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Influence of orthodontic archwire (nickel–titanium versus copper–nickel–titanium) on pain in adult patients in the aligning phase of treatment with self-ligating brackets (two months of follow-up): a prospective observational pilot study

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Abstract

Background The aim of this pilot study was to analyze the influence of a nickel–titanium archwire (NiTi) and a copper–nickel–titanium archwire (Cu-NiTi) on pain levels in adult patients during the first two months of orthodontic treatment with self-ligating brackets.

Methods This prospective observational pilot study was carried out at the Dental Clinic of the University of Salamanca between 2023 and 2024. This study analyzed 30 adult orthodontic patients who began treatment with self-ligating brackets. The participants were distributed into two study groups ($n=15$) for treatment with initial NiTi and Cu-NiTi archwires. At the beginning, a 0.014-inch archwire was used, and a 0.016-inch archwire was used after a month. The level of pain was measured using a visual analog scale (VAS) at the beginning of treatment (T0), at one month (T1), and at two months (T2). At each time point (T0, T1, and T2), pain was measured at baseline and at 4, 24, and 48 h after archwire placement or replacement. The data were analyzed using Spearman's correlation coefficient and the Mann–Whitney test ($p<0.05$).

Results The mean age of the participants ($n=30$) was 31.34 (±6.05) years. The maximum pain peak was in the first 48 h after placing the initial archwire (5.57 ± 1.72). The age and sex of the participants did not influence the pain levels in the sample studied. The composition of the orthodontic archwire only influenced the pain levels at the beginning of treatment (T0) ($p<0.05$); in this case, the NiTi group (1.73 ± 1.53) described a higher level of pain than that of the Cu-NiTi group (1.07 ± 1.36); in the rest of the follow-up period, no significant differences were observed.

Conclusions Within the limitations of this study, we observed that the orthodontic archwire material (nickel–titanium versus copper–nickel–titanium) only influenced pain levels at the beginning of orthodontic treatment.

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Keywords Archwire, Brackets, Cu-NiTi, NiTi, Orthodontics, Pain, Self-ligating brackets, Visual analog scale

Background

The literature reports that malocclusion has a negative effect on physical, social, and psychological well-being in adult patients [1]. Patients demand orthodontic treatment to improve their oral functionality, their orofacial esthetics, and their psychological well-being [1, 2]. However, pain and discomfort are inconveniences in orthodontic treatment that can significantly influence patients' satisfaction during their treatment [3, 4]. Pain is a disadvantage during orthodontic treatment, especially during treatment with brackets. A total of 90–95% of patients report some level of discomfort or pain after the bonding of the brackets and after each review visit during their treatment (mainly in the first phases of treatment) [5–7]. The pain described by patients during orthodontic treatment occurs as a result of the transient pulp inflammation that occurs in the teeth during their movement, as well as the compression of the periodontal ligament [8]. The pain that patients describe in their teeth is greater than the pain they perceive in the soft tissues due to trauma from the brackets [8, 9]. The pain described by patients during orthodontic treatment has a negative influence on their oral-health-related quality of life (OHRQoL).

Self-ligating bracket systems have not been shown to be statistically superior to conventional bracket techniques in improving patients' OHRQoL during their treatment [10, 11]. The use of self-ligating bracket systems has increased in recent years. Scientific literature has shown that self-ligating brackets are more effective and require less time in orthodontic treatment compared to conventional brackets. The advantages of self-ligating brackets include shorter treatment times, less subjective discomfort and better periodontal health [10, 12–15]. Different studies have compared pain levels in patients treated with brackets versus transparent aligners. Treatment with aligners has been reported to produce less pain in the first few days, but no statistically significant differences in pain levels have been observed in the phases after the start of treatment [9, 12–16]. Therefore, according to published studies, orthodontic treatment with transparent aligners does not represent a benefit concerning pain levels compared with fixed orthodontic appliances. However, patients treated with clear aligners have a better OHRQoL than that of patients treated with brackets, according to the majority of authors [2, 17–19].

