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Alignment efficiency of heat activated and superelastic nickel-titanium archwires in orthodontic patients over three months: A Single-center, randomized clinical trial

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Abstract

OBJECTIVE: The aim of this 2-arm parallel study was to evaluate the alignment efficiency of heat-activated nickel-titanium (NiTi-TE) and superelastic nickel titanium (NiTi-PSE) archwires over the first 3 months of orthodontic treatment and compare these groups.

SETTING AND SAMPLE POPULATION: Randomized, double-blind, controlled, single-center trial in 52 patients with fixed orthodontic appliances from an orthodontic graduate program in the permanent dentition and moderate crowding in the lower arch.

MATERIAL AND METHODS: Patients were randomly allocated to one of two interventions: NiTi-TE and NiTi-PSE archwires, 0.014-inch (3M Unitek™, CA, USA) with a follow-up period of 3 months. The primary outcome was the alignment efficiency determined by the reduction in Little's irregularity index (mm), measured in three points, T0: before the start of orthodontic treatment, T1: 1 month later, T2: 2 months later, T3: 3 months later. Data were analyzed using independent sample *t* tests and repeated measures ANOVA.

RESULTS: 52 patients (NiTi-TE $n = 26$; NiTi-PSE $n = 26$) were randomized and analyzed (average age: 21.73; standard deviation (SD): 6.07; average lower anterior irregularity: 5.20; SD: 0.76) for intention-to-treat (ITT) analysis. No statistically significant differences between the groups were found (mean of the differences: T1: 0.20; 95% CI: –0.558; 0.958; T2: 0.49: 95% CI: –0.339; 1.319; T3: 0.33; 95% CI: –0.308; 0.968). The resolution of crowding with each of the wires was significant ($P < 0.0001$) at all times. Twelve participants (2 treated with NiTi-TE and 10 treated with NiTi-PSE) lost follow-up due to face-to-face dental-procedures restrictions during the COVID-19 pandemic, the missing data was imputed.

CONCLUSIONS: NiTi-TE and NiTi-PSE wires of 0.014-inch were similar in their clinical efficiency for the resolution of crowding during the first 3 months of orthodontic treatment.

REGISTRATION: Clinical Trials NCT03256279.

Keywords:

Corrective, crowding, orthodontic wires, orthodontics

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Introduction

Alignment is the first phase of orthodontic treatment whose objective is the correction of crowding and rotations, thus reestablishing the contact points between the teeth.[1] Since the introduction of Nickel Titanium (NiTi) alloys in orthodontics in

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1972, it became a favorite to be used in the initial phases of orthodontic treatment due to its great flexibility and the transmission of low and continuous forces.[2] Nitinol, also known as classical NiTi, was initially described by William F. Bühler, it showed a stable martensitic structure without shape memory and superelasticity.[3] As of 1985, superelastic NiTi alloys appear, the first of which is the superelastic NiTi (NiTi-PSE) which has an active austenitic structure in which the transformation of the martensitic structure was induced by stress and load.[4–7] The second alloy appears in the 90's, which has an active martensitic structure and a thermo-activated behavior (NiTi-TE) that exhibits a thermally induced shape memory effect, which when increasing the temperature allows the wire to reach a range of transition temperature (RTT) converting the martensitic structure into austenitic.[8–10]

Currently the market offers a wide variety of NiTi alloys for use in orthodontics and each brand attributes unique properties to their archwires to increase their clinical efficiency. Several *in vitro* studies[4,6] have evaluated the mechanical properties of the different types of wires used in the alignment phase, such as stress at maximum tension, elasticity, yield stress and deflection. Gravina *et al*.[6] found that NiTi-PSE wire developed higher tensile strength values compared to NiTi-TE, concluding that NiTi-TE wires require less force to fracture and deform compared to NiTi-PSE wires. Similarly, Amaya *et al*.[11] found that NiTi-PSE archwires had significantly ($P < 0.05$) greater resistance to fracture, range, ultimate tensile strength (UTS), yield strength, springback, maximum tension, and flexural ultimate strength (FUS). These differences found in mechanical properties could affect the clinical performance of these alloys in relieving crowding in the alignment phase during orthodontic treatment. In addition, several studies,[12–16] have found that the clinical use of these archwires can change their mechanical properties due to their permanence in the oral environment, so the clinical efficiency of these archwires may be affected.

