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RESEARCH ARTICLE

EFFICIENCY OF TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION AND PIROXICAM TO ALLEVIATE PAIN DURING ORTHODONTIC TOOTH SEPARATION - A PROSPECTIVE STUDY

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Transcutaneous Electrical Nerve Stimulation (TENS), Piroxicam, TENS-Placebo, Pain Management, Separators, Visual Analog Scale

Abstract

Objective: This study was conducted to assess the effectiveness of TENS in comparison with TENS-Placebo and prophylactic Piroxicam (20 mg) for pain control before orthodontic tooth separation by Elastomeric separators, Brasswire and Kesling separators.

Study design: 108 patients seeking orthodontic treatment were categorically administered extraoral TENS, TENS-Placebo and Piroxicam (20 mg) using Elastomeric, Kesling and Brasswire separators prior to their orthodontic treatment. The subjects were instructed to rate their pain 2, 6, 12, 24 and 48 hours after the procedure on a Visual Analog Scale.

Results: No statistically significant difference was found in the mean VAS scores when TENS group was compared with Piroxicam. However, significant differences were found between the mean VAS scores when placebo TENS group was compared to the aforementioned groups. Maximum pain was perceived at 24 hours with elastomeric and Kesling springs, but brasswire separators were most painful 6 hours after placement altogether. At all time stamps, pain felt was significantly less with brasswire separators than elastomeric separators and Kesling springs.

Conclusion: TENS was found to be equally effective in reducing pain as Piroxicam. TENS could be thus stated as an effective pain management modality which is safe, comfortable and easy to use and also eliminates adverse drug effects of NSAIDs like GI irritation and reduced orthodontic tooth movement.

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Introduction:-

Dental treatment, in the eyes of the common masses, was often synonymous with an uncomfortably painful experience in the early years. But as the science advanced to give us newer concepts about the human body, research-based treatment modalities, techniques, armamentaria, investigatory tools, drugs, materials and an enormous cornucopia of innovations that eventually has led us to today, where practicing “painless” dentistry is not a dream anymore.

According to the International Association of the Study of Pain, pain can be defined as “an unpleasant sensory and emotional experience with actual or potential tissue damage or described in terms of such damage¹.”

One of the first steps in conventional fixed orthodontic treatment is the placement of orthodontic tooth separators across the teeth to be banded. Separator placement usually causes soreness, tension, pressure and pain which also hinder normal functions such as mastication, leading to malaise and the requirement of analgesics². Since most patients are new to such procedures, the ache experienced after the separator placement procedure often discourages them from taking interest in their treatment, expecting similar experiences during subsequent appointments. Literature has shown that about 8% of all orthodontic patients quit their treatment because of pain².

Various types of orthodontic tooth separators such as elastomeric ring separators, brass wire separators, Kesling separators, C separators, dumbbell separators, Kansal separators, NiTi spring separators, etc. are readily used in contemporary orthodontics. An ideal tooth separator should have ease in placement with minimal patient discomfort, should be radio-opaque, should not hamper oral hygiene and not get dislodged or lost³. Studies demonstrate that elastomeric separators though efficient in creating space, are more painful because of their rapid action³. When compared to the elastomeric ones, Kesling separators (0.018" Australian SS wire) have proven to effectively create space at a slower rate and up to a lesser extent but still enough so that banding could be done. For this reason, patients report with lesser pain when Kesling spring separators are used³.

The recent methods of controlling pain upon orthodontic tooth separation can be vaguely divided into pharmacological and non-pharmacological, among which NSAIDs are the most commonly and frequently used pharmacological method to relieve pain⁴. Preoperative administration of NSAIDs such as Ibuprofen, Acetaminophen, Aspirin, Naproxen Sodium, Meloxicam, Piroxicam and others of sorts has been proven to be effective to reduce post-procedural pain⁴. Since NSAIDs have been frequently used pharmacological method to alleviate orthodontic pain for a long time, their inherent adverse effects like GI irritation and restrictive effect on intended tooth movement cannot be overlooked⁵. Not every person seeking orthodontic treatment is eligible to receive analgesics for e.g. patients with specific allergies to drugs, severe adverse reactions, kidney or liver disorders, and patients under other drug regimens for any other ailment in their body which could potentially lead to undesired and unpredictable drug interactions, pharmacological pain management is contraindicated. In such cases, non-pharmacological means to provide analgesia is usually advised to be implemented⁵.

Transcutaneous electrical nerve stimulation (TENS), a non-pharmacological pain reduction modality, uses low intensity electric current to block the afferent small unmyelinated 'C' fibers and increase the input of large myelinated 'A' fibers. This results in closure of the gate control system in the substantia gelatinosa present in the spinal cord. Another explained mechanism is that TENS promotes the release of autogenous opioids from the spinal cord and/or by the activation of descending intrinsic analgesic pathways. The application of both intraoral and extraoral TENS to alleviate pain during orthodontic tooth movement has also shown promising results. In some cases, TENS can be used in conjunction with pharmacological therapy to reduce the requirement of drugs and reduce their adverse effects, which otherwise would have been prescribed in higher doses and frequencies^{1,2,5,6}.

Despite extensive research done on various methods to control pain during placement of orthodontic separators, there is still insufficient data on the utilization of TENS to manage pain subsequent to separator placement. So, the present study was conducted to assess the effectiveness of TENS in comparison with the Placebo of TENS and prophylactic Piroxicam (20 mg) for pain control before orthodontic tooth separation by Elastomeric separators, Brasswire and Kesling separators.

Materials and Method:-

Subjects

One-hundred and eight patient reporting to the Department of Orthodontics and Dentofacial Orthopedics (Institute of Dental Sciences, Bareilly International University, Bareilly, India) seeking orthodontic treatment consented to participate in this study. The sample size was derived using GPower version 3.0, keeping previous studies on orthodontic pain as a reference. Ethical clearance was granted by the institute's internal review board / Ethical Committee, which supervises an ethical clinical practice within the institute.

The inclusion criteria for the current study were established as: (1) age ranging between 18-26 years at the time of recording the data, (2) subjects with full sets of teeth excluding the third molars, (3) proper interproximal contact on the distal and mesial of maxillary first molars, and (4) subjects with no history of orthodontic treatment. In order to effectively demonstrate the idea of the study, certain exclusion criteria were set as: (1) subjects in whom Piroxicam and other NSAIDs were contraindicated, (2) inappropriate contact or spacing adjacent to the first molars, (3)

subjects with extracted teeth or scheduled surgical procedures before separator placement, (4) subjects with known cardiac arrhythmias and/or having pacemakers, (5) pregnant subjects, and finally, (6) subjects with medical illness that excludes the possibility of the procedures specified.

Procedure

Thirty-six subjects were assigned randomly to one of three experimental groups, namely the active TENS group, the Placebo TENS group and the pharmacological group where the drug of choice was Piroxicam (20 mg). The device used to provide TENS (Figure 1) was a portable Medansh 2 channel mini TENS device (Meddey Technologies Pvt. Ltd, New Delhi, India) which transmits low level electric current via a pair of extraoral electrodes, the location of which was extraorally over the site of separator placement along with the application of a conductive gel. The magnitude of electric current that the device delivers ranges from 0 to 60 mA. The electrodes were stabilized on the desired site with the help of Velcro straps (Figure 2). The subjects were administered their specific pain reduction modality half an hour before separator placement. The subjects in each of the aforementioned groups were further classified evenly in to three subgroups where the difference was in the type of separator used - Elastomeric separators (Morelli elastic separators, Ø 5/32" or 4 mm), Kesling spring separators (0.018" A. J. Wilcock wire / Australian Stainless Steel) and Brasswire separators (Orthomatix, 26 gauge/0.018").

Data Collection

In the present study the perceived amount of pain was rated by the test subjects at the 2, 6, 12, and 24-hour time stamps after the placement of separators on a provided VAS scorecard. The VAS scorecard had a 10 cm long line where the pain could be rated from "no pain at all" (0 mm) to "worst pain experienced" (100 mm) with brief instructions regarding the rating process. The subjects were requested to rate their perceived pain at the aforementioned time stamps upon posterior teeth contact/chewing with a light force with no food during the rating process. The subjects in the present study were instructed to submit their respective scorecards 3 days after the placement of separators, at which time the separators were removed. Linear measurements were taken from 0 to till the points marked by all the subjects and were tabulated and analyzed.

All of the 108 subjects participating in our study returned with their scorecards, therefore we report no attrition of the test sample.