The pain described by patients during orthodontic treatment is influenced by cognitive, environmental, and psychological factors [20]. Orthodontic pain usually begins in the first four hours after applying force on the teeth [21, 22], and the highest level of pain is described in the first 24–48 h after each orthodontic appointment; from the fifth–seventh day, the pain decreases to basal levels [5, 23–27]. An ideal bracket system should maximize efficiency in tooth movement and reduce discomfort in teeth and adjacent tissues [28]. The archwires used in orthodontic treatment with fixed appliances produce the necessary force, together with the brackets, to generate tooth movement. The idea is to apply continuous and light forces so that an efficient and non-injurious movement of the teeth occurs [29, 30].

The force generated by an orthodontic archwire depends on its physical and chemical characteristics [26]. Currently, the most commonly used archwires in the initial phases of orthodontic treatment are nickel–titanium (NiTi). To improve the properties of NiTi arcs, copper has been introduced. Copper is added to the NiTi alloy to decrease the load stress and, thereby, achieve more effective tooth movement [28, 30]. Friction during orthodontic treatment with brackets is a major challenge because it influences tooth movement. Different factors that may be directly related to the friction between the bracket and the orthodontic archwire (type of bracket, archwire material, archwire dimension, degree of dental crowding, applied forces, etc.) have been described [31, 32]. New compositions of materials are being applied in orthodontic clinical practice, such as copper–nickel–titanium (Cu-NiTi) wires. Published studies have evaluated—fundamentally in vitro—the use of these wires to analyze their efficacy [33, 34]. The Cochrane Review by Liu et al., in 2022 concluded that there was no scientific evidence regarding the efficacy of dental alignment and the time in which alignment occurs when purchasing NiTi and Cu-NiTi archwires. This recent review reported no studies that had previously evaluated pain comparing these two types of archwires [28].

There are few published studies evaluating the influence of the material (nickel–titanium versus copper–nickel–titanium) and the size of the orthodontic archwire (0.14 archwire and 0.16 archwire) on patient pain during the initial phase of orthodontic treatment. Azizi, F. described, in 2021, that there were no significant differences in the level of pain experienced by patients receiving NiTi archwires with respect to Cu-NiTi in the first six weeks of treatment [35].

Therefore, the objective of this pilot study was to analyze the influence of the dental archwire material (nickel–titanium versus copper–nickel–titanium) on pain levels during the first two months at the beginning of orthodontic treatment with self-ligating brackets. The null hypothesis of this study was that the type of material of initial orthodontic archwire material does not influence

the perception of pain in adult patients undergoing treatment with self-ligating brackets.

Methods

Study design

A prospective observational pilot study was designed at the Dental Clinic of the University of Salamanca. This study was conducted between October 2023 and July 2024. This study was approved by the Research Ethics Committee of the University of Salamanca (project no: 1073, date: 25/10/2023). All patients were informed of the study verbally and in writing. As per the Helsinki Declaration, each study participant gave their informed consent. This study adhered to the reporting requirements established by Building the Reporting of Observational Studies in Epidemiology (STROBE).

Two study groups were designed depending on the orthodontic archwire material used: one group in which the participants used nickel–titanium archwires (NiTi Group) and another group of patients with copper–nickel–titanium archwires (Cu-NiTi Group).

Eligibility criteria for participants

This study included patients aged 18 and over, patients with permanent dentition (without considering third molars), patients who had not previously undergone orthodontic treatment, patients with a Little's irregularity index of 1 to 3 (minimal crowding) [36], and patients who had no missing teeth (except for third molars).

This study excluded participants who had untreated caries; patients with untreated gingival and/or periodontal pathology; patients requiring orthodontic treatment with orthognathic surgery; patients diagnosed with temporomandibular joint pathology or symptoms thereof; patients under treatment with anti-inflammatory drugs, analgesics, anxiolytics, and/or antidepressants; pregnant patients; patients with systemic diseases; and patients with poor oral hygiene with a simplified oral hygiene index (OHI-S) of more than 1.5 [37].

