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Pain experience with copper-nickel-titanium versus nickel-titanium archwires in moderate crowding cases: A randomized controlled clinical trial

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Abstract
Purpose: To compare discomfort level felt when the traditional nickel titanium (NiTi) archwire and the copper nickel titanium (CuNiTi) archwire are used in fixed orthodontic appliance to alleviate mandibular anterior teeth crowding.
Methodology: A sample of 24 patients were randomly allocated with control; nickel titanium and intervention; copper nickel-titanium (Cu NiTi) archwire groups. Each archwire was ligated with a ligature wire for 10 weeks follow up. The primary outcome was measuring the pain level at first, second, third and seventh days of the study time through using 'Numeric Pain Rating Scale".
Results: The pain threshold scores between the two groups did not differ statistically significantly.
Conclusion: Patients using premium Tanzo copper nickel titanium (Cu-NiTi) archwires and Nickel titanium (NiTi) archwires experienced similar levels of pain.

Keywords: Class I crowding, levelling and alignment, pain level, discomfort, Cu-NiTi archwires, malocclusion

1. Introduction
It is commonly accepted that continual, low-intensity forces are necessary to shift teeth in their ideal positions. During tooth movement, these minimal forces prevent tissue damage and maintain a comparatively consistent stress in the periodontal ligament [1].
During leveling phase, Nickel-titanium (NiTi) considered the common archwire that can be used in this stage due to high elasticity and resilience and has low rigidity and elastic modulus [2]. Orthodontists have been able to draw closer to the objective of using light continuous force to shift teeth with little discomfort as biomaterials have improved throughout the course of the year [3].
Several elements were included in Nickel-titanium (NiTi) alloy in order to improve efficacy of alignment of teeth. Stress hysteresis can be reduced by adding copper, which stabilizes super elasticity feature against problem of cyclic deformation [2]. (Cu-NiTi*)* can generate a more constant force over a long activation span over Nickel-Titanium (NiTi*)*, better spring back and greater resistance to permanent deformation and less hysteresis [4].
Regarding efficacy and effectiveness, pain threshold, or potential side effects, there is inadequate literature to endorse the use of any arch wire type [5].
The goal of the study was to compare the level of pain experienced during the initial phase of leveling and aligning the mandibular anterior teeth when employing archwires made of copper nickel titanium (CuNiTi) as opposed to nickel titanium (NiTi).

Materials and Methods
Design of the trial: A randomized controlled clinical trial with a concurrent group, two arm, and a 1:1 allocation ratio trial design.

Trial Registration and Protocol

The trial has a unique identification assigned when it was registered at (ClinicalTrials.gov): NCT04815200. The Evidence Based Center at Cairo University's Faculty of Dentistry registered the Protocol, and it was approved by the research ethics committee with acceptance number: 25-1-21.

Participants

Eligibility criteria

The following were the eligibility criteria for the participants:

1) Adult patients aged (18-33) years.
2) Moderate crowding (4-8 mm) (6).
3) No extractions required.
4) Complete permanent dentition.
5) Proper oral hygiene.

The unqualified criteria for the participants were the following

1. People who have previously undergone orthodontic care.
2. Other teeth missing than the wisdom teeth.
3. Dental abnormalities in a patient.
4. Patient with deepbite, openbite, or crossbite.
5. Patients with any inherited, congenital, or systemic illnesses.

Measurement of sample size

Sample size is established by prior research as a guide (Azizi *et al*., 2021) [7]. This study found that the minimum acceptable sample size for each group was 10, the estimated mean difference was 3, the power was 80%, and the type I error probability was 0.05, when each subject group's responses had a standard deviation of 2.23 and were distributed normally. To account for the 15% dropout, the sample size was increased to 12 per group. Calculations of sample size were performed using P.S. Power 3.1.6.

Randomization

Two parallel groups were used in the study's randomized controlled trial design, and randomization will be carried out using a 1:1 allocation. The sequence of individuals in both intervention and the comparator groups will be done by using computer-generated random numbers.

Allocation concealment

Opaque sheets will be used for writing Sequence-generated random numbers will be written on opaque sheets, folded four times, sealed in impervious packets, and stored in a secure location.

Blinding

As they are unaware of the wire type being utilized, patients could end up blind. (Participants) and the assessor (neither main operator nor supervisors) performed the pre-and post-treatment measurements while remaining blind.