Statistical Analysis

The data were entered on a Microsoft Excel spreadsheet and imported into Statistical Package for Social Sciences (SPSS) version 23 for statistical analysis. The data was presented in mean and standard deviation. A one-way analysis of variance (ANOVA) to evaluate tests of hypothesis for differences between two or more treatments was used. In computing the significant difference between multiple means was evaluated using the One-Way Analysis of Variance – ANOVA along with post hoc tests were done to compare the estimates of variance between and within each of the sample groups. A P-value less than 0.05 was considered statistically significant and a P-value less than 0.001 was considered statistically highly significant.

Results:-

The comparison of the mean VAS scores using one-way ANOVA across each time period in the TENS groups (Table 1 and Graph 1) revealed highly significant differences ($P < 0.01$) between Elastomeric, Kesling and Brass wire separators at T2 (6 hours) and T4 (24 hours) and significant differences ($P < 0.05$) at T3 (12 hours) and T5 (48 hours). However, the mean VAS score was highest for Elastomeric separators at all given time stamps. These values indicate greatest pain perception with the use of Elastomeric separators at all given time stamps in the TENS group.

When the mean VAS score was compared with the same separators in the Piroxicam group (Table 2 and Graph 2), highly significant differences were found at T4 and T5 and significant differences were found at T3. The mean VAS score was greatest with the use of Elastomeric separators in the Piroxicam group as well, indicative of greatest pain perception with their use.

In the TENS-Placebo group (Table 3 and Graph 3), highly significant differences were found at T2, T3, T4, and T5 and significant differences were found at T1 (2 hours) among all the separators. Following suit, the elastomeric separators caused the greatest pain across all time periods in TENS-placebo group.

Multiple comparison using Post hoc LSD Test with the use of elastomeric separators (Table 4 and Graph 4) was performed to compare all the pain management modalities among each other. Although the mean VAS scores were marginally higher for TENS than Piroxicam, but this difference was statistically insignificant at all given time intervals when compared using elastomeric, Kesling and brasswire separators. Significant differences in the mean VAS scores were found between TENS and TENS-Placebo at T2, T3, T4 and T5 and between Piroxicam and TENS-Placebo at T3, T4 and T5 time stamps. Highly significant differences were found between TENS and TENS-Placebo at T1, and between Piroxicam and TENS-Placebo at T1 and T2

Similar results were found with the use of Kesling springs (Table 5 and Graph 5). Significant differences in the mean VAS scores were found between TENS and TENS-Placebo at T1, T2, T3, T4 and T5 and between Piroxicam and TENS-Placebo at T1, T2, T3 and T4 time stamps. The results obtained with the use of Brass wire separators (Table 6 and Graph 6) were similar demonstrating significant differences in the mean VAS scores between TENS and TENS-Placebo at T1, T2, T3 and T5 and between Piroxicam and TENS-Placebo at T1, T2, T3 and T5 time stamps. Highly significant differences in the mean VAS scores between the use of TENS and TENS-Placebo at T4 and between Piroxicam and TENS-Placebo at T4 time stamps were also seen.

The differences between TENS and TENS-Placebo, and Piroxicam and TENS-Placebo were found to be statistically significant, suggestive of greater pain perception and indicating a weak placebo effect. This clinically confirms the effectiveness of TENS in this regard.

Discussion:-

The prescription of pain medication such as NSAID's is the usual norm of a common orthodontic practice in the current era. Most patients respond well and have minimal concerns regarding the use of such drugs. However, not every patient is eligible to receive pharmacological pain management due to variety of reasons. In patients with specific allergies to certain NSAIDs, hormonal imbalance, adverse drug reactions like GI irritations, liver and kidney disorders, metabolic disorders and interactions with other drug regimen the patients may be under, pharmacological analgesic drug regimen is contraindicated. Clinicians in such a scenario opt for non-pharmacological pain management modalities to provide pain relief to the patients. These involve the use of techniques like transcutaneous electrical nerve stimulation (TENS), pulsed electromagnetic field (PEMF) therapy, vibratory stimulations, low-level laser therapy (LLLT), bite wafers, chewing gums, etc. with varying degrees of success. Amongst these, TENS has been intensively studied upon for its effectiveness in pain reduction, however its clinical application in dentistry is still under-reported.

TENS was firstly used to alleviate orthodontic pain by Roth and Thrash in the year 1986⁶. Since then numerous authors have tested the potency of TENS and found successful results confirming the analgesic properties of TENS. By definition, "TENS is any technique that passes electrical currents across the intact surface of the skin to activate underlying nerves⁵". The apparatus consists of a power source, a modulation device where amplitude (mA) and frequency (pps or Hz) can be adjusted, a pair of transmitting electrodes and some accessories. It delivers mild and tolerable pulses of electric current at calibrated frequencies to target and activate nerve stimulation.

TENS therapy is an affordable and non-invasive means to relieve both chronic and acute pain. No risk of adverse effects like allergic reactions or impeding of orthodontic movement of the teeth are seen with the use of TENS. In essence, TENS-associated pain relief occurs due to the over-stimulation of A-beta fibers which carry sensations like electrical stimuli, touch and pressure impulses which traverse at a quicker rate than A-delta fibers which carry noxious stimuli. Non-noxious stimulation causes inhibition of the pain gate located in substantia gelatinosa of the spinal cord in the dorsal horn, resulting in cessation of transmission of afferent pain stimuli. TENS has also been extrapolated to activate intrinsic analgesic mechanism, promoting the release of opiate-like peptides for example endorphins. Their increase in plasma concentration produces analgesia for longer durations^{2,7-9}.

In the present study the efficacy of single administration of TENS was compared to the efficacy of a single dose administration of Piroxicam 20 mg to impart pain relief. Piroxicam belongs to the group of NSAIDs, more specifically, it is a nonselective COX inhibitor. It has a long plasma half life ($t_{1/2}$) of about 50-60 hours and that allows a once-a-day frequency of consumption. For general analgesic uses, 20-30 mg per day administration of Piroxicam is usually recommended. As stated by Kohli and Kohli⁴, Piroxicam is more effective for pain control when compared to Ibuprofen and lactose placebo. Moreover, Piroxicam has an added advantage that it causes

significantly less GI irritation which is observed with the use of Ibuprofen, Naproxen Sodium and Aspirin^{4,5}. It is due to the aforementioned advantages of Piroxicam that it was selected in our study.

The present study was done to check the efficiency of TENS therapy to reduce the pain associated with orthodontic separation by using Elastomeric, Kesling and Brasswire separators. When TENS was given with Elastomeric separators, it was seen that maximum pain was felt at T4 (24 hours), followed by T5, T3, T2 and T1 time durations. Our findings are in coordination with the study done by **Kala Vani S.V. et. al.**¹ who also reported maximum pain perception at 24 hours of separator placement when extraoral TENS was used. Similar results were shown in the studies done by **Desai A.L. et. al.**⁵ and **Nath SK et. al.**¹⁰. Similar results were found when TENS was given with Kesling spring separators, and our findings are supported by **Tripathi T et. al.**³ and **Sandhu G.P.S. et. al.**¹¹.

With the administration of TENS, when Brasswire separation was used, maximum pain was felt at T1, followed by at T4, T2, T3 and T5 time intervals. Our findings are contradictory to the result obtained by **Sandhu G.P.S. et. al.**¹¹ who reported that maximum pain occurred at 24 hours with the use of Brasswire separators. This contrast can be attributed to the varying operator skills and material properties which can lead to differences in the amount of activation of the brasswire separators.

When Piroxicam was administered, with the use of Elastomeric separators, maximum pain was felt at T4 (24 hours) followed by at T3, T5, T2 and T1 time stamps. Our findings are in accordance with the result obtained by **S.S. Kohli, V.S. Kohli**⁴ who reported that pain was greatest at the 24 hour mark. **Desai A.L. et. al.**⁵ in their study also reported that pain increased from 2 to 24 hours and then decreased at 48 hours, supporting our results. Similar results were obtained by **Najafi H.Z. et. al.**¹² with elastomeric separation. However, contrary to our study, they used 7.5 mg Meloxicam which is another non-selective COX inhibitor similar to Piroxicam.

When Piroxicam was used with Kesling springs, it was seen that maximum pain was perceived at T4 (24 hours) followed by at T5, T3, T2 and T1 time stamps. Our findings correlate to the study conducted by **Tripathi T et. al.**³ who also reported maximum pain perception at day 1 (24 hours) with a mean VAS score of 3.00 ± 1.62 mm with the use of Kesling spring separators. Similar results were shown in the study done by **Law SLS et. al.**¹³ but they contrarily used Ibuprofen in their study, which is a similar NSAID.