Notwithstanding that several authors [1,17,18] have studied the efficiency of NiTi wires during the alignment phase, such evidence in the literature is still not conclusive. The comparison of different wire sizes,[19] different manufactures, small or very diverse samples and/or methodological flaws that affect the quality of the evidence, could be some of the causes of the inconsistency in the results of these studies. Although some clinical studies have found greater crowding resolution with NiTi-PSE archwires, these differences have not been statistically significant and the evidence is not conclusive enough to guide the clinician in choosing a more efficient alloy to meet the clinical goals of the alignment phase and complete crowding resolution.[20,21] Abdelrahman *et al*.[18] conducted a double-blind randomized clinical trial (RCT) to evaluate the efficiency of the alignment of three types of NiTi archwires in 0.014-inch (classical, TE and PSE) and concluded that the three wires were similar in terms of their efficiency in alignment. To this knowledge, the Abdelrahman *et al*.[18] study is the only one that compares NiTi 0.014-inch archwires from the same commercial company (3M Unitek™) during a 12-week period, however, although the sample of their study was not small, the population was very diverse in age, severity of crowding, treatment with or without extractions, and displaced teeth, which could have induced a bias in the results.

Due to the foregoing, it is necessary to have more clinical studies with better methodological designs and more uniform samples that may provide a higher level and quality of evidence, so that clinicians can make decisions based on evidence and can choose the most effective alloy for their achievement of objectives and not only because of the promises and advertising offer of commercial manufacture.

Specific Objectives or Hypotheses

The aim of this study was to evaluate the alignment efficiency of NiTi-TE and NiTi-PSE archwires over the first 3 months of orthodontic treatment and compare these groups. Our null hypothesis was that there would be no difference in alignment efficiency between the archwire groups and/or between study times.

Methods

Trial design and any changes after trial commencement

This was a single center, prospective, double blind RCT with 2 parallel arms with a 1:1 allocation ratio. This RCT followed the Consolidated Standards of Reporting Trials statement and guidelines,[22] and did not require changes in methods after trial commencement.

Participants, eligibility criteria, and setting

Patients were recruited at the orthodontic clinic of the CIEO-UniCIEO University (Bogotá, Colombia). The study was carried out under the ethical principles established in the Declaration of Helsinki, the participants and the parents of patients under 18 years of age gave their written informed consent for their participation. The study protocol was approved by the Ethics Committee of the CIEO-UniCIEO University, through ethical endorsement number 014 of deed 46 of November 16, 2016. This clinical trial was registered in ClinicalTrials.gov with the identifier NCT03256279.

Of 359 subjects reviewed during the recruitment period, 52 cases met the inclusion criteria, who were

patients aged 13 to 30 years old in permanent dentition, with moderate crowding (4--6 mm) in the lower arch requiring maxillary and mandibular orthodontic treatment with preadjusted edgewise appliances and who agreed to participate in the study. Patients who were taking bisphosphonates, corticosteroids, NSAIDs, antidepressants, ASA or thyroxin, with systemic compromise (arthritis, hyperthyroidism or hypothyroidism), or with oral habits, cavities, periodontal problems, treatment requiring extractions and/or stripping, use of intermaxillary elastics or coil springs during the first 3 months of orthodontic treatment in the lower arch were excluded.

Interventions

The interventions investigated were two types of NiTi alloy archwires in the lower jaw: (1) NiTi PSE 0.014-inch (3M Unitek ™, California, USA); and (2) NiTi TE 0.014-inch (3M Unitek ™, California, USA). All patients used a preadjusted edgewise appliance (0.022 x 0.028-inch slot), Gemini brackets MBT prescription from the same manufacturer (3M Unitek™, Gemini brackets, California, USA). The allocated archwires were ligated with elastomeric modules to all teeth at bond-up.

From a total sample of 100 lower NiTi 0.014-inch archwires (50 TE and 50 PSE) from the same lot, manufacturer and arch shape (Orthoform III), 52 arches were selected and randomly assigned in two groups of 26 participants (26 TE and 26 PSE) who were attended by different residents following the clinical protocol of the study and the standard protocol of the orthodontic clinic supervised by a faculty researcher.