Intervention

A sample of 24 patients (18-33) underwent full fixed orthodontic treatment with conventional Roth prescription brackets 0.022 x 0.028 -inch slot (mini master, American orthodontics, USA) and were randomly allocated with NiTi and Cu NiTi initial archwires. In the control group, patients received 0.014 round Nickel titanium NiTi archwire (Form I, American Orthodontics, USA) and was ligated using a ligature wire (0.011 performed ligature wires; American Orthodontics, USA). In the intervention group: Patient received 0.014 round Copper Nickel titanium archwire (Tanzo MID Cu-NiTi; American Orthodontics, USA) and was ligated using a ligature wire (0.011 performed ligature wires; American Orthodontics, USA). Follow up visits were scheduled every two weeks while wire remains ligated into the bracket for the whole study time 10 weeks (T1 -T5). (Fig 1&2)

After insertion and ligation of the wire to the patient pain assessment was done by giving the patient a written form of small questionnaire (Fig 3) including a "The Numeric Pain Rating Scale" [8] (Fig 4) on the day of the procedure which was completed by each patient and handed out to the operator the next appointment. The scale ranged from (0 -10), 0 score means no pain is felt while 10 score means severe pain is found. Patients were given instructions to complete numeric pain rating scale 4 times, on the first, second, third, and seventh days.

Results

30 patients were evaluated for eligibility; 6 were disqualified for failing to meet the criteria for eligibility. In both the intervention and control groups, only 24 patients were equally randomized in both groups. An explanation of the patient flow in this study is provided by the CONSORT diagram in (Fig. 5).

SPSS 20®, GraphPad Prism®, and Micro0soft Excel 2016 were utilized in the statistical investigation. All quantitative data were examined for normality using the Shapiro-Wilk Normality Test. and shown as minimum, maximum, median, means and standard deviation (SD) values.

The following tests were used: Comparing two sets of non-parametric data using the Mann-Whitney test (Difference); Shapiro-Wilk normality test for data exploration. Statistical significance was defined as a p-value of less than 5%.

Intergroup comparison (comparison between control (NiTi) and intervention (Cu NiTi)

Mean and standard deviation of pain threshold after 1st day, 2nd days, 3rd day and 1 week in (Cu NiTi) and (NiTi) groups was presented in (table 1) and (fig 6).

No significant differences were found between the two groups when independent t tests were employed to compare them as P= 0.92, 0.76, 0.87 and 0.70 regarding the 1st, 2nd, 3rd, and 7th days respectively.

Discussion

"The visual analogue scale (VAS)", a technique frequently utilized to assess pain and discomfort. The majority of patients can easily understand this procedure because it is short, consistent, and simple to score [9]. The present findings showed no discernible difference in pain score between NiTi and Cu-NiTi groups using VAS for the first, second, third, and seventh days after arch wire placement. The consistency of pain characteristics in both groups may be related to the similarity of the two archwires in terms of pain creation, which assures the lack of a substantial influence of analgesic use as a confounder.

According to Fernandes (LM, Øgaard B, 1998) [9], the two days immediately following the installation of the archwire are when pain is at its worst.

Previous findings from this investigation were consistent with (Azizi *et al*.,2021) [7] who reported no appreciable variation in patients' reported levels of discomfort by using 0.014 inch NiTi in comparison with 0.014-inch Cu NiTi archwires.

As well (Nabbat & Yassir, 2020) [10] comparing super-elastic

NiTi (SENT) and heat-activated NiTi (HANT), (Abdelrahman *et al*., 2015) [11] compared super-elastic NiTi, conventional NiTi, and thermos-elastic NiTi, (Mahmoudzadeha *et al*., 2018) [12] compared NiTi and HANT and they all came to the conclusion that there was no appreciable difference in patient discomfort between the two sets of archwires. (Gok, *et al*., 2018) [13]. Also stated that the results showed that the two archwires did not differ statistically significantly between NiTi and Cu Niti in terms of the patient's pain and discomfort.

In contrast to our findings, (Cioffi I *et al*., 2012) [14] found that the amount of pain at 2, 3 and 4 days after the insertion of the heat-activated NiTi (HANT) archwire was much lower than that experienced with the usage of the super-elastic NiTi (SENT) archwire. The adoption of different methodologies and archwires types may be the cause of this controversy.

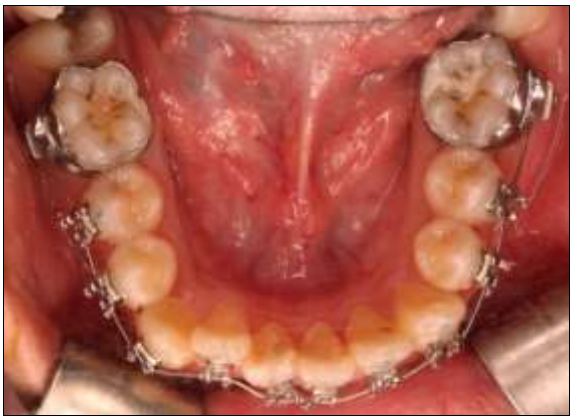

Fig 1: Intraoral photograph showing lower arch of the selected sample after bonding, wire placement and ligated with a ligature wire.

