Annals of R.S.C.B., Vol. 24, Issue 1, 2020, pp. 808- 828
Received 18April2020; accepted 23June2020

Effectiveness Of Pulsed Electromagnetic Field Therapy For Pain Relief In Adult Patients During The Initial Space Closure Phase Of Orthodontic Treatment Using Sliding Mechanics : A Single-Blind, Split-Mouth Randomized Clinical Trial

Saloni Hasmukh Mehta, Devaki Vijayalakshmi, N.M. Vijay Kumar, Nagachandran.K.S

Meenakshi Ammal Dental College,

Meenakshi Academy of Higher Education and Research, Chennai, Tamil Nadu, India

ABSTRACT

OBJECTIVE: To evaluate the effectiveness of Pulsed Electromagnetic field therapy (PEMF) on pain reduction during en masse space closure with sliding mechanics following three initial consecutive monthly activations in the resting and the biting condition. **MATERIALS AND METHODS:** The 2-arm trial included thirty patients, having undergone first premolar extractions andindicated for space closure using sliding mechanics. Randomization allocated the experimental and the placebo side for every patient. PEMF therapy (active on one and placebo devices on the other side) was prescribed for three consecutive nights after each posted arch activation. The pain assessment was done using the NRS scale through a Google survey form that was sent as a link via text message at 0, 4, 24, 48, 72 hours after every activation.**RESULTS:** A significant reduction in pain intensity was found in the experimental group as compared to the placebo group at 72 hours after the first activation, and 48 hours after the second and third activations at rest and bite condition. In the relaxed state, significant reduction in the pain occurred at 24, 48 and 72 hours as compared to 4 hours after all three activations in the experimental group while in the bite state, pain levels reduced significantly at 48 and 72 hours for the first activation and 24, 48, 72 hours for the second and third activations. **CONCLUSION:** PEMF is an effective modality for pain management in the relaxed and bite condition in the space closure phase of orthodontic therapy using friction mechanics.

KEYWORDS: orthodontic pain, sliding mechanics, pulsed electromagnetic field therapy, PEMF.

INTRODUCTION

Orthodontic force application to effect tooth movement results in the release of various inflammatory mediators elicitinghyperalgesia and pain.Pain isamong the most cited negative effects of orthodontic treatment[1], the chief aversion during, and the fourth major apprehension prior to orthodontic treatment.[2]Orthodontic forcesdecrease the differentiating capabilities of patients for up to 4 days, leading to reduction of pain threshold and disturbance of mechanisms associated with proprioception input from nerve endings.[3]Studies have reported a compromised masticatory efficiency, decreased bite force and change in the consistency of the food consumed in association with orthodontic pain.[4] Pain also has a significant impact on patient compliance,

daily activities and quality of life.[5] Despite its considerable clinical value, the degree of orthodontic pain experienced and associatedanalgesic consumption remains broadly underestimated.[6]Various modalities have been used for pain reduction including non-steroidal anti-inflammatory drugs (NSAIDS)[7], low-level laser therapy (LLLT) [8], chewing wafers[9], transcutaneous electrical nerve stimulation[10], vibratory therapy[11], cognitive therapy.[12] The use of NSAIDS has been associated with a negative influence on orthodontic tooth movementin addition to the systemic side effects.[13,14]

PEMF is a non-invasive modality that reduces pain by generating 'short bursts of current' without any disruption of physiological mechanisms. PEMF has been cleared by the US Food and Drug administration (FDA) for acute and chronic pain relief post-operatively and has found a place in the medical armamentarium with widespread applications.[15–18]In the field of dentistry, it has been used successfully for management of pain and soft tissue healing.[19,20]The efficacy of PEMF in reducing pain after placement of initial archwire has been established.[21] There is scarce literature assessing pain during en masse space closure using friction mechanics over a long term,none of which evaluated the efficacy of PEMF.[22] Therefore, further research is needed for stronger justification for implementation of PEMF in orthodontic practice.The aim of this trial was to evaluate the efficacy of PEMF in reducing orthodontic pain during the space closure phase of orthodontic treatment.

MATERIAL AND METHODS

Study Design

The randomized clinical trial was performed in a single-blind, split-mouth, 2-arm parallel design with a 1:1 allocation ratio from February 2020 to May 2020. The primary outcome of the study was to compare the inter-group pain scores at specific time intervalsupto 72 hours following each of the three consecutive monthly activations in the resting and the biting conditions. The secondary outcome included the assessment of intra-group pain scores over a period of 72 hours after each activationin the resting and the biting conditions. The trial was granted ethical approval by Institutional Review Board of Meenakshi Ammal Dental College, Chennai-600095 – MADC/IRB-XVI/2017/310 and was registered in Clinical Trial registry, India **CTRI/2020/01/023006**

Participants

The study, undertaken at the Department of Orthodontics, Meenakshi Ammal Dental College, Chennai, India, included 30 patients, both male and female, between the age group of 18 to 28 years. The inclusion criteria were systemically and periodontally healthy patients who had undergone first premolar extractions bilaterally and were indicated for space closure with sliding

Annals of R.S.C.B., Vol. 24, Issue 1, 2020, pp. 808- 828
Received 18April2020; accepted 23June2020

mechanics.Patients with systemic conditions, history of oral pain three weeks prior, and/or those on analgesics were excluded.

Intervention

The study was undertaken at the end of the aligning and levelling phase with 019 x 025 SS archwire in place with022 slot MBT brackets (Ormco series). The activation was done using the MBT prescribed type one module-ligature configuration, which was calibrated using Dontrix gauge to deliver 5.5 oz (≈ 155 gms) per side (Figure 1)

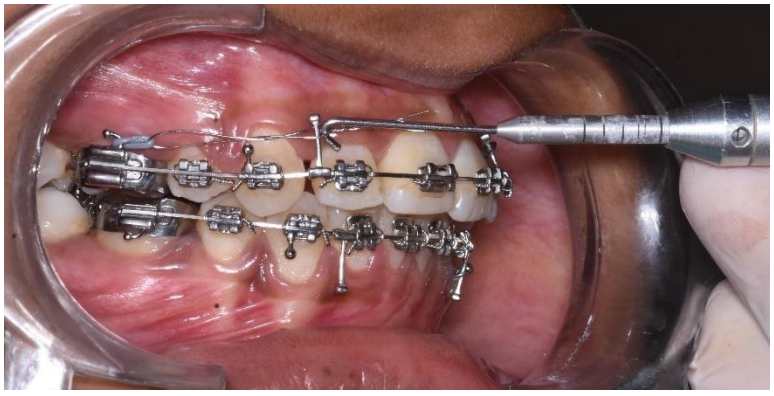


Figure 1: Force calibration for activation using the Dontrix gauge

The PEMF device used in the study was a miniaturized, portable device called Actipatch© (BioElectronics Corporation) that was battery operated with a carrier frequency of 27.12 MHz and pulse rate of 1,000 pulses/s. The treatment area of 100 cm^2 was confined to the loop. (Figure 2) One set of the PEMF devices (placebo), were rendered inactive by blocking the circuit from the battery source with a transparent sheet interposed between them. The LED lights on all devices were covered with the same colored tape so that there were no discernable differences between the experimental and placebo devices. (Figure 3) Patients were asked to wear the device extra orally, bilaterally on the cheeks using bio adhesive tapes over the extraction site for three consecutive nights after each activation for a period of eight hours. (Figure 4) The pain evaluation was done using a google survey form sent as a link through a text message at specific time intervals. (Figure 5). The pain evaluation was done at five intervals over a period of 72 hours for each activation. The first assessment was immediately after the activation at 0 (T0), and then 4(T1), 24 (T2), 48 (T3), and 72 (T4) hours after the activation for each side in resting and biting states. The NRS scale was used with 0-10 rating, where 0 indicated no pain while 10 indicated maximum pain perceived.

