A New Equation for Predicting Evolution of Oral Pain in Orthodontic Treatment: A Longitudinal, Prospective Cohort Study

Monica Larrea, PhD, MS
Collaborate Professor,
Department of Orthodontics,
Faculty of Medicine and Dentistry
University of Valencia
Valencia, Spain

Rosario Salvador, PhD
Full-time Professor
Department of Physiology
Faculty of Medicine and Dentistry
University of Valencia
Valencia, Spain

Rosa Cibrian, PhD
Full-time Professor
Department of Physiology
Faculty of Medicine and Dentistry
University of Valencia
Valencia, Spain

Jose Luis Gandia, PhD, MS
Full-time Professor and Chair of the Department of Orthodontics
Faculty of Medicine and Dentistry
University of Valencia
Valencia, Spain

Vanessa Paredes-Gallardo, PhD, MS
Full-time Professor
Department of Orthodontics
Faculty of Medicine and Dentistry
University of Valencia
Valencia, Spain

Correspondence to:
Dr Vanessa Paredes-Gallardo
Faculty of Medicine and Dentistry
University of Valencia
C/ Gasco Oliag nº1 Valencia 46010
Spain
Fax: +34 96 386 4537.
Email: Vanessa.paredes@uv.es

Aims: To develop an equation capable of relating the evolution of oral pain to the time elapsed, measured from the moment of dental archwire fitting and identifying when pain begins, peaks, and ends; and secondly, to compare pain during orthodontic treatment in relation to archwire material (steel or nickel-titanium [Ni-Ti]) and position (maxillary or mandibular) and patient age (child, teenager, or adult) and gender (male or female). **Methods:** A longitudinal prospective cohort study was conducted of 112 patients who filled in a scale to evaluate pain, noting the times when the pain occurred. The total sample consisted of 60 males and 52 females with a mean (± standard deviation [SD]) age of 19.8 ± 6.2 years. The sample was divided into five groups depending on archwire material and position, and patient age and gender. A univariate four-way ANOVA model was performed to compare mean pain levels between groups. Bonferroni test was used for multiple comparisons. A univariate non-linear regression model was carried out for pain level, 95% confidence intervals (95% CI) were calculated, and the statistic R^2 was used. **Results:** An equation was developed based on pain levels in relation to time elapsed, measured from the moment when the archwire had been fitted in the mouth. The equation had three coefficients related to mean pain values: overall pain, peak pain, and how pain decreased. It fitted all study groups with a correlation coefficient > 0.9. The model showed that pain levels were influenced by archwire material and patient gender and age, but not archwire position. **Conclusion:** The equation reproduced the data registered and can be applied to studies of pain derived from archwires, and this methodology could be used for other external agents fitted in the mouth. Patients receiving dental treatment involving external agents can be made aware of the pain they can expect to experience. This will enable them to distinguish expected pain from other pain, which will help them identify other pathologies requiring medical attention and to approach treatment with better motivation since the pattern of pain evolution is known in advance. *J Oral Facial Pain Headache 2017;31:172–179. doi: 10.11607/ofph.1723*

Keywords: *archwire, dental treatment, evolution of pain, mathematical equation, visual analog scale*

Orthodontic movement produces inflammatory reactions in the periodontium and pulp that stimulate the production of biochemical mediators and cause oral pain.[1,2] Patients experiencing this pain during orthodontic treatment have reported this condition as an important factor in their decision to reject or interrupt treatment.[3–6] Detailed and accurate information about the pain associated with each particular procedure will help patients cope with treatment. Various authors have described this type of oral pain and the different factors that modify it, which included gender, personality, and previous experience of pain in dental treatment. Several studies report that once orthodontic archwires are fitted in the mouth, oral pain appears approximately 4 hours after the archwires begin to apply force to the teeth and decreases after 24 hours, maintaining a plateau of lower intensity for 2 to 3 days. The pain finally starts to diminish on the fifth or sixth day, disappearing completely by the seventh day.[5,7–15] These reports have described pain evolution on the basis of personal observation, which has generated considerable

variation between reports. None have defined the exact times when pain increases or decreases or the factors influencing pain levels such as archwire material and position, and patient age and gender.

