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Research Article

Evaluation of Pain Perception and Analgesic Requirement during Initial Alignment Phase in Fixed Orthodontic Treatment

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ABSTRACT
Background: Pain following placement of the initial aligning archwire is one of the most common and clinically significant adverse effects of fixed orthodontic treatment, driven by an inflammatory response within the periodontal ligament. Despite its high prevalence, the full pain trajectory and its relationship with analgesic use and patient-related factors such as dental anxiety remain incompletely characterized in prospective, longitudinal cohorts.
Objectives: To characterize pain perception and analgesic consumption during initial alignment of fixed orthodontic treatment and identify predictors of a high pain and analgesic burden.
Methods: In this prospective, longitudinal, observational cohort study, 100 consecutive patients (58% female; mean age 21.5 ± 5.2 years) beginning fixed orthodontic treatment with an initial NiTi or Cu-NiTi archwire (0.012–0.016 inch) completed a pain diary recording visual analogue scale (VAS) scores at nine time points over 14 days and analgesic intake during week 1. Dental anxiety was assessed at baseline using the Modified Dental Anxiety Scale. Associations of pain burden, peak pain, and analgesic consumption with age, gender, archwire characteristics, anxiety, and prior orthodontic experience were tested using Mann-Whitney U, Kruskal-Wallis H, Spearman correlation, and multivariable regression.
Results: Pain rose sharply after placement, peaked between 24 hours and Day 2 (mean VAS 51.9 mm), and resolved by Day 14 (mean 8.3 mm; Friedman $x^2 = 546.95$, $p < 0.001$). Ninety-seven percent of patients used at least one analgesic (median 5 tablets), predominantly ibuprofen (55.7%). Dental anxiety was the only independent predictor of pain burden ($B = 14.95$, $p < 0.001$) and high analgesic use (OR = 1.13, $p = 0.044$); age, gender, archwire material/size, and prior experience showed no independent association.
Conclusions: Pain after initial archwire placement follows a predictable trajectory, peaking within 72 hours and resolving by two weeks. Dental anxiety, rather than demographic or appliance-related factors, is the dominant predictor of pain and analgesic burden, supporting routine anxiety screening in pre-treatment orthodontic counselling.

Keywords: Orthodontic Appliances, Fixed, Dental Anxiety, Pain Measurement, Visual Analog Scale, Analgesics, Prospective Studies.

INTRODUCTION

Fixed appliance therapy has been the most popular modality for treating malocclusion which is present in a significant percentage of the general population in all geographic regions globally [1]. Although the modern bracket and archwire systems are more efficient and accurate in the movement of teeth, the majority of patients report pain and discomfort post placement of the initial aligning archwire with pooled data from a series of randomized trials demonstrating a sharp increase in visual analogue scale (VAS) scores peaking around 24-48 hours after activation and subsiding over

the next week [2]. This early-treatment pain experience is now known to be one of the most consistent and clinically significant adverse responses that may occur during orthodontic therapy, and has repeatedly been shown to be associated with pre-treatment anxiety, lowered treatment compliance, and, in a small number of patients, early treatment termination [3]. The mechanism of this pain is well understood. This activation of the initial archwire is associated with a sustained mechanical load on the periodontal ligament, which leads to the release of prostaglandins, interleukin-1β, interleukin-6, and tumour necrosis factor-α from the immune cells and the fibres of the periodontal ligament, resulting in the activation of peripheral nociceptors and in the stimulation of the osteoclastic bone remodeling necessary for tooth movement, which intertwines tooth movement with pain [4,5]. Since there is no method available which would eliminate this inflammatory response without also slowing the rate of tooth movement, the modern approach to management focuses primarily on symptom control, primarily through counselling of the patient and patient-controlled analgesia. This symptom-control program in practice, however, is not consistently implemented. Different initial archwire materials and dimensions (stainless steel vs conventional vs copper nickel-titanium vs heat-activated alloys) have reported conflicting results on the effect on early pain scores [6]; chewing bite wafers and low-level laser/photobiomodulation therapy have shown, at best, marginal and inconsistent benefits over traditional analgesics [7,8]; and systematic reviews of pharmacologic trials have consistently described the evidence base for specific analytic regimens as heterogeneous and of variable methodological quality [9]. In this context, evidence-based guidance is seldom given, and patients are mostly left to self-medicate—observational data suggest that the overwhelming majority use at least one over the counter pain medication in the first week after archwire placement, often without professional advice about type of medication, dosage or timing [10]. Further, the intensity of pain and the urge to seek an analgesic are not consistently associated with patients — younger age, female sex, higher baseline dental anxiety, and no previous orthodontic experience have all been suggested to be correlates of increased pain burden, but the results are not consistent across studies [11,12]. The current literature provides a clear message that initial-alignment pain is common, biologically plausible, and clinically meaningful—but there is an important gap in the research literature as most of the evidence is derived from short-term, randomized trials or single-point, cross-sectional surveys, whereas a longer-term prospective, longitudinal study design that tracks the full pain trajectory, quantifies actual analgesic use, and incorporates independent patient-level predictors is yet to be done [2,13]. This is a lack of information which clinicians cannot use to give realistic pre-treatment counselling, anticipatory guidance on the use of analgesics, or identification of patients who may require more frequent follow-up or a modified initial protocol. The aim of this study was to fill this gap by offering a pragmatic dataset for counselling about the subsequent care of patients for pain trajectory, use of analgesics and their patient-level factors, and to provide a single clinical cohort in which these three parameters could be characterized together in a prospective fashion.