The follow-up of each of the patients was carried out during the first 3 months of treatment by taking an alginate impression (Orthoprint, Zhermack SpA, RO, IT) of the lower dentition at each of the established times as follows: (T0) before starting orthodontic treatment; (T1) at the end of the first month of treatment; (T2) at the end of the second month of treatment and (T3) at the end of the third month of treatment [Figure 1]. The plaster models (Quickstone Laboratory Stone, Whip Mix Corp, KY, USA) obtained from each patient were labeled and stored for their measurement.

Outcomes (primary and secondary) and any changes after trial commencement

The primary outcome was the alignment efficiency of the archwires; this was measured as the resolution of anterior crowding in the lower arch calculated by taking the difference in Little's irregularity index.[22] The measurements were taken by measuring the distance in millimeters between the contact points from mesial of the canine to mesial of the contralateral canine in the lower arch in the dental cast models at each of the established times. The measurement was carried out manually, by the same operator (AG) blinded and previously calibrated, using a Discovery brand digital calibrator (Ubermann 6-inch RM813 SODIMAC S.A, SCL, CL). The sums of the five readings were taken on the incisal edges of the anterior teeth with the active part of the calibrator perpendicular to the occlusal plane. The difference between each of the measurements in the established times showed the reductions in irregularity and alignment efficiency.

The secondary outcome was the arch breakage during its 3 months of clinical use.

Sample size calculation

The sample size was calculated in the software EPIDAT 4.2 (Conselleria de Sanidade, GAL, ES) using the mean differences formula, based on data from a previous study[18] and calculated on the ability to detect an inter-group difference of 1 mm in the irregularity index between the two groups over a 3-month period with a standard deviation of 1.20 mm for the NiTi-PSE group and 1.32 mm for the NiTi-TE group. It was determined that 26 patients per group would be required in order to detect a significant difference between the groups with 80% statistical power and a 5% level of significance.

Interim analyses and stopping guidelines

Not applicable.

Randomization (random number generation, allocation concealment, implementation) Randomization was performed before the study began using the virtual software http://www.randomization.com/. No blocks sizes were used in the randomization. Allocation concealment was achieved with sequentially numbered opaque and sealed envelopes containing the group allocation. Randomization generation, allocation concealment, and implementation of the study were performed by different persons.

Blinding

The type of archwire was blinded to clinicians, researchers, and patients. The blinding of the operator and the patient was possible thanks to the fact that the two types of archwires had the same commercial presentation in individual sealed envelopes, from which the part where the arch type was identified was hidden. The evaluation of the irregularity was also blinded by means of the labeling of the study casts using the sequential number of the envelopes.

Statistical analysis (primary and secondary outcomes, subgroup analyses)

Statistical analysis was performed with free R software (version 3.6.1; Bell Laboratories, Auckland,