Orthodontic archwires can be made of different materials such as steel or Nickel-Titanium (Ni-Ti), the latter being the most commonly used. They exert force in different ways since different materials have different stress-strain curves; ie, the bending moment applied by steel arches must be higher than that of Ni-Ti arches in order to achieve the same deflection.[16] It is possible that the differing behavior of different materials has no influence on pain, and although there is some controversy on this point, very few studies have investigated pain in relation to archwire type.[17,18]

In this context, the aims of this study were firstly to develop an equation capable of relating the evolution of oral pain to the time elapsed, measured from the moment of dental archwire fitting and identifying the points when pain begins, peaks, and ends; and secondly, to compare pain during orthodontic treatment in relation to archwire material (steel or Ni-Ti) and position (maxillary or mandibular), and patient age (children, teenagers, or adults) and gender (male or female).

Materials and Methods

The study protocol was approved by the Ethics Committee for Research Involving Human Subjects at the University of Valencia, Spain (H1337808714794). Rights have been protected by the Institutional Review Board. All subjects gave their informed consent to take part in the study. Any data that might disclose the identity of the subjects under study have been omitted. This longitudinal prospective cohort study was designed following the Helsinki declaration and the STROBE statement,[19] with pain levels as the outcome.

A total of 175 patients attending the Orthodontic Clinic at the University of Valencia (Spain) between January 2013 and March 2014 who were to undergo treatment with some type of fixed appliance were selected by one of the authors (V.P.). After receiving information about the study, a total of 160 patients were willing to take part; 15 did not wish to participate for personal reasons. The positive response rate was 91.4%.

Power analysis showed that a sample size of 100 patients would provide an 80% probability of detecting a medium effect (f = 0.2) associated with the interaction term, with an ANOVA model at a confidence level of 95% and assuming a correlation of 0.45 among repeated measurements.

Inclusion criteria were: Patients who were to undergo orthodontic treatment with brackets bonded to the maxillary and/or mandibular arch; orthodontic treatment not involving dental extractions; patients with good oral and periodontal health; dental class I malocclusion with arch discrepancy of less than 5 mm and teeth rotations less than 45 degrees (measured on stone casts); and patients to be fitted with ovoid form archwires.

Exclusion criteria were: patients taking any medication during treatment; and orthodontic treatment with molar bands or extraoral dental appliances that could cause additional pain during treatment.

The final total sample was 112 patients, divided into five different groupings depending on the four different variables that could affect pain levels: archwire material and position, and patient gender and age. The five groups were as follows:

1. One general study group: All 112 patients
2. Two archwire material groups: 63 Ni-Ti archwire patients and 49 steel archwire patients
3. Two archwire position groups: 70 maxillary patients and 42 mandibular patients
4. Two gender groups: 60 male patients and 52 female patients
5. Three age groups: 37 children under the age of 14 years; 29 teenagers between the ages of 14 and 18 years; and 46 adults over the age of 18 years

All patients were treated with Standard Edgewise brackets with a slot size of 0.18 in (Integra, Rocky Mountain Orthodontics-RMO), and all arches had the same arch form (Ovoid Arch Form–OrthoForm III, 3M Unitek). As soon as the orthodontic archwire—either 0.014-in stainless steel (single-stranded) or Ni-Ti archwire, both supplied by the same manufacturer (3M Unitek)—had been fitted in the mouth at the start of treatment, the patients filled in a scale designed as a combination of a verbal rating and a picture scale to evaluate pain (V-P scale) (Fig 1).

Patients were instructed in the use of the V-P scale. Each patient specified the level of pain experienced daily from day 1 to day 14, classifying the time pain was experienced.

Archwire ligation was performed with stainless steel ligatures achieving complete engagement. The assignation of either Ni-Ti or steel archwires was performed sequentially as patients attended the clinic.