The aim of the present study was to evaluate the pattern of pain perception and analgesic consumption among patients undergoing the initial alignment phase of fixed orthodontic treatment. The specific objectives were: (1) to measure and chart pain intensity at defined time points (2 hours, 6 hours, 24 hours, and days 2, 3, 5, 7, and 14) following placement of the initial archwire; (2) to identify the day of peak pain intensity during the alignment phase; (3) to record the type, frequency, and dosage of analgesics self-administered by patients; and (4) to assess the association between pain scores and analgesic consumption and patient-related variables, including age, gender, archwire material and size, dental anxiety, and previous orthodontic experience. Based on the inconsistent findings in prior literature, it was hypothesized that, among the candidate variables, baseline dental anxiety would show the strongest independent association with both pain burden and analgesic consumption, whereas archwire characteristics (material and size) and demographic factors would not retain independent predictive value after adjustment. Findings from this study are intended to inform more realistic patient counselling, evidence-based analgesic recommendations, and the identification of patients at risk of a higher pain burden in routine orthodontic practice.

METHODS

This study was a prospective, longitudinal, observational study to determine the perception of pain and the need for analgesics during the initial alignment phase of fixed orthodontic appliances. The study was conducted at a Tertiary Care Hospital of Lahore. The study is reported following strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement for cohort studies [14]. The study protocol was reviewed and approved by the Institutional Review Board of the institution, before recruitment and the study was carried out following the ethical principles of the Declaration of Helsinki [17]. All adult participants had written informed consent and for those under 18 years of age the parent/guardian consent was obtained along with the participant's assent. All clinical records and diaries were anonymized and securely stored to ensure confidentiality of the data throughout the study and analysis was carried out on the anonymised data.

Severe, persistent pain that did not respond to the usual clinical approach was treated as an exclusion criteria and the patient was asked to contact the clinic directly beyond the study protocol, thus participation never delayed or interfered with routine clinical care. The study was performed with the outpatient orthodontic department of Tertiary Care Hospital of Lahore. Until the pre-specified sample size was reached, recruitment continued. Study patients were identified at the study site and enrolled into the study at the time the first archwire was placed in the mouth of the patient. Patients aged 12-30 years who were starting with a fixed orthodontic appliance, with a nickel titanium (NiTi or Cu NiTi) initial aligning archwire (0.012″-0.016″) on both arches, and willing and able to fill out the self reported pain diary were eligible. One patient (P056) aged 12 years was included in the age range because this one was the only patient who was not in the age range and he was otherwise suitable for the study. Principal regression results were not influenced by this one case as confirmed by the pre specified sensitivity analysis (Table 12). The sample size was a priori determined by the need to have enough patients for the primary aim and multivariable regression models of the study, and was set to 100 patients. The calculation was made based on detection of clinically relevant difference in pain burden (area under the VAS-time curve [AUC]) between 2 important subgroups: the high dental anxiety group and the low dental anxiety group. A clinically relevant difference was taken to be a difference of 1.0-standard deviation (SD) in the mean AUC pain burden between these groups. The standard sample size calculation equation was used, with a minimum detectable difference ($\Delta = 1.0\sigma$) and an estimated standard deviation of the pain burden (σ): $N = [(Z_{\alpha/2} + Z_{\beta})^2 \times 2\sigma^2] / \Delta^2$, where the alpha level was 0.05 and the desired power was 80%, which resulted in a calculation of the required sample size. This equation solution results in the approximation of 64 patients, 32 in each group. This was increased by about 50% to compensate for a projected 20-25% drop-out or refusal to fill in a diary, and to assure the appropriate statistical strength for the planned multivariable linear and logistic regression models (at least 10 events per predictor variable). Furthermore, this number of subjects is adequate to detect a moderate correlation (Spearman's $\rho \geq 0.35$) between pain burden and continuous variables such as age and dental anxiety with a power of 80%. This resulted in an estimate of a final sample of 100 patients with complete diary data to be recruited.

The primary outcome was self-reported pain intensity (on a 100 mm visual analogue scale [VAS]) and secondary outcomes were the use of analgesics and the day of the peak pain intensity. The data from the repeated measurements (RM) (VAS data) were summarized by standard methods: pain burden (AUC, mm·day): area under the VAS–time curve (AUC) computed by trapezoidal integration of the VAS data over the series of diary time points, which are not evenly spaced; peak VAS: highest VAS score recorded by each patient, along with the corresponding peak time point. Record of analgesic use obtained from the patient's diary, recording the name of the painkiller, the dosage and number of tablets taken each day which was summarised by the number of tablets taken over the course of week 1. Independent variables comprised age (years, at recruitment), gender (male/female), archwire material (NiTi or Cu-NiTi) and size (0.012″, 0.014″, or 0.016″) as per the clinical record, previous orthodontic experience (yes/no, self-reported), and dental anxiety, measured once at baseline using the Modified Dental Anxiety Scale (MDAS) [15], a validated five-item, 25-point instrument. At the time of initial archwire placement, a structured pain diary was distributed to each patient, and completed at the following time points during the observation period: baseline (pre-

placement) and eight post placement time points: 2 hours, 6 hours, 24 hours (Day 1), and Days 2, 3, 5, 7, and 14. Longitudinal analysis of the change of pain was performed at the eight time points after placement.