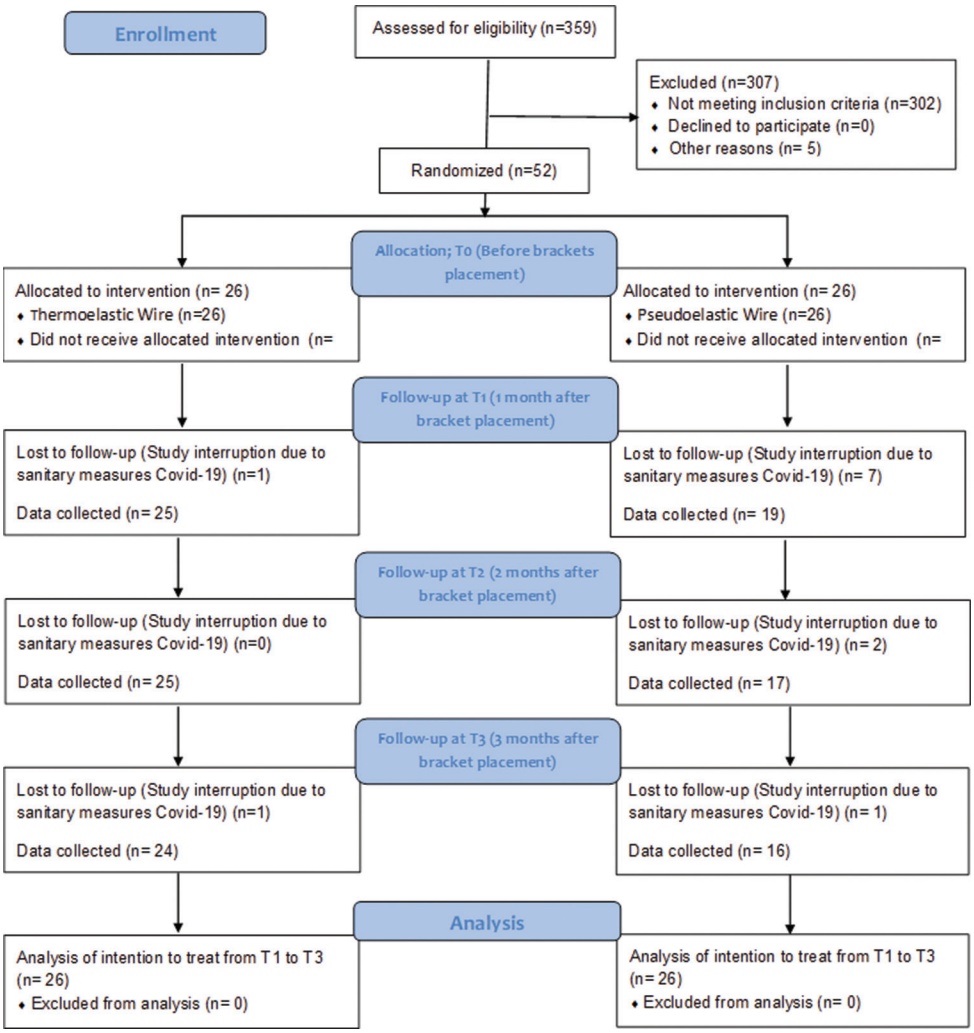

Figure 1: Flow chart

New Zealand). The statistician (L.L) was blinded to the treatment groups. The normality of the data distribution was determined by using the Anderson-Darling (AD) statistic, for which parametric tests were used. To compare crowding resolution (Little's irregularity index) with the different changes between the different times studied, a repeated measurements ANOVA with Bonferroni correction with multiple tests were used. In order to evaluate intergroup differences, the Huynh–Feldt statistic was used because sphericity was not assumed and the epsilon was greater than 0.70. The data analysis between the two groups was performed by an intention to treat (ITT) analysis, since there were missing data due to follow-up losses, an imputation of these data was carried out by means of algorithms based on regression methods. Statistical significance was established at $P < 0.05$.

Reproducibility

Intra-operator reproducibility of the Little's irregularity index measurements in the dental casts was assessed by performing the measures at 2 weeks interval. Reliability was evaluated with Bland Altman plots, and method error, with the paired *t* test (systematic error) and the Dahlberg formula (random error).

Results

Study reproducibility

The intraoperator reproducibility (Bland Altman plots) indicated a high concordance in the measurement of the irregularity index (–0.54 mm to 0.41 mm). The results of the Dalhberg formula for Little's index showed low random errors (0.48 mm) and there were no systematic errors ($P > 0.49$).

Participant flow (include flow diagram, early stopping, and time periods)

The clinical trial took place from July 27, 2017 to March 12, 2020. A total of 359 patients were assessed for eligibility; X were excluded because they did not meet the inclusion criteria and X declined to

participate. Fifty-two patients were randomized in 1:1 allocation ratio [Figure 1]. The arches were in the mouth for 3 months (approximately 12 weeks). Due to the restrictions to face-to-face dental procedures during Covid-19 pandemic, the follow-up of 12 patients was interrupted. By means of the data imputation method (Annex 1), the imputed data in T1 were 8 (NiTi-TE n = 1 and NiTi PSE n = 7), in T2 there were 10 (NiTi-TE n = 1 and NiTi PSE n = 9) and in T3 there were 12 (NiTi-TE n = 2 and NiTi PSE n = 10). When comparing the imputed data with the original data using the matrix equality test, it was evidenced that there were no significant differences.

