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Original Article

Evaluation of the Effects of TENS Therapy and Acetaminophen on Pain Alleviation in Initial Orthodontic Treatment

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Main Points

- Pain associated with initial archwire alignment during orthodontic treatment can be managed with Transcutaneous Electric Nerve Stimulation (TENS) therapy.
- Both acetaminophen and TENS equally relieve pain in fixed orthodontic treatment.
- Repeated application of TENS can improve pain management better than acetaminophen.

ABSTRACT

Objective: This prospective study aimed to evaluate the analgesic effects of acetaminophen and Transcutaneous Electric Nerve Stimulation (TENS) therapy for pain control.

Methods: Forty orthodontic patients who underwent fixed orthodontic treatment were randomly assigned to one of 3 groups: (1) acetaminophen, (2) TENS therapy, or (3) control. Pain was evaluated at 12, 24, 36, and 48 hours after the placement of both 0.014" NiTi and 0.016" NiTi archwires using a 10 cm visual analogue scale (VAS). Because the data were found to be non-normal, Kruskal-Wallis test was employed for both stage I and stage II intra-group comparisons.

Results: For both stage I and stage II, evaluation of the VAS scores for all 3 groups at different time intervals showed that the difference between groups A and B was statistically insignificant ($p>0.05$). The scores of Group A compared to Group C were significant, and Group B compared to Group C showed significant values.

Conclusion: Both TENS and acetaminophen reduced the pain experienced by patients compared with the placebo group. The acetaminophen group showed VAS results similar to those of the TENS group.

Keywords: Acetaminophen, orthodontic, pain, transcutaneous electric nerve stimulation, visual analogue scale

INTRODUCTION

The most commonly reported sequelae of orthodontic treatment that affect quality of life are pain and discomfort. Several studies have found that the pain associated with an initial aligning archwire is perceived after 4 hours, is significantly more intense at the 24th hour, and later decreases by the 3rd day, lasting approximately 5 days.[1-6]

To overcome the post-adjustment pain and discomfort associated with the initial alignment of archwires and separator placements, many authors have suggested various modalities. Chumbley and Tuncay[7], in their study, used pharmacologic means of analgesia, such as indomethacin, a non-steroidal anti-inflammatory drug

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(NSAID), to reduce discomfort and pain after orthodontic adjustment. They concluded that indomethacin was effective in reducing pain; however, it had a detrimental effect on the rate of orthodontic tooth movement. Kehoe et al.[8] investigated the deleterious effect of NSAIDs on the rate of orthodontic tooth movement and recommended acetaminophen as the analgesic of choice during orthodontic treatment.

Further, it was found that Transcutaneous Electric Nerve Stimulation (TENS), a non-invasive, non-pharmacological therapy, has been reported to be efficient for pain alleviation during separator placement and debonding procedures.[9,10]

Prolonged analgesia induced by TENS is attributed to the secretion of endogenous opioids. Endorphins have long-lasting effects on the central nervous system; thus, TENS-produced analgesia persists for hours even after the cessation of electrical stimulation. The secreted opioids produce analgesia at peripheral, spinal, and supraspinal sites. Other neurochemicals have also been found to be responsible for producing TENS-induces analgesia, including GABA, acetylcholine, 5-HT, noradrenaline, and adenosine.[11] Maximum analgesia is produced when TENS generates a strong, non-noxious electrical sensation beneath the electrodes. The onset of pain relief is rapid and disappears shortly after TENS is turned off.[11]

In clinical practice, TENS therapy is mostly used to relieve pain. In addition, there is an increasing use of TENS in other spheres of medicine like antiemetics and for restoration of blood flow to ischemic tissue and wounds.[12] However, limited research is available on the role of TENS in orthodontic patients. Hence, the present study aimed to evaluate and compare the analgesic effects of acetaminophen and TENS therapy for the control of pain during orthodontic treatment.

METHODS

The present study received ethical clearance from the Institutional Review Board of Santosh Deemed to be University (F. No. SU/2019/1531[15], date: 22.10.2019). The study was conducted at the Department of Orthodontics and Dentofacial Orthopedics, Santosh Dental College and Hospital. The subjects included in the study were patients undergoing non-extraction fixed orthodontic treatment between the ages of 13 and 35 years. Both male and female patients with permanent dentition and good oral hygiene were included.

Patients with crowding greater than 2 mm, pacemakers, patients with a known history of allergy to acetaminophen, epileptic patients, cerebrovascular problems, cleft lip, cleft palate, or both, and patients who did not provide consent for the study were excluded from the study.

The sample size was calculated using the G*Power 3.1 software (Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany). The power of the study was considered to be 80% with a confidence interval of 95%. A total sample size of 40 patients was selected based on an old study on the effect of TENS on controlling pain associated with tooth movement.[9] Forty patients were divided into three groups randomly using an online number list generator:

Group A (n=10): Patients in Group A received TENS therapy.