Since pain scales for children and preadolescent patients have been shown to be less reliable when they use terms such as no pain, mild, moderate, or severe pain, or even numbers (0, 1, 2, or 3), the study used faces since the faces pain rating scale has exhibited validity and reliability in terms of children's

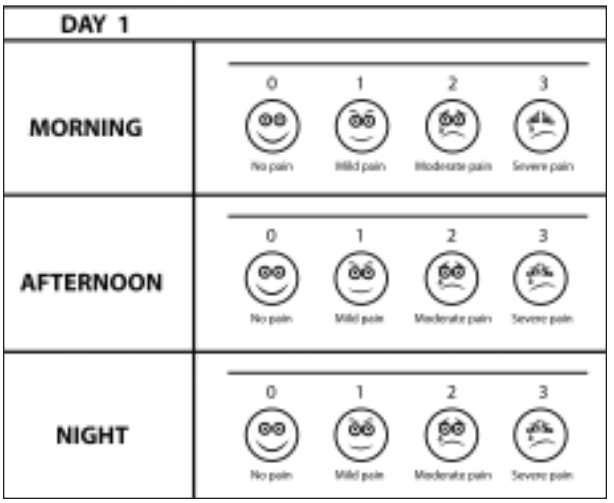

Fig 1 Combination of a verbal rating and a picture pain assessment scale. 0 = no pain; 1 = mild pain; 2 = moderate pain; 3 = severe pain.

Table 1 Mean Values of Pain Duration Obtained from Surveying the Study Groups

Group	Mean value	SD	Min	Max	*P* value
General	4.76	2.2	0	10	
Archwire material					
Ni-Ti	4.43	2.2	0	10	.04*
Steel	5.21	2.4	2	10	
Patient gender					
Male	4.73	2.2	2	10	.912
Female	4.78	2.3	0	10	
Patient age					
Children	3.20	0.8	2	4	.06
Teenagers	4.50	2.2	1	10	
Adults	5.29	2.3	0	10	
Archwire position					
Maxillary	4.78	2.4	0	10	.995
Mandibular	4.80	2.0	2	10	

SD = standard deviation. *Statistically significant differences at $P < .05$.

pain perception.[20] All subjects were also asked to specify the time of day when they experienced pain. Patients stopped filling in the V-P scale when 2 consecutive days with no pain had passed.

The three variables considered in the study were:

1. Mean pain duration: Mean time of pain duration played the role of an outcome and is described according to the independent variables archwire material, archwire position, patient gender, and patient age in Table 1.
2. Time elapsed: Time elapsed from the moment when the archwires were fitted. Time of day indicated on the scale was transformed into a time criterion: 4 hours after leaving the clinic, and thereafter every 8 hours. Theoretically, the pain scale covered a 14-day period (although the study came to a natural end after 10 days as patients no longer experienced pain) after starting orthodontic treatment, expressed as units/hours. Time elapsed was taken as a predictor variable in the non-linear regression model.
3. Mean pain level for each time interval: The mean pain level was the primary research outcome and played the role of dependent variable in the non-linear model.

Statistical Analysis

Data obtained were entered on a spreadsheet using Microsoft Excel 2011 (Microsoft Corp) by ML and RS and transferred to the statistical software package SPSS v.19.9 for analysis.

A univariate four-way ANOVA model was performed to compare mean pain levels between archwire material, archwire position, patient age, and patient gender groups. The Bonferroni test was used for multiple comparisons. Differences were considered significant when the *P* value was < .05.

A univariate non-linear regression model was carried out for pain level as outcome or dependent variable, expressed as a continuous scale, and time as predictor or exposure variable when the archwire was fitted (Time). One model for each level of each independent factor was obtained. The type of model used was an additive combination of an exponential term with an order 3 polynomial. No confounders were regarded in the analysis. Each level of a factor (archwire material, archwire position, patient age, patient gender) was assumed as strata from which a different regression equation was obtained.

Confidence intervals (95% CI) for the fitting parameters were calculated, and the statistic R^2 was used to estimate the goodness of fit.[21] Fitting parameters were considered to provide a statistically significant difference whenever a 95% CI did not overlap.