Annals of R.S.C.B., Vol. 24, Issue 1, 2020, pp. 808- 828
Received 18April2020; accepted 23June2020

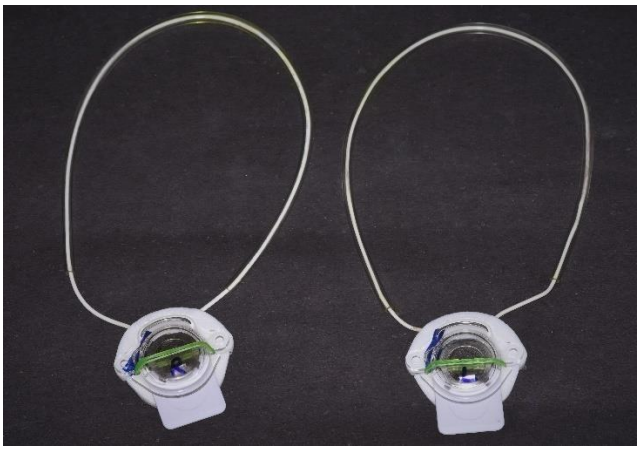


Figure 2: The PEMF device (Actipatch©) used in the study.

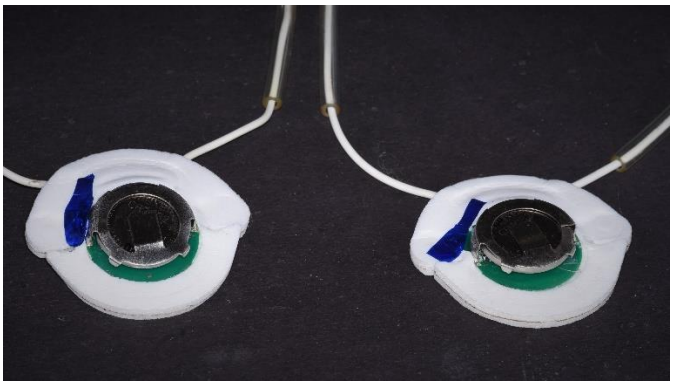
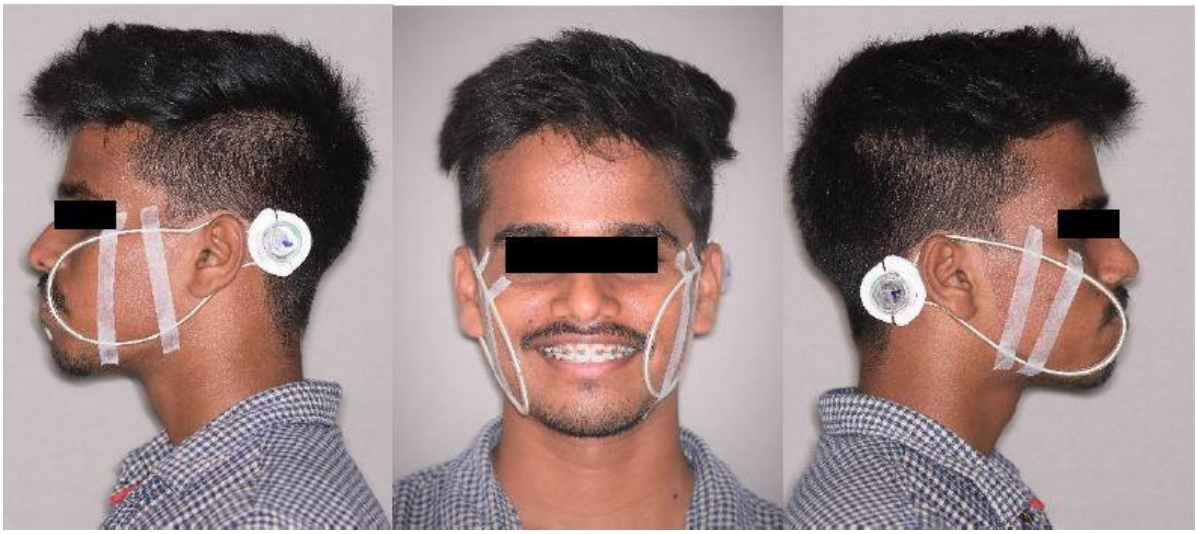
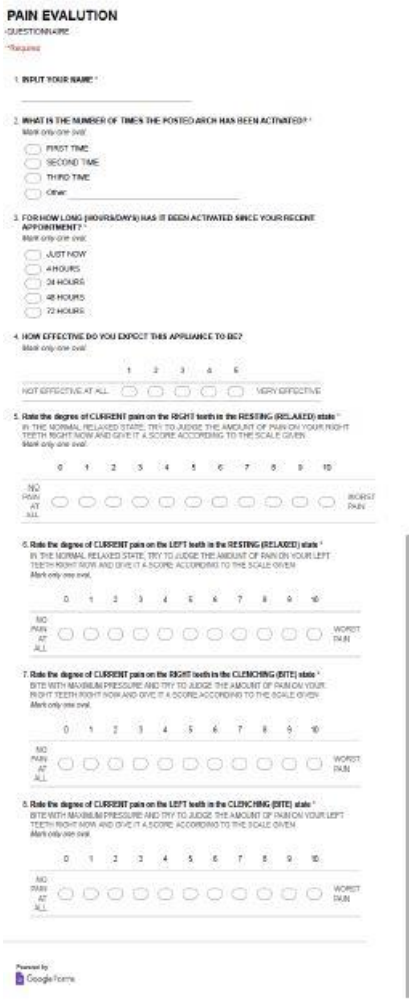


Figure 3: The module consisting of the battery and the circuit. The experimental and placebo devices with the LED bulb concealed with opaque tapes.



Annals of R.S.C.B., Vol. 24, Issue 1, 2020, pp. 808- 828
Received 18April2020; accepted 23June2020

Figure 4: The device worn on the cheek using bio adhesive tapes.