Interventions

The participants were consecutively recruited from patients in need of orthodontic treatment at the Dental Clinic of the University of Salamanca. Patients who consumed anti-inflammatory drugs and/or analgesics during the follow-up period were not included in the study.

This study used the Damon Q passive bracket system (Ormco, CA, USA) with a slot of 0.022 and standard torque values for the MBT prescription. All teeth (from the second molar to the contralateral second molar), both upper and lower, were bonded in the same session using the direct cementation technique. The archwire sequence was 0.014-inch NiTi (Ormco, California, USA) (NiTi group) or Cu-NiTi (Ormco, California, USA) (Cu-NiTi group) at baseline and 0.016-inch NiTi (Ormco, California, USA) (NiTi group) or Cu-NiTi (Ormco, California, USA) (Cu-NiTi group) one month after starting treatment. The distribution of patients in each study group was randomised. The two groups of patients were treated by the same professional (A.C.).

Pain analysis

A visual analog scale (VAS) was used. The VAS consisted of a 100 mm line labeled at the extremes with 'no pain' and 'maximum pain'. The distance from the zero point to the perpendicular line was measured and taken to indicate pain severity. All removal force and VAS measurements were obtained by one operator (A.C.) [38]. The VAS had to be completed by patients at the bracket-bonding appointment (T0), one month after starting treatment (T1), and two months later (T2). At each measurement, pain was assessed at baseline and 4, 24, and 48 h after each appointment; therefore, pain was assessed at 12 time points. The quantification of pain at the beginning of each appointment was carried out in the consultation itself. Patients were asked to return the VAS form on the third day after each appointment. Participants received written instructions on how to complete the pain questionnaire, as well as a reminder to ensure that patients recorded pain at the required times. Patients were reminded via text messages to record their pain level.

Randomization and blinding

Participants in this study were randomly assigned to each study group (NiTi group and Cu-NiTi group). The randomization sequence was created using Excel software (Microsoft, Redmond, WA, USA) with a 1:1 allocation. Allocation was concealed with numbered, sealed and opaque envelopes containing the group allocation cards.

There was partial blinding in the study: the examiner who recorded the patient data, the Little irregularity index, and pain scores did not know the allocation of participants to each study group. The creation of the randomization sequence and the allocation concealment were applied by a researcher independent of the examining investigator. The person responsible for the statistical analysis did not know the type of arc used in each group. The participants were blind, because they could not distinguish between two types of archwire.

Statistical analysis

The statistical analysis was carried out with the IBM-SPSS Statistics computer application, version 28. In the description of variables, the mean and median were used. For the study of the association between numerical variables, Spearman's correlation coefficient was used, and

for the contrast between group means, the Mann–Whitney test was used.

Results

Baseline data

The mean age of the total sample ($n = 30$) was 31.34 (± 6.05) (NiTi Group = 32.45 ± 4.22; Cu-NiTi Group = 30.23 ± 7.49) years old, with the population being homogeneous in relation to sex (men = 43.3% and women = 56.7%).

When analysing the baseline characteristics of the participants in each group, it was observed that in NiTi group there were 53.3% males ($n = 8$) and 46.7% ($n = 8$), the mean age of the participants in this group was 30.3 ± 5.085 years, and the mean Little's irregularity index was 2.33 ± 1.2 mm. In Cu-NiTi group there were 60% males ($n = 9$) and 40% females ($n = 6$), the mean age of this group was 32.3 ± 7.025 years, and the mean Little's irregularity index was 1.95 ± 1.1 mm. No statistically significant differences were observed in the distribution of the sample studied when analysing gender, age and Little's irregularity index ($p > 0.05$).

Pain analysis

A descriptive analysis of the pain levels described by the patients was carried out during the two months of follow-up, and the pain was evaluated at different time points (T0, T1, and T2) (Table 1).

