced, a stronger vertical vector of force is applied to the teeth. This additional force is augmented by the addition of elastics,

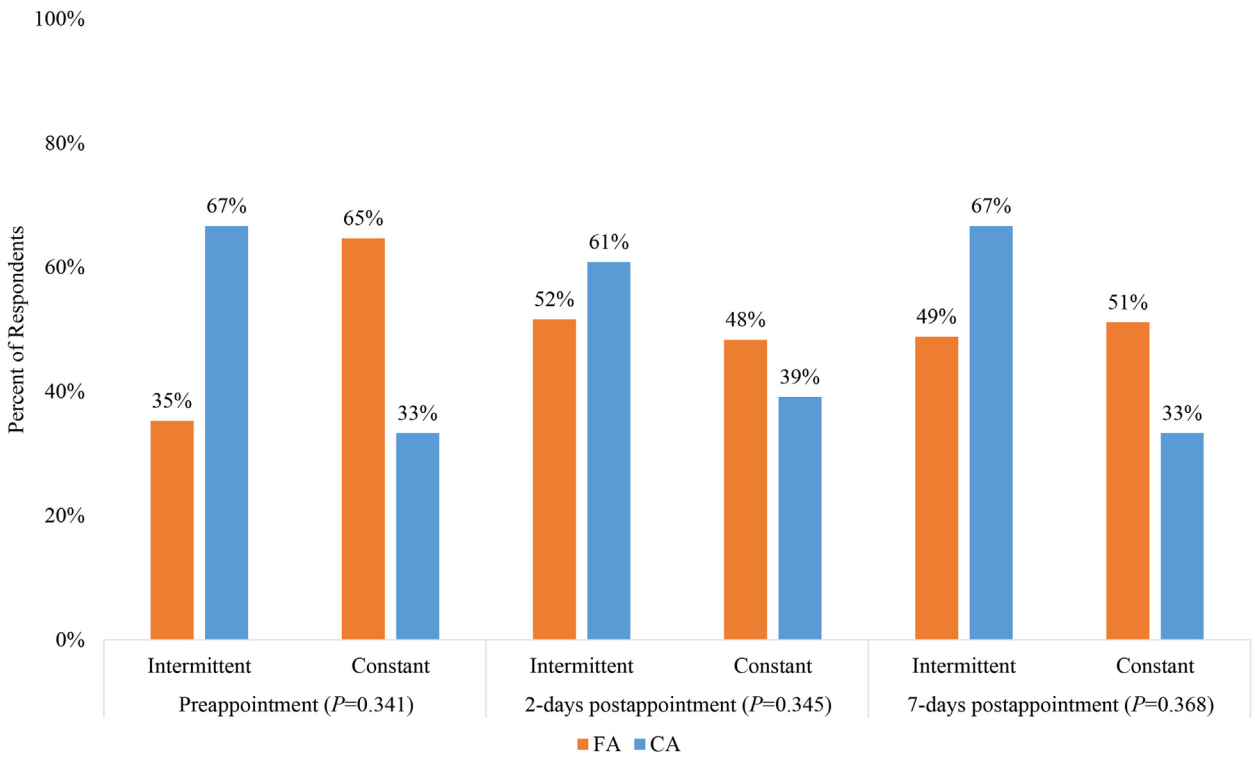

Fig 3. Pain frequency by treatment group. Sample sizes are as follows: FA: n = 10, 59, and 31 for preappointment, 2 days postappointment, and 7 days postappointment, respectively; CA: n = 13, 49, and 27 for preappointment, 2 days postappointment, and 7 days postappointment.

which were consistently prescribed at the time rigid wires were introduced. Another factor may be that crowding and deflection in the NiTi wire are at their maximum at the first appointment, which exerts greater force and discomfort on patients' teeth than an individual aligner that has preset tooth movement velocity maximums. These reasons may explain our novel findings that 7 days after the first and fifth appointments, the FA group's median pain intensity remained elevated.[6-9,11] Knowing this, an orthodontist may choose not to introduce stainless steel wires if bracket placement is idealized initially with an indirect bonding setup, and alignment is the only major goal. Although not used routinely in this study, it would be interesting to observe the effect of titanium molybdenum alloy archwires on pain, as the load deflection rate is approximately half that of stainless steel.

Increasing the size or changing the dimension from round to rectangular archwires seems to follow the same trend in the rate and intensity of pain found in previous studies investigating the first 7 days of FA orthodontic treatment. For the second and third appointments, when smaller NiTi wires were typically replaced with either larger or rectangular dimension wires, a pain intensity peak was observed at 2 days postappointment (24.5 and 33 for the second and third appointments, respectively) followed by a decline to baseline at 7 days postappointment (0 and 0 for the second and third appointments, respectively). Although the wires placed at these appointments are new orthodontic stimuli, they do not seem to cause the previously discussed lingering pain or slower return to baseline associated with introducing a new wire material.