Group B (n=10): Patients in this group were given acetaminophen tablets.

Group C (n=20): Patients in this group did not receive either of the following treatments: this was the control group.

All patients were pre-examined using the standard protocol, which included facial and intraoral photographs, dental modal analysis, panoramic radiography, and cephalometric analysis.

Patients were enrolled according to the inclusion criteria, and all were treated with a 0.022" slot prescription pre-adjusted edgewise appliance system. Initial leveling and alignment of the upper and lower arches were performed using sequential NiTi wires, with the diameters of the wires progressively increased from 0.014" NiTi to 0.016" NiTi. After placement of the wires, Group A received TENS therapy for 20 minutes at 0.5 Hz and 500 microamperes (Figures 1 and 2). In Group B, patients were administered 500 mg of acetaminophen. Patients were asked to take their first dose 2 hours before the appointment and continue taking it orally every 6 hours for 48 hours. Group C was the control group, which was given nothing for pain management. Patients were asked to mark their pain level using the visual analogue scale (VAS)[13] at four intervals of 12 hours for a total period of 48 hours. Patients in the TENS and control groups were asked to take the tablet with a combination of paracetamol (325 mg) and ibuprofen (400 mg) as rescue medicine in case of unbearable pain. Patients were asked to record the number of tablets they consumed. Patients who required rescue medicines were excluded from the study.

Scoring System for Pain and Discomfort

Pain and discomfort were measured during the first two days after the placement of the aligning archwire. Scores were assessed using the VAS[13] scale of 10 cm in length. Marks were made at 1-cm intervals from 0 to 10.0 on the scale. 0, no pain, and 10, unbearable pain. The score can be interpreted as follows:

Score 0: No pain.

Score 1-3: Mild pain.

Score 4-6: Moderate pain.

Score 7-10: Severe pain.

Statistical Analysis

All data were entered into an Excel spreadsheet (version 2007) and then imported into SPSS (Statistical Package for Social Sciences, version 23.0, IBM, NY, USA). After applying the Kolmogorov-Smirnov test, the data showed a non-normal

distribution, so they were expressed as median ± interquartile range. The Kruskal-Wallis test was employed at both stage I and stage II for inter-group comparisons. A two-tailed p-value <0.05 was considered significant. The reliability of the study was calculated as 0.736 using Cronbach's alpha.

RESULTS

The mean ages of the participants in groups A, B, and group C were around 20.10±4.654, 19.60±4.858, and 20.80±5.126 years, respectively (Table 1). Upon examination, the median VAS scores in stage I (0.014" NiTi) for group A were 2.5±1.0, 3.5±1.0, 4.0±1.0, and 3.0±1.0 at 12, 24, 36, and 48 hours, respectively.

Figure 1. Transcutaneous electrical nerve stimulation machine with surface electrodes

Figure 2. Patient receiving TENS therapy demonstrating electrode placement on the left side

The median VAS scores for group B were 2.0±1.0, 4.0±1.0, 3.0±1.0, and 3.0±1.0 at 12, 24, 36, and 48 hours, respectively. On the other hand, the median VAS scores for group C were 7.0±1.0, 7.0±1.5, 6.0±1.0, and 5.0±1.0 at 12, 24, 36, and 48 hours, respectively. All readings were found to be highly significant (Table 2).

In stage II (0.016" NiTi), the median VAS scores for group A were 2.0±1.0, 3.0±1.0, 3.0±1.0, and 3.0±0.0 at 12, 24, 36, and 48 hours, respectively. The median VAS scores for group B were 3.0±1.0, 3.5±1.0, 3.0±0.0, and 2.0±1.0 at 12, 24, 36, and 48 hours, respectively. On the other hand, the median VAS scores for group C were 6.0±1.5, 6.0± 1.0, 5.0±1.0, and 5.0±1.0 at 12, 24, 36, and 48 hours, respectively. All readings were found to be highly significant (Table 3).

In stage I, when the VAS scores for all three groups were compared at different time intervals, the scores of Group A and Group B were comparable, and the difference between the two was statistically insignificant (p>0.05, Kruskal-Wallis test). The scores of Group A compared to Group C were highly significant for 12 and 24 hours and significant for 48 hours. The VAS scores of Group B compared to Group C showed highly significant values for all time intervals (Table 4).

Similar results were observed in stage II. The scores of groups A and B were comparable, and the difference between the two was statistically insignificant (p>0.05, Kruskal-Wallis test). The scores of Group A compared to Group C and Group B compared to Group C showed highly significant values (Table 5).