With the administration of Piroxicam, when Brasswire separation was used, maximum pain was felt at T2 (6 hours) followed by at T3, T1, T4 and T5 time stamps. Similar results have been reported by **Shaikh M. et. al.**¹⁴ who found that pain was maximum around the first 4 hours of brasswire separator placement.

When TENS-Placebo was used with Elastomeric separators, maximum pain was perceived at T4, followed by at T3, T2, T5 and T1 time durations. This is consistent with the results obtained by **Tripathi T et. al.**³ and **S.S. Kohli, V.S. Kohli**⁴ who reported that pain was greatest at the 24 hour mark when Elastomeric separation with placebo was used. Similar results were seen in the studies conducted by **Wilson et. al.**¹⁵ and **Law SLS et. al.**¹³.

When TENS Placebo was administered with the use of Kesling springs, maximum pain was felt at T4 (24 hours), followed by at T3, T5, T2 and T1 time stamps. Our findings are similar to the reporting of **Tripathi T et. al.**³, **Kala Vani S.V. et. al.**¹ and **Sandhu GPS et. al.**¹¹ who stated that pain at 24 hours was greatest with the use of Kesling springs amongst all the observed times.

With the administration of TENS-Placebo, when Brasswire separation was used, maximum pain was felt at T3 (12 hours), followed by at T4, T2, T1 and T5 time stamps. Our findings are in contrast to the study conducted by **Sandhu GPS et. al.**¹¹ who reported maximum pain perception at 24 hours after Brasswire separator placement.

The comparison of pain perception with VAS scale with different pain reduction modalities used - TENS, Piroxicam and Placebo TENS at different time intervals using Elastomeric separators showed no significant differences in the mean VAS scores between the use of TENS and Piroxicam at all given time intervals. However, the mean VAS scores were higher for TENS than Piroxicam at all given time intervals suggestive of greater pain perception with the use of TENS when Elastomeric separators were placed. Our findings concur with the results obtained by **Desai A.L. et. al.**⁵ who also reported insignificant differences between the pain perception between TENS and Piroxicam at all given time stamps. Significant differences in the mean VAS scores were found between TENS and TENS-Placebo at T2, T3, T4 and T5 and between Piroxicam and TENS-Placebo at T3, T4 and T5 time stamps when

Elastomeric separators were used. Similar results were obtained by **Roth and Thrash**⁶ who also reported significant differences between TENS and Placebo with the use of Elastomeric separators. These values suggest greater pain perception with TENS-Placebo at all given time stamps. Highly significant differences in the mean VAS scores between the use of TENS and TENS-Placebo at T1 and between Piroxicam and TENS-Placebo at T1 and T2 time stamps. These values suggest greater pain perception with TENS-Placebo when compared to TENS and Piroxicam when Elastomeric separators were used. Our findings are similar to the study conducted by **S.S. Kohli, V.S. Kohli**⁴ who also reported greater pain perception with the use of placebo. However, contrary to our study, they used a lactose placebo capsule.

The comparison of pain perception with VAS scale with different pain reduction modalities used - TENS, Piroxicam and Placebo TENS at different time intervals using Kesling spring separators showed no significant differences in the mean VAS scores between the use of TENS and Piroxicam at all given time intervals. Significant differences in the mean VAS scores were found between TENS and TENS-Placebo at T1, T2, T3, T4 and T5 and between Piroxicam and TENS-Placebo at T1, T2, T3 and T4 time stamps when Kesling spring separators were used. These values suggest greater pain perception with TENS-Placebo when compared to TENS and Piroxicam when Kesling spring separators were used. Our findings of higher pain perception with Elastomeric separators when Placebo was administered are supported by a study conducted by **Kala Vani S.V. et. al.**¹ who also used Kesling springs and reported greater pain with separators when TENS-Placebo was used.

The comparison of pain perception with VAS scale with different pain reduction modalities used - TENS, Piroxicam and Placebo TENS at different time intervals using Brasswire separators showed no significant differences in the mean VAS scores between the use of TENS and Piroxicam at all given time intervals. Significant differences in the mean VAS scores were found between TENS and TENS-Placebo at T1, T2, T3 and T5 and between Piroxicam and TENS-Placebo at T1, T2, T3 and T5 time stamps when Brasswire separators were used. These values suggest greater pain perception with TENS-Placebo at all given time stamps. Highly significant differences in the mean VAS scores between the use of TENS and TENS-Placebo at T4 and between Piroxicam and TENS-Placebo at T4 time stamps were found. These values suggest greater pain perception with TENS-Placebo when compared to TENS and Piroxicam when Brasswire separators were used. Unfortunately, our research did not reveal any research article or publication comparing Brasswire as the separator with TENS, Piroxicam, or TENS-Placebo as the mode of analgesia. This opens up a new area of research which will support or deny our claims.

Conclusion:-

The results of our study led us to the following conclusions:

1. TENS was found to be an effective pain management modality for management of pain with separator placement.
2. Piroxicam was also found to be an effective pain management modality with separator placement.
3. TENS was found to be equally effective in pain management when compared to Piroxicam. Mean VAS scores with TENS were although higher when compared to Piroxicam but were found to be statistically insignificant across all time periods.
4. TENS could be thus stated as an effective pain management modality which is safe, comfortable and easy to use and also eliminates any adverse drug effects of NSAIDs like GI irritation and reduced orthodontic tooth movement.

Based on our conclusions, we deem it fit to state that TENS is a viable, safe, comfortable and painless pain reduction modality and can be used instead of or in adjunct with pain relieving NSAIDs like Piroxicam to alleviate pain during orthodontic separation. Our research and findings suggest that TENS is as effective in reducing pain as any other NSAID available and also requires significantly less frequencies of administration than drugs with literally no side effects. Therefore, we recommend the use of TENS in regular orthodontic practice due to its several advantages over NSAIDs to provide pain relief, and also being more compatible with both the patients' and the clinician's perspective.

Conflict of Interest

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Figure 1:- Apparatus for TENS - Electrode pads with leads, Velcro strap, TENS device and Conductive gel.



Figure 2:- Electrodes placed extraorally over the site of separator placement with conductive gel and stabilized using Velcro straps.

