ORIGINAL ARTICLE

INTERNATIONAL JOURNAL OF RESEARCH IN PHARMACEUTICAL SCIENCES

Published by JK Welfare & Pharmascope Foundation Journal Home Page: https://ijrps.com

A randomized clinical trial investigating pain associated with Bio-kinetic plus nickel–titanium and Conventional nickel-titanium archwires during the initial hours of levelling and aligning the phase of orthodontic treatment

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Article History:

Received on: 14.10.2018
Revised on: 21.03.2019
Accepted on: 24.03.2019

Keywords:

Acute inflammatory, Visual Analogue Scale, Nickel-titanium

ABSTRACT

Orthodontic force application leads to periodontal ligament tissue injury and the initiation of acute inflammatory processes. Therefore, it is recommended that light force should be used during orthodontic treatment to minimise tissue damage and subsequent pain and discomfort. The present study was aimed to assess the pain perception between two types of nickel-titanium wires. To investigate and compare the effects of Bio-kinetics plus nickel–titanium and conventional nickel-titanium archwires on pain during the initial hours of the initial phase of orthodontic treatment. To compare and evaluate the pain perception using a Visual Analogue Scale (VAS) between 0.016 Conventional NiTi (Group 1) and Bio-Kinetix Plus NiTi (Group 2) at regular intervals of 24 hours, 48 hours and 72 hours each consisting of a sample size of 7. A total of 14 subjects participated in the study, each group consisting of 7 subjects. The mean pain perception score was 1.71±0.48 and 1.71±0.48 at 0 hours, 2.42±0.97 and 2.71±0.48 at 24 hours, 3.42±0.97 and 2.85±0.69 at 48 hours, 3.85±0.69 and 2.57±0.53 at 72 hours, for Group 1 and Group 2 respectively. There is no significant difference between the two groups, but there is a significant difference (p=0.001) in group 2, by 72 hours, indicating there is a decrease in pain perception. For overall pain, there was no statistically significant difference between the two wires. However, subjects with bio-kinetix plus nickel–titanium archwires had a significantly lower pain at peak level.

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ISSN: 0975-7538

DOI: https://doi.org/10.26452/ijrps.v10i2.533

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INTRODUCTION

Orthodontic force application leads to periodontal ligament tissue injury and the initiation of acute inflammatory processes. Subsequent production of proinflammatory mediators such as prostaglandins, substance P and cytokines plays an important role in the mediation of orthodontic pain. (Giannopoulou C, 2006) Therefore, it is recommended that light force should be used during orthodontic treatment to minimize tissue damage and subsequent pain and discomfort. (Reitan K, 1957; Weinstein S, 1967; Storey E, 1952; Gianelly A, 1971) Nickel-titanium (NiTi) alloy archwires are commonly used during the initial levelling and aligning phase of fixed orthodontic treatment because these wires are closest to fulfilling the ideal requirements of an initial archwire. (Quintao, 2009)

Besides clinical efficiency, another important consideration for initial archwire selection should be minimal pain and discomfort because the prevalence of pain during the initial phase of fixed orthodontic treatment is high. (Erdinc AM, 2004 & Scheurer PA, 1996) Surprisingly, this important topic has been largely ignored in clinical practice

as well as research, as evidenced by the scarcity of publications.

As pain is a subjective response, it can be significantly influenced by several factors, including age (Jones M, Chan C, 1992) and sex (Bergius M, 2002) and clinical characteristics such as orthodontic force level. (Luppanapornlarp S, 2010) The degree of crowding has a direct effect on inter-bracket distance, which can significantly influence deactivation forces of initial archwires. (Huskisson EC, 1983). Therefore, the present study was designed as a randomized clinical trial to investigate and compare the effects of conventional nickel titanium and bio-kinetix plus nickel titanium archwires on orthodontic pain over a period of 72 hours.

MATERIALS AND METHODS

We conducted a randomized controlled trial in India between October to November 2016. A total of 14 subjects met all inclusion criteria and were enrolled in the study after providing written informed consent. The study protocol was approved by a local ethics review committee of Saveetha University.

Inclusion criteria were:

1. Patients who required fixed orthodontic treatment along with the extraction of first premolars;
2. Moderate to severe crowding (4–9 mm) in the mandibular anterior segment that was not severe enough to prevent bracket engagement;
3. the eruption of all mandibular anterior teeth;
4. no history of medical problems/medication that could influence pain perception; and informed and witnessed consent from the minor participant and their parent/guardian.

Exclusion criteria were:

1. Presence of a severe deep bite that could affect bracket placement on the mandibular anterior teeth;
2. Malocclusion correction required treatment procedures other than continuous archwire mechanics;
3. Subjects that have periodontally compromised teeth and are taking pain medications for chronic pain;
4. Subjects with a positive history of dental pain or pain in the orofacial region;
5. A medical condition that precluded the use of a fixed orthodontic appliance (e.g. allergy to nickel, the recent history of an epileptic seizure or physician's consent could not be obtained, etc.)