PAIN EVALUTION

QUESTIONNAIRE

*Required

1. INPUT YOUR NAME *

2. WHAT IS THE NUMBER OF TIMES THE POSTED ARCH HAS BEEN ACTIVATED? *
Mark only one oval.
- FIRST TIME
- SECOND TIME
- THIRD TIME
- Other:

3. FOR HOW LONG (HOURS/DAYS) HAS IT BEEN ACTIVATED SINCE YOUR RECENT APPOINTMENT? *
Mark only one oval.
- JUST NOW
- 4 HOURS
- 24 HOURS
- 48 HOURS
- 72 HOURS

4. HOW EFFECTIVE DO YOU EXPECT THIS APPLIANCE TO BE? *
Mark only one oval.

	1	2	3	4	5	
NOT EFFECTIVE AT ALL	◯	◯	◯	◯	◯	VERY EFFECTIVE

5. Rate the degree of CURRENT pain on the RIGHT teeth in the RESTING (RELAXED) state *
IN THE NORMAL RELAXED STATE, TRY TO JUDGE THE AMOUNT OF PAIN ON YOUR RIGHT TEETH RIGHT NOW AND GIVE IT A SCORE ACCORDING TO THE SCALE GIVEN
Mark only one oval.

	0	1	2	3	4	5	6	7	8	9	10	
NO PAIN AT ALL	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	WORST PAIN

6. Rate the degree of CURRENT pain on the LEFT teeth in the RESTING (RELAXED) state *
IN THE NORMAL RELAXED STATE, TRY TO JUDGE THE AMOUNT OF PAIN ON YOUR LEFT TEETH RIGHT NOW AND GIVE IT A SCORE ACCORDING TO THE SCALE GIVEN
Mark only one oval.

	0	1	2	3	4	5	6	7	8	9	10	
NO PAIN AT ALL	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	WORST PAIN

7. Rate the degree of CURRENT pain on the RIGHT teeth in the CLENCHING (BITE) state *
BITE WITH MAXIMUM PRESSURE AND TRY TO JUDGE THE AMOUNT OF PAIN ON YOUR RIGHT TEETH RIGHT NOW AND GIVE IT A SCORE ACCORDING TO THE SCALE GIVEN
Mark only one oval.

	0	1	2	3	4	5	6	7	8	9	10	
NO PAIN AT ALL	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	WORST PAIN

8. Rate the degree of CURRENT pain on the LEFT teeth in the CLENCHING (BITE) state *
BITE WITH MAXIMUM PRESSURE AND TRY TO JUDGE THE AMOUNT OF PAIN ON YOUR LEFT TEETH RIGHT NOW AND GIVE IT A SCORE ACCORDING TO THE SCALE GIVEN
Mark only one oval.

	0	1	2	3	4	5	6	7	8	9	10	
NO PAIN AT ALL	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	WORST PAIN

Powered by Google Forms

Figure 5: The survey form

Randomization

Randomization was done using sequentially numbered sealed, opaque envelopes with cards that were numbered zero or one. The cards marked with zero allotted the right side as the experimental side while the left side as the placebo side and vice versa for the cards marked one. The envelopes were prepared before the trial commenced and were handled by the principal investigator.

Blinding

Annals of R.S.C.B., Vol. 24, Issue 1, 2020, pp. 808- 828
Received 18April2020; accepted 23June2020

The allocation was not blind to the principle investigator. However, the participants were blinded to the allocation. The data analyst was blinded to the allocation during data analysis.

Sample size calculation

The sample size was calculated based on detecting clinically relevant differences in the NRS pain scores between the experimental and placebo groups (primary outcome) in the first published study about PEMF.[21] Effect size (Cohen d) was estimated at 0.94 and subsequently sample size was evaluated to be 26 with the Alpha error of 5 % and power of 90%. Overall, 30 patients were recruited for the trial estimating dropouts, non-compliance.

Statistical Analysis

Descriptive analysis was carried out to deduce the mean and standard deviations of the pain scores for each time interval between the two groups. Inter-group analysis was carried out using the Mann-Whitney U test for comparison of the pain scores at T0, T1, T2, T3, T4 in resting and biting condition for all the three activations. Greenhouse-Geisser test was used to assess whether there was a significant difference in the pain perception at different hours at each activation. Generalised linear models with Bonferronni corrections wasused to evaluate the difference across the timeline for all possible combinations. The level of significance was established at $p < 0.005$.

RESULTS

Four patients had to be excluded due to inability to answer the survey at the prescribed times. Data analysis was carried out for 26 patients. **Tables 1 and 2** provide the mean and standard deviations of the NRS scores for each time interval in the experimental group and placebo groups respectively.

	Mean	Std. Deviation
1st mon(0hr)- rest	3.65	2.828
1st mon(0hr)- bite	4.12	2.747
1st mon(4hr)-rest	5.12	2.535
1st mon(4hr)-bite	5.50	2.267
1st mon(24hr)-rest	3.42	2.517
1st mon(24hr)-bite	3.92	2.667
1st mon(48hr)-rest	2.42	1.770
1st mon(48hr)-bite	3.04	1.907
1st mon(72hr)-rest	1.38	1.835
1st mon(72hr)-bite	1.38	1.899

Annals of R.S.C.B., Vol. 24, Issue 1, 2020, pp. 808- 828
Received 18April2020; accepted 23June2020

2nd mon(0hr)-rest	3.50	2.846
2nd mon(0hr)-bite	3.88	3.115
2nd mon(4hr)-rest	4.77	2.178
2nd mon(4hr)-bite	4.92	2.785
2nd mon(24hr)-rest	3.19	2.450
2nd mon(24hr)-bite	3.69	2.724
2nd mon(48hr)-rest	2.31	1.914
2nd mon(48hr)-bite	2.92	2.448
2nd mon(72hr)-rest	1.35	1.355
2nd mon(72hr)-bite	1.50	1.606
3rd mon(0hr)-rest	3.46	2.731
3rd mon(0hr)-bite	3.92	3.045
3rd mon(4hr)-rest	4.92	2.348
3rd mon(4hr)-bite	5.23	2.338
3rd mon(24hr)-rest	3.46	2.140
3rd mon(24hr)-bite	3.69	2.510
3rd mon(48hr)-rest	2.12	1.558
3rd mon(48hr)-bite	2.73	1.867
3rd mon(72hr)-rest	1.12	.909
3rd mon(72hr)-bite	1.31	1.258

Table I: MEAN AND STANDARD DEVIATON OF THE NRS SCORES FOR EACH TIME INTERVAL IN THE EXPERIMENTAL GROUP (GROUP 1)

	Mean	Std. Deviation
1st mon(0hr)- rest	3.12	2.286
1st mon(0hr)- bite	4.19	2.757
1st mon(4hr)-rest	4.15	2.461
1st mon(4hr)-bite	5.46	2.213
1st mon(24hr)-rest	4.15	2.588
1st mon(24hr)-bite	5.00	2.698
1st mon(48hr)-rest	3.46	2.267
1st mon(48hr)-bite	3.81	2.608
1st mon(72hr)-rest	2.35	2.019
1st mon(72hr)-bite	2.31	2.112
2nd mon(0hr)-rest	3.23	2.215
2nd mon(0hr)-bite	3.69	2.558
2nd mon(4hr)-rest	4.65	1.999

Annals of R.S.C.B., Vol. 24, Issue 1, 2020, pp. 808- 828
Received 18April2020; accepted 23June2020