Table 1 Descriptive analysis of the pain of the total sample during the study´s follow-up period

	Mean	Range	Median	Standard deviation
$T0_0$	1.40	0.60–2.20	1.80	2.14
$T0_1$	4.57	3.82–5.32	4.50	2.01
$T0_2$	5.27	4.63–5.90	5.00	1.70
$T0_3$	5.57	4.93–6.21	6.00	1.72
$T1_0$	1.47	0.68–2.25	1.00	2.10
$T1_1$	4.67	3.94–5.39	5.00	1.94
$T1_2$	5.13	4.43–5.84	5.00	1.89
$T1_3$	4.93	4.18–5.69	5.00	2.02
$T2_0$	1.20	0.73–1.67	1.00	1.27
$T2_1$	1.73	1.18–2.29	2.00	1.48
$T2_2$	3.50	2.99–4.01	3.00	1.36
$T2_3$	2.87	2.14–3.59	3.00	1.94

$T0_0$: T0– Start
$T0_1$: T0–4 h
$T0_2$: T0–24 h
$T0_3$: T0–48 h
$T1_0$: T1– Start
$T1_1$: T1–4 h
$T1_2$: T1–24 h
$T1_3$: T1–48 h
$T2_0$: T2– Start
$T2_1$: T2–4 h
$T2_2$: T2–24 h
$T2_3$: T2–48 h

In the total sample, it was observed that the highest levels of pain were described in the first 48 h at the beginning of treatment, and in the first and second months, the peak of pain was reported at 24 h. Peak pain was highest at baseline ($T0_3$) (5.57 ± 1.72), with a decrease in pain score observed throughout the follow-up period of the study. At the beginning of each appointment, the lowest level of pain was recorded (1.40 ± 2.14, 1.47 ± 2.10, and 1.20 ± 1.27, respectively). In conclusion, we observed that the highest levels of pain were described in the first 24–48 h at the beginning and in the first month of treatment, while a considerable decrease in pain scores was reported in the second month. At the beginning of each treatment appointment ($T0_0$, $T1_0$, $T2_0$) a low level of pain was observed.

Analysis of the influence of age and sex on pain levels

We analyzed the possible influence of the age and sex of the study participants on the pain levels at the different time points evaluated (Table 2). In the sample studied, we did not observe that there was a statistically significant relationship between the age and sex of the participants and their pain levels during the study's follow-up period, although we observed a slight trend in which women described higher levels of pain compared with men.

Comparison of the influence of the orthodontic archwire material on pain levels

When analyzing the influence of the orthodontic archwire material (NiTi and Cu-NiTi) on pain levels throughout the follow-up period, we observed that there were only statistically significant differences at the first appointment (T0) at the beginning of treatment, and for the remaining time points, there were no significant differences. At the beginning of treatment, we observed that patients who had a NiTi archwire described a higher level of pain (1.73 ± 1.53) than that of patients in the Cu-NiTi group (1.07 ± 1.36). It was also observed that participants reported the highest levels of pain at the same time points regardless of the study group (Fig. 1).

Discussion

This pilot study analyzed the possible influence of orthodontic archwire materials (NiTi versus Cu-NiTi) on pain levels during the first two months of orthodontic treatment. The addition of copper to NiTi can produce more efficient tooth movement in orthodontics [30].

To analyze pain, a visual analog scale was used. This tool for quantifying pain has been widely used in previous studies that have evaluated pain during orthodontic treatment. The visual analog scale is an easy-to-use and reproducible tool [25, 27, 39–41].

