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Comparison of The Efficiency of Pulsed Electromagnetic Field and Transcutaneous Electric Nerve Stimulation in Reducing Pain During Initial Orthodontic Teeth Alignment: A Single-Blind, Randomized Control Trial

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ABSTRACT

OBJECTIVES: To collate the efficiency of Transcutaneous Electric Nerve Stimulation (TENS) and Pulsed Electromagnetic Field Therapy (PEMF) during the initial phase of the orthodontic treatment in alleviating the pain. **MATERIALS AND METHODS**: The split mouth randomized, prospective, clinical trial was performed in forty-eight patients, at the start of the orthodontic treatment. Randomization was done twice, one for allotment of the type of intervention and second, for selection of the experimental and control side. After placement of initial 0.014 Niti arch wire, Transcutaneous electric nerve stimulation was done by the clinician on the dental chair for patients in TENS group and two nights of pulsed electromagnetic field therapy were prescribed for those in PEMF group. Pain scores were assessed with the Numerical rating scale at 0, 2, 6, 24 and 48 hours. **RESULTS**: Maximum pain was discovered at 6 hours in PEMF experimental group, whereas the TENS group had most pain at 2 hours. The pain scores in TENS and PEMF when compared, were found to be statistically identical at every time interval. **CONCLUSION:** Both TENS and PEMF have been shown to be viable methods for managing orthodontic pain that could be effectively used by the patients with very minimal side effects

KEYWORDS: Orthodontic Pain, Transcutaneous Electric Nerve stimulation, TENS, Pulsed Electromagnetic field, PEMF, Initial alignment

INTRODUCTION

Pain is a highly unpleasant feeling that occurs as a result of noxious stimuli. Fear of discomfort remains the most prevalent reason for not undergoing orthodontic treatment. Various studies have documented that physical discomfort during orthodontic treatment had a detrimental impact on patient's compliance during the treatment and their quality of life. Despite its significant clinical significance, Krukemeyer et al reported that orthodontic pain is largely disregarded and under appreciated along with the number of patients who used analgesics between the appointments.

Various orthodontic procedures starting from the separator placement, placement of initial alignment and levelling wire, headgear or facemask application have all been found to be associated with some amount of pain. Stress on teeth causes an inflammatory response with pain and bone resorption, which is necessary for tooth movement.[1-3] First week immediately after treatment with initial arch wires, the patients are uncomfortable and experience pain due to the force application and it gradually reduces to normal levels in 7 days. So, intervention during this stage prevents treatment discontinuation and enhances patient co-operation.

Different methods have been proposed to relieve orthodontic pain ranging from oral analgesics,[4] plastic wafers,[5] anaesthetic gels, xylitol chewing gums,[6] vibratory stimulation of the periodontal ligament,[7] transcutaneous electric nerve stimulation, Low-level laser therapy[7] and Pulsed electromagnetic field. Although the pharmacological approach is found to be the most effective, Nonsteroidal anti-inflammatory medicines (NSAIDs) disrupt the osteoclastic mechanisms responsible for tooth movement and reduce the efficacy of orthodontic treatment. So, the non-pharmacological methods of pain reduction play an important role in enhancing the treatment.

Among the non-pharmacological methods available, Pulsed electromagnetic field (PEMF) and Transcutaneous Electric Nerve Stimulation (TENS) devices are gaining more importance as they are user-friendly and have minimal side effects. TENS generates an electrical stimulation that is quicker than a pain impulse which reaches the substantia gelatinosa in the dorsal horn, closing the pain gate and reducing pain intensity. Initially, Roth and Thrash devised a nonpharmacological,

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non-invasive TENS technique that used large external sponge-pad electrodes or internal probe electrodes. Although this device was effective in reducing periodontal pain after separator placement, they were relatively large and expensive.[8] Since then, portable and less priced TENS devices have been developed to effectively manage orthodontic pain.

PEMF is a non-invasive treatment that lowers pain and swelling by generating 'short bursts of current' without affecting the body's main physiological functions. PEMF is widely used in the fields of orthopedics and plastic surgery to treat pain, inflammation, and bone repair following surgery.[9-14] PEMF devices have been effectively utilized in dentistry to control pain caused by TMJ dysfunction,[15] as well as post-operative pain management and soft tissue healing following third molar extractions.[16] Only one Randomized clinical trial in the orthodontic literature looked at the efficiency of PEMF after the initial 0.014 NiTi arch wire was placed, and it found PEMF to be useful in lowering discomfort following arch wire placement.[17]

However, no literature is available to compare the efficacy of these two important modalities in reducing orthodontic pain. So this clinical trial aimed to compare the effectiveness of these two non-pharmacological methods in reducing the pain during the initial arch wire placement.

