ASSESSMENT OF PAIN CONTROL DURING SEPARATORS PLACEMENT USING TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION DEVICE (TENS) : A SPLIT – MOUTH STUDY (Research Article)

[1] Dr.K.Sai Sruthi,[2] Dr.P. Bravin Paul,[3] Dr.M.M. Varadharaja
[1][2]Department of Orthodontics and Dentofacial Orthopedics, CSI College Of Dental Sciences and Research, Madurai
[3] Professor & Head, Department of Orthodontics and Dentofacial Orthopedics

ABSTRACT

AIM : To assess the level of pain control achieved using transcutaneous electric nerve stimulation device (TENS) during orthodontic elastomeric separator placement.
Methods : Ninety subjects were randomly assigned to three groups, the first group received low-frequency TENS and placebo, the second group received high-frequency TENS and placebo, the third group received high- and low-frequency TENS respectively. In each group, elastomeric separators were placed mesial and distal to the maxillary first molar in both the quadrants. A scientific medical system TENS was used to deliver the electric current. A visual analogue scale (VAS) was used to evaluate the pain.
Result : There was a statistically significant difference correlation between TENS group and control group. No statistically significant results between high and low frequency TENS group. **Conclusion:** The present study suggests that orthodontic separator pain can be effectively reduced by TENS, either at high frequency or at low frequency.
KEY WORDS: Pain, Transcutaneous electrical nerve stimulation, Separators, Visual analog scale

INTRODUCTION

The International Association of the Study of Pain has defined pain as “an unpleasant sensory and emotional experience with actual or potential tissue damage or described in terms of such damage [1]. Pain is a subjective response, has large individual variations, and depends on factors such as age, gender, individual pain threshold, present emotional state and stress, cultural differences, and previous pain experiences. In orthodontics, patients experience pain as a result of separator placement, insertion of aligning archwires, headgear wear, retraction, and rapid palatal expansion of which separators placement has been documented to have increased pain response.

Orthodontic tooth movement requires force application to the tooth which generally causes pain. There are reports that one of the discouraging factors for seeking orthodontic treatment is the individual’s fear for the related pain and discomfort [2]. Several methods have been non pharmacological means like TENS, LLLT, Bite wafers, etc.

One such widely used noninvasive pain control technique is transcutaneous electrical nerve stimulation (TENS). TENS is one of the most inexpensive and safest procedures that are used to control both acute and chronic pain[3,11]. A form of stimulation-produced analgesia, TENS is delivered via surface electrodes placed over the painful area or within the nerve innervating the painful area’s distribution. It has been reported that the initial tooth movement caused by using orthodontic separators

causes pain and immediately releases the biochemical mediator substances into the gingival fluid [4]. Giannopoulou et al study revealed that there is a marked increase in the prostaglandin E2 levels to the initial intensity of the pain, and the increase in interleukin (IL)-1 to the intensity of pain 1 day later. Lim et al reported that 90% of patients undergoing orthodontic treatment complained of pain, and that 30% had considered the possibility of prematurely terminating the treatment because of the painful experiences [5]. Therefore, the objective of this study was to assess the level of pain control using transcutaneous electric nerve stimulation device during orthodontic separators placement.

MATERIAL AND METHODS

This was a double-blinded, placebo-controlled, split- mouth study. The related research protocol was approved by the institutional review board (CSICDSR/IEC/0128#). The informed consents were signed by all patients before beginning of the treatment.

The following inclusion criteria were observed: (1) age >15 years, (2) presence of erupted permanent first and second lower molars, (3) presence of erupted first and second premolars, The exclusion criteria were having pre-existing pain conditions, History of epilepsy, cardiac pacemakers, cardiovascular problems, subject unable to comply with the restriction on using any analgesic drugs, Parafunctional habits, pregnant women, presence of one or more diastema in the region of the molars and/or premolars.
Patients who had opted to not participate in the study received the standard recommended treatment. A total of 90 patients were included in this study, age 15-35 yrs reporting to the department of orthodontics at CSI Dental college, Madurai for the fixed orthodontic treatment. Subjects (n = 90) were randomly and equally assigned to the following groups using the random sampling method:

GROUP A :

Patients receiving low-frequency TENS in one quadrant and placebo in the other quadrant

GROUP B :

Patients receiving high-frequency TENS in one quadrant and placebo in the other quadrant

GROUP C :

Patients receiving low-frequency TENS in one quadrant and high-frequency TENS in the other quadrant.