Baseline data (include baseline table)

At baseline both groups showed similar characteristics of age, sex and irregularity index variables and there were no statistically significant differences [Table 1]. A total of 16 women and 10 men were assigned to the NiTi-TE group with an average age of 21.34 (SD: 6.85); and 12 women and 14 men with an average age of 22.11 (SD: 5.29) to the NiTi PSE group.

Numbers analyzed for each outcome, estimation and precision, subgroup analyses

Table 2 shows the numbers analyzed for each outcome (mean and precision) and the results of the bivariate analysis comparing the two groups of wires in each of the times (T0 to T3). No statistically significant differences were found at any of the times ($P > 0.05$) [Figure 2].

When comparing the reduction in crowding over time between the two wires, there was no statically significant difference ($P > 0.05$). When comparing the effectiveness of crowding resolution in each wire at different times, there were statistically significant differences ($P < 0.001$) in both of the groups [Table 3].

As for the archwires breakage, these occurred in the area between the second premolar and the first molar, in three patients, 1 in T1 and 1 in T2 of the NiTi-TE group and 1 in T2 in the NiTi-PSE group. The crowding was completely corrected in five patients, 1 (3.84% of the total) in the NiTi-TE group in T3 and 4 in the NiTi-PSE group (1 in T2 and 3 in T3) (15.38% of the total).

Table 1: Intergroup comparisons for sex ratio, age and Little's Irregularity Index at baseline (T0)

Variable	TE n=26 *n* (%)	PSE *n*=26 *n* (%)	*P*
Sex			
Female	16 (61.5%)	12 (46.1%)	
Male	10 (38.4%)	14 (53.8%)	0.266Δ
	Mean (SD)	Mean (SD)	
Age (y)	21.34 (6.85)	22.11 (5.29)	0.652ǂ
Little's Irregularity Index	5.3 (0.76)	5.11 (0.76)	0.392ǂ

Δ Chi² test; ǂ *t* test; T0. Before receiving the intervention; Statistically significant at *P*<0.05; TE=Thermoelastic, PSE=Pseudoelastic

Discussion

Main findings in the context of the existing evidence, interpretation

For clinicians, the choice of the alloy in the initial stages of orthodontic treatment is of great importance in order to achieve an efficient alignment with the ideal forces. In the present study, no significant differences were found ($P = 0.630$) in the relief of crowding during the first 3 months of orthodontic treatment between the two archwires (0.014-inch NiTi-TE and 0.014-inch NiTi-TE). Several *in vivo* studies [18,21,23] have not been able to demonstrate superiority in alignment efficiency in the lower arch among the types of NiTi wires studied so far. Likewise, as per the upper arch irregularity as reported by Ezgi Atik *et al.*[24] between the NiTi-TE premium Tanzo Cu-NiTi and NT3 superelastic NiTi

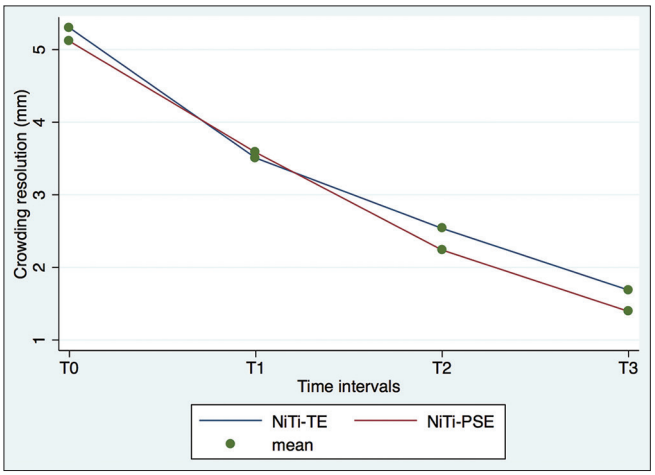

Figure 2: A profile plot with two wires a-Thermoelastic and b-Pseudoelastic to four measurements in times with imputed data

Table 2: Intergroup comparisons

Time	TE *n*=26 Mean (SD)	PSE *n*=26 Mean (SD)	Difference of the mean (SD)	95% CI Upper, Lower	*P*
T0	5.30 (0.76)	5.11 (0.76)	0.190 (6.11)	(-0.233; 0.613)	0.372
T1	3.54 (1.34)	3.34 (1.38)	0.200 (56.89)	(-0.558; 0.958)	0.598
T2	2.67 (1.58)	2.18 (1.39)	0.490 (41.81)	(-0.339; 1.319)	0.241
T3	1.76 (1.18)	1.43 (1.11)	0.330 (0.76)	(-0.308; 0.968)	0.304