RESULTS

The mean age of the group was 21.5 years (SD 5.2) and 58% were female. Most patients (81%) had no previous orthodontic treatment experience and just under half (49%) were started on Cu-NiTi as opposed to 51% of patients on conventional NiTi. The mean level of dental anxiety (MDAS) was 11.9 (SD 3.8) and 97% of patients took some form of pain-killer during week 1.

Table 1. Sample Characteristics (N = 100)

Characteristic	Value
Age, years, mean (SD)	21.48 (5.18)
Age, years, median (IQR)	21.5 (17.8–26.0)
Gender: Female	58 (58.0)
Gender: Male	42 (42.0)
Archwire material: NiTi	51 (51.0)
Archwire material: Cu-NiTi	49 (49.0)
Archwire size: 0.012 inch	35 (35.0)
Archwire size: 0.014 inch	43 (43.0)
Archwire size: 0.016 inch	22 (22.0)
Previous orthodontic experience: No	81 (81.0)
Previous orthodontic experience: Yes	19 (19.0)
Anxiety score (MDAS), mean (SD)	11.91 (3.78)
Took ≥1 analgesic in week 1	97 (97.0)
Total tablets, week 1, median (range)	5 (0–11)

Values are n (%) unless otherwise indicated. IQR = interquartile range.

The average pain of each group was higher than the baseline at 2 hours following the initial archwire activation, peaked at Day 2 (mean 51.9 mm), and then gradually decreased through Day 14 (mean 8.3 mm), reflecting the typical time course after the first archwire activation. Table 2.

Table 2. VAS Pain Score (mm) by Time Point (N = 100)

Time point	Mean (SD)	Median	IQR	Range
2 h	20.80 (11.49)	21.15	13.70–27.20	0.0–59.4
6 h	34.17 (12.31)	34.50	26.58–43.25	0.0–65.8
24 h	48.01 (12.06)	46.70	40.42–56.72	14.3–74.6
Day 2	51.92 (11.38)	51.80	43.80–59.30	25.1–82.4
Day 3	44.85 (11.49)	45.45	36.75–51.20	14.4–79.4
Day 5	26.94 (11.11)	26.55	20.23–35.15	0.0–50.3
Day 7	14.52 (10.61)	13.40	5.57–22.45	0.0–38.6
Day 14	8.32 (8.90)	5.10	0.00–15.28	0.0–29.9

VAS = Visual Analogue Scale, 0–100 mm. IQR = interquartile range (Q1–Q3).

VAS scores were normally distributed at all-time points except Day 7 and 14 when most patients pain had resolved and the scores were right-skewed towards zero, as determined by Shapiro-Wilk testing. This encouraged the use of the non-parametric Friedman test (Table 4) instead of repeated measures ANOVA for the omnibus comparison across time.

Table 3. Shapiro-Wilk Test for Normality of VAS Scores at Each Time Point

Time point	W statistic	p
2 h	0.976	0.070
6 h	0.986	0.402
24 h	0.992	0.791
Day 2	0.990	0.643

Day 3	0.989	0.595
Day 5	0.986	0.390
Day 7	0.948	0.001*
Day 14	0.851	<0.001*

The Friedman test confirmed that pain intensity changed significantly across the 8 diary time points.

Table 4. Friedman Test for Change in VAS Pain Score across Time (N = 100)