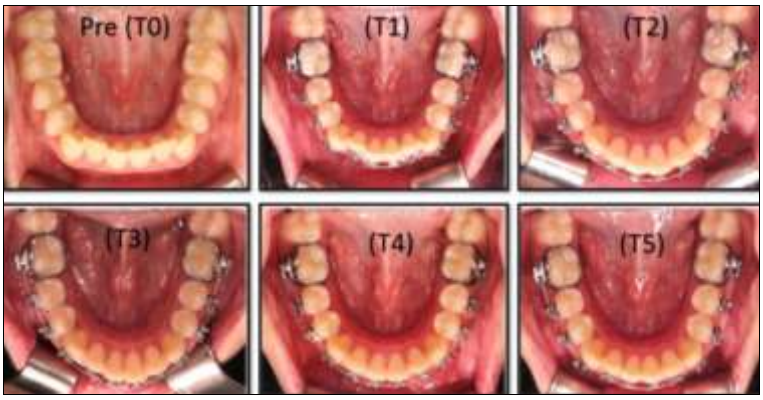

Fig 2: Intraoral photographs showing follow-up visits of the lower arch of a selected sample for 10 weeks (T0= pretreatment, T2= 2, T3= 4, T4= 8 and T5= 10 weeks follow up).

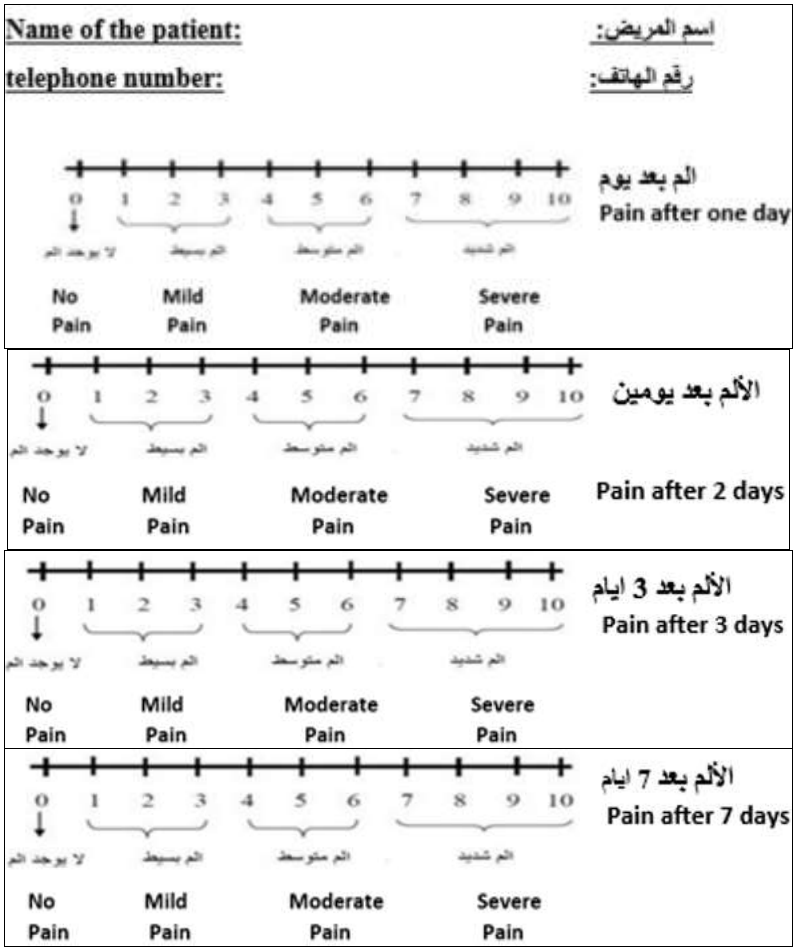

Fig 3: A questionnaire for the patients including the numeric pain rating scale at, 1 day, 2days, 3days and 7 days.

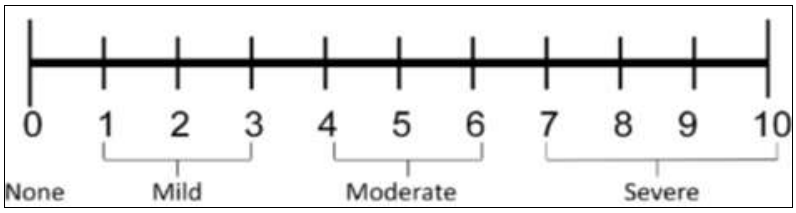

Fig 4: The Numeric Pain Rating Scale.