MATERIALS AND METHODS

The study was approved by the Ethical committee of Meenakshi Ammal Dental College (MADC/IRB-XXXI/2019/491). The randomized Prospective Clinical trial was done in a split-mouth design in the Department of Meenakshi Ammal Dental College, Chennai from 2020 to 2022

Patient selection

Patients, ranging in age from 16 to 24, reporting to the department in need of orthodontic treatment were selected. All of the subjects had routine dental exams and had good oral hygiene. Anterior crowding in the lower arch was estimated using vernier calliper (Figure 1) and patients who had moderate to severe (4-9 mm) anterior crowding in the lower arch, according to Little's irregularity index[18] were selected (Table 1). The study protocol was verbally explained and a consent form was obtained from the patients and only those willing were included in the study.

Figure 1: Vernier caliper used to assess crowding in dental cast

Table 1: Little's irregularity index - Scoring

DEGREE OF CROWDING	LITTLE'S INDEX
0 mm	Perfect alignment
1-3 mm	Minimal crowding
4-6 mm	Moderate crowding
7-9 mm	Severe crowding
10mm >	Very severe crowding

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The following were the criteria for inclusion:

- Patients in the age group between 16 to 24 years
- Patients receiving fixed orthodontic treatment
- Patients in the initial stage of orthodontic treatment
- Patients who had good periodontal status
- Patients who had moderate to severe crowding

The following were the criteria for exclusion:

- Presence of local infections or any other dental pain
- Patients under pain or anxiety medications
- Patients with cardiac pacemakers and cardiac arrhythmias
- Patients with systemic diseases
- Epileptic patients

SAMPLE SIZE

G power version 3.1.9.2 of the Sampling programme was used to evaluate the sample size. Effect size (Cohen d) was calculated from the mean difference in the test groups for mean values. The sample size was evaluated to be 24 per group with an alpha (type 1 error) of 5% and power of the study (type 2 error) as 95%

RANDOMIZATION

Sealed envelopes were used for randomization. Randomization was done twice, both for the selection of the device and for the selection of the experimental and control sides.

INTERVENTION

The trial was carried out at the start of the orthodontic treatment with initial arch wire – 0.014 Niti (G4™ Niti Europa™ Form I; G&H Wire Company, Franklin, USA) with 0.022 x 0.028" slot MBT prescription brackets (Mini Diamond™; ORMCO Corporation, California, USA).

TRANSCUTANEOUS ELECTRIC NERVE STIMULATION

The TENS device used in this study is designed by UltraCare PRO (Zealmax Innovations Pvt. Ltd, Gujarat, India).(Figure 2) It is a dual-channel rechargeable TENS unit made for pain relief and had a compact, portable design made for easy operation with four reusable self-adhesive electrode pads to be used, two on each side. The device produced a rhythmic pulse and a maximum current of 10mA with a net neutral charge at a pulse rate of 90hz and a pulse width of 200uS. Patients were informed that they would be testing a pain-relieving gadget that delivered a modest electric current and were also told that the stimulus might be anything from sub-sensory to a little tingle.

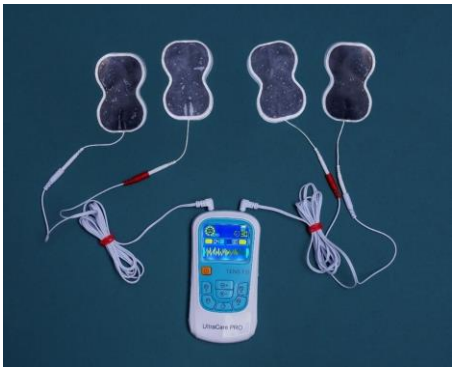

Figure 2: Transcutaneous Electric Nerve Stimulation

Following randomization immediately after the placement of the arch-wire, for those patients who had chosen TENS, two electrodes were placed on the experimental side and two electrodes on the contralateral side.(Figure 3)Electrical impulses were generated only on the experimental side for two intervals of 5 minutes with a 2-minute break in between the two applications.