For most appointments, the FA group showed a pain intensity peak at 2 days postappointment with a reduction by 7 days postappointment. The CA group exhibited this trend only at the first appointment (Fig 1) despite our subjects changing aligners weekly instead of the protocol used in White et al[7] (every 2 weeks). Our FA results contradict the findings of White et al,[7] who reported no peak in pain for patients treated with FAs after the 1-month and 2-month adjustments.[7] Our data favor CAs as a less painful treatment modality than FAs for mild to moderate malocclusions.

FA patients (67%) are more likely than CA patients (29%) to take analgesics in the week after starting treatment.[6,7] These rates of analgesic usage are similar to those observed by Miller et al[6] and White et al.[7]

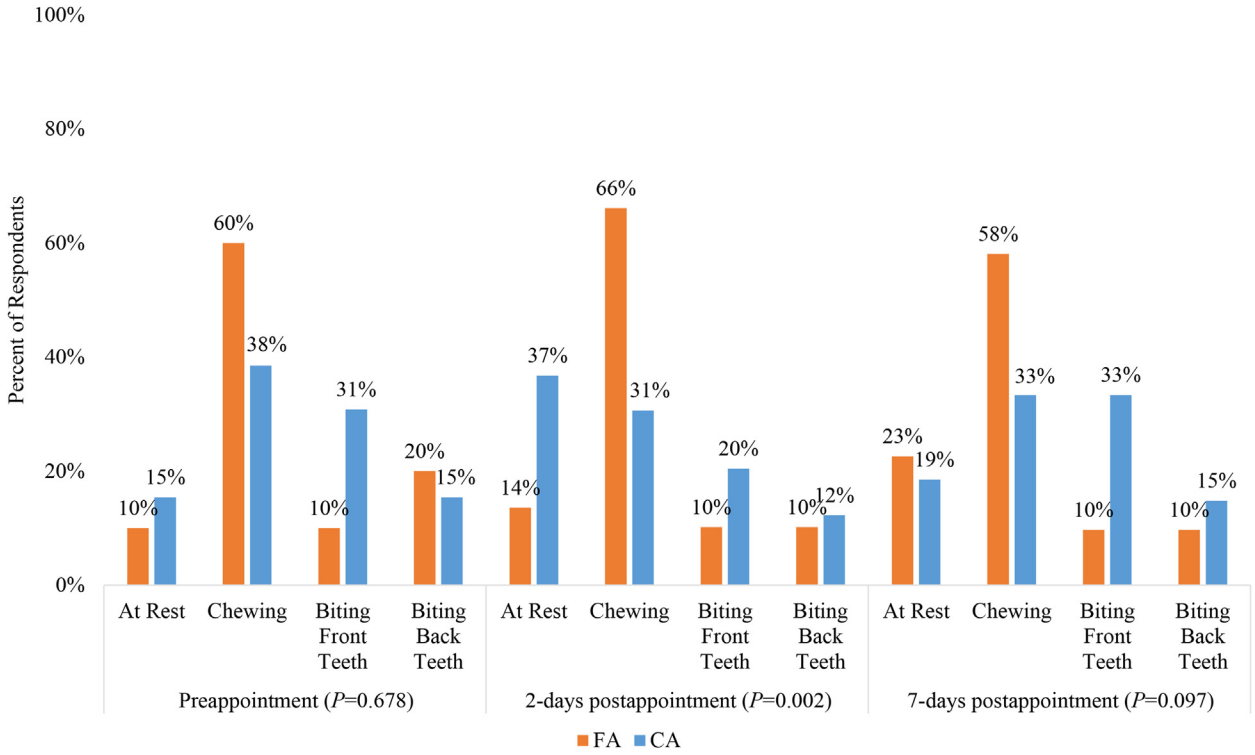

Fig 4. Most painful function by treatment group. Sample sizes are as follows: FA: n = 10, 59, and 31 for preappointment, 2 days postappointment, and 7 days postappointment, respectively; CA: n = 13, 49, and 28 for preappointment, 2 days postappointment, and 7 days postappointment.

Analgesic use in the CA group decreased from 29% after the first appointment to 0% after the fourth appointment. Similarly, by the sixth day of a 2-week treatment, Shalish et al[12] found a decrease in analgesic use in their CA group to 0%.