Statistically significant at *P*<0.05; *t* test; SD. standard deviation; CI. confidence interval; T0. Before receiving the intervention; T1: at the first month; T2: at the second month; T3: at the third month; TE=Thermoelastic, PSE=Pseudoelastic

Table 3: Comparison of the differences in irregularity index between and within the groups

Time	TE *n*=26				PSE *n*=26				Time x group			
	Mean of the difference	(SE)	IC 95%	P[a]	Mean of the difference (SD)	(SE)	IC 95%	P[a]	Mean square	*F*	*P*[b]	Estimated effect size
T1-T0	-1.684	0.181	(-2.189; -1.179)	*P*<0.0001*	-1.767	0.151	(-2.182; -1.351)	*P*<0.0001*	0.315	0.525	0.630	0.834
T2-T0	-2.838	0.206	(-3.410; -2.265)	*P*<0.0001*	-2.783	0.170	(-3.250; -2.316)	*P*<0.0001*				
T3-T0	-3.647	0.172	(-4.126; -3.169)	*P*<0.0001*	-3.609	0.140	(-3.994; -3.224)	*P*<0.0001*				
T2-T1	-1.154	0.129	(-1.512; -0.795)	*P*<0.0001*	-1.016	0.124	(-1.358; -0.674)	*P*<0.0001*				
T3-T1	-1.963	0.159	(-2.407; -1.520)	*P*<0.0001*	-1.842	0.138	(-2.220; -1.464)	*P*<0.0001*				
T3-T2	-0.810	0.104	(-1.100; -0.519)	*P*<0.0001*	-0.826	0.088	(-1.069; -0.583)	*P*<0.0001*				

Repeated measure ANOVA with Bonferroni correction was used to compare changes occurred with time to evaluate the intergroup differences, Huynh-Feldt results were used, as the Sphericity was not assumed CI, confidence interval; SE, standard error; p[a], *P* value for the changes within the groups p[b], *P* value for the changes between the groups Statistically significant at **P*<0.0001

arches in 0.014-inch. Which could suggest that although the manufacture and composition of the different NiTi alloys make them different in their mechanical properties, as has been demonstrated in *in vitro* studies of as-received NiTi wires, the clinical environment, the contact with saliva, food components, different food temperatures and chewing forces could cause all NiTi wires to behave the same in the oral environment over time in terms of their effectiveness in correcting crowding.[11]

In the present study, the mean reduction of the crowding over the 3 months was 3.65 mm (SD: 0.172; 95% CI: –4.126; –3.169) for NiTi-TE archwires and 3.61 mm (SD: 0.172; 95% CI: –3.994; –3.224) for NiTi-PSE archwires. Similar results were found by other authors, Pandis *et al*.[23] compared NiTi-classic and CuNiTi archwires in 0.016-inch and found a total reduction of 50% of the crowding in patients with moderate irregularity index in 3.5 months. Ong *et al*.[21] compared three NiTi-PSE archwires sequences from different manufactures (3M Unitek™, GAC® and ORMCO®), finding a mean reduction in crowding of 4.40 mm in 10 weeks with the 0.014-inch archwire from 3M Unitek™, 4.80 mm from GAC®, and 3.70 mm from ORMCO®. Abdelrahman *et al*.[18] compared the 0.014-inch classic NiTi, TE and PSE archwires from 3M Unitek™, finding a mean reduction in crowding of 4.76 mm for the NiTi-PSE and 4.86 mm for the NiTi-TE in 8 weeks. Some of these values are higher than those reported in our study, this could be due to the fact that their samples included more diverse patients as with extractions, different irregularities or biomechanics. Aydin *et al*.[25] compared two NiTi archwire sequences 0.014-inch and 0.016-inch; CuNiTi 0.014-inch and 0.016-inch for 6 weeks each arch, reporting a reduction in crowding for the 0.014-inch NiTi arch of 3.31 mm and for the 0.014-inch CuNiTi of 3.51 mm and at 12 weeks with the 0.016-inch NiTi arch it reduced 3.91 mm and the 0.016-inch CuNiTi 3.78 mm. However, of the aforementioned studies, the only one that also compared the 0.014-inch NiTi-TE and NiTi-PSE archwires, 3M Unitek™ brand, as in the present study was that of Abdelrahman *et al*.[18]