Initial crowding assessment was done by using Little's Irregularity index. Decisions regarding extraction, as and when required, were based on comprehensive diagnosis and treatment planning. After extractions, subjects were scheduled for appointments at least 2week post extraction to allow a standardized minimum healing time since one of the prerequisites before trial initiation was that subjects should be pain-free.

On the first day of orthodontic treatment but before the bonding procedure, booklets containing the pain assessment scale and written instructions were provided to subjects for the baseline pain assessment. Verbal instructions and guidance during the baseline assessment were provided to familiarise the subjects with the pain assessment procedure. For all subjects, the bonding procedure and initial wire placement were carried out in the morning, though on different days, keeping the time on the check. This was to ensure that the follow-up time points for pain assessment were the same.

Pre-adjusted Edgewise Appliances (PEA) with 0.022×0.028inch slot twin brackets (MBT prescription, Gemini Metal Brackets; 3M Unitek Corporation, Monrovia, CA, USA) were bonded directly to the mandibular dentition using light cure composite resin (Transbond XT; 3M Unitek Corporation). We employed either 0.016-inch Bio-Kinetix Plus (Unitek™ Coaxial Wire; 3M Unitek Corporation) or 0.016inch conventional nickel-titanium (3M Unitek Corporation) as interventions.

Only the mandibular arch was bonded until the completion of the study. After initial archwire placement, subjects were discharged with the booklets containing the pain assessment scale and written instructions. Subjects were requested to report back after every 24 hours (follow up period), unless they experienced an emergency, such as mucosal injury or damage to the appliance.

The outcome was assessed by using the Visual Analogue Scale (VAS), which is a 100mm long horizontal line where one end corresponds to 'no pain', and the other end indicates 'worst pain possible'. (Breivik H, 2008) The VAS is a valid and reliable scale for pain assessment. (Davidovitch Z, 1988) The pain was assessed at baseline and every 24 hours pre-specified follow up (post wire placement) time points.

Subjects marked a line across the scale corresponding to perceived pain at each time point. The mark was measured from the left margin of the line to the nearest millimetre to quantify the pain and recorded a VAS score in mm.

RESULTS

A total of 14 subjects who met the inclusion criteria were included in the study.

Table 1: The Mean VAS scores at each point for both Group 1 and Group 2

	Groups	N	Mean	Std. Deviation	Std. Error Mean
0 hours	1.00	7	1.7143	.48795	.18443
	2.00	7	1.7143	.48795	.18443
24 hours	1.00	7	2.4286	.97590	.36886
	2.00	7	2.7143	.48795	.18443
48 hours	1.00	7	3.4286	.97590	.36886
	2.00	7	2.8571	.69007	.26082
72 hours	1.00	7	3.8571	.69007	.26082
	2.00	7	2.5714	.53452	.20203

Table 2: Statistical analysis of Group 1 and Group 2 VAS scored (Independent test)

		Levene's Test for Equality of Variances		t-test for Equality of Means		
		F	Sig.	T	Df	Sig. (2-tailed)
0 hours	Equal variances assumed	.000	1.000	.000	12	1.000
	Equal variance not assumed			.000	12.000	1.000
24hours	Equal variances assumed	3.208	.099	-.693	12	.502
	Equal variance not assumed			-.693	8.824	.506
48 hours	Equal variances assumed	1.278	.280	1.265	12	.230
	Equal variance not assumed			1.265	10.800	.233
72 hours	Equal variances assumed	.000	1.000	3.897	12	.002
	Equal variance not assumed			3.897	11.294	.002

Table 2: Statistical analysis of Group 1 and Group 2 VAS scored (Independent test) (Contd…)

		t-test for Equality of Means			
		Mean Diff.	Std.Error Diff.	95% confidence interval of the Difference	
				Lower	Upper
0 hours	Equal variances assumed	.00000	.26082	-.56828	.56828
	Equal variance not assumed	.00000	.26082	-.56828	.56828
24hours	Equal variances assumed	-.28571	.41239	-1.18424	.61281
	Equal variance not assumed	-.28571	.41239	-1.22146	.65004
48 hours	Equal variances assumed	.57143	.45175	-.41286	1.55572
	Equal variance not assumed	.57143	.45175	-.42513	1.56798
72 hours	Equal variances assumed	1.28571	.32991	.56689	2.00454
	Equal variance not assumed	1.28571	.32991	.56188	2.00955

There was no statistically significant difference between conventional nickel – titanium and Bio-kinetix plus arch wires for mean average VAS score across all time points (*F* value = 0.00, df = 12.00, *P* = 01.00 at 0 hours; *F* value = 3.28, df = 8.82, *P* = 0.506 at 24 hours; *F* value = 1.278, df = 10.88, *P* = 0.280 at 48 hours; *F* value = 0.00, df = 11.294, *P* = 01.00 at 72 hours).