There has been no guiding literature to help orthodontists describe expected pain to inquiring prospective patients. This study suggests that most orthodontists can describe FA and CA pain as dull, which would be an accurate description throughout at least the first 6 months of treatment. Providers may preemptively warn their FA patients that 2-day postappointment pain could present as throbbing or sharp 20% and 31% of the time, respectively. Orthodontists may influence patient preferences in treatment modality by informing them that throbbing or sharp 2-day postappointment pain only presents 14% and 12% of the time with CA treatment. To combat the more likely throbbing or sharp pain in FA patients, a recommendation to premedicate with analgesics may be indicated, especially because FA analgesic usage rate ranged 33%-67% at 2 days postappointment. One possible explanation for the differing pain quality between the treatment modalities could be that both FA and CA stimulate low-threshold periodontal mechanoreceptors, but only FA delivers forces capable of stimulating high-threshold nerve endings.[17]

At 2 days postappointment, chewing was the most painful function for the FA group, whereas it was resting for the CA group. The magnitude and quality of nociceptive stimuli delivered by FAs and CAs differ, as discussed previously. CAs are removable and can deliver intermittent, lighter forces compared with FAs, which deliver relatively heavy and continuous force.[18] With the exception of "at rest," all of the functions listed in the survey are masticatory functions. They compress and tense the periodontal ligament, resulting in the aggravation of an already painful acute inflammatory reaction.[19] Homecare instructions for CAs involve removing them from the mouth when eating. The break from the orthodontic force when eating may explain why the most pain in the CA group was not while chewing (such as in the FA group) but at rest when the CAs should be seated and actively applying force to the teeth. Whether or not a CA patient describes rest as being the most painful may be related to their teeth being disoccluded at rest.

Unequal adjustment intervals (4-8 weeks for FA and 2-3 months for CA) for the treatment modalities make

drawing comparisons between the FA and CA groups imperfect. Completely controlling this variable is not possible because one factor influencing a patient's choice of CA treatment is having fewer adjustment appointments, and another center of this study was a private practice with multiple office systems revolving around these adjustment intervals.

Neither staging of IPR, the total number of aligners in the CA group, nor archwire progression in the FA group were controlled. To customize treatment plans for each patient's unique malocclusion, providers could not guarantee a patient would be ready for IPR or the next archwire at a given appointment. Every attempt was made to increase the size or dimension of the archwire if alignment allowed, and IPR was always staged in Clincheck to be performed when all interproximal contacts were aligned to prevent ledging and unideal outcomes. Because of these tendencies, FA patients usually received a larger dimension NiTi archwire at the first through third appointments, retying of the same NiTi archwire at the fourth appointment, a stainless steel archwire at the fifth appointment, and retying of the same stainless steel archwire at the sixth appointment. Future studies should seek to explore the effects of these adjustments more precisely by attempting to set a standardized treatment progression for both FA and CA patients.

As with any survey study, there is a possibility of nonrespondent bias. Those who experience pain may be more inclined to respond to the survey than those who do not. With a response rate of 51%, the results should be interpreted with caution. Regardless, there were still no differences between the genders for any of the variables studied.

The conclusions drawn on pain quality and most painful function are from a smaller subsample of the total sample size. The data had to come from patients reporting pain, and the rate of pain experienced in the CA group was significantly lower than in the FA group at 2 days postappointment after the second, third, and fourth appointments. Although this study conducted a power analysis, a larger total sample size would yield more data for these outcomes.

CONCLUSIONS

The results of this study document and compare pain perception between patients treated with FA and CA over 6 months.

1. After the first 2 days of treatment, both FAs and CAs produce a similar rate of pain and pain intensity, but after that, CA treatment has a lower rate and intensity of pain.
2. FA pain intensity peaks at 2 days postappointment and decreases to baseline at 7 days postappointment, but the introduction of certain orthodontic stimuli (stiffer archwires or elastics) makes FA pain remain elevated longer than 1 week.
3. One advantage of CAs is the ability to stage all stimuli (elastics and IPR) at the first appointment, which may explain why CA pain intensity only follows this trend for the first appointment.
4. Most of FA and CA pain is dull, but an appreciable proportion of FA patients will report sharp (20%) or throbbing (31%) pain at 2 days postappointment.
5. FA patients are more likely than CA patients to take analgesics within the first 2 days of treatment.

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AUTHOR CREDIT STATEMENT

Victor Chan contributed to conceptualization, methodology, funding acquisition, investigation, and original draft preparation; Bhavna Shroff contributed to conceptualization, methodology, manuscript review and editing, and project administration; Caroline Carrico contributed to software, formal analysis, data curation, and visualization; Neal D. Kravitz contributed to investigation; Daniel Hawkins contributed to supervision; Phuong Tran contributed to data curation; and Steven Lindauer contributed to methodology and supervision.

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