2nd mon(4hr)-bite	5.27	2.570
2nd mon(24hr)-rest	3.73	2.491
2nd mon(24hr)-bite	4.54	2.846
2nd mon(48hr)-rest	3.50	2.285
2nd mon(48hr)-bite	4.35	2.560
2nd mon(72hr)-rest	2.23	2.065
2nd mon(72hr)-bite	2.65	2.465
3rd mon(0hr)-rest	3.31	2.241
3rd mon(0hr)-bite	3.85	2.556
3rd mon(4hr)-rest	4.65	2.153
3rd mon(4hr)-bite	5.46	2.249
3rd mon(24hr)-rest	4.23	2.160
3rd mon(24hr)-bite	4.73	2.677
3rd mon(48hr)-rest	3.23	1.966
3rd mon(48hr)-bite	3.77	2.286
3rd mon(72hr)-rest	1.77	1.394
3rd mon(72hr)-bite	2.00	1.470

Table II: MEAN AND STANDARD DEVIATON OF THE SCORES FOR EACH TIME INTERVAL IN THE PLACEBO SAMPLE (GROUP 2)

Comparison of Inter-group pain levels

For the resting state, the pain scores were significantly lower in the experimental group at 72 hours following the 1st activation, and 48 hours after the second and third activations as compared to the placebo group. **(Table 3)** During the biting state, the pain scores were significantly lower in the experimental group at 72 hours after the first activation, 48 hours in the 2nd activation as compared to the placebo group. **(Table 4)**

TIME INTERVALS (in h)	GROUP	NRS MEAN	P VALUE
1ST MONTH			
T0 (0)	EG PG	3.65 3.12	0.618
T1 (4)	EG PG	5.12 4.15	0.135
T2 (24)	EG PG	3.42 4.15	0.297
T3 (48)	EG PG	2.42 3.46	0.083

Annals of R.S.C.B., Vol. 24, Issue 1, 2020, pp. 808- 828
Received 18April2020; accepted 23June2020

Table III: COMPARISON OF THE PAIN SCORES BETWEEN GROUP 1 AND GROUP 2 AT T0, T4, T24, T48, T72 IN RESTING STATE OVER 3 MONTHS.

TIME INTERVALS (in h)	GROUP	NRS MEAN	P VALUE
1ST MONTH			
T0 (0)	EG PG	3.46 3.31	0.867
T1 (4)	EG PG	4.12 4.19	0.963
T2 (24)	EG PG	3.50 3.46	0.970
T3 (48)	EG PG	3.40 3.92	0.135
T4 (72)	EG PG	2.13 3.00	**0.028**
2RD MONTH			
T0 (0)	EG PG	3.50 3.23	0.796
T1 (4)	EG PG	4.77 4.65	0.816
T2 (24)	EG PG	3.19 3.73	0.354
T3 (48)	EG PG	2.31 3.50	**0.041**
T4 (72)	EG PG	1.38 2.35	**0.029**
2ND MONTH			
T0 (0)	EG PG	3.50 3.23	0.796
T1 (4)	EG PG	4.77 4.65	0.816
T2 (24)	EG PG	3.19 3.73	0.354
T3 (48)	EG PG	2.31 3.50	**0.041**
T4 (72)	EG PG	1.35 2.23	0.095
2RD MONTH			
T0 (0)	EG PG	3.46 3.31	0.867
T1 (4)	EG PG	4.12 4.19	0.963
T2 (24)	EG PG	3.50 3.46	0.970
T3 (48)	EG PG	3.40 3.92	0.135
T4 (72)	EG PG	2.13 3.00	**0.028**
3RD MONTH			
T0 (0)	EG PG	3.50 3.23	0.796
T1 (4)	EG PG	4.77 4.65	0.816
T2 (24)	EG PG	3.19 3.73	0.354
T3 (48)	EG PG	2.31 3.50	**0.041**
T4 (72)	EG PG	1.38 2.35	**0.029**
2ND MONTH			
T0 (0)	EG PG	3.50 3.23	0.796
T1 (4)	EG PG	4.77 4.65	0.816
T2 (24)	EG PG	3.19 3.73	0.354
T3 (48)	EG PG	2.31 3.50	**0.041**
T4 (72)	EG PG	1.35 2.23	0.095
2RD MONTH			
T0 (0)	EG PG	3.46 3.31	0.867
T1 (4)	EG PG	4.12 4.19	0.963
T2 (24)	EG PG	3.50 3.46	0.970
T3 (48)	EG PG	3.40 3.92	0.135
T4 (72)	EG PG	2.13 3.00	**0.028**
3RD MONTH			
T0 (0)	EG PG	3.50 3.23	0.796
T1 (4)	EG PG	4.77 4.65	0.816
T2 (24)	EG PG	3.19 3.73	0.354
T3 (48)	EG PG	2.31 3.50	**0.041**
T4 (72)	EG PG	1.38 2.35	**0.029**
2ND MONTH			

Annals of R.S.C.B., Vol. 24, Issue 1, 2020, pp. 808- 828
Received 18April2020; accepted 23June2020

T0 (0)	EG PG	3.88 3.69	0.926
T1 (4)	EG PG	4.92 5.27	0.579
T2 (24)	EG PG	3.69 4.54	0.186
T3 (48)	EG PG	2.92 4.35	**0.028**
T4 (72)	EG PG	1.50 2.65	0.069
3RD MONTH			
T0 (0)	EG PG	3.92 3.85	0.941
T1 (4)	EG PG	5.23 5.46	0.681
T2 (24)	EG PG	3.69 4.73	0.076
T3 (48)	EG PG	2.73 3.77	0.062
T4 (72)	EG PG	1.31 2.00	0.085

Table IV: COMPARISON OF THE PAIN SCORES BETWEEN GROUP 1 AND GROUP 2 AT T0, T4, T24, T48, T72 IN CLENCHING STATE OVER 3 MONTHS.

Annals of R.S.C.B., Vol. 24, Issue 1, 2020, pp. 808- 828
Received 18April2020; accepted 23June2020

Comparison of Intra-group pain levels

Greenhouse-Geisser test revealed statistically significant differences in pain scores from the time of activation (T0) to 72 hours (T4) for both the groups in the resting and the biting states for every activation.(**Table 5 and 6**)The pain was found to decrease in both the groups over a period of 72 hours for all the activations. (Figure 6,7,8,9,10,11)

TIME	p VALUE	
	GROUP 1	GROUP 2
1st month (T0-T4)	**0.000**	**0.002**
2nd month (T0-T4)	**0.000**	**0.000**
3rd month (T0-T4)	**0.000**	**0.000**

Table V: COMPARISON OF THE RESTING STATE PAIN SCORES ACROSS 72 HOURS FOR MONTHLY ACTIVATION IN BOTH THE GROUPS

TIME	p VALUE	
	GROUP 1	GROUP 2
1st month (T0-T4)	**0.000**	**0.002**
2nd month (T0-T4)	**0.000**	**0.000**
3rd month (T0-T4)	**0.000**	**0.000**