Results

Of 117 patients originally included in the study, 5 who had filled out the V-P scale incorrectly or had forgotten to record data at some time were later eliminated from the study (a dropout rate of 4.2%; 3 females and 2 males, mean age of 21.2 years). So the final sample consisted of 112 patients (60 males and 52 females) with a mean (± SD) age of 19.8 ± 6.2 years, ranging from 9.5 to 34.2 years of age. A total of 49 patients were treated with steel archwires (mean age of 19.2 years) and 63 patients with Ni-Ti archwires (mean age

of 24.1 years). Of the patients fitted with steel archwires, 31 were fitted to the maxillary arch and 18 to the mandibular arch; for Ni-Ti archwires, 39 were fitted to the maxillary arch and 24 to the mandibular arch.

The total sample was divided into five different groupings, depending on the four variables (archwire material, archwire position, patient age, and patient gender), which played the same roles in the models as predictor variables.

The ratios of males to females within each type of archwire, the position of the archwires, and age groups showed no statistically significant differences (P = .746; P =. 766; and P = .091, respectively).

Pain Duration

Table 1 shows the mean duration of pain obtained from the scale data by study group. Mean pain duration in the whole sample (general study group) was 4.8 ± 2.2 days. Statistically significant differences were found in relation to archwire material and patient age group. Pain lasted an average of 3.2 days among children, 4.5 days among teenagers, and 5.3 days among adults. None of the patients reported pain after the tenth day, which meant that the study focused on the period between 4 and 224 hours after archwire fitting.

These results can also be seen in the pain evolution model, as follows.

Model of Pain Level Dependence Over Time Related to Study Variables

Figure 2 shows mean pain levels in the general study group over time from 4 hours after archwire fitting to 224 hours, and the maximum pain duration reported by patients. From about 20 hours after fitting the archwire, the pain level seemed to undergo an exponential decrease given by $b \times e^{-c \times T}$, where b corresponds to the pain level at time zero, and c represents the speed with an exponential trend toward zero as time passes; initial pain values (before 20 hours) did not fit this exponential decrease but started at low values, increased, and reached a peak, after which they followed the exponential decrease described. So, in order to fit the initial pain level values, it was necessary to subtract much larger values from the exponential to bring them closer to zero. This is a reciprocal function ($-a \times T^{-3}$), as the factor T^{-3} tends toward infinity as time tends to zero, and the coefficient a modulates the value of the function for fitting. Furthermore, T^{-3} decreases rapidly for large T values, so after a few hours this term becomes negligible and pain level evolution is characterized by exponential decay.

When these factors were taken into consideration, pain level data was fitted to the following function: Pain level = $-a \times T^{-3} + b \times e^{-c \times T}$, where T is the time elapsed from the moment when the archwire was fitted and a, b, and c are the fitting coefficients, illustrated in Table 2 (general group). The fitted curve is shown in Fig 2 with SD values for the mean data. The equation's coefficient a represents the pain level reached at peak pain during the first hours after the archwires were fitted. Coefficient b represents the pain level during the study period, and c represents the speed of decrease in pain.

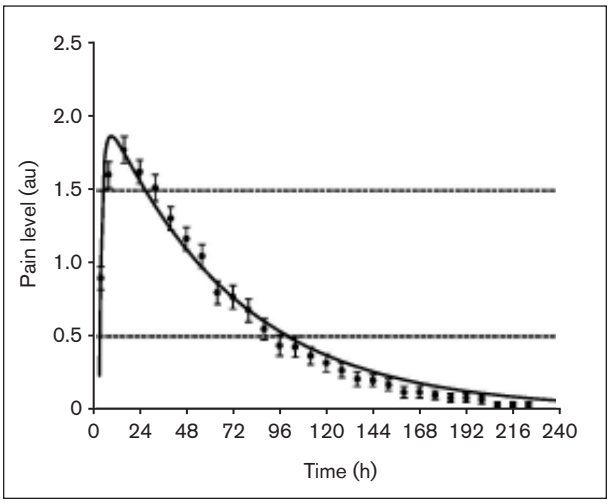

Fig 2 Main pain level in arbitrary units (au) vs time elapsed from archwire placement to the tenth day for the general patient group (n = 112). The horizontal dashed lines represent the cut-off values for pain level between acute and moderate, and between moderate and mild. The fitted line corresponds to ($PL = -a \times T^{-3} + b \times e^{-c \times T}$), where a, b, and c are the fitting coefficients. Standard deviation (SD) values for the mean data are provided.