Outcome	df	χ2	p
VAS pain score, 8 time points	7	546.95	<0.001*

** p < .05. df = degrees of freedom (number of time points − 1).*

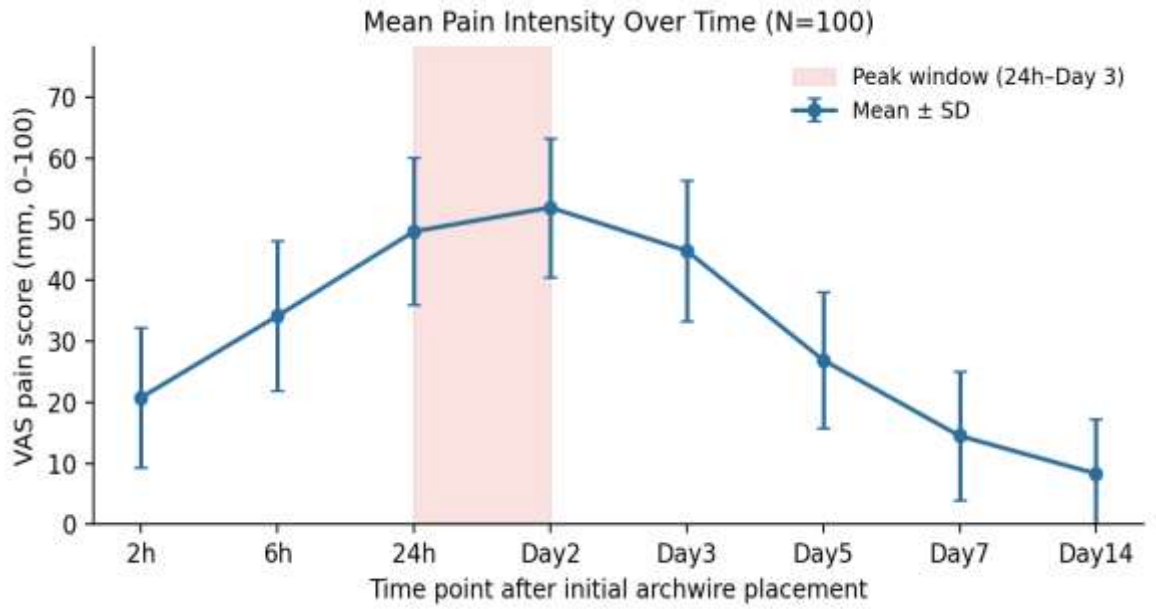

Figure 1. Mean VAS pain score (± SD) at each diary time point (N = 100).

Shaded band marks the group-level peak window (24h–Day 2).
One-third of patients (33%) had their peak pain at 24 hours, more than half (52%) at Day 2, a smaller number (14%) at Day 3 and one patient patients. Table 5.

at Day 5. No patient's pain was worse in the first 6 hours or day 5 or beyond, suggesting that the first 24 hours to day 3 hit essentially the peak of pain for all

Table 5. Distribution of Individual Peak-Pain Time Point (N = 100)

Time point	n	%
2 h	0	0.0
6 h	0	0.0
24 h	33	33.0
Day 2	52	52.0
Day 3	14	14.0
Day 5	1	1.0
Day 7	0	0.0
Day 14	0	0.0

Peak time point = the diary time point at which each patient recorded their single highest VAS score.

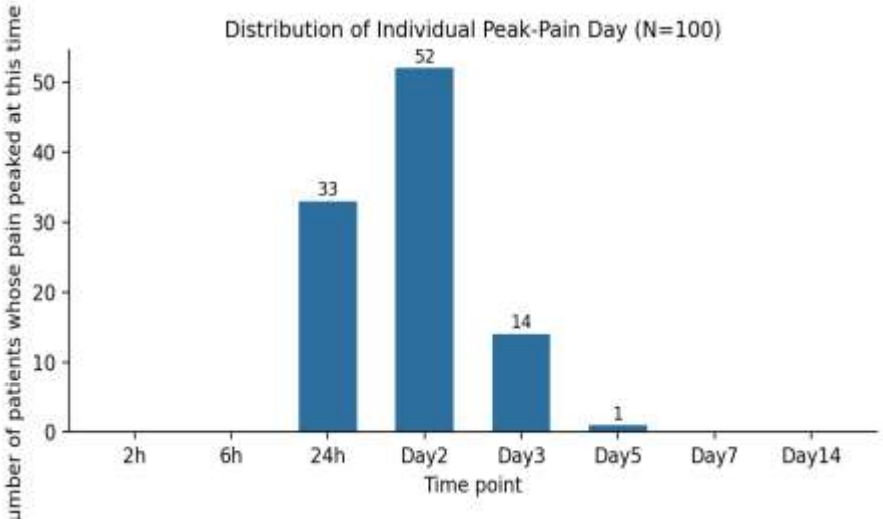

Figure 2. Histogram showing the number of patients whose individual peak pain occurred at each time point (N = 100).

In week 1, almost all patients (97%) used at least one analgesic, mainly ibuprofen (more than half of the patients taking analgesics), followed by paracetamol alone and both together.

Table 6. Analgesic Type Used, Among Analgesic Users (n = 97)

Analgesic type	n	% of users
Ibuprofen	54	55.7
Paracetamol	27	27.8
Ibuprofen + Paracetamol	16	16.5

Median total tablets taken in week 1 (all patients, N = 100): 5 (IQR 3–6, range 0–11).

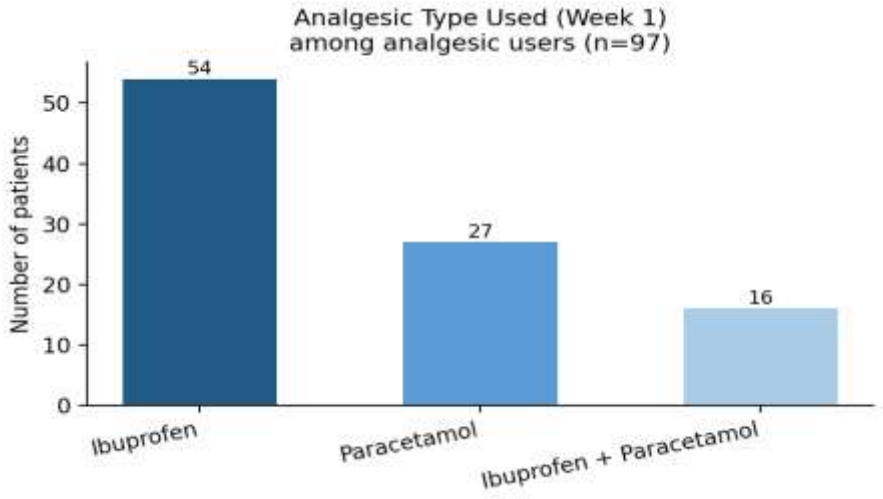

Figure 3. Analgesic type distribution among the 97 patients who used any analgesic in week 1.