Table VI: COMPARISON OF THE BITING STATE PAIN SCORES ACROSS 72 HOURS FOR MONTHLY ACTIVATION IN BOTH THE GROUPS

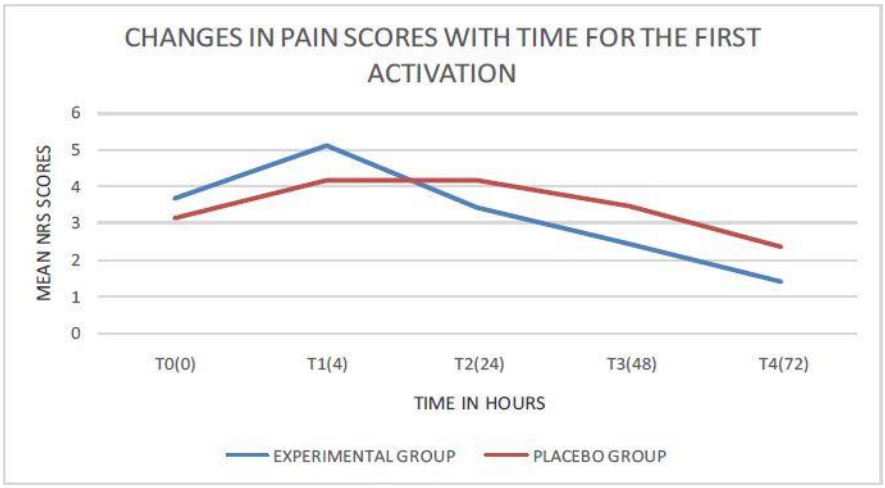


Figure 6: Pain scores over 72 hours after first activation in the resting state

Annals of R.S.C.B., Vol. 24, Issue 1, 2020, pp. 808- 828
Received 18April2020; accepted 23June2020

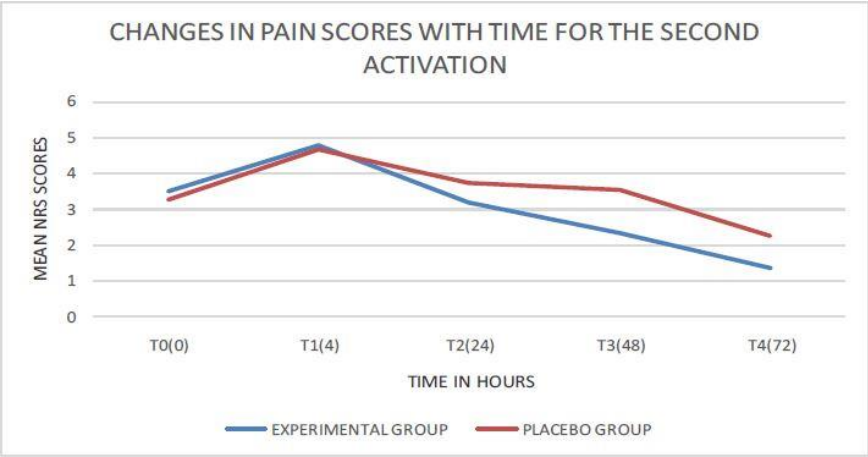


Figure 7: Pain scores over 72 hours after second activation in the resting state

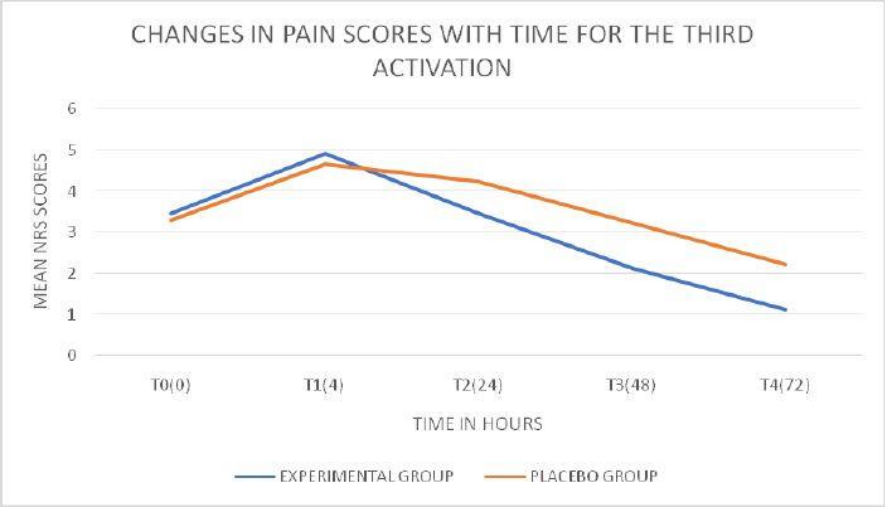


Figure 8: Pain scores over 72 hours after third activation in the resting state

Annals of R.S.C.B., Vol. 24, Issue 1, 2020, pp. 808- 828
Received 18April2020; accepted 23June2020