Figure 3 shows the results of applying the same equation to mean pain levels in each of the other study groups: archwire material, archwire position, gender, and age. SD values for the mean data varied from 0.02 to 0.16.

The values of the corresponding coefficients are shown in Table 2, together with the 95% CI for these parameters and the value of R^2 for each fitting. These values indicate a statistically significant difference between values for all three coefficients in the cases of archwire material (Ni-Ti/steel) and age. There was also a statistically significant difference between a and b for gender, but arch position (maxillary or mandibular) did not show statistically significant differences between any of the coefficients.

Evolution of Pain Over Time

By applying the equation detailed above, it is possible to predict the mean pain level at any point in time. Therefore, the peak pain value, peak pain time, peak pain duration, and time from fitting the arch to mild pain could be quantified for all the groups analyzed. These are the most relevant values for analyzing pain evolution.

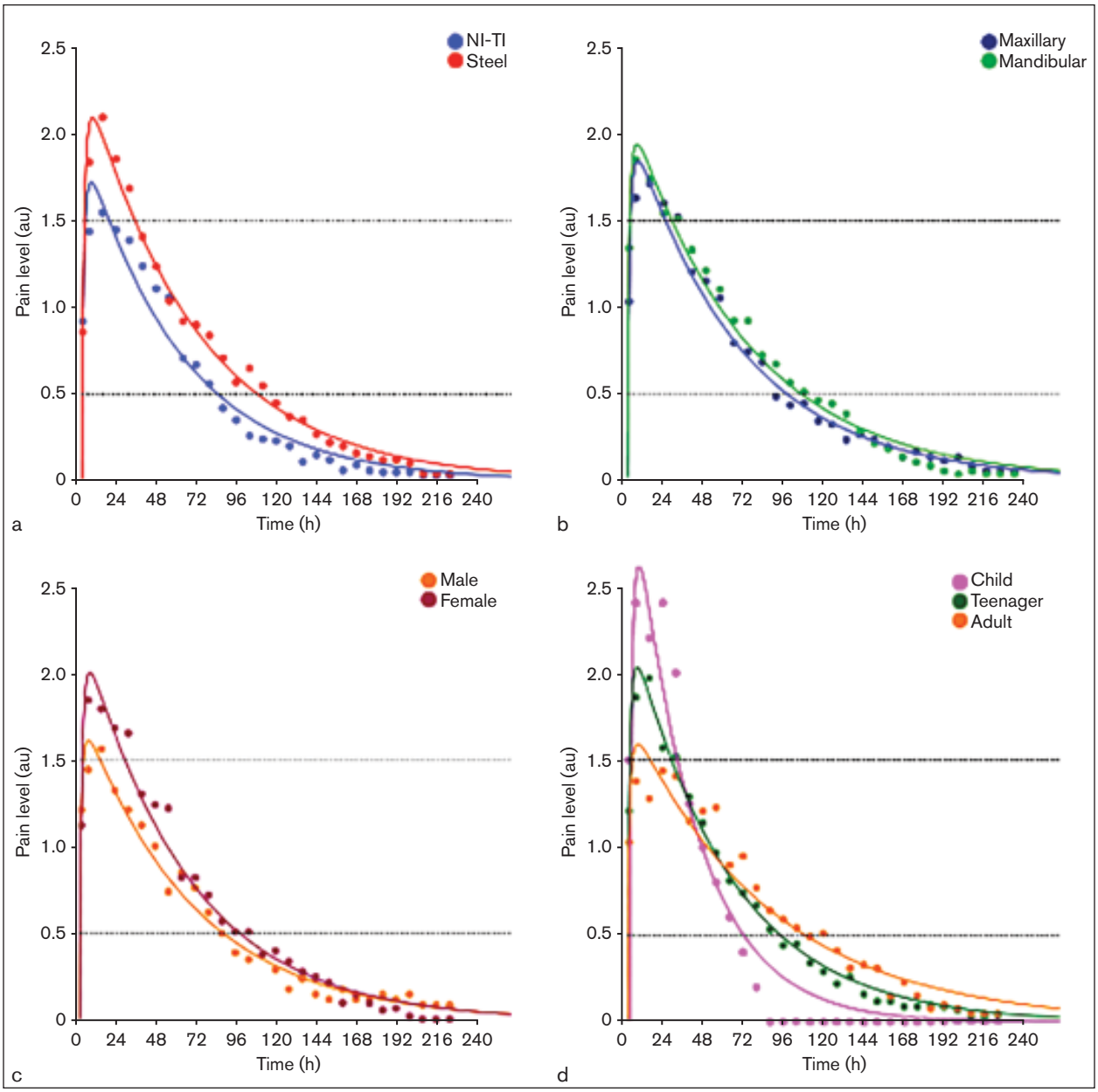

Fig 3 Pain level (in au) vs time (h) elapsed from archwire placement to the tenth day for the four variables: **(a)** archwire material (Ni-Ti and steel), **(b)** archwire position (maxillary and mandibular), **(c)** gender (male and female), and **(d)** age (children, teenagers, and adults). The horizontal dashed lines represent the cut-off values for pain level between acute and moderate, and between moderate and mild. The fitted lines correspond to ($PL = -a \times T^{-3} + b \times e^{-c \times T}$), where a, b, and c are the fitting coefficients. Standard deviation values for the mean data varied from 0.02 to 0.16.

To formulate this categorization, the peak pain value for the total sample (general study group) was considered to be 1.85 arbitrary units (au) (Fig 2). Therefore, mild pain was considered to be < 0.5 au (approximately 30% of peak pain), moderate pain to be between 0.5 and 1.5 au, and acute pain to be more than 1.5 au (about 75% of maximum peak pain). These cut-off values are shown in Figs 2 and 3. In this way, applying the equation to the data makes it possible to determine the moment of each cut-off value (0.5 au and 1.5 au). Table 3 shows peak pain value, peak pain time, peak pain duration, and time to mild pain in each study group.