There was no significant difference between analgesic users and non-users but this comparison is heavily underpowered (only 3 non-users) and complete test statistics are presented with all other Mann Whitney comparisons in Table 8. All three-level comparisons of archwire size were compared with pain burden and/or peak pain using the Kruskal-Wallis H test; all two-group comparisons were compared with pain burden and/or peak pain using the Mann-Whitney U test; and the two continuous variables (age and anxiety) were compared to pain burden and/or peak pain using the Spearman rank correlation test. The results of each test type are combined into one table below. The strongest and most

consistent associations were seen with dental anxiety for each of the outcomes tested; gender was associated with pain burden only.

Pain burden did not differ significantly across the three initial archwire sizes.

Table 7. Kruskal-Wallis Test: Pain Burden (AUC) Across Archwire Sizes

0.012" (n = 35)	0.014" (n = 43)	0.016" (n = 22)	H (df = 2)	p
336.0 (279.8–424.6)	303.0 (228.0–383.2)	327.7 (241.1–364.8)	1.71	0.426

Kruskal-Wallis H test. Values are median (IQR) pain burden (AUC, mm·day).

Pain burden was significantly higher among female patients, and peak VAS was higher but non-significant. Other factors, such as the type of archwire used, previous orthodontic treatment, and being an analgesic user, were found not to have a significant relationship to any other outcome measured.

Table 8. Mann-Whitney U Test Results — All Two-Group Comparisons

Variable	Outcome	Group 1, median (IQR)	Group 2, median (IQR)	U	p
Gender	Pain burden (AUC)	Female (n=58): 338.5 (263.8–430.7)	Male (n=42): 293.0 (231.0–356.4)	1523.0	0.033*
Gender	Peak VAS	Female: 57.6 (51.0–64.0)	Male: 53.5 (46.1–61.8)	1496.0	0.053
Gender	Total tablets	Female: 5.0 (3.0–6.0)	Male: 5.0 (3.0–6.8)	1241.5	0.871
Archwire material	Pain burden (AUC)	NiTi (n=51): 333.2 (247.9–429.6)	Cu-NiTi (n=49): 318.3 (229.5–368.6)	1385.0	0.352
Archwire material	Peak VAS	NiTi: 56.1 (50.0–63.7)	Cu-NiTi: 55.2 (49.6–61.8)	1343.5	0.519
Prior experience	Pain burden (AUC)	Yes (n=19): 333.2 (277.0–406.5)	No (n=81): 319.4 (237.7–417.8)	825.0	0.629
Prior experience	Peak VAS	Yes: 57.6 (51.7–61.8)	No: 55.2 (49.6–62.3)	822.5	0.645
Analgesic use	Pain burden (AUC)	Users (n=97): 326.4 (242.2–420.3)	Non-users (n=3): 244.5 (235.4–254.2)	219.0	0.148

** p < .05. Mann-Whitney U test throughout. AUC = area under the VAS-time curve (mm·day).*

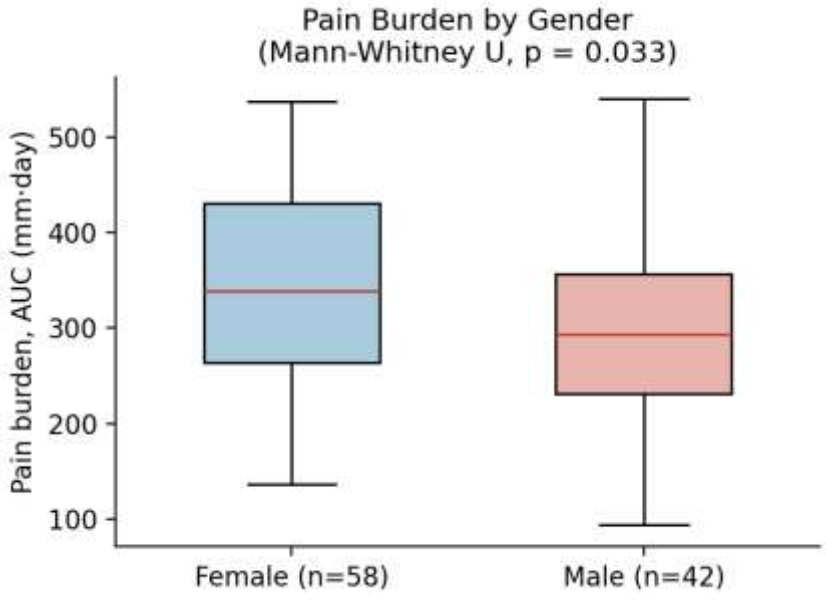

Figure 4. Pain burden (AUC) by gender (Mann-Whitney U, p = 0.033).

There were no significant correlations between age and pain burden and/or analgesic use. Within this study, the only highly significant positive correlation was between dental anxiety and pain burden, with both of these variables being moderately correlated, and the strongest and most consistent of all variables tested was the moderate and highly significant positive correlation found between dental anxiety and peak pain.