However, the significant interaction between the same group and Time (*P* = 0.005 and 0.001 at

Table 3: Pair-wise comparisons of conventional NiTi archwire for effect on pain at each time point

		Paired Differences				
		Mean	Std, Deviation	Std. Error Mean	95% confidence interval of the Difference	
					Lower	Upper
Pair 1	0-24	-.71429	.95119	.35952	-1.59399	.16542
Pair 2	0-48	-1.71429	.95119	.35952	-2.59399	-.83458
Pair 3	0-72	-2.14286	.69007	.26082	-2.78106	-1.50465
Pair 5	24-72	-1.42857	1.27242	.48093	-2.60536	-.25178
Pair 6	48-72	-.42857	1.27242	.48093	-1.60536	.74822

Table 3: Pair-wise comparisons of conventional NiTi archwire for effect on pain at each time point (Contd…)

		t	df.	Sig. (2-tailed)
Pair 1	0-24	-1.987	6	.094
Pair 2	0-48	-4.768	6	.003
Pair 3	0-72	-8.216	6	.000
Pair 5	24-72	-2.970	6	.025
Pair 6	48-72	-.891	6	.407

Table 4: Pair-wise comparisons of Bio kinetix plus NiTi archwire for effect on pain at each time point

		Paired Differences				
		Mean	Std, Deviation	Std. Error Mean	95% confidence interval of the Difference	
					Lower	Upper
Pair 1	0-24	-1.00000	.57735	.21822	-1.53396	-.46604
Pair 2	0-48	-1.14286	.69007	.26082	-1.78106	-.50465
Pair 3	0-72	-.85714	.37796	.14286	-1.20670	-.50758
Pair 4	24-48	-.14286	.37796	.14286	-.49242	.20670
Pair 5	24-72	-.14286	.37796	.14286	-.20670	.49242
Pair 6	48-72	.28571	.48795	.18443	-.16556	.73699

Table 4: Pair-wise comparisons of Bio kinetix plus NiTi archwire for effect on pain at each time point (Contd….)

		t	df.	Sig. (2-tailed)
Pair 1	0-24	-4.583	6	.004
Pair 2	0-48	-4.382	6	.005
Pair 3	0-72	-6.000	6	.001
Pair 4	24-48	-1.000	6	.356
Pair 5	24-72	1.000	6	.356
Pair 6	48-72	1.549	6	.172

48hours and 72 hours respectively for Group 2) highlights the fact that the difference for VAS score between conventional nickel–titanium and Bio kinetix plus archwires was not insignificant across all the time points.

Values illustrated in Table 3 indicates that there is a significant increase in the VAS scores across 24 hours to 72 hours, while values illustrated in Table 4 indicates that there is a significant decrease in the VAS scores across 24 hours to 72 hours. This implies that there is lesser pain perception by subjects under Bio – Kinetix Plus nickel – titanium archwires.

DISCUSSION

In this clinical trial, orthodontic pain began 1 h after initial archwire placement, reached a peak on the morning of day 1 (24h), and gradually increased after for subjects with conventional NiTi archwires (Table 3), and gradually decreased after for subjects with Bio-kinetix plus NiTi archwires (Table 4). There was no statistically significant difference between conventional nickel–titanium and bio-kinetix plus archwire for overall pain during the entire study. However, compared to bio-kinetix plus archwire, subjects who received conventional nickel-titanium wire reported greater pain at the peak from 24 h after placement.

The observed trend of pain perhaps reflects the underlying biological responses to orthodontic force application. Interleukin1beta (IL1beta) is the first mediator to regulate bone remodelling in response to orthodontic force, and it also plays a significant role in orthodontic pain by inducing the secretion of pain-producing pro inflammatory mediators (1,15). A recent study (Luppanapornlarp S, 2010) demonstrated that the IL1beta concentration increases after one h of orthodontic force application, peaks after 24h, and subsequently declines approximately to baseline in 1week to the 1month time period.

There is much controversy regarding the question of whether light versus heavy forces has any effect on orthodontic tooth movement and associated pain. (Reitan K, 1957; Weinstein S, 1967 & Storey E, 1952) Various histological studies and clinical trials suggest that light forces are capable of producing efficient tooth movement with less tissue damage and subsequent pain, whereas heavy forces cause greater periodontal compression and thus more pain. However, few authors reported that application of heavier forces per unit area increases the rate of biological response (Hixon EH, 1969), and there are no statistically significant correlations among the initial tooth positions, applied force levels and experienced pain (Jones ML, 1985).

However, one of the most recent studies carried out to examine the relationship between amount of force (heavy versus low) concluded that application of heavy force does not significantly enhance the rate of tooth movement, but compared to light force, it does produce significantly greater pain at the peak level of pain, i.e. 24 h after force application.

The weaknesses and limitations of this study mostly pertain to the non-consideration of a few factors that could have influenced the outcome. Although an attempt was made to control all such factors (age, sex and initial crowding), psychological factors such as anxiety/depression and hormonal fluctuation in females during menstruation cycle were not taken into account and could have influenced the outcome of the trial. Future studies should take into account all such factors that can influence pain perception.

CONCLUSION

During the peak level of pain following the placement of an initial aligning arch wire (12 hours to 48 hours), subjects with conventional nickel-titanium wire reported significantly greater pain compared to those with Bio-kinetix plus Niti archwire. However, there was no statistically significant difference between these archwires for mean average pain across all time points.

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