ISSN: 1110-435X
ONLINE ISSN: 281-5258

Egyptian
Orthodontic Journal

Pain perception following placement of conventional and superelastic nickel-titanium initial archwires: a randomized controlled trial

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ABSTRACT

Aim: The aim of this trial was to investigate and compare pain level accompanying the placement of conventional (CNT) and superelastic nickel-titanium (SENT) initial archwires.

Materials and methods: 52 patients were equally randomized to receive either a CNT or an SENT initial aligning wire in the first orthodontic visit. The patients were given visual analogue scale (VAS) to record their pain level at 10 time points over a period of one week after initial archwire placement. Instruction about avoidance of using analgesics and how to record the pain level using the VAS were given to the patients.

Results: Although the pain level was lower in SENT during the first 24 hours, the statistical difference was significant at bedtime only. From day 2 to day 7, the pain was lower in CNT with no significant difference between the two groups.

Conclusion: Both types of archwires showed comparable pain levels when used as the initial aligning archwires.

Keywords: Initial archwires, NiTi alloys, Superelasticity, Alignment, Pain

INTRODUCTION

Orthodontic treatment is widely used to treat malocclusions and improve dental esthetics. The placement of archwires, which serve as the foundation for subsequent tooth movement, is the first stage of orthodontic therapy. However, patients frequently report pain and discomfort following archwire installation, which can have a detrimental impact on treatment adherence and outcomes. The pain experienced as a result of archwire placement has been found to be of higher intensity and longer duration as compared to that associated with dental extraction [1].

The pain is frequently described as a dull ache, and it is thought to be caused by the application of forces to the teeth and surrounding tissues, which causes inflammation and tissue damage. It is well documented that the initial placement of archwires, particularly nickel-titanium (NiTi) archwires, causes a considerable increase in pain for patients. The pain can linger for several days and impair the patient's ability to eat and communicate [2].

The application of orthodontic force causes

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periodontal ligament tissue injury and the onset of acute inflammatory processes. The subsequent synthesis of pro-inflammatory mediators like as prostaglandins, substance P, and cytokines is critical in the treatment of orthodontic discomfort [2]. Therefore, to minimize tissue injury and associated pain and discomfort, it is recommended that mild force be used during orthodontic treatment [3-5].

Pain and discomfort are subjective perceptions that can be impacted by a variety of factors, including the substance of the archwire. Recent advances in orthodontic materials have resulted in the development of superelastic NiTi (SENT) archwires, which have several advantages over conventional NiTi (CNT) archwires, including lower stiffness, lower friction, and longer working ranges, and allow the orthodontist to apply an almost continuous light force [6-8].

Consequently, this randomized controlled trial (RCT) was designed to investigate and compare pain produced after installation of CNT and SENT initial archwires.

MATERIALS AND METHODS

The Ethics Panel of Faculty of Medicine, Assiut University, Assiut, Egypt approved the protocol (No. 17300678) of this two-arm randomized controlled trial (RCT). The sample used in this RCT was the same as in a previous study in which the size of the sample to be included was calculated [9].

The inclusion criteria were: 20 to 24 years old patients; scheduled for fixed orthodontic treatment with no additional appliances; medically fit with no systemic health problems that could affect pain sensation; healthy gingival and periodontal tissues; and no history of previous orthodontic treatment.

The exclusion criteria were: patients with cleft lip and palate, syndromes, and mental problems; pregnant women; smokers; chronic pain necessitating taking analgesics; medical situation prohibited treatment with fixed orthodontic appliance; and history of any dental or orofacial pain.

After obtaining the patients' agreement and consent for participation, a sample of 52 subjects was randomized to acquire two equal groups (1 : 1 ratio): CNT and SENT with a mean age of 22.25 + 0.95 and 21.97 + 1.02, respectively. A spreadsheet (Microsoft Excel, Microsoft Office 2016, Microsoft, Redmond, Wash) formula generated by a specialized statistician was used for the equal group randomization. Consecutively numbered opaque sealed envelopes were used for obscuring the allotment.

In one appointment, each patient received a maxillary preadjusted edgewise appliance (PEA) with 0.022 x 0.028-inch slot twin metal MBT brackets (DB Orthodontics, Silsden, Keighley, UK) and either a CNT or SENT 0.014-inch initial archwire (3M Uniteck, Monrovia, California, USA). The method of ligating the wire to the brackets was standardized by using the same type of elastomeric ligature (3M Uniteck, Monrovia, California, USA). All patients were given instructions on how to brush their teeth and the type of food that should be avoided to prevent fixed appliance breakage. The patients were instructed not to use any kind of analgesics or

pain killer. In case of taking analgesics, the patient was asked to record the type, frequency, and dose.

The treatment of all patients was provided by the two authors. To ensure blinding of the operators the information on wire packets was hidden by placing of a piece of black cardboard on both sides of the packet. Number one or two, which represented the two groups, was written on the black cardboard to allow us to differentiate the groups after data analysis. Data manipulation and analysis were done by a blinded statistician.