For all the patients in groups A, B, and C, elastomeric separators (3M Unitek) were placed manually. The separators were placed on the mesial and distal sides of the first permanent molars on the left and right sides (FIG.1). The portable TENS device used in this study is the scientific medical system, Physio-Multi TENS STIMULATOR –Dual Channel (FIG.2). was designed for one-button operation, with one output for a safe and stable range of stimulation. This device is a dual-channel output i.e two pairs of electrodes can be used simultaneously. The patient as well as the first operator were blinded as a second operator operated the TENS device.

After placing the separators, TENS were given in the upper arch with two probes, it had equal appearance, shape, size, and weight. The current was applied directly to the teeth by placing one pen electrode (FIG.3)on the crown of each tooth and the other electrode on the palatal mucosa adjacent to the tooth. TENS unit consists of an AC adapter, pen electrodes, and lead wires(FIG.2). Gauze or cotton is soaked in Normal Saline and wrapped on the pen electrodes before placing it on the tooth, it provides better conductivity of electric current over teeth. The intervention group received the TENS and the duration of application in one quadrant in the upper arch for 10 secs and teeth exposed to TENS are – 2nd premolar, 1st molar, 2nd molar. The TENS unit was set to a current frequency of 2 Hz with an intensity of 6 mA in the low-frequency TENS group, and 120 Hz with an intensity of 6 mA in the high-frequency TENS group. The electric current produces a tingling non-painful sensation at the TENS given site. The other quadrant in the same arch receives the placebo by just placing the probes without the electric current for the same period which is 10secs.
A questionnaire along with VAS(Visual Analogue Scale) (FIG.4) was used to assess the pain control. It consists of pictures with a description of “no pain” on the left side and “severe pain” on the right side of the scale[6]. It is a direct pain scaling method in which patients are advised to fill the form which is scoring, about the present condition of pain intensity after the placement of the separator. The VAS was given for

both the quadrants in the questionnaire form. The advantages of using the VAS over observational, the higher sensitivity, reproducibility, self-report, behavioral, physiological, or verbal rating scales, and reliability of direct scaling technique[7,8]. The intensity of pain was reported by the patients 1hr, 24hrs(1day), and 48hrs(2days) after orthodontic separator placement.

STATISTICAL ANALYSIS

Statistical analysis was performed using the STATA 16.1 statistical software (StataCorp., college station, Texas) with a 5% level of significance. Shapiro-Wilk's test was performed to check the normality of the distribution. As the distribution of the variables assessed was found to be skewed, non-parametric tests were performed to test the level of significance. Intra-group & Inter-group comparison was done using Dunn's post hoc analysis after testing the overall significance with the Kruskal Wallis test.

RESULTS

Subjects receiving low frequency as well as high-frequency TENS reported statistically highly significant differences in VAS scores compared to the placebo group both immediately and after 1 hour ($p<0.001$) (Table 1). There was a statistically significant difference in VAS scores for subjects receiving low frequency ($p=0.0426$) as well as high-frequency TENS ($p=0.0434$) in comparison with the control group after 24 hours (Table 1). There was no statistically significant difference in VAS scores for subjects receiving low frequency as well as high-frequency TENS in comparison with the control group after 48 hours (Table 1). But no statistically significant difference was found between the high and low-frequency TENS group (Table1). The intragroup comparison showed that there was no significant difference in VAS scores after 48 hours (Table 2).

DISCUSSION

Orthodontics is currently undergoing consistent advances, regarding tooth movement control. However, the experience of pain still constitutes a constant concern for the clinician, as it is recognized that such experience can influence patients' decisions and reduce the acceptability of orthodontic treatment. The first application of TENS in dentistry was for myofascial pain dysfunction(MPDS) given by Denholtz M. [10]. Roth & Thrash evaluated the orthodontic separator pain by applying TENS and concluded that it is one of the best non-pharmacological methods to control the pain [9]. Weiss and Carver found that TENS reduces the pain associated with orthodontic procedures like debonding and they further suggested that it can be used during incisor recontouring procedures and proximal stripping [14].