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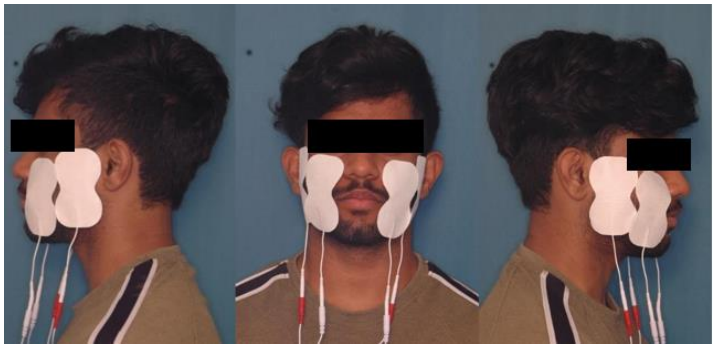

Figure 3: TENS electrodes placed on the cheeks ion device(UltraCarePRO) used in the study

PULSED ELECTRO MAGNETIC FIELD

The PEMF device utilized in the study was ActiPatch™ (Bioelectronics Corporation Ltd, USA). It was a tiny, portable device that weighed about 8 g and had a pulse rate of 1,000 pulses per second with each pulse lasting 100 microseconds. The device (Figure 4) had an antenna that was 12cm in diameter, with a treatment area of 100 sq. cm, a carrier frequency of 27.12 MHz, a 720-hour on/off capacity and a power of 73 microwatts per cm2. The device has an active power unit that generates the electromagnetic waves and a wire loop that transmits these waves over the loop area.

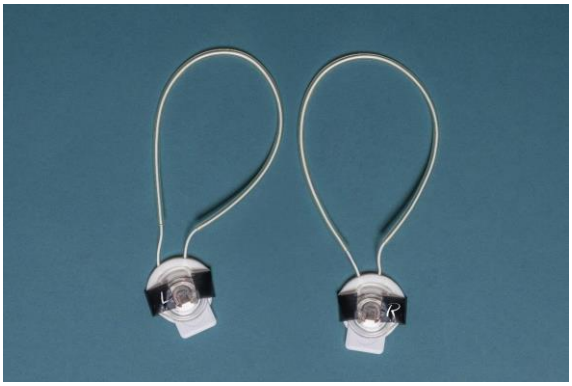

Figure4:Pulsed Electro Magnetic Field device(Actipatch™)used in the study.

The devices were marked as R and L for the right and left sides respectively and after randomization, the control PEMF device was rendered inert by interposing a translucent sheet between the circuit and the battery supply, which served as a placebo. The LED lights on all devices were covered with the same-coloured tape, making it impossible to tell which gadgets were experimental and which were placebo. Patients were requested to wear the device extra orally, bilaterally on the cheeks with bio-adhesive tapes for 8 hours a day for two consecutive days(Figure 5) Patients were shown how to handle and use the gadget and were told to stick to the survey schedules religiously.

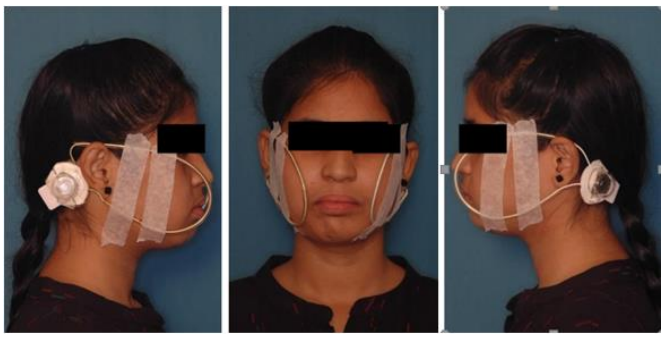

Figure 5: PEMF device placed on the cheeks bilaterally using bio-adhesive tapes

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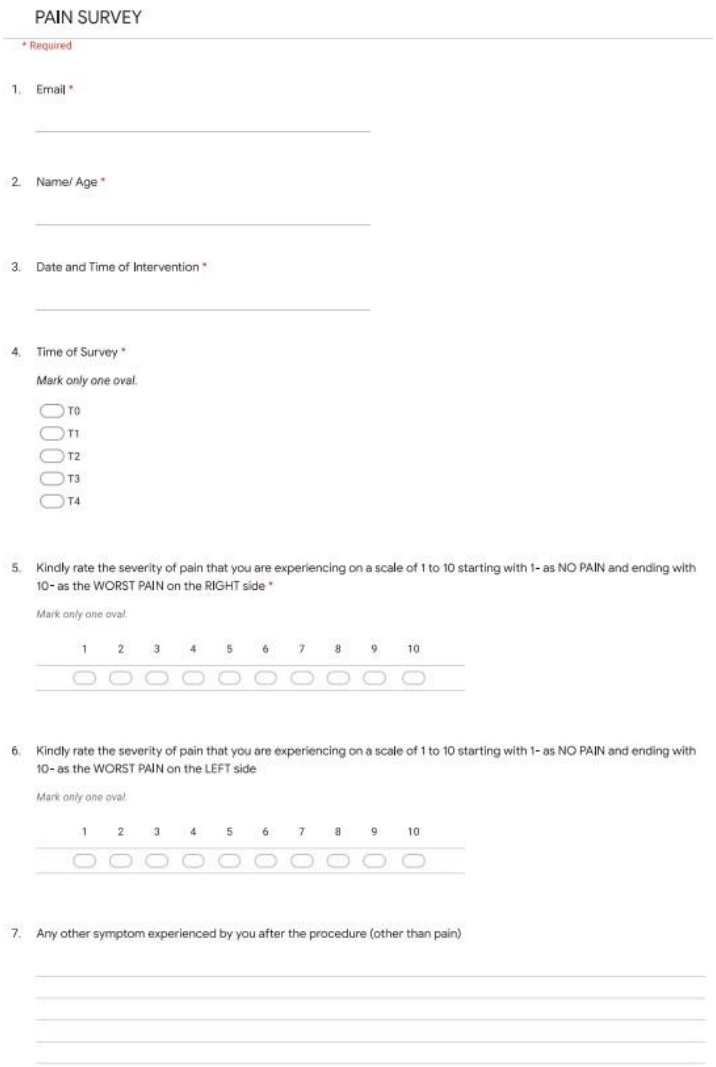
SURVEY