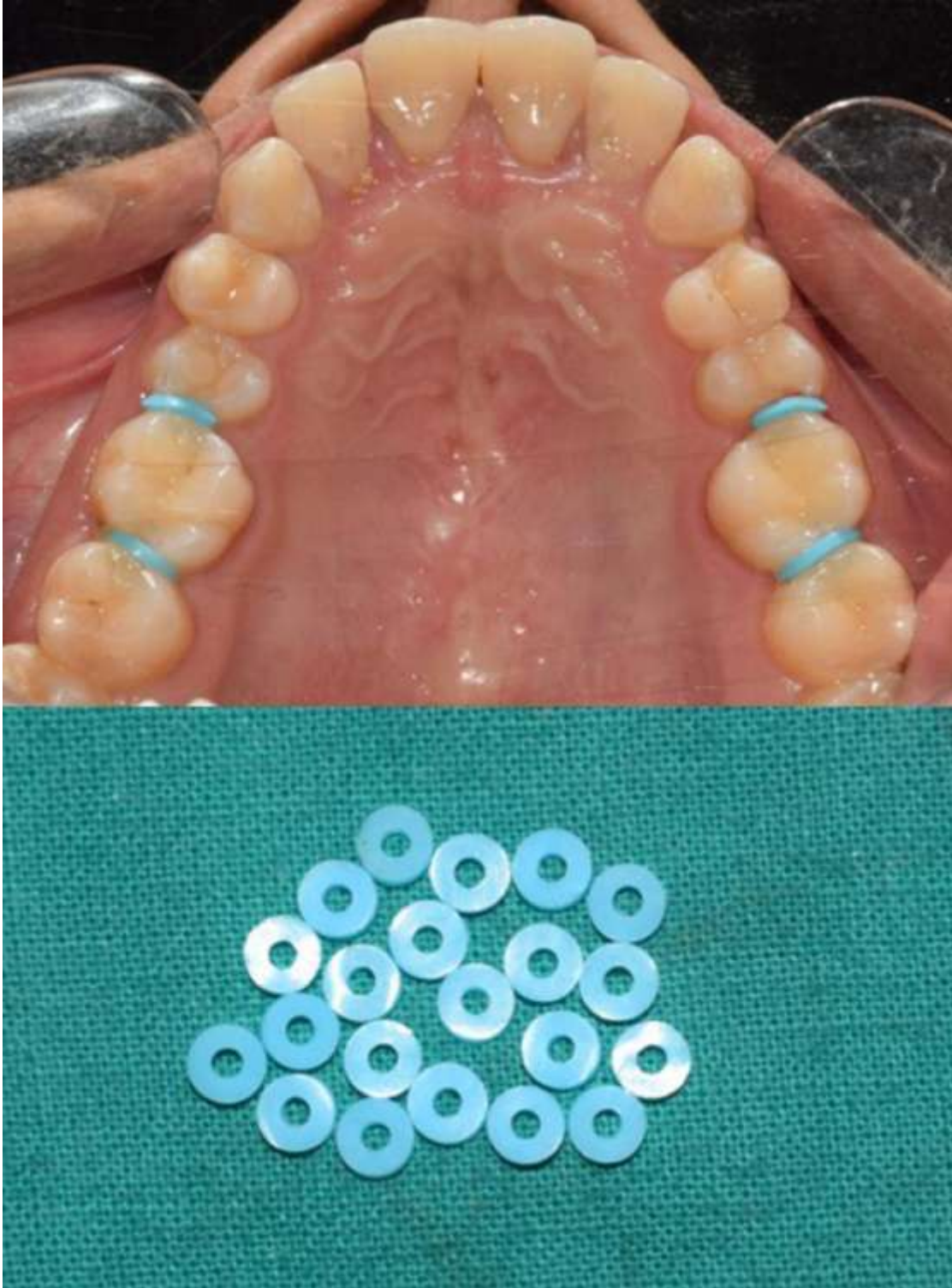


Figure 3:- Elastomeric separators.

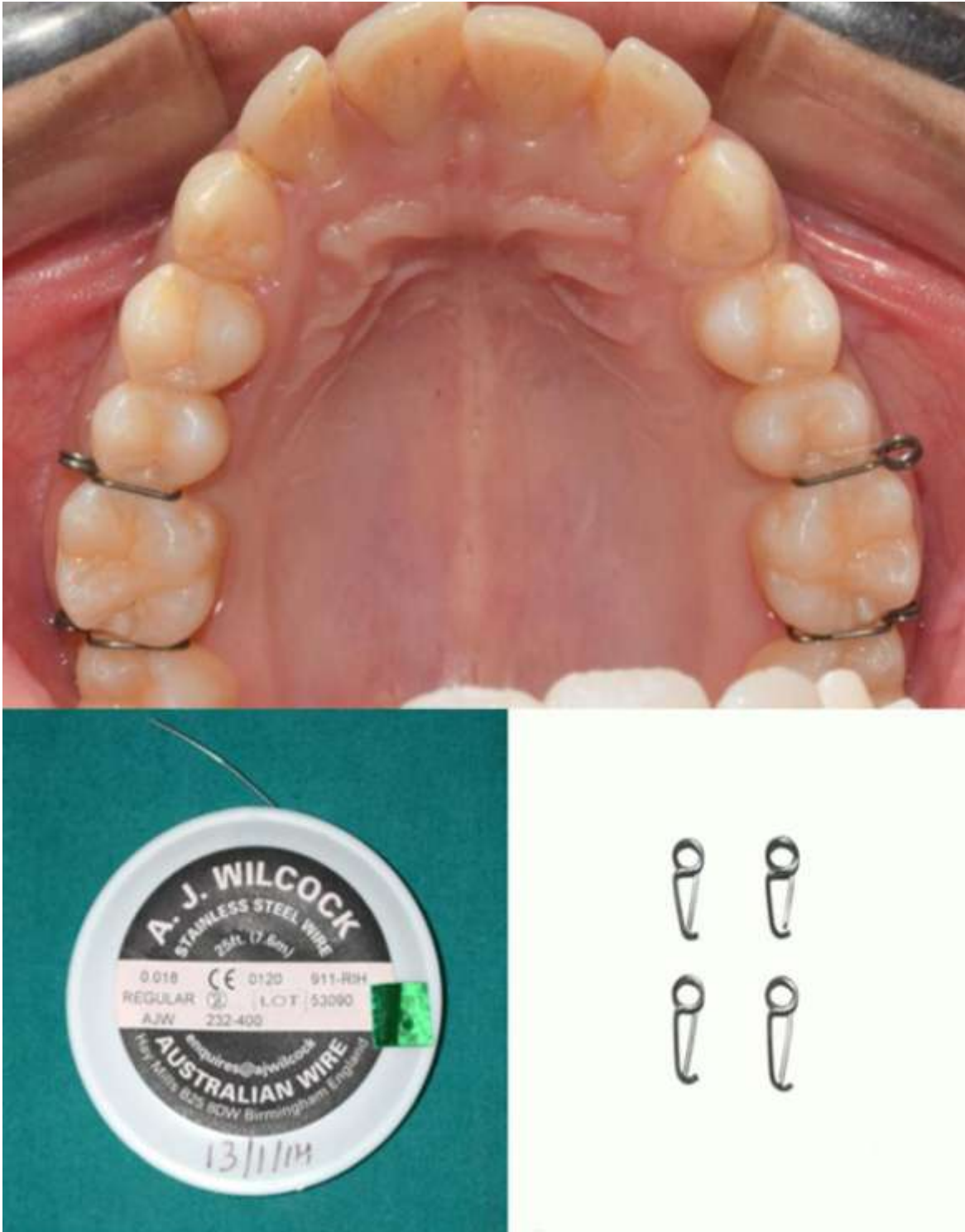


Figure 4:- Kesling Separators.



Figure 5:- Brass wire separators.

Table 1:- Comparison of mean VAS scores across each time period in the TENS group.

Mean VAS scores across each time period in the TENS group					
Type of separator	T1 (2 hours)	T2 (6 hours)	T3 (12 hours)	T4 (24 hours)	T5 (48 hours)
Elastomeric	3.76 ± 4.28	9.96 ± 10.03	21.79 ± 27.88	28.36 ± 31.76	24.74 ± 26.08
Kesling	1.62 ± 1.52	5.85 ± 4.91	7.91 ± 13.44	19.75 ± 11.57	14.81 ± 25.63
Brasswire	0.91 ± 2.26	0.40 ± 0.96	0.36 ± 0.9	0.84 ± 1.57	0 ± 0
F-Value	3.071	6.583	4.436	6.231	4.172

P-Value	0.060# (not significant)	0.004** (highly significant)	0.020* (significant)	0.005** (highly significant)	0.024* (significant)
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#P>0.05(statistically not significant), *P<0.05(statistically significant), ** statistically highly significant.

Graph 1:- Mean VAS scores across each time period in the TENS group.