Discussion

This study has provided information about the characteristics of orthodontic pain and set out to develop a formula on the basis of patients' self-reported perception of pain, a subjective phenomenon, rather than on the physiologic basis of the pain. The V-P scale used for registering pain in the present study had just four scores while other scales award 10 possible scores; this 0–3 scale model was chosen because of its simplicity, since over half the study sample (66 patients) were under the age of 18 years (37 children under the age of 14 years and 29 adolescents between the ages of 14 and 18 years). The study also used a four-face pain rating scale (directly matched to the 0–3 scores), which has been shown to exhibit validity and reliability for pain perception among children who may be unfamiliar with or misinterpret terms such as mild, moderate, severe, etc.[20] This allowed an adequate degree of homogeneity among the total sample of patient responses (children, teenagers, and adults) and is an important feature of the study design.

Orthodontic fixed appliances are known to induce pain and discomfort in patients, and this may depend on a range of factors. But pain perception is individual in nature and may have been influenced by factors that were not considered in the study, such as the differences in pain perception between children, teenagers, and adults caused by subjective and objective factors (bone density, velocity of tooth movement, previous pain experiences, etc).

The force release of orthodontic archwires depends largely on their dimensions and shape,[18] and so the study used a single steel and Ni-Ti ovoid form 0.014-in wire. All wires were supplied by the same manufacturer, as wires from different manufacturers may behave differently.