A 10 cm (from 0 to 10) visual analogue scale (VAS) with 0 denoting no pain and 10 denoting the highest pain possible was used to assess the pain. We explained to patients how to use the VAS by writing a number from 0 to 10, which corresponds to the level of pain experienced, on the place opposite to each time point. The pain level was assessed at 10 time points over a period of seven days after the placement of the initial archwire: at 2 and 6 hours; at bedtime; at 24 hours; and then at 9:00 PM for the following six consecutive days. After the patients returned the VAS, the data were extracted in a spreadsheet (Microsoft Excel, Microsoft Office 2016, Microsoft, Redmond, Wash) ready to be analyzed.

All statistical analyses in this RCT were executed using Statistical Package for the Social Sciences software (SPSS, Windows version 26, SPSS Inc., Chicago, Illinois, USA) with the significance level set at a *P* value less than 0.05. Shapiro-Wilk test was used to check the normal distribution of the data; and Mann–Whitney test was used to explore whether there was a difference between the groups. The age and gender data were examined using independent t-test and Chi-square test, respectively.

RESULTS

Table 1 shows no statistically significant differences between the two groups with regard to baseline demographic characteristics. There were no missing data due to lost to follow up, treatment discontinuation, or not returning the VAS; and none of the patients took analgesics (Figure 1).

Table (1) Demographic baseline characteristics of the included patients.

	CNT (n = 26)	**SENT (n = 26)**	***P* value**
Age (years)			
Range	20.4 - 24	20.1 – 23.8	
Mean ± SD	22.25 ± 0.95	21.97 ± 1.02	0.314
Gender			
Male	11 (42.3%)	13 (50.0%)	0.578
Female	15 (57.7%)	13 (50.0%)	

SD= standard deviation.