Pain evaluation was done over a period of 48 hours for a total of five times each. The first assessment was made immediately after the arch-wire placement at 0 hours (T0), and then subsequent assessments were made at 2 hours (T1), 6(T2), 24 (T3), and 48 (T4) hours after the first evaluation for both the groups.

Throughout the trial, a Google survey form was established for the goal of collecting data on the patient's pain perception.(Figure 6) To ensure that replies were collected at precise time intervals, the patient was provided a link to the survey form by SMS and Whatsapp. The pain measure utilized was the Numeric Rating Scale, which ranged from 0 to 10, with 0 indicating no pain and 10 indicating the most severe pain possible.


PAIN SURVEY

* Required

1. Email *

2. Name/ Age *

3. Date and Time of Intervention *

4. Time of Survey *

Mark only one oval.

- T0
- T1
- T2
- T3
- T4

5. Kindly rate the severity of pain that you are experiencing on a scale of 1 to 10 starting with 1- as NO PAIN and ending with 10- as the WORST PAIN on the RIGHT side *

Mark only one oval.

1 2 3 4 5 6 7 8 9 10

6. Kindly rate the severity of pain that you are experiencing on a scale of 1 to 10 starting with 1- as NO PAIN and ending with 10- as the WORST PAIN on the LEFT side

Mark only one oval.

1 2 3 4 5 6 7 8 9 10

7. Any other symptom experienced by you after the procedure (other than pain)

Figure 6: Pain survey form used in the study

RESULTS

STATISTICAL ANALYSIS

The data were tabulated in Microsoft Excel 2010 and statistical analysis was performed in statistical package version 4.1.1 (10 - 08- 2021 release) from Core Team (2021): A language and environment for statistical computing' Foundation for Statistical Computing, Vienna, Austria. Descriptive statistics were given by Mean, Standard Deviation, Minimum, Maximum and Mode. Control and Test groups

were compared using Mann Whitney U test (PEMF vs PEMF Control; TENS vs TENS Control). The pain score over five different time periods – T0, T1, T2, T3,

T4 for every group were analyzed by Friedman's repeated measures ANOVA with post hoc Conover test. PEMF and TENS at every time interval were compared using Mann Whitney U test. P value less than 0.05 was considered significant.

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Descriptive Statistics

Table 2. Pain scores in PEMF Experimental Group

	T0	T1	T2	T3	T4
Mean	2.5652	3.3478	3.6087	2.8696	2.4783
SD	1.9265	2.0362	2.0832	1.2175	1.2011
Min	1	1	1	1	1
Max	7	7	7	5	5
Median	2	3	3	3	2
Mode	1	2	2	2	2

Table 2 shows the descriptive statistics of pain scores in the PEMFexperimental group. Maximum pain was found in T2 time interval.

Table 3. Pain Scores in PEMF-Control Group

	T0	T1	T2	T3	T4
Mean	2.5652	3.3478	3.6087	4.0000	4.4348
SD	1.9265	2.0362	2.0832	1.3143	1.5905
Min	1	1	1	2	2
Max	7	7	7	7	7
Median	2	3	3	4	4
Mode	1	2	2	5	4

Table 3 shows the descriptive statistics of pain scores in the PEMFcontrol group. Maximum pain was found in T4 time interval.