Table 2 Correlation between pain and the age and sex of the participants

	Age		Sex		
	Coef. RS	*P*-Value	Men, mean (SD)	Women, mean (SD)	*P*-Value
$T0_0$	-0.11	0.288^{NS}	1.00 (± 1.37)	1.92 (± 2.84)	0.432
$T0_1$	-0.22	0.127^{NS}	4.47 (± 1.59)	4.69 (± 2.53)	0.805
$T0_2$	-0.20	0.141^{NS}	5.06 (± 1.49)	5.54 (± 1.98)	0.592
$T0_3$	0.14	0.232^{NS}	5.24 (± 1.60)	6.00 (± 1.83)	0.363
$T1_0$	-0.13	0.254^{NS}	1.29 (± 1.61)	1.69 (± 2.66)	0.773
$T1_1$	-0.18	0.173^{NS}	4.24 (± 1.72)	5.23 (± 2.13)	0.183
$T1_2$	-0.20	0.140^{NS}	4.76 (± 1.48)	5.62 (± 2.29)	0.123
$T1_3$	-0.16	0.192^{NS}	4.59 (± 1.62)	5.38 (± 2.43)	0.300
$T2_0$	-0.08	0.334^{NS}	1.29 (± 1.40)	1.08 (± 1.12)	0.807
$T2_1$	-0.12	0.259^{NS}	1.47 (± 1.55)	2.08 (± 1.38)	0.251
$T2_2$	-0.19	0.155^{NS}	3.29 (± 1.36)	3.77 (± 1.36)	0.243
$T2_3$	-0.10	0.307^{NS}	2.76 (± 2.17)	3.00 (± 1.68)	0.538

SD: Standard deviation

$T0_0$: T0– Start

$T0_1$: T0–4 h

$T0_2$: T0–24 h

$T0_3$: T0–48 h

$T1_0$: T1– Start

$T1_1$: T1–4 h

$T1_2$: T1–24 h

$T1_3$: T1–48 h

$T2_0$: T2– Start

$T2_1$: T2–4 h

$T2_2$: T2–24 h

$T2_3$: T2–48 h

Table 3 Comparison in pain levels between study groups

	Mean (SD)			
	NiTi group ($n=15$)	Cu-NiTi group ($n=15$)	Mann–Whitney Test	*P*-Value
$T0_0$	1.73 (± 1.53)	1.07 (± 1.36)	2.03	0.042*
$T0_1$	4.20 (± 1.93)	4.93 (± 2.09)	0. 59	0.055
$T0_2$	5.27 (± 1.10)	5.27 (± 2.19)	0.49	0.627
$T0_3$	5.53 (± 1.41)	5.60 (± 2.03)	0.06	0.949
$T1_0$	1.67 (± 1.59)	1.27 (± 2.55)	1.68	0.092
$T1_1$	4.47 (± 1.88)	4.87 (± 2.03)	0.13	0.899
$T1_2$	5.27 (± 1.33)	5.00 (± 2.36)	0.36	0.719
$T1_3$	5.20 (± 1.57)	4.67 (± 2.41)	0.66	0.510
$T2_0$	1.40 (± 1.30)	1.00 (± 1.25)	0.97	0.367
$T2_1$	2.00 (± 1.56)	1.47 (± 1.41)	0.92	0.389
$T2_2$	3.53 (± 1.60)	3.47 (± 1.12)	0.04	0.967
$T2_3$	3.33 (± 2.06)	2.40 (± 1.76)	0.97	0.345

SD: Standard deviation

$T0_0$: T0– Start

$T0_1$: T0–4 h

$T0_2$: T0–24 h

$T0_3$: T0–48 h

$T1_0$: T1– Start

$T1_1$: T1–4 h

$T1_2$: T1–24 h

$T1_3$: T1–48 h

$T2_0$: T2– Start

$T2_1$: T2–4 h

$T2_2$: T2–24 h

$T2_3$: T2–48 h

*: Significant ($p<0.05$)

This study only included participants with a Little's irregularity index of 1 to 3 mm, patients with a mild degree of crowding. In the present study, we did not want to include patients with a higher degree of crowding so that this factor would not be a possible influencing factor on the pain levels of the study participants. It can be assumed that patients with a higher degree of crowding, patients with a high Little's irregularity index, may perceive greater pain at the start of orthodontic treatment.

A previous study similar to the one presented here was carried out by Azizi, F. et al. in 2021. Their study compared the level of pain between a group of patients with a NiTi archwire ($n=44$) and a group with a Cu-NiTi archwire ($n=44$). These authors observed no significant differences ($p=0.487$) in pain levels between the treatment groups on the visual analog scale during the first six weeks of treatment. In the NiTi group, the mean pain value was 5.84 (± 2.04), and in the Cu-NiTi group, it was 6.16 (± 2.23). It should be noted that in this study, the patients were allowed to take an analgesic (325 milligrams of acetaminophen), which could influence the results. These authors observed that the mean time interval between orthodontic archwire placement and the onset of pain was slightly longer in patients with Cu-NiTi archwires than in patients with NiTi archwires [35].