Pain varies at different stages of orthodontic treatment, so the present study focused on pain experienced in the initial stage in order to eliminate a possible bias. Force release is also dependent on the amount and type of tooth displacement that the archwire is required to perform, so one of the inclusion criteria was to recruit patients with dental Class I malocclusion and arch discrepancies of less than 5 mm and teeth rotations less than 45 degrees,

Table 2 Values of Parameters a, b, and c, and 95% Confidence Intervals (95% CI) Corresponding to the Nonlinear Equation (Pain Level = $-a \times T^{-3} + b \times e^{-c \times T}$) Developed for the Study of the Pain Level from the Time from Fitting Archwires for the Studied Groups

				95% CI		
Group	Coefficient	Value	Typical error	Lower limit	Upper limit	R^2
General	a	75.2	5.4	64.2	86.2	.987
	b	2.26	0.06	2.15	2.38	
	c	0.015	0.0001	0.014	0.016	
Archwire Material						
Steel	a	100.8	6.1	88.2	113.3	.987
	b	2.56	0.06	2.43	2.68	
	c	0.015	0.001	0.014	0.016	
Ni-Ti	a	70.4	8.8	52.4	88.5	.964
	b	2.12	0.09	1.93	2.32	
	c	0.017	0.001	0.015	0.019	
Gender						
Male	a	61.7	7.3	46.6	76.8	.971
	b	2.02	0.09	1.93	2.32	
	c	0.015	0.001	0.013	0.016	
Female	a	94.1	7.8	78.1	110.1	.977
	b	2.45	0.08	2.28	2.62	
	c	0.016	0.001	0.015	0.018	
Age						
Children	a	102.5	7.0	88.2	116.8	.986
	b	2.77	0.09	2.59	2.94	
	c	0.022	0.001	0.021	0.024	
Teenagers	a	104.0	13.3	76.7	131.3	.947
	b	2.71	0.13	2.44	2.97	
	c	0.013	0.001	0.011	0.015	
Adults	a	65.8	8.8	47.6	84.0	.951
	b	1.87	0.08	1.70	2.05	
	c	0.013	0.001	0.011	0.014	
Archwire Position						
Maxillary	a	77.0	6.6	63.3	90.6	.984
	b	2.42	0.07	2.28	2.56	
	c	0.016	0.001	0.015	0.017	
Mandibular	a	89.3	7.3	74.3	104.4	.976
	b	2.26	0.08	2.10	2.41	
	c	0.016	0.001	0.014	0.017	

a, b, and c are fitting coefficients; a represents the pain level reached at peak pain during the first hours after the archwires were fitted; b represents the pain level during the study period; and c represents the speed of decrease in pain.

Table 3 Values of the Peak Pain Level, Peak Pain Time, Peak Pain Duration, and Mild Peak Time

Group	Peak pain level (au)	Peak pain time (h)	Peak pain duration (h)	Mild peak time (h)
General	1.87	9.5	22	100
Archwire material				
Ni-Ti	1.73	9.0	14.5	86
Steel	2.10	9.5	31	109
Patient gender				
Male	1.68	9.0	13	88
Female	1.99	9.5	25	98
Patient age				
Children	1.59	9.0	10	104
Teenagers	2.03	9.0	24.5	96
Adults	2.52	10.0	28	77
Archwire position				
Maxillary	1.92	9.0	25	94
Mandibular	1.85	9.0	28.5	98

Peak pain time = the mean time elapsed from archwire fitting to peak pain; Mild peak time = the mean time elapsed from archwire fitting to mild pain; au = arbitrary units.

excluding other malocclusions that might involve greater and/or different tooth displacements.

The pain assessment scale registered data from 112 patients. Pain was seen to cease 3 days after archwire fitting at the earliest and up to 10 days at the latest, so the study focused on this period. Indeed, pain ceased within this time frame without exception.