Table 4. Pain Scores in TENS Experimental Group

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	T0	T1	T2	T3	T4
Mean	2.5652	3.2609	2.9565	2.2609	1.9130
SD	1.9265	1.6016	1.2961	0.8100	0.9002
Min	1	1	1	1	1
Max	7	7	5	4	4
Median	2	3	3	2	2
Mode	1	2	2	2	2

Table 4 shows the descriptive statistics of pain scores in the TENSexperimental group. Maximum pain was found in T1 time interval.

Table 5. Pain Score in TENS-Control Group

	T0	T1	T2	T3	T4
Mean	2.5652	3.6522	4.1739	3.0870	2.3043
SD	1.9265	1.4957	1.2304	0.9960	0.8221
Min	1	2	2	1	1
Max	7	7	6	5	4
Median	2	3	4	3	2
Mode	1	3	3	4	2

Table 5 shows the descriptive statistics of pain scores in the TENS control group. Maximum pain was found in T2 time interval

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Table 6. Comparison of Groups at every time interval

	P Values of Mann Whitney U Test				
Group	**T0**	**T1**	**T2**	**T3**	**T4**
PEMF vs PEMF Control	1	1	1	0.0057*	0.00009*
TENS vs TENS Control	1	0.2979	0.0043*	0.0056*	0.0801*

The difference between control and PEMF was not significant till T2.However, at times T3 and T4 the groups were significantly different

In the case of TENS vs TENS Control, there was a significantdifference from T2 itself.

Table 7. Statistical Analysis of pain score in every group over thetime intervals – PEMF Experimental

	T 1	**T 2**	**T 3**	**T 4**	**T 5**
Sample size	23	23	23	23	23
Median	2	3	3	3	2
Sum of ranks	54	78.5	84.5	70	58
Mean of the ranks	2.347826	3.413043	3.673913	3.043478	2.521739
χ^2-score	15.485714				
Degree of Freedom (df)	4				
p-value	0.003792916228277				
The result is very Significant at p < 0.05					

Table 8. Post hoc analysis with pairwise comparisons usingConover's test

	T 1	**T 2**	**T 3**	**T 4**	**T 5**
T 1	1	3.86E-08	4.81E-11	1.66E-04	3.28E-01

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T 2	3.86E-08	1	1.44E-01	3.95E-02	2.46E-06
T 3	4.81E-11	1.44E-01	1	5.90E-04	4.35E-09
T 4	1.66E-04	3.95E-02	5.90E-04	1	4.06E-03
T 5	3.28E-01	2.46E-06	4.35E-09	4.06E-03	1

All pairs are statistically significant

Tables 7 & 8 show the statistical Analysis of pain score in every group over the time intervals – PEMF Experimental Group. The groups significantly differed (P=0.003). Further, the difference in pain score between every time interval was significant.

Table 9. Statistical Analysis of pain score in every group over the time intervals – PEMF-Control

	T 1	**T 2**	**T 3**	**T 4**	**T 5**
Sample size	23	23	23	23	23
Median	2	3	3	4	4
Sum of ranks	44	64	68.5	81	87.5
Mean of the ranks	1.913043	2.782609	2.978261	3.521739	3.804348
χ^2-score	23.863517				
Degree of Freedom (df)	4				
p-value	8.51E-05				
The result is very Significant at p < 0.05					

Table 10. Post hoc analysis with pairwise comparisons using Conover's test

	T 1	T 2	T 3	T 4	T 5
T 1	1	2.96E-06	2.55E-08	1.31E-14	0
T 2	2.96E-06	1	2.64E-01	5.39E-05	7.59E-08
T 3	2.55E-08	2.64E-01	1	2.43E-03	8.00E-06

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T 4	1.31E-14	5.39E-05	2.43E-03	1	1.08E-01
T 5	0	7.59E-08	8.00E-06	1.08E-01	1

All values are statistically significant

Tables 9 & 10 show the statistical Analysis of pain score in every group over the time intervals – PEMF control group. The groups significantly differed ($P<0.0001$). Further, the difference in pain score between every time interval was significant.