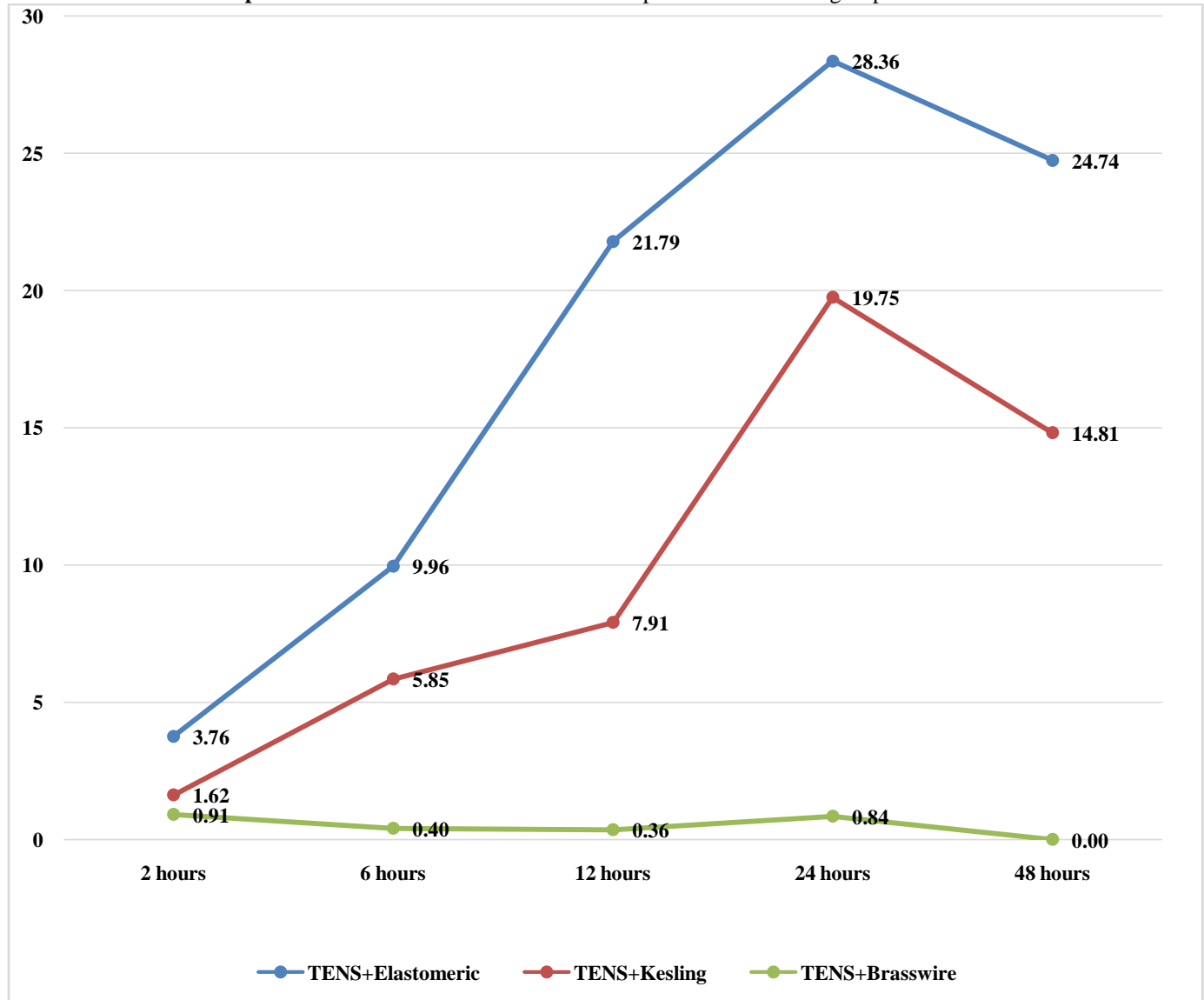


Table 2:- Mean VAS scores across each time period in the Piroxicam group.

Mean VAS scores across each time period in the Piroxicam group					
Type of separator	T1 (2 hours)	T2 (6 hours)	T3 (12 hours)	T4 (24 hours)	T5 (48 hours)
Elastomeric	2.66 ± 4.49	3.63 ± 4	16.33 ± 20.2	25.18 ± 26.93	15.79 ± 12.7
Kesling	2.41 ± 3.22	5.33 ± 6.42	7.83 ± 11.54	15.65 ± 17.24	12.61 ± 15.42
Brass wire	0.88 ± 1.32	1.36 ± 2.27	0.91 ± 2.49	0.52 ± 0.77	0 ± 0
F-Value	1.037	2.290	3.922	5.442	6.290
P-Value	0.366# (not significant)	0.117# (not significant)	0.030* (significant)	0.009** (highly significant)	0.005** (highly significant)

#P>0.05(statistically not significant), *P<0.05(statistically significant), ** statistically highly significant.

Graph 2:- Mean VAS scores across each time period in the Piroxicam group.

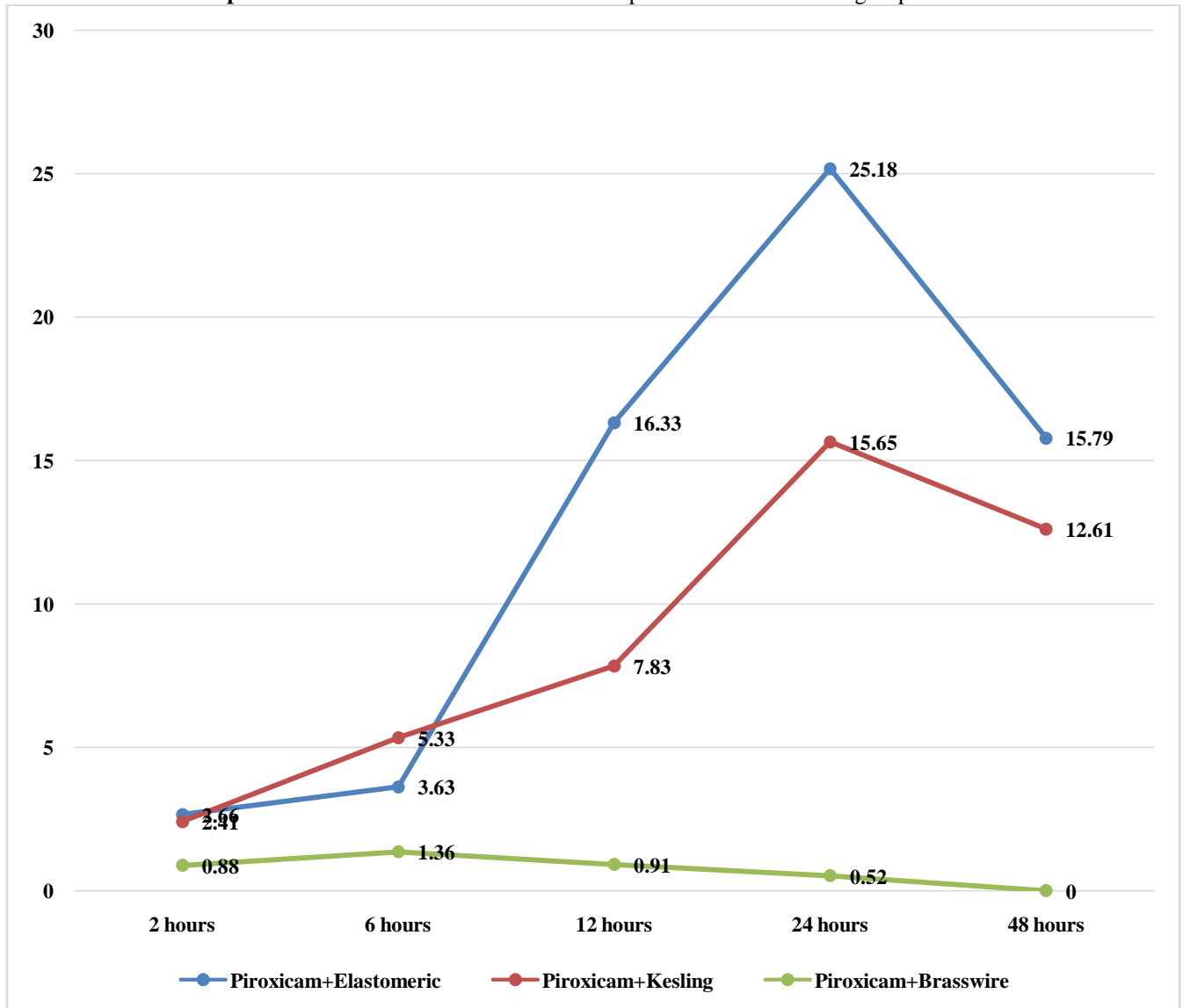


Table 3:- Comparison of mean VAS scores across each time period in TENS-Placebo group.

Mean VAS scores across each time period in the TENS Placebo group					
Type of separator	T1 (2 hours)	T2 (6 hours)	T3 (12 hours)	T4 (24 hours)	T5 (48 hours)
Elastomeric	11.51 ± 7.94	18.10 ± 8.79	27.92 ± 14.74	41.52 ± 14.99	17.06 ± 8.48
Kesling	6.66 ± 8.01	12.20 ± 8.81	23.08 ± 23.24	30.62 ± 20.91	12.91 ± 12.92
Brasswire	2.80 ± 1.96	3.24 ± 1.3	6.65 ± 10.93	4.84 ± 6.24	2.09 ± 2.64
F-Value	3.902	9.067	4.595	13.470	6.070
P-Value	0.030* (significant)	0.001** (highly significant)	0.017** (highly significant)	0.000** (highly significant)	0.006** (highly significant)

#P>0.05(statistically not significant), *P<0.05(statistically significant), ** statistically highly significant.

Graph 3:- Mean VAS scores across each time period in the TENS-Placebo group.