Table 9. Spearman Correlation Results — Age and Dental Anxiety (MDAS)

Variable	Outcome	n	Spearman ρ	p
Age (years)	Pain burden (AUC)	100	0.095	0.349
Age (years)	Total tablets	100	−0.009	0.932
Dental anxiety (MDAS)	Pain burden (AUC)	100	0.562	<0.001*
Dental anxiety (MDAS)	Peak VAS	100	0.512	<0.001*
Dental anxiety (MDAS)	Total tablets	100	0.206	0.040*

** p < .05. Spearman rank correlation throughout. MDAS = Modified Dental Anxiety Scale.*

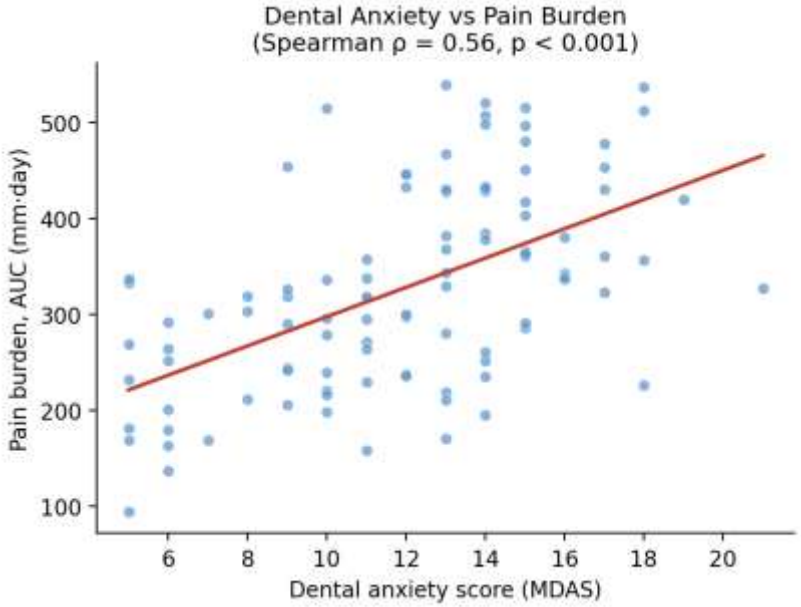

Figure 5. Relationship between dental anxiety (MDAS) and pain burden (AUC), with linear fit (Spearman ρ = 0.562, p < 0.001).

A multivariable linear regression was performed in order to determine which patient variables, after controlling for each other, significantly predicted pain burden (AUC). The overall model was significant, accounting for about a third of the variance in pain burden. The only independent predictor which was statistically significant was dental anxiety, with each additional point of the MDAS scale corresponding to 14.95 mm·day of pain burden. After adjusting, gender was associated with a borderline non-significant trend, which was weaker than its unadjusted association (Table 8), indicating that some of the raw association between gender and the outcome is mediated by anxiety. None of the other variables was an independent predictor.

Table 10. Multivariable Linear Regression — Predictors of Pain Burden (AUC, mm·day)

Predictor	B	SE	t	95% CI	p
Intercept	180.45	49.56	3.64	82.02 to 278.87	<0.001*
Anxiety score (MDAS)	14.95	2.41	6.20	10.16 to 19.74	<0.001*
Gender (Male vs. Female)	−34.93	19.27	−1.81	−73.20 to 3.34	0.073

Archwire size 0.014″ (vs. 0.012″)	−16.55	20.97	−0.79	−58.18 to 25.09	0.432
Archwire size 0.016″ (vs. 0.012″)	−3.71	25.14	−0.15	−53.64 to 46.23	0.883
Archwire material (Cu-NiTi vs. NiTi)	−8.18	18.38	−0.45	−44.67 to 28.32	0.657
Age (years)	−0.18	1.82	−0.10	−3.80 to 3.44	0.920
Prior orthodontic experience (Yes vs. No)	−5.27	23.20	−0.23	−51.35 to 40.82	0.821

** p < .05. Model: F(7, 92) = 6.80, p < .001. R^2 = 0.341, adjusted R^2 = 0.291, N = 100. Reference categories: Female (gender), NiTi (material), 0.012″ (size), No prior experience.*

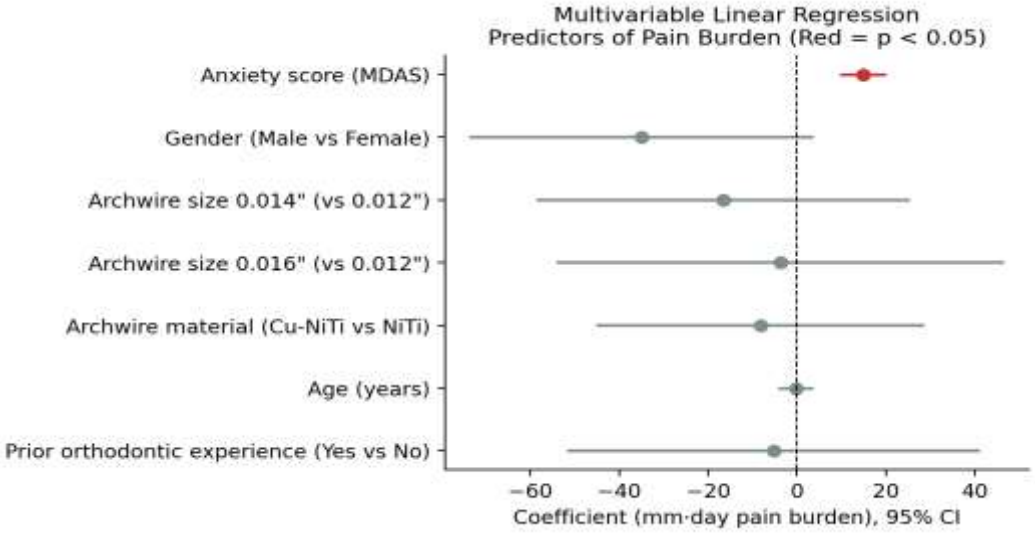

Figure 6. Forest plot of adjusted regression coefficients with 95% CIs. Red markers indicate p < .05.