DISCUSSION

In any dental treatment, including orthodontics, besides a positive treatment outcome, the most important aspect of the treatment is the management or elimination of pain, which can often be experienced by patients. In Orthodontics, tooth pain is often experienced by patients. Oliver and Knapman[12] surveyed two centers to investigate the attitudes of patients and parents undergoing orthodontic therapy. The results revealed that both patients and parents were happy with the treatment outcome. However, pain related to the appliance and its appearance was the main discouraging factor.[1]

Pain is experienced by patients during nearly all phases of orthodontic treatment. One of the first experiences of pain

Table 1. Age distribution in all 3 groups

Group	Number of participants	Mean age (Years)	95% Confidence interval for mean	
			Lower bound	Upper bound
A (TENS)	10	20.10±4.654	16.77	23.43
B (Acetaminophen)	10	19.60±4.858	16.12	23.08
C (Control)	20	20.80±5.126	18.40	23.20
Total	40	20.33±4.848	18.77	21.88

and discomfort occurs immediately after the insertion of the initial aligning archwire. Erdinç and Dinçer[3] found that pain and discomfort after the insertion of initial aligning archwire during orthodontic treatment was first perceived at the 4th hour. The discomfort then increased significantly by 24 hours. The study also found that the discomfort decreased to a more bearable degree by the 3rd day.[3] Under pharmacological modalities, many analgesics, such as ibuprofen, naloxone, ketorolac, and acetaminophen, are effective for orthodontic pain control.[14] Although analgesics have been found to reduce pain and discomfort, in most cases they do not fully eliminate it. To overcome this issue, higher doses of medications have been administered, but as a result, many clinicians observed a delay in the orthodontic treatment time. NSAIDs control pain by inhibiting cyclooxygenase activity and thus retarding the production of prostaglandins.[15-17] This characterizes the involvement of prostaglandins in orthodontic tooth movement. Chumbley and Tuncay[7] conducted a study on indomethacin, an aspirin-like drug, and a potent inhibitor of PG synthesis. The study found that indomethacin delayed orthodontic tooth movement, and the authors recommended that aspirin-like drugs should not be administered to patients undergoing orthodontic tooth movement as they may extend the treatment time.[7] Kehoe et al.[8] studied the effect of acetaminophen, ibuprofen, and misoprostol on prostaglandin synthesis and orthodontic tooth movement. The study reported a significant difference in mean tooth separation among the drugs. The acetaminophen group showed the least effect on the rate of tooth movement. Thus, the authors recommended acetaminophen as the analgesic of choice during orthodontic treatment.[8] It is also believed to have fewer and rare side effects like nausea, and rashes, compared to other NSAIDs. In isolated antipyretic doses, acetaminophen is safe and well-tolerated.[18]

Although pharmacological methods are convenient and easy to use, the biggest drawbacks of these methods are allergic reactions observed in patients and side effects caused by prolonged use of the medication. It is for this reason that non-pharmacological pain control methods have piqued the interest of many clinicians and patients alike.

Recently, major developments have been observed in the understanding of pain mechanisms and new approaches to the management of pain. Various methods have been developed over the years like low-level laser therapy, vibratory devices, and transcutaneous electrical nerve stimulation (TENS). One study measured pain levels over 7 days and concluded that TENS was effective in reducing pain associated with separator placement. It is also worth noting that a single application of TENS produced a satisfactory analgesic effect for the entire duration of the study.[9]

In the present study, it was planned to evaluate the effect of TENS therapy to control pain associated with initial aligning archwire insertion and further compare the effect of this non-pharmacological TENS therapy with that in subjects who were on pharmacological therapy, such as acetaminophen, to control pain associated with the insertion of the initial aligning archwire during the initial phase of orthodontic treatment. A VAS was used to evaluate the pain experienced by the patients. The VAS scale was preferred over other scales because of its simplicity; it is more understandable and easier to use by patients. The scale does not include any words; thus, it is independent of language. The VAS was found to be the most reliable method for pain assessment.[13]

Table 2. Median VAS values recorded in stage 1 (0.014" NiTi wire) in all 3 groups at different time intervals

Group	Group A (TENS)		Group B (Acetaminophen)		Group C (Control)		p-value
	Median	Interquartile range	Median	Interquartile range	Median	Interquartile range	
Time							
12 hours	2.5	1	2	1	7	1	0.00*
24 hours	3.5	1	4	1	7	1.5	0.00*
36 hours	4.0	2	3	1	6	1	0.00*
48 hours	3	1	3	1	5	1	0.00*

VAS, visual analogue scale, *p<0.05

Table 3. Median VAS values recorded in stage 2 (0.016" NiTi wire) in all 3 groups at different time intervals