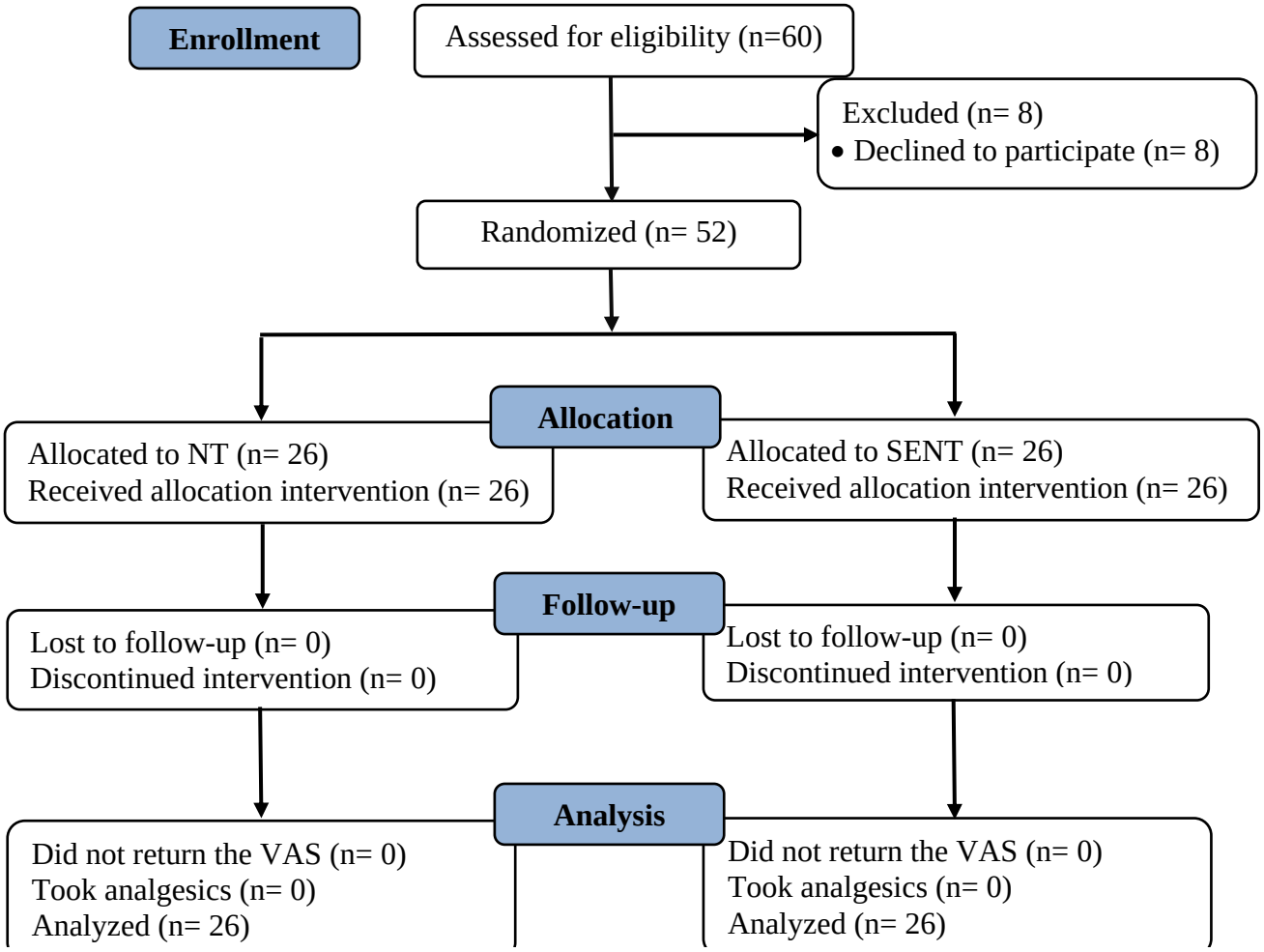

Figure 1: Consolidated Standards of Reporting Trials (CONSORT) flow diagram of the patients through the trial

The mean pain scores were lower in the SENT at 2 hours, 6 hours, bedtime, and at 24 hours, but the difference was only significant at bedtime. Form day 2 to 7, there was no statistically significant difference with the pain level being lower in the CNT as compared to SENT (Table 2).

Mean pain scores data revealed an increase in the level of pain sensation over time to attain its maximum at 24 hours; thenceforth, the pain level showed a steady fall to the lowest at day 7.

Time	Conventional nickel-titanium (CNT) (n= 26) Mean ± SD Median (min, max)	Superelastic nickel-titanium (SENT) (n= 26) Mean ± SD Median (min, max)	P value*
2 hours	2.92 ± 1.02 3 (1, 5)	2.77 ± 1.11 3 (1, 5)	0.579
6 hours	3.54 ± 1.17 3 (1, 5)	3.08 ± 0.98 3 (1, 5)	0.150
At night	4.69 ± 0.79 5 (3, 6)	3.85 ± 0.93 4 (2, 5)	0.002*
24 hours	4.77 ± 0.82 5 (3, 6)	4.31 ± 0.74 4 (3, 5)	0.061
Day-2	3.31 ± 0.74 3 (2, 5)	3.54 ± 0.58 3.5 (3, 5)	0.246
Day-3	2.62 ± 0.70 3 (1, 4)	2.77 ± 0.65 3 (2, 4)	0.464
Day-4	2.00 ± 0.63 2 (1, 3)	2.35 ± 0.63 2 (1, 3)	0.052
Day-5	1.77 ± 0.65 2 (1, 3)	1.96 ± 0.60 2 (1, 3)	0.255
Day-6	1.08 ± 0.69 1 (0, 2)	1.42 ± 0.58 1 (0, 2)	0.066
Day-7	0.92 ± 0.74 1 (0, 2)	1.08 ± 0.56 1 (0, 2)	0.398

Table (2) Mean Pain scores at different time points in the two groups.

*Significance at P ≤ .05.

DISCUSSION

The success of any dental treatment especially orthodontic treatment is largely dependent on managing and controlling pain that may be an inevitable consequence for the afforded care. In addition, controlling pain during and after the first visit is paramount to gain patient confidence and compliance during the lengthy orthodontic treatment. Therefore, our aim in this RCT was to compare the pain levels produced by CNT and SENT to help choose the initial archwire with the lowest pain possible.

Our results showed that the difference in pain scores between the two groups was not statistically significant except at bedtime with the pain being lower in SENT during the first 24 hours and lower in CNT from day 2 to 7.

Despite the subjective nature of pain, the visual analogue scale employed in this study is a valid, accurate method for measuring pain levels and easily understood by most patients [10,11]. The statisticians and operators were blinded, and the double-blind design was used to reduce any potential sources of bias.

The findings of this study are in accordance with the two earlier published articles in this topic that found no appreciable difference between CNT and SENT archwires in terms of pain levels. Abdelrahman et al, studied the pain

that patients experienced during alignment comparing SENT, thermoelastic and CNT initial wires, and concluded that there was no significant difference in pain intensity during initial orthodontic aligning stage [12].

The results reported in the second article, in which the pain scores were assessed along 11 hours during the first day, indicated that SENT archwires caused less pain during the 11 hours when compared with CNT orthodontic wires, but the results showed significant variation in the pain intensity at 4 hours only.[7]

The finding that the pain level increased over time and peaked at 24 hours is consistent with previous studies. This increase in pain may be attributed to the initial inflammatory response and the activation of nociceptors in the periodontal ligament. However, the pain level decreased gradually after 24 hours, which is consistent with the resolution of the inflammatory response [13-15].

CONCLUSION

In conclusion, the present study showed that pain levels associated with placement of CNT and SENT as the first aligning archwires were similar. However, further research is needed to confirm these findings and to investigate the long-term effects of initial archwire selection on pain levels during orthodontic treatment.

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