Patients were dichotomized at the sample median (5 tablets) into "high" (>5 tablets, n = 46) versus "low/normal" (≤5 tablets, n = 54) week-1 analgesic consumption, and the same predictor set was fitted via multivariable logistic regression. Anxiety was again the only significant independent predictor: each 1-point increase in MDAS score was associated with 13% higher odds of high analgesic consumption. Overall model fit was weak and the likelihood-ratio test was not significant, indicating that beyond anxiety, this predictor set explains relatively little of who becomes a high analgesic user.

Table 11. Multivariable Logistic Regression — Predictors of High Analgesic Use (>5 Tablets)

Predictor	**OR**	**SE (logit)**	**z**	**95% CI (OR)**	**p**
Intercept	0.29	1.19	−1.03	0.03 to 3.02	0.301
Anxiety score (MDAS)	1.13	0.06	2.01	1.00 to 1.27	0.044*
Gender (Male vs. Female)	1.50	0.46	0.88	0.61 to 3.68	0.380
Archwire size 0.014″ (vs. 0.012″)	1.61	0.50	0.95	0.60 to 4.28	0.343
Archwire size 0.016″ (vs. 0.012″)	1.56	0.61	0.73	0.47 to 5.11	0.467
Archwire material (Cu-NiTi vs. NiTi)	0.49	0.45	−1.59	0.20 to 1.18	0.112
Age (years)	0.97	0.04	−0.78	0.89 to 1.05	0.434
Prior orthodontic experience (Yes vs. No)	1.10	0.55	0.18	0.38 to 3.22	0.859

** p < .05. OR = odds ratio; SE and z are on the log-odds scale. Likelihood-ratio $\chi2(7)$ = 7.74, p = 0.356. McFadden pseudo-R^2 = 0.057, N = 100. Reference categories as in Table 10.*

The protocol specifies an inclusion range of 13–30 years; patient P056 (age 12) was retained in the primary analysis under a widened 12–30-year criterion. The pain-burden regression was re-run excluding P056 to test robustness After excluding patient P056 (aged 12), the sample size was N = 99. The anxiety coefficient (B = 14.89) and its significance ($p < 0.001$) were virtually identical to the full-sample estimates, confirming that the principal finding is not an artifact of this single protocol deviation (Table 12).

Table 12. Sensitivity Analysis: Linear Regression Results With vs. Without Patient P056

Sample	N	R^2	Anxiety B	Anxiety p
Full sample (widened 12–30 criterion)	100	0.341	14.95	<0.001*
Strict sample (13–30 criterion, excludes P056)	99	0.341	14.89	<0.001*

* $p < .05$. B = unstandardized regression coefficient for anxiety score (MDAS), from the same model specification as Table 10.

DISCUSSION

A prospective cohort study was performed to describe the entire pain experience and analgesic use during the first phase of fixed orthodontics in 100 patients. The quantity of pain was very high after archwire placement, reaching a peak at the group level between 24 hours and Day 2, and subsequently decreasing in a graded manner until Day 14, when almost all patients (99%) had their peak pain between 24 hours and Day 2. Almost all patients (97%) used at least one analgesic during the initial seven days, with ibuprofen being the most frequently used. The baseline assessment of dental anxiety on the MDAS was the most consistently strong and reliable correlate of pain burden, peak pain and analgesic consumption, and was the only independent correlate after multivariable adjustment. Gender had a significant unadjusted association with pain burden that was significantly reduced after adjustment for anxiety, while age, archwire material and size and previous orthodontic experience did not have an independent association with any pain outcome tested. It is noteworthy that the observed pain course is very similar to the pain course reported by the pooled meta-analysis of randomized trials [2] that showed a similar sharp increase to a peak around 24–48 hours, followed by a gradual decrease in the subsequent week. The current results augment this by demonstrating that, at the patient level, there is no clear time where the peak occurs, but rather a relatively compact window of 24 hours to Day 3, with important implications around the timing of when anticipatory counselling with analgesics is most appropriate. The absence of a significant difference between archwire materials and sizes is consistent with previous mixed and null results with initial archwire selection in other comparative studies [6] and indicates that the selection of the conventional or copper nickel–titanium wire in the 0.012”–0.016” range is unlikely, in itself, to have a meaningful impact on a patient's early pain experience. This association between dental anxiety with the most important factors associated with the perception of pain, peak pain and analgesic use is consistent with the evidence that other psychological and personality factors were shown to be associated with orthodontic pain perception [3,11,12]. More recent orthodontic-specific data has also demonstrated that there is a significant percentage of patients who have clinically relevant anxiety levels on initiating orthodontic treatment, and that the level of anxiety correlates with the patients' treatment experience [18]. The observed associations – a moderate to strong positive correlation with pain burden, a moderate positive correlation with peak pain and a smaller but still significant correlation with analgesic consumption – indicate that anxiety is not just correlated with pain, but rather may also play a causal role in increasing the perception of pain, as anxiety has been understood as a central sensitization that lowers the effective pain threshold in anxious people. This is also the peripheral inflammatory mechanism mentioned above [4,5] which could be experienced more intensely by those anxious-awake patients: the same peripheral mechanism of prostaglandin- and cytokine-mediated nociceptor sensitization that causes orthodontic pain in all patients might be increased in intensity in anxious-awake patients. The almost universal use of analgesics recorded here (97%) is higher, but generally comparable, to previous observational estimates of analgesic self administration in patients who had been fitted with archwires [10] and the greater number of patients taking ibuprofen rather than paracetamol reflects the general preference of patients for a non-steroidal anti-inflammatory