In 2024, Liu, C. et al. published a systematic review in which they analyzed the different orthodontic archwires used during the first phases of treatment. Their study observed, based on previously published studies, that superelastic NiTi archwires produced a higher level of pain in the first 24 h than that of thermal NiTi archwires. This review also concluded that the different orthodontic archwires used at the beginning of treatment did not influence the degree of effectiveness in alignment, the prevalence of root resorption, or the level of pain described by patients during the first stages of treatment [28].

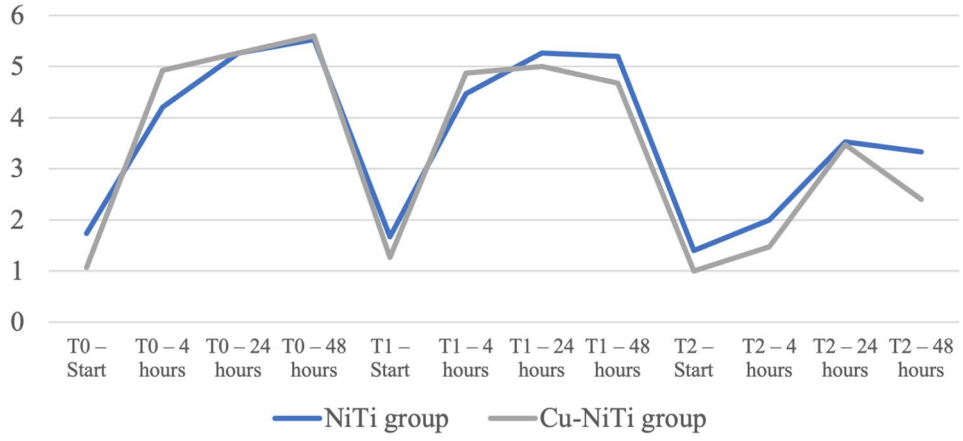

Fig. 1 Evolution of pain scores (VAS) in the groups of study during follow-up period

In this study, the highest level of pain was observed 48 h after the initial placement of the orthodontic archwire. This result is consistent with the results reported by other authors [42–44]. At the follow-up appointments after one month (T12) and two months (T22), the peak of pain described by the patients was at 24 h (5.13 ± 1.89 and 3.50 ± 1.36, respectively).

In the present study, the only statistically significant differences ($p < 0.05$) in pain were observed at the beginning of treatment (at the placement of the orthodontic archwire). The patients in the NiTi group (1.73 ± 1.53) described a higher level of pain than that of the patients in the Cu-NiTi group (1.07 ± 1.36). In the rest of the study's follow-up period, there were no reports of the influence of the archwire material on pain.

In relation to the analysis of the influence of the type of friction and/or bracket system on pain during orthodontic treatment, the different studies published report that self-ligating bracket systems produce a lower level of pain compared to conventional ligating brackets. Also, self-ligating brackets will have less negative impact on patients' OHRQoL when compared to conventional brackets. Therefore, the type of brackets influences the pain perception scores of patients during their orthodontic treatment [25, 40, 45].

Noori RM et al., in 2023, studied a sample of 33 patients in which he analysed the influence of the type of orthodontic archwire material in two study groups (NiTi group versus Cu-NiTi group) on pain levels, and on the degree of root resorption of mandibular central incisors. This author analysed the level of pain during the first seven days after insertion of each orthodontic archwire. In the NiTi group, a 0.016-inch initial archwire and a 0.018-inch second archwire were used; while in the Cu-NiTi group, a 0.014-inch first archwire and a 0.018-inch second archwire were used. This study reported that the orthodontic archwire material had no statistically significant ($p > 0.05$) influence on the pain score of the study participants or on the level of root resorption of the teeth studied, although a trend was observed in which patients in the Cu-NiTi group described a greater decrease in pain compared to the NiTi group. A similar study by Mohamed et al., in 2023, ($n = 24$) reported similar results to those described by Noori RM and by the present manuscript. Pain scores of patients with NiTi archwires were similar to the scores of patients with Cu-NiTi archwires [46, 47].