Per Hansson & Anders Ekblom studied the effect of high frequency, low frequency & placebo TENS on acute oro-facial pain in a controlled experimental design [12].

TENS produces short and low amplitude electrical impulses that travel between two electrodes placed on the tooth. The signal from the electrical stimulation of beta fibers reaches the central nervous system before the signals from the slower A and C fibers. Thus, the beta impulse blocks or "closes the gate" to the pain impulses. The electric impulse also stimulates the production of a local analgesic (beta-endorphin) and/ or substance "P" in the Nerve cells and serotonin in the brain, raising the patient's pain tolerance [13].

Kvam et al study shows that females reported more pain/discomfort than males[15]. But in this study, there was no statistically significant difference between genders in the pain responses. Fernandes et al [16], Bondemark et al [17] studies also found that there were no significant results from gender differences in pain control.

In this study, we have used a Split-mouth design, because it removes the inter-subject variability and increases the power of the study compared to the whole-mouth design. The present study shows that significant differences were found between the TENS and placebo groups, such that the TENS group presented lower means of pain scores over the almost entire period, in all reported situations. There are few objective findings on which the assessment of pain can rely.

Pain is a subjective phenomenon and, therefore, the main assessment lies in the patient's reporting, using a validated scale as the VAS [7,8]. However, as the perception of pain intensity is variable for each individual, biases can be introduced by comparing the mean difference between groups. Therefore, as a secondary outcome, the frequency of reporting no pain (VAS = 0), a more objective measure, was analyzed. Again, important differences were

observed when comparing these groups, with higher proportions of reports of the absence of pain in the group receiving TENS in all measures.

The current study found that the pain was more in the control group (Placebo) without using TENS. So using TENS relieves the separator-induced pain. But there was no significant difference between the application of high frequency and low-frequency TENS. The results of the current study were in accordance with the study done by Hansson P, Ekblom A [12]. The TENS as a treatment modality to control pain during orthodontic tooth separation has the advantage of being non-invasive, having no adverse tissue reactions, and also easy to administer.

LIMITATIONS

Sample size Split mouth study – possibility of a carry-across effect Additional Research required – for an appropriate duration of TENS application, effective voltage & current amplitude

CONCLUSION:

Based on this study we can conclude that TENS, either at High Frequency 120 Hz or Low-Frequency 2Hz provides significant relief from separator induced pain. But the difference in the effect of pain relief produced by high frequency & low-frequency TENS is insignificant and it suggests that TENS is an effective non-pharmacological and safest method of controlling post- separation orthodontic tooth pain.

Future investigations should focus on randomized control trials, comparing pharmacological and non-pharmacological approaches, duration of TENS therapy, the amount of current amplitude, and frequency.