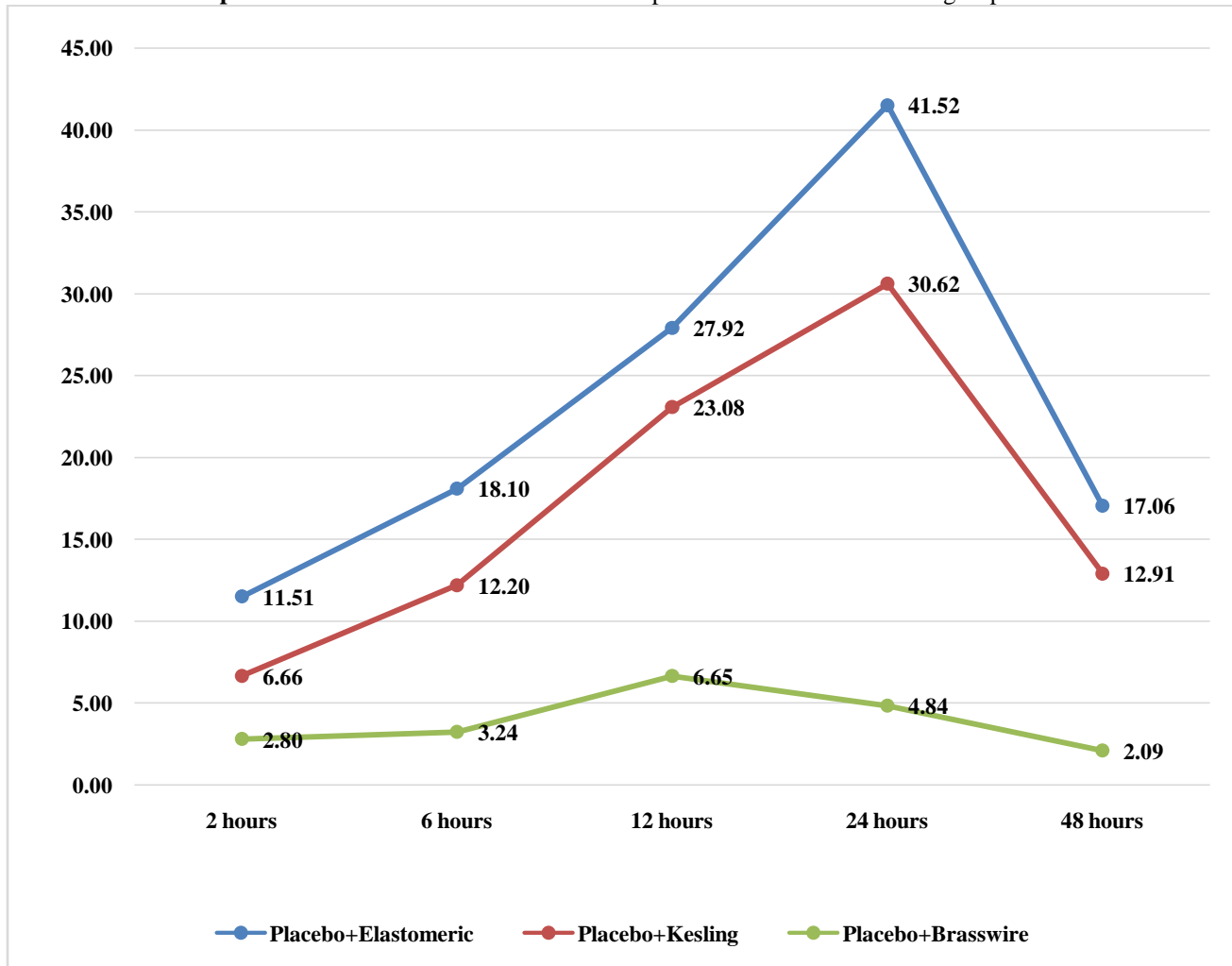


Table 4:- Multiple comparison by using Post Hoc LSD Test in Elastomeric separators.

Time Duration	Pain relief modality-1	Pain relief modality-2	Mean ± SD 1	Mean ± SD 2	Mean Difference (1-2)	P-Value (Result)
T1 (2 hours) Elastomeric	TENS	Piroxicam	3.76 ± 4.28	2.66 ± 4.49	1.10	0.646#(not significant)
	TENS	Placebo	3.76 ± 4.28	11.51 ± 7.94	-7.75	0.003**(highly significant)
	Piroxicam	Placebo	2.66 ± 4.49	11.51 ± 7.94	-8.85	0.001**(highly significant)
T2 (6 hours) Elastomeric	TENS	Piroxicam	9.96 ± 10.03	3.63 ± 4.0	6.33	0.063#(not significant)
	TENS	Placebo	9.96 ± 10.03	18.10 ± 8.79	-8.14	0.018*(significant)
	Piroxicam	Placebo	3.63 ± 4.0	18.10 ± 8.79	-14.47	0.000**(highly significant)
T3 (12 hours) Elastomeric	TENS	Piroxicam	21.79 ± 27.88	16.33 ± 20.2	5.46	0.554#(not significant)
	TENS	Placebo	21.79 ± 27.88	27.92 ± 14.74	-6.13	0.048*(significant)

	Piroxicam	Placebo	16.33 ± 20.2	27.92 ± 14.74	-11.59	0.039*(significant)
T4 (24 hours) Elastomeric	TENS	Piroxicam	28.36 ± 31.76	25.18 ± 26.93	3.18	0.766#(not significant)
	TENS	Placebo	28.36 ± 31.76	41.52 ± 14.99	-13.15	0.021*(significant)
	Piroxicam	Placebo	25.18 ± 26.93	41.52 ± 14.99	-16.34	0.0123*(significant)
T5 (48 hours) Elastomeric	TENS	Piroxicam	24.74 ± 26.08	15.79 ± 12.7	8.95	0.227#(not significant)
	TENS	Placebo	24.74 ± 26.08	17.06 ± 8.48	7.68	0.346*(significant)
	Piroxicam	Placebo	15.79 ± 12.7	17.06 ± 8.48	-1.27	0.049*(significant)

#P>0.05(statistically not significant), *P<0.05(statistically significant), ** statistically highly significant.

Graph 4:- Multiple comparison by using Post hoc LSD Test in Elastomeric separators.

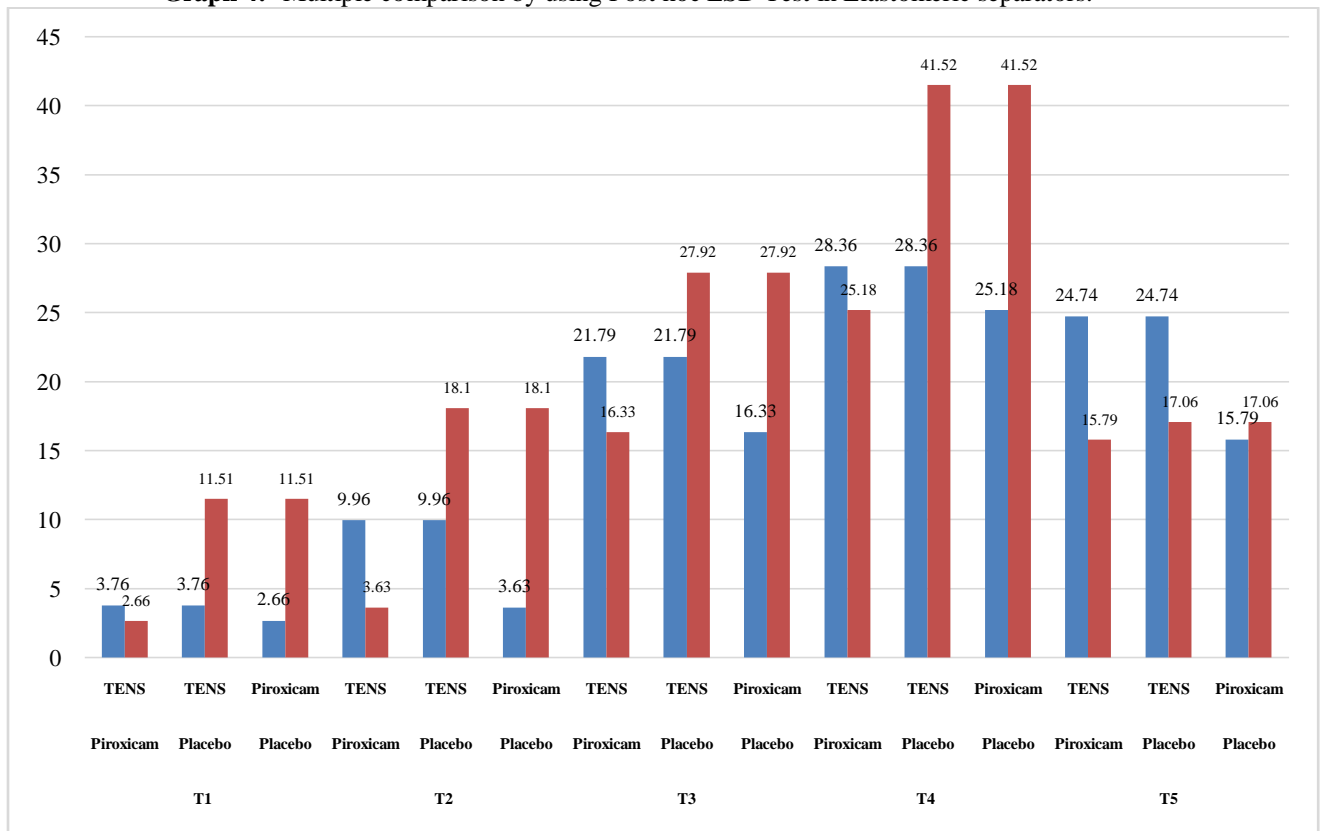


Table 5:- Multiple comparison by using Post Hoc LSD Test in Kesling springs.