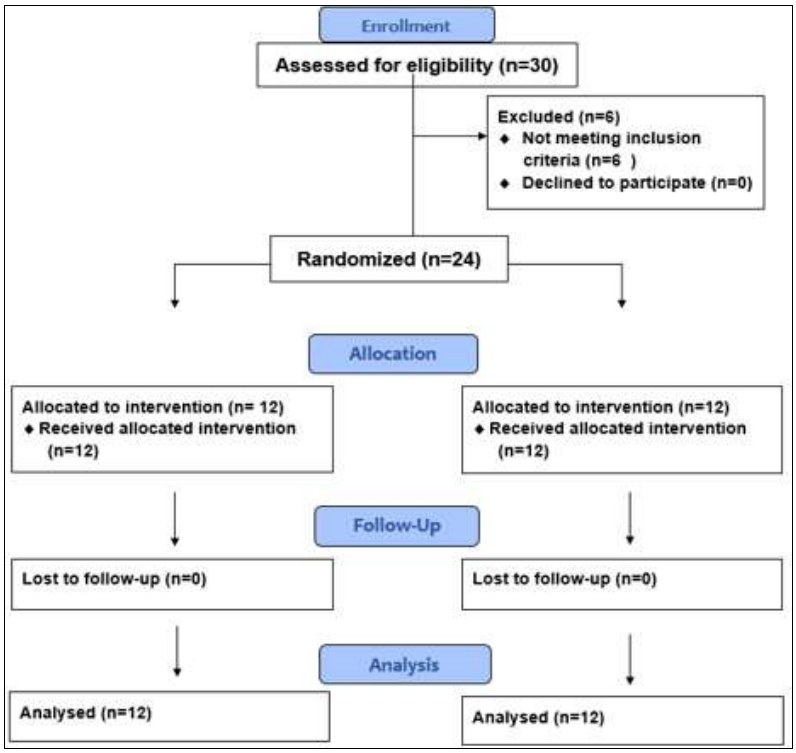

Fig 5: A CONSORT flow map demonstrating patient's flow throughout the investigation.

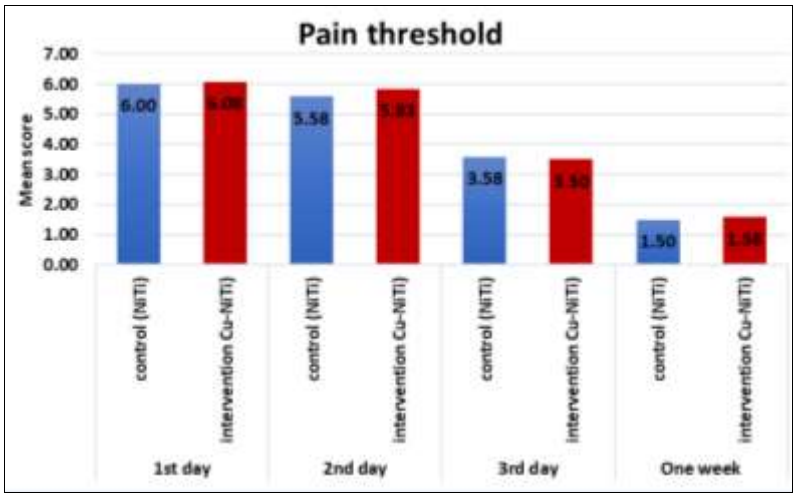

Fig 6: Bar chart representing Pain threshold at different intervals in both groups

Table 1: Mean and standard deviation of pain threshold in control and intervention groups and comparison between them using independent t test:

Interval	Group	M	SD	t-test for Equality of Means				
				MD	SEM	95% CI		P value
						L	U	
1st day	Control (NiTi)	6.00	2.30	-0.08	0.86	-1.86	1.69	0.92
	Intervention Cu-NiTi)	6.08	1.88					
2nd day	Control (NiTi)	5.58	1.44	-0.25	0.80	-1.91	1.41	0.76
	Intervention Cu-NiTi)	5.83	2.37					
3rd day	Control (NiTi)	3.58	1.24	0.08	0.49	-0.94	1.10	0.87
	Intervention Cu-NiTi)	3.50	1.17					

One week	Control (NiTi)	1.50	0.52	-0.08	0.21	-0.52	0.36	0.70
	Intervention Cu-NiTi)	1.58	0.51					

M: mean SD: standard deviation
MD: mean difference SEM: standard error mean
CI: confidence interval L: lower arm U: upper arm

Conclusion
No significant difference was detected regarding the pain level experienced by patients between super elastic nickel titanium (NiTi) and premium heat-activated Tanzo copper nickel titanium (Cu-NiTi).

Conflict of Interest
Not available

Financial Support
Not available

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