In addition, in our study, when comparing the intragroup alignment efficiency over time, statistically significant differences ($P < 0.0001$) were found for both of the groups, where the NiTi-PSE wire in T1 showed a reduction in crowding of 33.20% compared to T0; in T2 compared to T1 it decreased to 24.57% and in T3 compared to T2 it decreased to 34.08%. NiTi-TE wire showed a 34.63% reduction in crowding in T1 compared to T0, in T2 compared to T1 it reduced 34.73%, and in T3 compared to T2 it decreased 34.40%. Total reduction in crowding was only achieved in one patient in the NiTi-TE group and in four patients in the NiTi-PSE group. Similar results were found in different studies.[18,21,24] Likewise, Ezgi Atik *et al*.[24] in their study found that the two wires, PSE and TE, were effective in resolving crowding at all times in the maxilla. Pandis *et al*.[23] did not find significant differences in the time necessary for the total relief of crowding between the NiTi and Cu-NiTi archwires, 0.016-inch, with a median of 142.5 days and 116.5 days, respectively, compared to this study that was carried out in 90 days, reaching a lower proportion of the total resolution of crowding, which may be due to the smaller caliber and treatment time. Another reason could be the need to increase the wire caliber to 0.016-inch to achieve total resolution of the crowding. However, Montasser *et al*.[26] found that increasing the arc diameter from 0.014 to 0.016 inches does not automatically lead to an increase in the amount of crowding correction, generally only an increase in correction of 15% is achieved.

The secondary outcome that was evaluated in this study was the breakage of the arches, finding that only in three patients the arch was fractured at the level of the second premolar and first molar (1 in T1 and 1 in T2 in the NiTi-TE group and 1 in T2 in the NiTi-PSE group), the archwires were maintained in this way during the study period, because it did not alter the anterior area. In *in vitro* studies, it has been reported that with clinical use, the ultimate tensile strength (UTS) is reduced more in TE wires than in PSE wires, so they are more prone to fracture, however, under normal conditions it is not very common for this to occur, but it is important to take

this factor into consideration for clinicians who recycle these arches.[11]

One of the greatest strengths of this study was its careful methodological design in order to reduce biases. Various systematic literature reviews[1,27,28] on the efficiency of alignment archwires have concluded that clinical studies on the subject had a high risk of bias.

Limitations

Among the limitations of this study were the follow-up losses that occurred in 12 patients due to periods of mandatory isolation decreed by the national government due to the COVID-19 pandemic, which prevented the clinical follow-up of some of the patients. In addition, this loss of follow-up was not the same in the two arms of the study but was greater in the NiTi PSE group (n = 10) than in the NiTi-TE group (n = 2). Despite the fact that the missing data was imputed using advanced statistical techniques that validated the handling of the lost data in an adequate way, the results of the present study could be influenced by this cause.

Another limitation was the diversity of operators due to the fact that the study was carried out in an orthodontic postgraduate program, despite the fact that a strict clinical protocol was equally used for all patients, the influence of the operator in the placement of the brackets could influence the results. However, the two groups had multiple operators. Wang *et al*.[27] suggest that the number of clinical operators and their calibration represent an uncontrolled variable that can influence orthodontic treatment results.

It would be recommended that in future studies the resolution of the crowding on digital models could be measured and increase the sequence of arches until completing the total resolution of the crowding.

Generalizability

Generalizability of the results of the present study must be taken with caution, because the individual variability and response of the patients to the tooth movement could differ between them according to diverse variables.

Conclusions

The 0.014-inch NiTi-TE and NiTi-PSE wires were similar in their alignment efficiency over the first 3 months of orthodontic treatment, with no statistically significant differences.

It was evidenced that both the NiTi-TE and NiTi-PSE arches were efficient in resolution of crowding in the first 3 months of treatment, finding significant differences. However, only 9.6% of all patients (1 with TE and 4 with PSE) had a total resolution of crowding at the end of the follow-up period.

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Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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