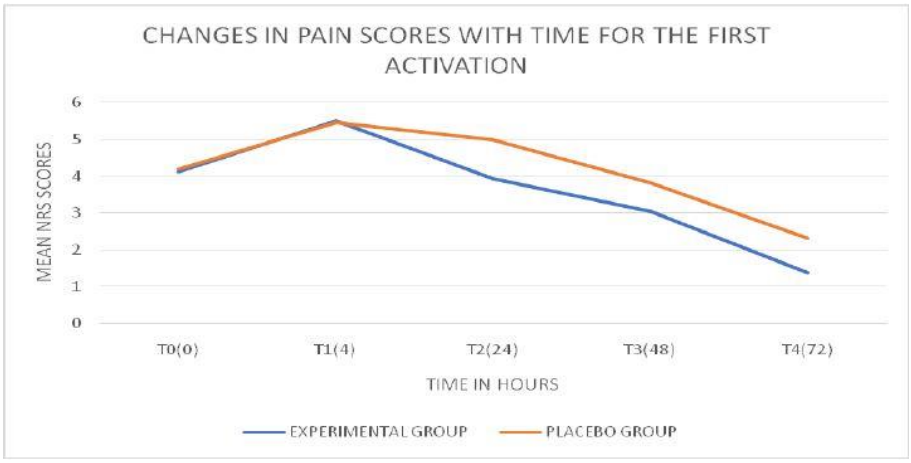


Figure 9: Pain scores over 72 hours after first activation in the biting state

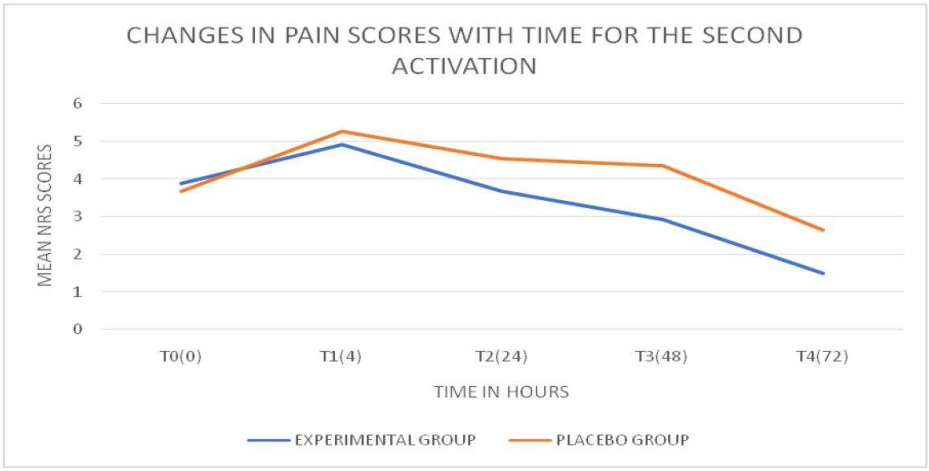


Figure 10: Pain scores over 72 hours after second activation in the biting state

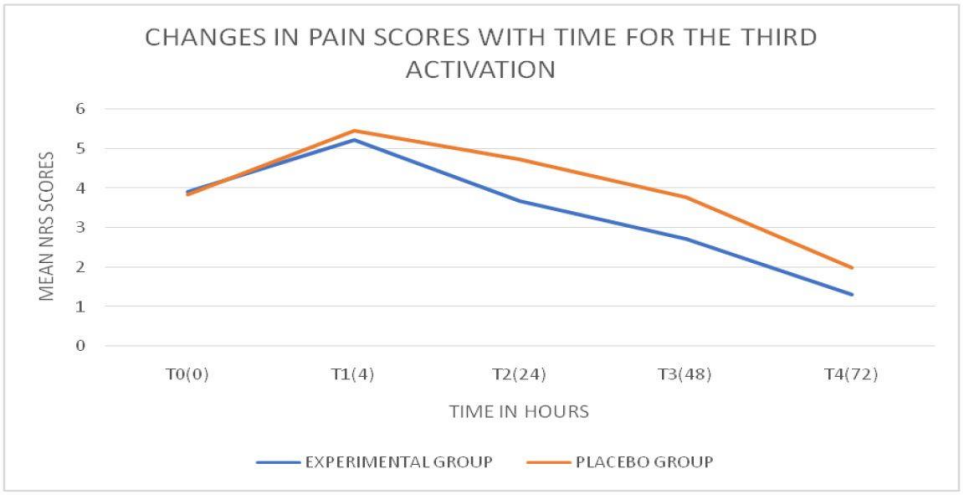


Figure 11: Pain scores over 72 hours after third activation in the biting state

Annals of R.S.C.B., Vol. 24, Issue 1, 2020, pp. 808- 828
Received 18April2020; accepted 23June2020

Table 7 shows the statistically significant differences in pain perception across each time interval for all three activations in the resting state. The experimental group showed a statistically significant reduction in the pain intensity at 24, 48 and 72 hours (after PEMF) compared to 4 hours (before PEMF) following all the three activations. (p value = 0.000). The pain levels at 72 hours were significantly lower than 24 hours for all three activations. Significant reduction in pain levels were also found at 48 hours for the first and the third activations compared to 24 hours. Pain levels significantly reduced from 48 to 72 hours for the second and third activations. Therefore, pain reduction was significant after each exposure to PEMF therapy. The placebo group on the other hand experienced no significant reduction in pain levels at 24 and 48 hours (after PEMF) compared to 4 hours (before PEMF) following all three activations. Significant pain reduction was found only at 72 hours when compared to 4 hours. The pain levels decreased significantly only from 48 to 72 hours for all the three activations. For the third activation, pain reduced significantly even from 24 to 48 hours.

	TIME INTERVALS (in hours)	P VALUE
1ST MONTH		
EG	T1(4)*T2(24)	0.00
	T1(4)*T3(48)	0.00
	T1(4)*T4(72)	0.00
	T2(24)*T3(48)	0.00
	T2(24)*T4(72)	0.00
	T3(48)*T4(72)	0.04
PG	T1(4)*T4(72)	0.01
	T2(24)*T3(48)	0.04
	T2(24)*T4(72)	0.00
	T3(48)*T4(72)	0.00
2ND MONTH		
EG	T0(0)*T4(72)	0.00
	T1(4)*T2(24)	0.00
	T1(4)*T3(48)	0.00
	T1(4)*T4(72)	0.00
	T2(24)*T4(72)	0.00
	T3(48)*T4(72)	0.00
PG	T1(4)*T4(72)	0.00

Annals of R.S.C.B., Vol. 24, Issue 1, 2020, pp. 808- 828
Received 18April2020; accepted 23June2020

	T3(48)*T4(72)	0.00
3RD MONTH		
EG	T0(0)*T4(72)	0.00
	T1(4)*T2(24)	0.00
	T1(4)*T3(48)	0.00
	T1(4)*T4(72)	0.00
	T2(24)*T3(48)	0.00
	T2(24)*T4(72)	0.00
	T3(48)*T4(72)	0.00
PG	T1(4)*T4(72)	0.00
	T2(24)*T3(48)	0.00
	T2(24)*T4(72)	0.00
	T3(48)*T4(72)	0.00

Table VII: RESTING STATE - SIGNIFICANT DIFFERENCES OF PAIN SCORE ACROSS THE TIMELINE IN THE TWO DIFFERENT GROUPS USING GLM MODELS WITH BONFERRONI CORRECTION

Table 8 shows the statistically significant differences in pain perception across each time interval for all three activations in the biting state. The experimental group showed a statistically significant reduction in the pain intensity at 24, 48 and 72 hours (after PEMF) compared to 4 hours (before PEMF) following second and third activations. (p value = 0.000). For the first activation pain reduced significantly at 48 hours after the second exposure to PEMF. Significant reduction in pain levels occurred between 48 and 72 hours but not from 24 to 48 hours for all three activations. The placebo group experienced no significant reduction in pain after 24 hours compared to 4 hour pain levels for all three activations. Initial pain (4 hours) reduced significantly only at 48 hours for the first and third activations while the same was at 72 hours for the second activation. Significant reduction in pain was experienced from 48 to 72 hours for all three activations.