Group	Group A (TENS)		B (Acetaminophen)		Group C (Control)		p-value
	Median	Interquartile range	Median	Interquartile range	Median	Interquartile range	
Time							
12 hours	2	1	3	1	6	1.5	0.00*
24 hours	3	1	3.5	1	6	1	0.00*
36 hours	3	1	3	0	5	1	0.00*
48 hours	3	0	2	1	5	1	0.00*

VAS, visual analogue scale, Kruskal-Wallis test, *p<0.05

Table 4. Difference between VAS values recorded in stage 1 (0.014" NiTi wire) in all 3 groups at different time intervals

Time interval	Group		p-value
12 hours	A	B	1.000
	A	C	0.000*
	B	C	0.000*
24 hours	A	B	1.000
	A	C	0.000*
	B	C	0.000*
36 hours	A	B	0.759
	A	C	0.016
	B	C	0.000*
48 hours	A	B	0.759
	A	C	0.001*
	B	C	0.000*

VAS, visual analogue scale, Kruskal-Wallis test, *p<0.05

Table 5. Difference between VAS values recorded in stage 2 (0.016" NiTi wire) in all 3 Groups at different time intervals

Time interval	Group		p-value
12 hours	A	B	1.000
	A	C	0.000*
	B	C	0.000*
24 hours	A	B	0.988
	A	C	0.000*
	B	C	0.000*
36 hours	A	B	0.988
	A	C	0.000*
	B	C	0.000*
48 hours	A	B	0.055
	A	C	0.000*
	B	C	0.000*

VAS, visual analogue scale, Kruskal-Wallis test, *p<0.05

Our study found that all 20 subjects in the control group who had not undergone any pain therapy experienced different intensities of pain at each time interval. Most patients experienced pain by the 12th hour after the insertion of the initial aligning archwire. Later, most subjects in the control group experienced peak pain at 24 hours. By the 2nd day, many subjects experienced moderate pain, which gradually reduced by the 3rd day after the initial alignment of the archwire. These findings are consistent with those of other studies.[2-5]

In the present study, patients receiving TENS therapy experienced significant reduction in pain from the 4th hour to the 4th day. This finding could be attributed to TENS therapy. The subjects in the acetaminophen group also showed consistently decreased pain scores at 12, 24, 36, and 48 hours after archwire placement compared with the control group. The data obtained align with the findings from a study comparing the effects of three drugs: ibuprofen, misoprostol, and acetaminophen, which concluded that acetaminophen was the drug of choice for controlling orthodontic pain.[8]

Further, acetaminophen is believed to have fewer side effects such as nausea and rashes which are rare. In isolated antipyretic doses, acetaminophen is safe and well-tolerated.[18] Finally, the main aim of this study was to compare the effects of TENS and acetaminophen. In the present study comparing the TENS and acetaminophen groups, the results showed that both acetaminophen and TENS were equally effective in reducing pain in patients undergoing orthodontic therapy.

It is worth noting that although TENS and acetaminophen were effective in reducing pain, the TENS therapy group experienced slightly more discomfort than the acetaminophen group after 24 hours. Furthermore, in the TENS group, the initial onset of analgesic effect at 12 hours was comparatively greater, the duration of pain reduction was very effective, and the mean pain scores at 24 hours were highly reduced; however, this did not occur after 24 hours. To better control pain, repeated TENS sessions can be administered on the second day; however, it requires an additional dental visit, and thus, it might be inconvenient for patients.

In the present study, we found that TENS therapy and acetaminophen were extremely effective in controlling pain and providing relief to patients during the initial phase of orthodontic treatment.

Study Limitations

The limitations of the study include the fact that blinding was not possible because of the obvious differences between the study groups. The study did not take into consideration the level of anxiety and fear of pain experienced by the participants after bonding. In addition, when investigating outcomes that are self-reported by patients, subjectivity always has the opportunity to creep in, and these obvious limitations inherently affect reliability. Further studies with larger sample sizes are recommended to compare both systems in detail. Studies have also correlated the variation of pain with age and diurnal variation of pain.

CONCLUSION

The following conclusions can be drawn from this study:

- TENS therapy can effectively control pain associated with initial archwire alignment during orthodontic treatment.
- TENS is as effective in controlling pain as acetaminophen.

Ethics

Ethics Committee Approval: The present study received ethical clearance from Institutional Review Board of Santosh Deemed to be University (F. No. SU/2019/1531[15], date: 22.10.2019).

Informed Consent: Informed consent was obtained from the patients.

Author Contributions: Concept - K.S.; Design - K.S.; Supervision - R.A., S.G., T.C.; Fundings - K.S.; Materials - K.S.; Data Collection and/or Processing - K.S.; Analysis and/or Interpretation - K.S.; Literature Review - K.S.; Writing - K.S.; Critical Review - R.A., S.G., T.C.

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