Time Duration	Pain relief modality-1	Pain relief modality-2	Mean ± SD 1	Mean ± SD 2	Mean Difference (1-2)	P-Value (Result)
Dependent Variable	I	J	Mean ± SD I	Mean ± SD J	Mean Difference (I-J)	P-Value(Result)
T1 (2 hours) Kesling	TENS	Piroxicam	1.62 ± 1.52	2.41 ± 3.22	-0.79	0.704#(not significant)
	TENS	Placebo	1.62 ± 1.52	6.66 ± 8.01	-5.04	0.02*(significant)

	Piroxicam	Placebo	2.41 ± 3.22	6.66 ± 8.01	-4.25	0.048*(significant)
T2 (6 hours) Kesling	TENS	Piroxicam	5.85 ± 4.91	5.33 ± 6.42	0.52	0.871#(not significant)
	TENS	Placebo	5.85 ± 4.91	12.2 ± 8.81	-6.35	0.040*(significant)
	Piroxicam	Placebo	5.33 ± 6.42	12.2 ± 8.81	-6.87	0.038*(significant)
T3 (12 hours) Kesling	TENS	Piroxicam	7.91 ± 13.44	7.83 ± 11.54	0.09	0.990#(not significant)
	TENS	Placebo	7.91 ± 13.44	23.08 ± 23.24	-15.17	0.035*(significant)
	Piroxicam	Placebo	7.83 ± 11.54	23.08 ± 23.24	-15.25	0.034*(significant)
T4 (24 hours) Kesling	TENS	Piroxicam	19.75 ± 11.57	15.65 ± 17.24	4.1	0.595#(not significant)
	TENS	Placebo	19.75 ± 11.57	30.62 ± 20.91	-10.87	0.0465*(significant)
	Piroxicam	Placebo	15.65 ± 17.24	30.62 ± 20.91	-14.97	0.028*(significant)
T5 (48 hours) Kesling	TENS	Piroxicam	14.81 ± 25.63	12.61 ± 15.42	2.2	0.782#(not significant)
	TENS	Placebo	14.81 ± 25.63	12.91 ± 12.92	1.9	0.049*(significant)
	Piroxicam	Placebo	12.61 ± 15.42	12.91 ± 12.92	-0.3	0.970#(not significant)

#P>0.05(statistically not significant), *P<0.05(statistically significant), ** statistically highly significant.

Graph 5:- Multiple comparison by using Post hoc LSD Test in Kesling springs.