	TIME INTERVALS	P VALUE

Annals of R.S.C.B., Vol. 24, Issue 1, 2020, pp. 808- 828
Received 18April2020; accepted 23June2020

	(in hours)	
1ST MONTH		
EG	T0(0)*T4(72)	0.00
	T1(4)*T3(48)	0.00
	T1(4)*T4(72)	0.00
	T2(24)*T4(72)	0.00
	T3(48)*T4(72)	0.00
PG	T1(4)*T3(48)	0.00
	T1(4)*T4(72)	0.00
	T2(24)*T3(48)	0.00
	T2(24)*T4(72)	0.00
	T3(48)*T4(72)	0.00
2ND MONTH		
EG	T0(0)*T4(72)	0.00
	T1(4)*T2(24)	0.00
	T1(4)*T3(48)	0.00
	T1(4)*T4(72)	0.00
	T2(24)*T4(72)	0.00
	T3(48)*T4(72)	0.00
PG	T1(4)*T4(72)	0.00
	T2(24)*T4(72)	0.00
	T3(48)*T4(72)	0.00
3RD MONTH		
EG	T0(0)*T4(72)	0.00
	T1(4)*T2(24)	0.00
	T1(4)*T3(48)	0.00
	T1(4)*T4(72)	0.00
	T2(24)*T3(48)	0.01
	T2(24)*T4(72)	0.00
	T3(48)*T4(72)	0.00
PG	T0(0)*T4(72)	0.00
	T1(4)*T3(48)	0.00
	T1(4)*T4(72)	0.00
	T2(24)*T3(48)	0.00
	T2(24)*T4(72)	0.00
	T3(48)*T4(72)	0.00

Table VIII: SIGNIFICANT BITING STATE – OF PAIN SCORE DIFFERENCES TIMELINE IN ACROSS THE DIFFERENT THE TWO GLM MODELS GROUPS USING BONFERRONI WITH CORRECTIONS

DISCUSSION

Various studies have evaluated the pain experience between sexes reporting no differences.[23] Jung et al checked the efficacy of PEMF in only female orthodontic

patients therefore, the present trial recruited both male and female patients. [21]The subjectivity of pain pertaining to age has been studied with conflicting results.[24–26] Therefore, the age group in the study was restricted to 18 to 28 years to eliminate the age-related differences.

PEMF produces a higher blood and lymph flow by primarily inducing nitric oxide release through nitric oxide synthase, which is released with the increased rate of 'binding of calcium ions with calcium modulated protein. It also acts on cGMP second messenger, facilitates growth factor production, promotes wound healing and tissue repair.[18,21]The miniature, wearable device gives the orthodontist a more adaptable tool for pain management away from the office. The device provided at 27.12 MHz,a frequency used for most medical purposes and allocated by The Federal Communications Commission. Patients reported no discomfort, tingling or heating associated. The device was prescribed for use only at night for esthetic reasons.

In a study, a higher force of 150 g resulted in greater IL-β levels and pain scores as compared to 50 g for canine retraction with no difference in the rate of tooth movement.[27] Forces ranging from 50cN to 100cN were found most favorable for bodily movement considering the efficiency of movement, pain and root resorption in a recent systematic review.[28]Therefore, the force magnitude was standardized at 150 g per side to reduce the errors in pain responses because of varied force magnitudes.

Since pain perception is highly subjective due to individual pain threshold, psychological and emotional parameters, this trial was conducted in a split-mouth design to prevent ambiguity. Survey links were sent at specific time intervals so that responseswere recorded at the accurate time. Participants could not modify the responses once submitted. The pain intensity was quantified using the NRS as it is a more sensitive scale compared to the VRS or VAS.[29]This trial was conducted over a period of three consecutive activations to assess the reliability of PEMF over multiple appointments in reducing pain as opposed to the previous short term studies. [22,30]

For the resting and biting state, statistically significant differences between the experimental and placebo groups at 48 and 72 hours signifies the efficacy of PEMF in substantially reducing post activation pain earlier (within 48 to 72 hours) after the orthodontic visit. The side that was not subjected to PEMF therapy experienced relatively increased pain two to three days after the visit for each activation.

Jung et al reported that the pain reduction using PEMF in the experimental group was significant at 24, 48 and 72 hours after force application.[21] In this study, there was no significant reduction of pain at 24 hours (the first exposure to PEMF) in the resting and biting state. This may be attributed to the fact that by the time the patient reaches the space closure phase the pain threshold of the patient may have increased.[21]

The intra-group analysis was done to evaluate the effect of PEMFon pain after each exposure. In the resting state, there was a significant decrease in the pain levels after the PEMF intervention (24, 48 and 72 hours) as compared to before PEMF (4 hours) for all three activations. The placebo group reported a reduction in the pain that was not statistically significant even at 48 hours as compared to 4 hours. Previous studies have stated that pain gradually decreases after 48 hours even without any intervention.[31] Significant reduction in pain levels were similarly found from 48 to 72 hours in both the groups. However, the pain levels were significantly lower at 72 hours for the experimental group in the inter-group analysis, which establishes the effectiveness of PEMF in pain reduction.

In the biting state, the pain levels similarly decreased significantly after the PEMF intervention in comparison to the pain levels experienced before PEMF for the second and the third activations. For the first activation, the difference was significant only at 48 and 72 hours. In contrast, the placebo group showed no significant reduction at 24 hours (after PEMF) compared to 4 hours (before PEMF). The pain reduction was significant only after 48 and 72 hours. However, like in the resting state, the pain levels were significantly lower at 48 and 72 hours for the experimental group in the inter-group analysis, thus proving the efficacy of PEMF in pain reduction compared to placebo. The null hypothesis stating that there would be no effect of PEMF on pain levels during the space closure phase of orthodontic treatment using friction mechanics was rejected for both thestates.The mean NRS scores did not increase significantly from immediately after activation up to 4 hours in both the groups implying similar baseline characteristics before PEMF intervention.

In this study, the interval between each activation was 4 to 6 weeks. [32]The modules that provided the retraction force were changed at every visit to ensure that the standardized force of 150 g was applied at every activation since the force decay of the module is dependent on factors like individual oral hygiene that would affect the force levels and indirectly, the pain perception.

Limitations

Limitations could be: rare chances of cross-arch influence, variable soft tissue thickness influencingthe potency of the therapy at site, differing effective force levels after overcoming the friction and binding of archwires affecting pain scores.

CONCLUSION

- In the resting and biting state, PEMF caused an overall significant pain relief at 72 hours after 1st activation, and 48 hours after the 2ndactivations in the experimental group compared to the placebo group.
- PEMF caused a significant pain reductionwithin 24 hours in the resting state and 48 hours in the bite state,which continued to decrease after subsequent exposures to PEMF therapy over 72 hours.
- Therefore, PEMF may be an alternative therapy for reducing pain during space closure outside the dental office.