In this study, no statistically significant influence ($p < 0.05$) was observed when analysing the age and sex of the study participants on the pain scores on the visual analogue scale. The results described in the present study are in agreement with those reported by other authors [7, 12, 22, 45, 48] who also described no significant influence of sex and age on the level of pain in patients undergoing orthodontic treatment with fixed appliances. Previous studies [35, 46, 47] did not evaluate these two factors on pain levels.

In the present study, a significant decrease in the mean pain scores on the visual analogue scale was observed when comparing the start of treatment (T0) (4.1 ± 1.9) and two months after starting orthodontic treatment (T2) (2.3 ± 1.5). These results are consistent with the results described by other authors who indicate that, as orthodontic treatment progresses during the initial phases of treatment, the level of pain described by patients decreases [28, 35, 45–47]. Perhaps it is possible to think that the system of adhesion of the brackets to the teeth could be a factor that influences the perception of pain described by the patients. It would be interesting to consider in future studies the analysis of different protocols and/or systems of adhesion of the brackets to the teeth to analyse their possible influence on pain.

Strengths and limitations

This work is the first study to evaluate the influence of the composition of the orthodontic archwire

(nickel–titanium and copper–nickel–titanium) on pain levels in adult patients during the first two months of treatment with self-ligating brackets. In this study, the two groups were homogeneous with respect to their age and sex, which increased the reliability of the results described here. In addition, blinding was performed to reduce the risk of bias. An important point of this study was the two-month follow-up period. Presently, there are no published studies that evaluate pain by comparing NiTi and Cu-NiTi archwires with a follow-up period of more than six weeks.

The main limitation of this study was the sample size. The authors have taken into consideration the sample size used in previous similar studies that have also examined pain in patients undergoing orthodontic treatment [5, 12, 13, 24, 25, 27, 41, 43, 44, 46, 47]. In future studies, it would be interesting to expand the sample size, as well as to evaluate the influence of the size and material of different orthodontic archwires. Professionals must interpret the results of this study with caution and plan orthodontic treatment according to the individual needs and requirements of each patient.

Conclusions

- In the sample studied, the highest level of pain was observed in the first 48 h after the cementing of the brackets (5.57 ± 1.72).
- The type of orthodontic archwire used (NiTi or Cu-NiTi) did not significantly influence the pain levels of the participants in this study, except at the beginning of treatment, where patients with NiTi archwires experienced a higher level of pain (1.73 ± 1.53) than that of the Cu-NiTi group (1.07 ± 1.36) ($p < 0.05$); but may not be clinically significant.
- Age and sex did not influence the pain levels of the sample analyzed.

Abbreviations

Cu-NiTi	Copper–nickel–titanium
NiTi	Nickel–titanium
NS	Not significant
OHI-S	Simplified oral hygiene index
OHRQoL	Oral-health-related quality of life
SD	Standard deviation
STROBE	Strengthening the reporting of observational studies in epidemiology
VAS	Visual analog scale

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Conceptualization, R.M., A.A., and A.C.; methodology, R.M., and A.C.; formal analysis, R.M., D.C., and A.C.; investigation, R.M., A.A., D.C., and A.C.; data curation, R.M., D.C., and A.C.; writing—review and editing, R.M., A.A., D.C., and A.C. All authors have read and agreed to the published version of the manuscript.

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Data availability
The datasets generated during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
The approval of the Research Ethics Committee of the University of Salamanca was obtained (protocol number 1073; date: 25/10/2023). Written informed consent was obtained from parents or caregiver of patients after full explanation of the study, in according to the Declaration of Helsinki.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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