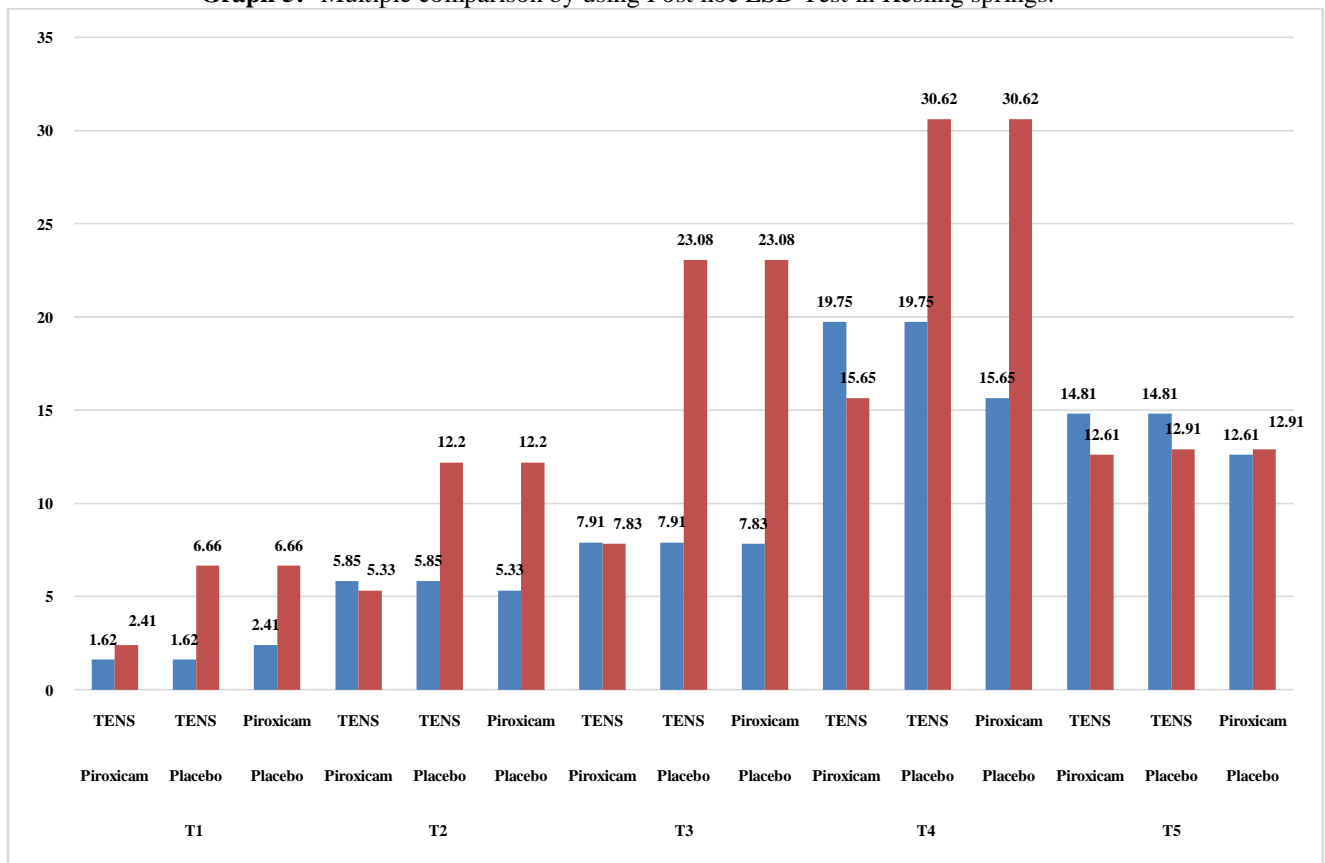


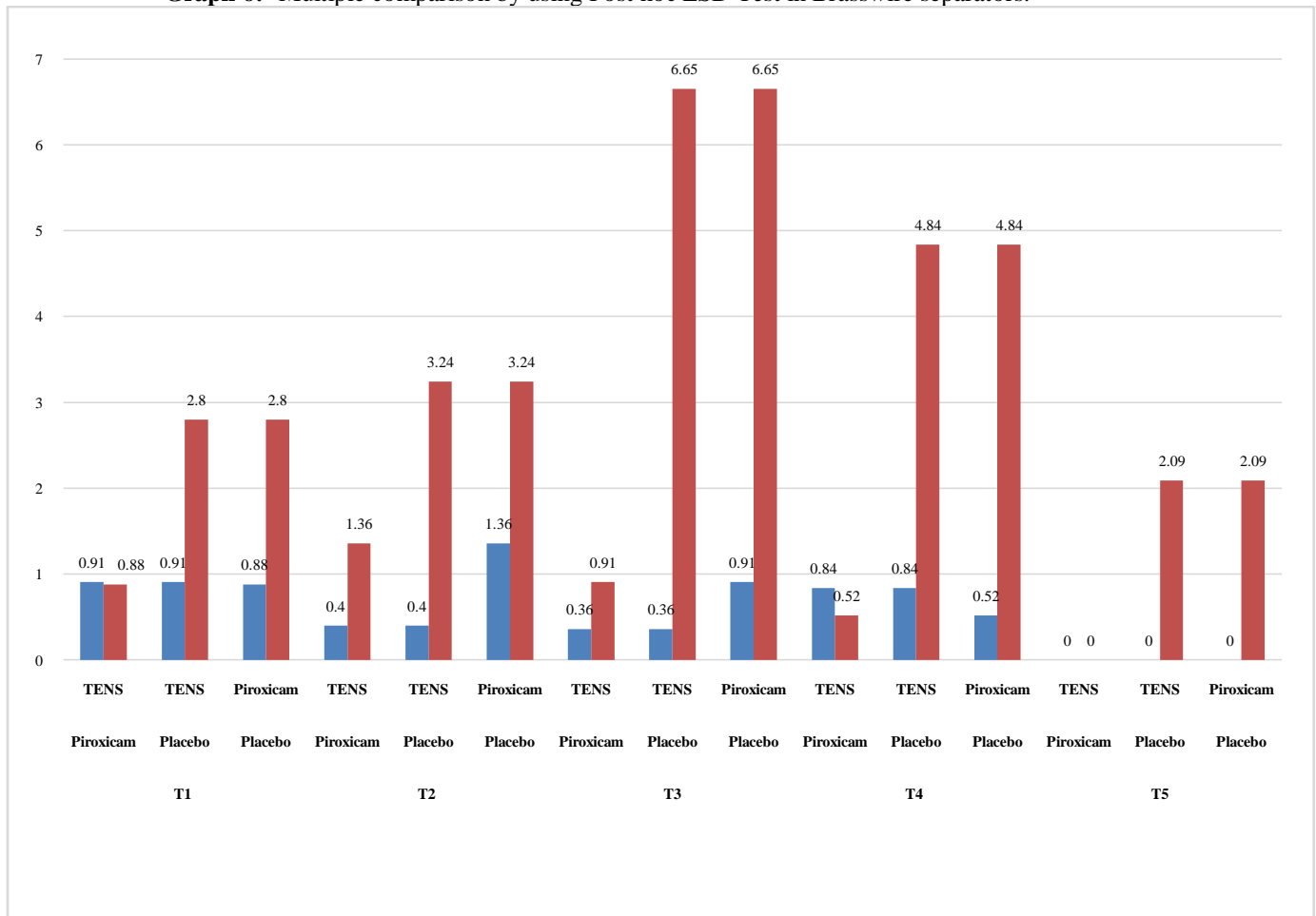
Table 6:- Multiple comparison by using Post Hoc LSD Test in Brasswire separators.

Time Duration	Pain relief modality-1	Pain relief modality-2	Mean ± SD 1	Mean ± SD 2	Mean Difference (1-2)	P-Value (Result)
Dependent Variable	I	J	Mean ± SD I	Mean ± SD J	Mean Difference (I-J)	P-Value(Result)
T1 (2 hours) Brasswire	TENS	Piroxicam	0.91 ± 2.26	0.88 ± 1.32	0.03	0.986#(not significant)
	TENS	Placebo	0.91 ± 2.26	2.8 ± 1.96	-1.89	0.039*(significant)

	Piroxicam	Placebo	0.88 ± 1.32	2.8 ± 1.96	-1.92	0.010*(significant)
T2 (6 hours) Brasswire	TENS	Piroxicam	0.4 ± 0.96	1.36 ± 2.27	-0.96	0.491#(not significant)
	TENS	Placebo	0.4 ± 0.96	3.24 ± 1.3	-2.84	0.032*(significant)
	Piroxicam	Placebo	1.36 ± 2.27	3.24 ± 1.3	-1.88	0.020*(significant)
T3 (12 hours) Brass wire	TENS	Piroxicam	0.36 ± 0.9	0.91 ± 2.49	-0.55	0.837#(not significant)
	TENS	Placebo	0.36 ± 0.9	6.65 ± 10.93	-6.29	0.024*(significant)
	Piroxicam	Placebo	0.91 ± 2.49	6.65 ± 10.93	-5.74	0.038*(significant)
T4 (24 hours) Brass wire	TENS	Piroxicam	0.84 ± 1.57	0.52 ± 0.77	0.32	0.834#(not significant)
	TENS	Placebo	0.84 ± 1.57	4.84 ± 6.24	-4.0	0.013** (highly significant)
	Piroxicam	Placebo	0.52 ± 0.77	4.84 ± 6.24	-4.32	0.008** (highly significant)
T5 (48 hours) Brass wire	TENS	Piroxicam	0 ± 0	0 ± 0	0.000	1.000#(not significant)
	TENS	Placebo	0 ± 0	2.09 ± 2.64	-2.09	0.011*(significant)
	Piroxicam	Placebo	0 ± 0	2.09 ± 2.64	-2.09	0.011*(significant)

#P>0.05(statistically not significant), *P<0.05(statistically significant), ** statistically highly significant.

Graph 6:- Multiple comparison by using Post hoc LSD Test in Brasswire separators.



References:-

1. Kala Vani S.V, Jagathesh Natarajan, Madhavi O., Hima Bindu S., Sunil Krishna Kumar P., Ramesh P.. Efficiency of Tens in Controlling Pain During Separation Using two Different Orthodontic Separators. *Int J Cur Adv Res* 2019;08(04):18055-60.
2. Cosmo Haralambidis. Pain-Free Orthodontic Treatment with the Dental Pain Eraser. *J Clin Orthod* 2019;53(4):234-42.
3. Tripathi T, Singh N, Rai P, Khanna N. Separation and pain perception of Elastomeric, Kesling and Kansal separators. *Dental Press J Orthod.* 2019 Mar-Apr;24(2):42-8.
4. Sarvaraj Singh Kohli, Virinder Singh Kohli. Effectiveness of Piroxicam and ibuprofen premedication on orthodontic patients' pain experiences. *Angle Orthod* 2011;81(6):1097-102.
5. Asavari L Desai, Nandita Shenoy, Srikant Natarajan, Supriya Nambiar. Comparison of analgesic effect of Piroxicam and transcutaneous electrical nerve stimulation therapy on pain associated with orthodontic separator placement: A single blind randomized controlled trial. *World J Dent* 2018;9(4):284-90.
6. Peter M Roth, William James Thrash. Effect of transcutaneous electrical nerve stimulation for controlling pain associated with orthodontic tooth movement. *Am J Orthod Dentofacial Orthop* 1986;90(2):132-8.
7. Black RR. Use of transcutaneous electrical nerve stimulation in dentistry. *J Am Dent Assoc.* 1986;113(4):649-652.
8. Vikrant Kasat, Aditi Gupta, Ruchi Ladda, Mitesh Kathariya, Harish Saluja, Anjum-Ara Farooqui. Transcutaneous electric nerve stimulation (TENS) in dentistry- A review. *J Clin Exp Dent* 2014;6(5):562-8.
9. Johnson M. Transcutaneous Electrical Nerve Stimulation: Mechanisms, Clinical Application and Evidence. *Rev Pain.* 2007;1(1):7-11.
10. Nath SK, Goswami P, Mahalakshmi S, Kaur I, Mengi A, Bandyopadhyay B. Comparative evaluation of effect of TENS on controlling pain associated with orthodontic separator placement—A clinical study. *J Pharm Bioall Sci* 2024;16:S577-9.
11. Sandhu, Gurinder & Kanase, Anup & Naik, CR & Pupneja, Pankaj & Sudan, Sahira. Separation Effect and Perception of Pain and Discomfort from Three Types of Orthodontic Separators. *The Journal of Indian Orthodontic Society* 2013.47.6-9.
12. Zarif Najafi H, Oshagh M, Salehi P, Babanouri N, Torkan S. Comparison of the effects of preemptive acetaminophen, ibuprofen, and meloxicam on pain after separator placement: a randomized clinical trial. *Prog Orthod.* 2015;16:34.
13. Law SLS, Southard KS, Law AS, Logan HL, Jakobsen JR. An evaluation of ibuprofen treatment of pain associated with orthodontic separator placement. *Am J Orthod Dentofacial Orthop.* 2000;118:629–635.
14. Shaikh M, Sultan T, Shahzad A, et al. Discomfort and Pain Perceptions due to Brass Wire and Elastomeric Separators: A Cross-sectional Study. *World J Dent* 2020;11(5):421–424.
15. Wilson S, Ngan P, Kess B. Time course of the discomfort in young patients undergoing orthodontic treatment. *Pediatr Dent.* 1989;11:107–110.