REFERENCES

1. Oliver RGBDS, Sc MD, Knapman YMBDS. Attitudes to Orthodontic Treatment Attitudes to Orthodontic Treatment. 2016;(August). doi:10.1179/bjo.12.4.179
2. Connor PJO, Rcs D. Patients ' Perceptions Before , During , and After Orthodontic Treatment. 2000;XXXIV(10):591-592.
3. Soltis JE, Nakfoor PR, Bowman DC. Changes in Ability of Patients to Differentiate Intensity of Forces Applied to Maxillary Central Incisors During Orthodontic Treatment. *J Dent Res*. 1971;50(3):590-596. doi:10.1177/00220345710500031101
4. Trein MP, Mundstock KS, Maciel L, Rachor J, Gameiro GH. Pain, masticatory performance and swallowing threshold in orthodontic patients. *Dental Press J Orthod*. 2013;18(6):117-123. doi:10.1590/S2176-94512013000600018
5. Sergl HG, Klages U, Zentner A. Pain and discomfort during orthodontic treatment: causative factors and effects on compliance. *Am J Orthod Dentofacial Orthop*. 1998;114(6):684-691. doi:10.1016/S0889-5406(98)70201-X
6. Krukemeyer A, Arruda A, Inglehart M. Pain and Orthodontic Treatment Patient Experiences. *Angle Orthod*. 2009;79(6):1175-1181. doi:10.2319/121308-632.1
7. Ngan P, Wilson S, Shanfeld J, Amini H. The effect of ibuprofen on the level of discomfort inpatients undergoing orthodontic treatment. *Am J Orthod Dentofac Orthop*. 1994;106(1):88-95. doi:10.1016/S0889-5406(94)70025-7
8. Tortamano A, Lenzi DC, Haddad ACSS, Bottino MC, Dominguez GC, Vigorito JW. Low-level laser therapy for pain caused by placement of the first orthodontic archwire: A randomized clinical trial. *Am J Orthod Dentofac Orthop*. 2009;136(5):662-667. doi:10.1016/j.ajodo.2008.06.028
9. Hwang JY, Tee CH, Huang AT, Taft L. Effectiveness of thera-bite wafers in reducing pain. *J Clin Orthod*. 1994;28(5):291-292.
10. Roth PM, Thrash WJ. Effect of transcutaneous electrical nerve stimulation for controlling pain associated with orthodontic tooth movement. *Am J Orthod Dentofac Orthop*. 1986;90(2):132-138. doi:10.1016/0889-5406(86)90045-4

11. Marie SS, Powers M, Sheridan JJ. Vibratory stimulation as a method of reducing pain after orthodontic appliance adjustment. *J Clin Orthod*. 2003;37(4):2554923.
12. Wang J, Jian F, Chen J, et al. Cognitive behavioral therapy for orthodontic pain control: A randomized trial. *J Dent Res*. 2012;91(6):580-585. doi:10.1177/0022034512444446
13. Sostres C, Gargallo CJ, Arroyo MT, Staff P, Lanas A, Chief C. Best Practice & Research Clinical Gastroenterology Adverse effects of non-steroidal anti-inflammatory drugs (NSAIDs , aspirin and coxibs) on upper gastrointestinal tract. *Best Pract Res Clin Gastroenterol*. 2010;24(2):121-132. doi:10.1016/j.bpg.2009.11.005
14. Bartzela T, Türp JC, Motschall E, Maltha JC. tooth movement : A systematic literature review. *YMOD*. 2009;135(1):16-26. doi:10.1016/j.ajodo.2008.08.016
15. Iannitti T, Fistetto G, Esposito A, Rottigni V, Palmieri B. Pulsed electromagnetic field therapy for management of osteoarthritis-related pain, stiffness and physical function: Clinical experience in the elderly. *Clin Interv Aging*. 2013;8:1289-1293. doi:10.2147/CIA.S35926
16. Andrade R, Duarte H, Pereira R, et al. Pulsed electromagnetic field therapy effectiveness in low back pain: A systematic review of randomized controlled trials. *Porto Biomed J*. 2016;1(5):156-163. doi:10.1016/j.pbj.2016.09.001
17. Rohde CH, Taylor EM, Alonso A, Ascherman JA, Hardy KL, Pilla AA. Pulsed Electromagnetic Fields Reduce Postoperative Interleukin-1β, Pain, and Inflammation: A Double-Blind, Placebo-Controlled Study in TRAM Flap Breast Reconstruction Patients. *Plast Reconstr Surg*. 2015;135(5):808e-817e. doi:10.1097/PRS.0000000000001152
18. Strauch B, Herman C, Dabb R, Ignarro LJ, Pilla AA. Evidence-Based Use of Pulsed Electromagnetic Field Therapy in Clinical Plastic Surgery. *Aesthetic Surg J*. 2009;29(2):135-143. doi:10.1016/j.asj.2009.02.001
19. Stocchero M, Gobbato L, De Biagi M, Bressan E, Sivolella S. Pulsed electromagnetic fields for postoperative pain: A randomized controlled clinical trial in patients undergoing mandibular third molar extraction. *Oral Surg Oral Med Oral Pathol Oral Radiol*. 2015;119(3):293-300. doi:10.1016/j.oooo.2014.11.017
20. Al-Badawi EA, Mehta N, Forgione AG, Lobo SL, Zawawi KH. Efficacy of pulsed radio frequency energy therapy in temporomandibular joint pain and dysfunction. *Cranio*. 2004;22(1):10-20. doi:10.1179/crn.2004.003
21. Jung JG, Park JH, Kim SC, et al. Effectiveness of pulsed electromagnetic field for pain caused by placement of initial orthodontic wire in female orthodontic patients: A preliminary single-blind randomized clinical trial. *Am J Orthod Dentofac Orthop*. 2017;152(5):582-591. doi:10.1016/j.ajodo.2017.04.022
22. Article O. Low-Level Laser Therapy: A Noninvasive Method of Relieving Postactivation Orthodontic Pain—A Randomized Controlled Clinical Trial. 2019:228-231. doi:10.4103/jpbs.JPBS
23. Bergius M, Kiliaridis S, Berggren U. Pain in orthodontics. A review and discussion of the

literature. *J Orofac Orthop*. 2000;61(2):125-137. doi:10.1007/BF01300354

24. Scheurer PA, Firestone AR, Bürgin WB. Perception of pain as a result of orthodontic treatment with fixed appliances. *Eur J Orthod*. 1996;18(4):349-357. doi:10.1093/ejo/18.4.349
25. Brown DF, Moerenhout RG. The pain experience and psychological adjustment to orthodontic treatment of preadolescents , adolescents , and adults. :349-356.
26. Fernandes LM, Ogaard B, Skoglund L. Pain and discomfort experienced after placement of a conventional or a superelastic NiTi aligning archwire. A randomized clinical trial. *J Orofac Orthop*. 1998;59(6):331-339. doi:10.1007/BF01299769
27. Luppanapornlarp S, Kajii TS, Surarit R, Iida J. Interleukin-1 b levels , pain intensity , and tooth movement using two different magnitudes of continuous orthodontic force. 2010;32(June):596-601. doi:10.1093/ejo/cjp158
28. Theodorou CI, Kuijpers-jagtman AM, Bronkhorst EM, Wagener FADTG. Optimal force magnitude for bodily orthodontic tooth movement with fixed appliances: A systematic review. *Am J Orthod Dentofac Orthop*. 156(5):582-592. doi:10.1016/j.ajodo.2019.05.011
29. Williamson A, Hoggart B. Pain : a review of three commonly used pain rating scales. 2005;1994(Spence 2000):798-804.
30. Eslamian L, Dehghani F, Amraie H. Comparison of Ketoprofen Gum and Ketoprofen Gel for Pain Relief after Activation of Orthodontic Appliances. *J Islam Dent Assoc IRAN*. 2016;28(4):142-148. doi:10.30699/jidai.29.4.142
31. Long H, Wang Y, Jian F, Liao L, Yang X, Lai W. Current advances in orthodontic pain. 2016;(14):1-9. doi:10.1038/ijos.2016.24
32. Bennett JC, McLaughlin RP TJ. *Systemized Orthodontic Treatment Mechanics.* Mosby-Wolfe; 2001.