Pain Duration

Mean pain duration (number of days with pain) was approximately 4.8 days, a similar finding to previous studies,[5,7,9,10,18,22] which have found that pain after archwire insertion persists for an average of 5 days. Statistically significant differences were found for the archwire material variable: Patients with Ni-Ti archwires suffered pain for approximately 4.4 days, a significantly shorter time than the 5.2 days endured by patients fitted with steel archwires. There were also differences between the three age groups: pain lasted an average of 3.2 days among children, 4.5 days among teenagers, and 5.3 days among adults. No statistically significant differences were identified for the variables archwire position or patient gender.

Pain Level Dependence Over Time Related to the Four Study Variables

With regard to the evolution of pain over time (pain level), the developed equation reproduced the qualitative observations made by other authors.[1,5,9,23–25] All groups showed an initial increase in pain that peaked some 10 to 15 hours after the archwire was fitted; thereafter, pain decreased progressively until it became mild. This last period varied from 3.5 to 4.5 days, depending on the group. Pain had disappeared completely in all groups within 10 days after archwire fitting.

No other study has used an equation to predict pain levels or to identify the moment of peak pain produced by orthodontic treatment, so the present results cannot be compared with any other research. The equation developed in the study made it possible to predict the evolution of pain: when pain is likely to peak, how long peak pain will continue, and when pain is likely to diminish to a level of mild discomfort. Logically, this equation applies only to the first archwire.

The following sections analyze the influence of the four variables on pain levels and on the evolution of pain over time.

Variable 1: Material

Patients with steel archwires suffered a higher initial pain level than those with Ni-Ti archwires (statistically significant difference in coefficient a) and higher pain throughout the rest of the study period (statistically significant difference in coefficient b). However, a parallel decrease in pain levels was produced during both periods (statistical equality in coefficient c). Pain peaked at the same time in both groups, but was higher with steel archwires and lasted longer. Patients with Ni-Ti archwires also reached the mild pain level more quickly than patients with steel archwires. Few studies have compared pain in relation to archwire material, and there is some controversy regarding the material's influence on pain as, contrary to the present results, some studies have found no difference in pain between the two archwire materials.[10,18]

Variable 2: Gender

It was found that females reported more pain than males when pain reached its peak, but also that their pain decreased more rapidly (statistically significant differences in coefficients a and c, respectively). However, the average level of pain during the whole study period was similar (no statistically significant difference in coefficient b). Although females experienced higher peak pain (1.99 au for females versus 1.68 au for males) and it lasted 12 hours longer, pain evolution after that point was such that both males and females reported mild pain at approximately the same time, 4 days after the arch was fitted. These results agree with research by Erdinç and Dinçer,[14] as well as Krishnan,[1] who claimed that females were more sensitive to pain while males tolerated it better.

Variable 3: Age

Peak pain was more pronounced in children and lasted an average of 28 hours, but then reduced quickly to a mild level in 3.2 days. The pattern was different for adults, who experienced peak pain for an average of 11 hours that diminished to mild pain levels in 4.3 days. Teenagers were in between these two groups in terms of peak pain level, which lasted an average of 25 hours and diminished to a mild level within 4 days. Most authors have concluded that adult patients experience more pain than young people,[5,7,10,12,22,25] although some studies have reported that teenagers experience more pain than adults.[1] These findings are reflected in the evolution of pain observed in the present study: Although children and teenagers experienced higher levels of peak pain, the pain diminished faster than in adults.

Variable 4: Position

With respect to the influence of archwire position (maxilla or mandible) on pain, the present study showed that there was no statistically significant difference in any fitting coefficient, so position was found to have no effect on pain levels.

On the basis of the information obtained in the present study, it is possible to provide patients with an account of the kind of pain they can expect to experience after receiving an archwire, as well as how long it is likely to endure. This is a great help in preparing and motivating the patients before treatment begins and has the added advantage of enabling the patients to differentiate between pain arising from orthodontic treatment and other forms of dental pain.

Conclusions

The equation developed in this study accurately predicts the evolution of pain derived from fitting orthodontic archwires. It can predict the level, time, and duration of peak pain and the moment when patients can expect the pain to diminish to a level of mild discomfort according to the archwire material selected and the patient's gender and age group.

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