REFERENCES

1. Wall P, Melzach R. Text book of pain. p 904, 3rd edition, 1994, Longman Group UK. Limited.
2. Oliver RG, Knapman YM. Attitudes to orthodontic treatment. Br J Orthod 1985; 12:179- 88.
3. Mello LF, Nóbrega LF, Lemos A. Transcutaneous elec-trical stimulation for pain relief during labor: a system-atic review and meta-analysis. Rev Bras Fisioter. 2011; 15: 175- 184.
4. Giannopoulou, C., Dudic, A., and Kiliriadis, S. (2006). Pain discomfort and crevicular fluid changes induced by orthodontic elastic separators in children. J. Pain 7, 367–376.
5. Lim, H.M., Lew, K.K., and Tay, D.K. (1995). A clinical investigation of the low level laser therapy in reducing orthodontic postadjustment pain. Am. J. Orthod. Dentofacial Orthop. 108, 614–22.
6. Mc Grath PA. The measurement of human pain. Endod Dent Traumatol 1986;2:124-29.
7. Huskisson EC. Visual analogue scale. In: Melzack R (ed). Pain measurement and assessment, p 33-37. New York 1983, Raven Press.
8. Duncan GH, Bushnell MC, Lavingne GJ. Comparison of verbal and visual analogue scale for measuring the intensity and unpleasantnessof experimental pain. Pain 1989;37: 295-303.
9. Roth PM, Trash WJ. Effect of Transcutaneous electrical nerve stimulation for controlling pain associated with orthodontic patients, Am J Orthod 1986; 90:132–138.
10. Denholtz M. Treatment of the myofascial pain dysfunction syndrome with transcutaneous electrical nerve stimulation. In Ersek RA (editor): Pain control with T.E.N.S., principles and practice. St. Louis, 1981, Warren H. Green, Inc.
11. Ihalainen, V. and Perkki, K., The effect of transcutaneous nerve stimulation (TNS) on chronic facial pain, Proc. Finn. dent. Sot.. 74(1978) 86-90.
12. Hansson P, Ekblom A. Transcutaneous electrical nerve stimulation (TENS) as compared to placebo TENS for the relief of acute oro - facial pain. Pain 1983;15:157-165.
13. Esposito, C.J.; Shay, J.S.; and Morgan, B. Electronic dental anesthesia: A pilot study, Quintess. Int 1993;24:167-170.
14. Weiss.D, Carver. D. Transcutaneous electrical neural stimulation for pain. J Clin Orthod 1994;28:670-671.
15. Kvam E, Bondevik O, Gjerdet N R. Traumatic ulcers and pain in adults during orthodontic treatment. Community Dentistry and Oral Epidemiology 1989;17:154–157.
16. Fernandes L M , Øgaard B , Skoglund L. Pain and discomfort experienced after placement of a conventional or super elastic NiTi aligning

archwire. A randomized clinical trial. J Orofac Orthop 1998;59:33 – 339.

17. Bondemark.L, Fredricksson.K, Susanna.I. Separation effect and perception of pain and discomfort from two types of orthodontic separators. World J Orthod 2004;5:172-176.

LIST OF FIGURES

FIG.1 Seperators placed in the maxillary arch by using plier

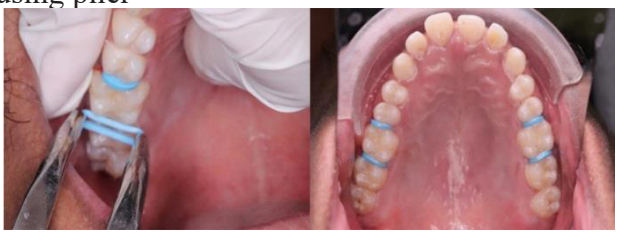

FIG.2 TENS unit with electrodes (a. TENS unit, b.AC adapter, c. Normal saline, d. Pen electrodes, e.Gauze/Cotton, f. Lead wires)

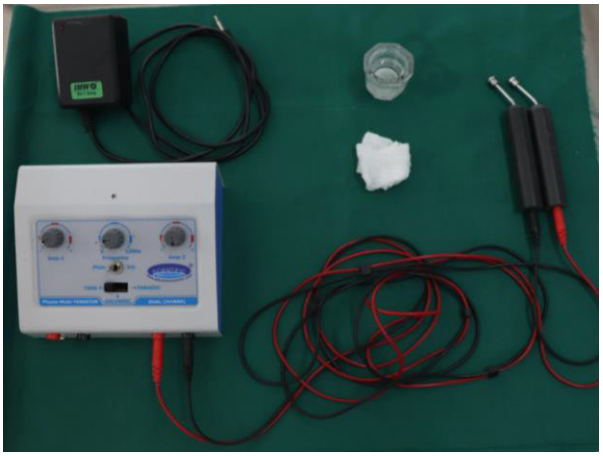

FIG.3 Application of TENS in maxillary arch using pen electrode

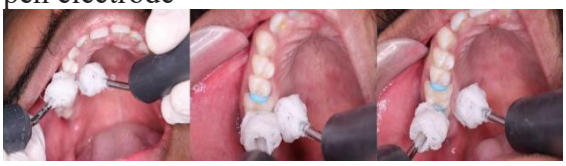

FIG.4 VAS (Visual Analogue Scale)