Table 11. Statistical Analysis of pain score in every group overthe time intervals – TENS Experimental

	T 1	**T 2**	**T 3**	**T 4**	**T 5**
Sample size	23	23	23	23	23
Median	2	3	3	2	2
Sum of ranks	63	91	79	62.5	49.5
Mean of the ranks	2.73913	3.956522	3.434783	2.717391	2.152174
χ^2-score	22.912088				
Degree of Freedom (df)	4				
p-value	0.000131851008993				
The result is very Significant at p < 0.05					

Table 12. Post hoc analysis with pairwise comparisons using Conover's test

	T 1	T 2	T 3	T 4	T 5
T 1	1	2.99E-10	1.06E-04	8.99E-01	9.34E-04
T 2	2.99E-10	1	3.07E-03	1.67E-10	0
T 3	1.06E-04	3.07E-03	1	6.69E-05	5.14E-11
T 4	8.99E-01	1.67E-10	6.69E-05	1	1.40E-03
T 5	9.34E-04	0	5.14E-11	1.40E-03	1

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All values are statistically significant

Tables 11 & 12 show the statistical Analysis of pain score in every group over the time intervals – TENS experimental Group. The groups significantly differed (P=0.0001). Further, the difference in pain score between every time interval was significant

Table 13. Statistical Analysis of pain score in every group overthe time intervals – TENS-Control

	T 1	**T 2**	**T 3**	**T 4**	**T 5**
Sample size	23	23	23	23	23
Median	2	3	4	3	2
Sum of ranks	49.5	84.5	96.5	68	46.5
Mean of the ranks	2.152174	3.673913	4.195652	2.956522	2.021739
χ^2-score	37.964736				
Degree of Freedom (df)	4				
p-value	1.14E-07				
The result is very Significant at p < 0.05					

Table 14. Post hoc analysis with pairwise comparisons using Conover's test

	T 1	T 2	T 3	T 4	T 5
T 1	1	2.22E-15	0	2.07E-06	4.12E-01
T 2	2.22E-15	1	1.41E-03	1.82E-05	0
T 3	0	1.41E-03	1	1.03E-11	0
T 4	2.07E-06	1.82E-05	1.03E-11	1	6.44E-08
T 5	4.12E-01	0	0	6.44E-08	1

All Values are statistically significant

Tables 13 & 14 show the statistical Analysis of pain score in every group over the time intervals – TENS –Control Group. The groups significantly differed (P<0.0001). Further, the difference in pain score between every time interval

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was significant.

Table 15. Statistical Analysis of Comparing PEMF andTENS test groups for every time interval

T0	T1	T2	T3	T4
1	0.839536447	0.400420566	0.108222609	0.088986313

(All values are insignificant)

In table 15, when pain scores in TENS and PEMF were compared, it was observed that pain score at every time interval in TENS and PEMF was statistically similar. It implies that TENS and PEMF are similar in controlling pain.

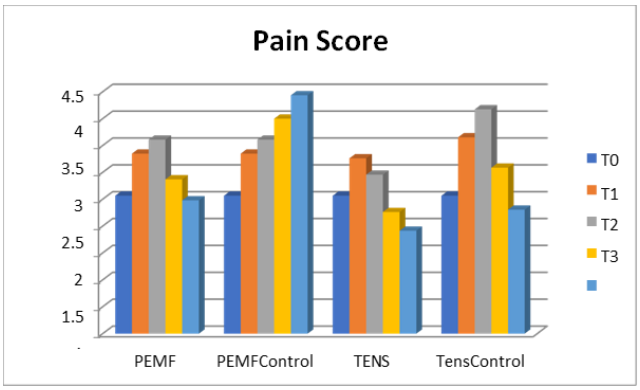

Figure 7: Inferential Statistics

DISCUSSION

Orthodontic pain is a subjective phenomenon and is affected by multitude of factors such as age, gender, pain threshold, and psychological factors. Recent evidence suggests that age and sex have a substantial influence on pain perception from adolescence onwards due to the emergence of differences in pain response especially after puberty. [19] Exclusively female orthodontic patients were studied by Jung et al. and he found that PEMF was effective. As some studies show the influence of age and gender on pain during orthodontic treatment whereas few of them show no gender or age preferences.[20] The absence of consensus is due to the heterogeneity of the population and age of the subjects. Thus, in the current study, both males and females were involved and not separated by gender.

The subjectivity of pain in relation to age has been investigated with mixed results. The effect of aging on pain is not well documented. In orthodontics, Bergius et al found that older patients had higher pain levels, but the relationship was not linear. Hence, the study's age group was limited to 16 to 24 years old to avoid age - related differences. A split- mouth design was utilized in this study to exclude all components relating to subject differences.

During orthodontic treatment, separator placement, arch-wire insertion, activation, elastic wear, application of orthopedic forces, and debonding are some of the procedures that induce pain. Owing to this the patients perceive pain as pressure, tension or tooth discomfort. Thus, pain and discomfort

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during the initial stages of the treatment can consequentially diminish the patient' s co -operation throughout the treatment and might potentially result in early discontinuation. As a result, the emphasis of this research was on pain perception during early tooth movement caused by 0.14" NiTi wire in the aligning and levelling phase.