drug over a pure antipyretic/analgesic drug when they are in an inflammation induced pain state. This is however mirrored by the present group with the lack of standardisation in choice of the drug, dose, and timing of analgesics, with patients choosing their own drug, dose, and timing and typically consuming a wide range of total tablets in week 1 (0–11 tablets). These findings support three practical changes to routine clinical management. First, the window of pain being a reliable predictor of when it will be most severe is from 24 hours to Day-3, rather than generic post placement advice, and counselling and anticipatory guidance should be timed and presented inside this window. Secondly, since dental anxiety (but not age, gender, archwire type or previous orthodontic experience) was the only factor which was independent and consistently predictive of a higher pain and analgesic demand, a short validated dental anxiety screening (eg the MDAS) during the initial bonding appointment could enable the clinician to identify, prior to treatment, the groups of patients most likely to have an uneventful first week, and the groups most likely to have a difficult first week, allowing for greater follow-up, increased reassurance or a structured behavioural intervention. Third, the large variation in type of analgesics and doses used, which is observed here, indicates a definite chance for the orthodontist to give simple, standardized and evidence-based guidance on analgesics at the time of placement of the archwire instead of leaving the patient to self-prescribe without professional advice; such guidance should, of course, be tailored to each patient and provided by a competent prescriber.

The advantages of this study are that the design is prospective, longitudinal with 9 structured assessment points over 14 days, that a validated instrument of anxiety (MDAS) was used as well as objective archwire and treatment variables, that a composite pain-burden measure (AUC) was used (which captured the entire course of the study and not just the single time point of the treatment period), that several candidate predictors were analysed simultaneously (in a multivariable fashion), and that a pre-specified sensitivity analysis was performed, ensuring that the main findings were not driven by the one patient who was enrolled outside the original age spectrum of the study. The data presented was reported according to the pattern of STROBE reporting for observational cohort studies [14] in order to increase transparency and comparability with other studies in this field. These results should be interpreted with caution, due to several limitations. While the sample size of 100 patients was sufficient for the primary analysis, the multivariable logistic regression for high analgesic use had a relatively poor overall model fit and less power to detect smaller effects; the results need to be confirmed in larger, multicentre samples. The patient diary was used to record pain and the use of analgesics, although this was explained by one calibrated examiner to reduce interexaminer variability, there is a risk of recall and reporting bias, and the dosage of the analgesics was not independently verified against the pharmacy or prescription records. A small number of archwire materials and wire sizes within a narrow initial-alignment range were represented, restricting generalizability to other archwire materials, such as stainless steel; larger-gauge wires; or fully custom sequences; and to clear aligner therapy. Analgesics were neither randomized nor protocolized, and the small number of patients who did not take any analgesics (n = 3) made the comparisons between these groups dubiously powerful and the differences in the outcomes of interest could simply be due to the choice of type and dose of analgesic according to the level of pain. Lastly, the 14-day observation period only reflects the first phase of alignment, and does not provide any information regarding pain at subsequent archwire changes or throughout treatment.

Multicentre prospective cohorts with larger numbers of patients should be the primary focus of further study to confirm the link between anxiety and pain, and to allow for sufficient powering of the multivariable models of analgesic consumption. The finding of anxiety is strong and consistent and it makes sense that one should consider conducting randomized trials to determine whether any of the structured interventions used to reduce anxiety prior to treatment in other areas of dentistry would be effective in reducing pain burden and analgesic consumption during orthodontic alignment. Objective analytical verification of analgesics usage, a more extensive group of archwire systems, and follow-up across the entire treatment period could also be useful in generalizing the results beyond the period of initial alignment focused in the present study.

CONCLUSION

A consistent pattern of pain after the initial archwire placement was observed, with maximum pain occurring from 0 to 3 days post-surgical with resolution at 14 days; also, nearly all the patients used self-directed analgesics. Fear of the dentist, not age, gender, nature of archwires or previous orthodontic treatment, was the major and only independent factor found to be associated with an increased pain and analgesic burden. The results justify providing some brief screening on anxiety prior to the start of pre-treatment counselling, and the creation of guidelines for analgesics that are standardized and based on evidence when a patient first enters into fixed orthodontic treatment, especially if they are identified as being more anxious.

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