Several authors have presented the scope and importance of pharmacological management of pain during orthodontic treatment. Various NSAIDs have been studied regarding their efficacy for the above purpose. In addition, the dosage to be used, duration of action of these drugs have also been reported. Ibuprofen, paracetamol, and acetylsalicylic acid have been commonly used. However, it has been reported that NSAIDs are cleared from blood much before the orthodontic movement starts, as these drugs are administered only initially during the therapy. [21] Oscar et al, [22] in their study demonstrated that nonsteroidal anti -inflammatory analgesicslike aspirin and ibuprofen reduce the number of osteoclasts by blocking prostaglandin production, resulting in less orthodontic tooth movement. Pharmacological management with anaesthetic agents likelocal lidocaine/prilocaine were also tried. [20,23]

To overcome the disadvantages of the drug therapy, various non- pharmacological modalities like, chewing gum, [6] plastic bitewafers, [5] vibratory pressures [7] and laser therapy were utilized for management of orthodontic pain. These methods have been studied extensively in the literature and have reported several disadvantages. Chewing gum, plastic wafers and vibration require high amount of patient cooperation. Low-level laser therapy is associated with highercost factor. [7]

PEMF therapy is described as a non-invasive technique that produces short bursts of electrical current in tissues without causing heat or altering key biologic systems, making it beneficial as a supplementary therapy in the treatment of postoperative pain and edema. The common frequency used in clinical practice is 27.12 MHz, and it is described to have no known negative effects. However, in the past, PEMF appliances were not portable and were hence usedonly in a clinical setup. Recently, portable devices are made available thus, the concept of its home–use has emerged. It is reported to be more cost- effective, smaller, wearable, and even disposable. PEMF therapy can now be used to treat postoperative pain and edema not just in the dental office but also at home, providing dentists with a more adaptable pain management option.

PEMF increases blood and lymph flow by increasing nitric oxide release via nitric oxide synthase, which is generated in response to an increased rate of calcium ion binding to calcium-regulated protein. It also inhibits the generation of growth factors and promotes wound healing and tissue repair by acting on the cGMP second messenger. [24] In the literature, it is reported that there was no discomfort, tingling, or heating reported by the patients. [17] As PEMFis an extraoral device which is not esthetically acceptable by patients, they were prescribed for exclusive night time wear.

Another non-pharmacological pain control modality is the use of TENS. It is worthwhile to note that FDA has approved TENS as early as 1972, for pain control. The principle of TENS is as follows: During TENS therapy, pulsed electrical current would be generated and delivered across the intact skin surface, by using electrodes to stimulate superficial nerves for localized pain relief. Since its advent, TENS is frequently used by health professionals for acute and chronic pain management. [25]

TENS generates an electrical stimulus that is faster than a pain impulse that reaches the substantia gelatinosa located at the dorsal horn, closing the pain gate and reducing pain intensity. TENS also causes opiate- like peptides, like endorphins, to be activated. TENS has been used to manage pain in dentistry in several trials. [8]

Thus in this split mouth study the patients were divided into groups and subjected to PEMF and TENS respectively for orthodontic pain management.

In this study, pain scores at five different time intervals were recorded. Among which three of the pain scores – T0, T1 and T2 were taken on the day of the initial strap- up at 0, 2 and 6 hours respectively, after the placement of the arch-wire. T3 was the pain score recorded after 24 hours and T4 was recorded at 48 hours after the first arch-wire placement.

Koritzansky et al [26] in their study on pain and discomfort in orthodontic treatment found that within four hours of initial arch-wire placement, the pain begins, intensifies over a period of 24 hours and subsides in less than seven days which was also evident in the control group of the current study where pain score increased upto T2 and then gradually reduced after 24 hours. Similar findings were reported by Ngan et al and Scheurer et al [27,28]: a considerable rise in pain after24 hours, followed

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by a return to pre-placement levels in 7 days.

Because pain is subjective, there is no gold standard for assessing it. The Numerical rating scale (NRS), verbal rating scale and visual analog scale are three pain-rating scales that are routinely used for pain evaluation. For pain studies, Hoggart [29] found that Verbal rating scale or Visual analog scale are not as effective as Numerical rating scale. Since the visual analog scale was not available on google survey the patients were requested to fill in the survey using the Numerical Rating scale (NRS) in google surveyforms. This helped in assessing the pain scores and patients were duly reminded before each recording.

In the PEMF group, the findings showed that no significant difference was evident at the time intervals T1 and T2 between the experimental and control group and at 24 hours (T3), and 48 hours (T4) after the initial orthodontic wire was inserted, so PEMF devices demonstrated a considerable potential to reduce orthodontic discomfort after 24 hours, which concurred with the findings of the study by Jung et al in 2007[17]. In PEMF experimental group, maximum reduction was seen in T3 time interval which was also similar to the observation by Niezgoda et al.[13]

In the TENS experimental group, at T1 (2 hours) there was no significant reduction in pain, which was similar to the findings by Roth. [8] Desai et al, [30] conducted a study to assess and compare the effects of TENS treatment and piroxicam on the amount of discomfort caused by orthodontic separator installation and have evaluated the pain score at 2 hours, 6 hours, 24 hours, and 48 hours after the separator was installed. The pain reported by patients in the piroxicam group grew steadily from 2 to 48 hours, but the pain in the TENS group was dramatically decreased starting a t 6 hours. Similar to this study, the findings in the present study showed that TENS was effective in reducing the pain from T2 (6 hours) following the initial arch-wire placement.

At the end of T4, (48 hours) TENS device was found consistently effective in comparison to the control group. This finding correlated with the findings of Roth et al, [8] who found that a single application of TENS was proven to be as effective as two or three TENS treatments in decreasing pain for more than 48 hours. Melzack[31] has also proved that a single TENS application can provide long-lasting analgesia. Johnson et al[32] suggest patients should take

breaks from treatment and alter the positioning of electrode pads over time for effective usage. So, in this clinical trial, TENS device application was done for two 5 - minute periods with a 2 - minute rest between each session, on the same day of initial arch-wire activation.

In PEMF and TENS test groups, maximum pain reduction was seen in the T3 (P=0.005) and T2 (P=0.004) intervals respectively. This was to be expected because the time of intervention with TENSis on the dental chair, immediately following arch-wire placement and was effective with only 10 minutes of active usage, while PEMF application can only be done at night on the day of initial arch-wire placement. This means that TENS was more effective than PEMF in reducing the severity of pain immediately after the arch-wire placement. Further research is needed to maximize the efficiency of PEMF with only a short effective application time making it viablefor use at chairside or to be designed more aesthetically for normal day-to-day usage.

Every group was analyzed for statistical difference in pain scale over the time intervals using Friedman's repeated measuresANOVA, the difference was found to be statistically significant in both PEMF and TENS experimental groups. The shape of the pain change curve showed a gradual decline change between the control and the experimental group as the pain scores showed reduction in the control group only at T3 and T4. Whereas the apex of the curve was advanced in both intervention group.

No previous literature is available that compares the efficiency of these two modalities in reducing orthodontic pain. When PEMF and TENS were compared in this study, they were all statistically similar, implying that both treatments were equally efficient in reducing the pain score caused due to orthodontic therapy.

While NSAIDs and non- pharmacological means of pain control are compared, NSAIDs may still offer better efficacy. However, the adverse effects of NSAIDs along with the safety margin concerns, point the attention to non-pharmacological means. TENS and PEMF treatments have significantly more benefits than drawbacks since they are non-invasive, safe, and effective, which leads to better patient acceptance. So, with respect to the results of the study, we can say that both PEMF and TENS offer similar pain control.

However, the major limitation of this study is that the method and duration of application of both the devices were different. PEMFis designed for use over a longer period to be effective, while TENSis only applied for a short duration of about 5 minutes. Also, since the TENS application is done by the clinician on the chair, there is a lesser chance of incorrect device usage with the TENS, as opposed to PEMF where patient compliance is paramount. Additionally, this clinical trial only took into account the non-extraction cases and further studies could be conducted to include extraction cases and also compare the pain scores between extraction and non - extraction cases. Furthermore, age and gender-specific studies could also beconducted at different stages and phases of orthodontic treatment. In addition, pain is a subjective phenomenon and the threshold to pain drastically varies between different patients. So, further research is needed to better standardize all the possible variables to more reliably and accurately evaluate and compare the efficiency of these two devices in relieving orthodontic pain.

CONCLUSION

Within the limitations of the study following conclusions were made:

1. The pain experienced during the initial 48 hours after placement of conventional 0.016/0.014 Ni-Ti arch-wire during initial alignment and levelling after intervention with Pulsed electromagnetic field using a Numerical rating scale was mildly reduced compared to control.

2. The pain experienced during the initial 48 hours after placement of conventional 0.016/0.014 Ni-Ti arch-wire during initial alignment and levelling after intervention with Transcutaneous electric nerve stimulation using a Numerical rating scale was much reduced compared to the control.

On comparing the efficiency of Pulsed electromagnetic field and Transcutaneous electric nerve stimulation in reducing pain during initial teeth alignment, it was found that both the techniques were equally efficacious and the difference was statistically insignificant.

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