# COMPARISON OF LIDOCAINE/PRILOCAINE (EMLA) AND BENZOCAINE IN REDUCING IMMEDIATE PAIN DURING ELASTOMERIC SEPARATOR PLACEMENT: A QUASI-EXPERIMENTAL NON-RANDOMIZED CONTROLLED STUDY

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## ABSTRACT

**Objective:** To compare the effectiveness of 5% lidocaine/prilocaine cream (EMLA) and 20% benzocaine gel in reducing immediate pain during elastomeric separator placement in orthodontic patients.

**Methods:** This quasi-experimental non-randomized controlled study included 60 orthodontic patients aged 16–35 years. Participants received EMLA or benzocaine based on clinical allocation, and placebo was applied on the opposite side without random selection. Topical anesthetic was applied to the gingiva and separators. After 2 minutes, elastomeric separators were placed. Pain intensity was recorded using a Visual Analogue Scale (VAS) at 2, 4, 6, 8, and 10 minutes. Pain scores were analyzed using paired t-tests for within-group comparisons and independent t-tests for intergroup comparisons. Data were analyzed using paired t-tests and chi-square tests. A *p*-value <0.05 was considered significant.

**Results:** Group A showed significantly lower mean pain scores than placebo at all time intervals ($p<0.05$). Group B showed significantly lower pain at 2 and 4 minutes ($p<0.05$), but no significant difference at 6, 8, and 10 minutes. Intergroup comparison revealed that EMLA was more effective than benzocaine in reducing pain at all time intervals.

**Conclusions:** Topical application of EMLA before separator placement significantly reduced immediate pain compared with benzocaine and placebo. Using EMLA may improve patient comfort and compliance during the first orthodontic visit.

**Keywords:** Orthodontic pain, Lidocaine-Prilocaine, Benzocaine, Elastomeric separators, Visual analogue scale

## INTRODUCTION

Pain is a frequent concern during orthodontic treatment. Elastomeric separators are routinely placed at the start of treatment to create space for molar bands. Their placement often causes immediate pain, which can reduce comfort and patient cooperation and, in some cases, delay treatment adherence. A cross-sectional study of 130 orthodontic patients reported that 63.8% experienced pain after separator insertion, with females reporting more pain and older patients experiencing greater chewing discomfort [1].

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Pain from separators results from compression of the periodontal ligament, stretching of gingival tissues, and release of inflammatory mediators. These changes trigger rapid pain signals soon after placement. If not managed, this pain can reduce trust between clinician and patient and may discourage patients early in treatment.

Several approaches have been tried to reduce orthodontic pain, including systemic analgesics, low-level laser therapy, vibratory stimulation, and chewing adjuncts. Each method has benefits and limitations. Systemic drugs such as NSAIDs are effective but may cause gastric or systemic side effects [2]. Non-drug methods like vibration or laser therapy require equipment and are more suitable for delayed pain, not the first minutes after separator placement [3,4]. Hence, a safe, fast-acting, and non-invasive option is desirable for chairside use.

Topical anesthetics meet these criteria. They act locally, have rapid onset, and are easy to apply. Benzocaine is a common choice in dental practice. It works quickly but may have a short duration. Another option is the eutectic

mixture of lidocaine and prilocaine (EMLA). This combination lowers the melting point of the agents, improving mucosal penetration and providing potentially deeper and longer anesthesia than benzocaine. EMLA and its gel formulation, Oraqix, have been successfully used for procedures such as periodontal probing, root planing, and palatal injections [5,6].

Recent evidence highlights the importance of choosing the right formulation for specific clinical tasks. A 2024 randomized trial in children compared 5% EMLA, 8% lidocaine gel, and 20% benzocaine before inferior alveolar nerve block and found that all topical agents reduced pain, but none was clearly superior [7]. However, a 2024 split-mouth randomized trial during rubber-dam clamp placement reported significantly lower pain scores with EMLA compared to benzocaine at 3 minutes, suggesting a possible advantage for EMLA in short-interval procedures [8].

Evidence specific to separator placement is growing. A 2024 split-mouth study of 2% lidocaine gel showed significant pain reduction at 10 and 15 minutes compared with placebo, though early minutes were not significantly different [9]. These findings emphasize the need to evaluate pain within the first few minutes after separator placement — the time of highest discomfort. Managing this pain may improve the patient's first impression and overall compliance.

Non-pharmacological strategies remain useful for later pain peaks. A 2024 network meta-analysis showed that chewing gum, laser therapy, vibration, and acupuncture effectively reduce pain in the first 24–48 hours of treatment [4]. Another meta-analysis confirmed that chewing gum reduces pain without increasing bracket breakage [10]. However, these approaches are not designed to control the immediate pain of separator placement, which is the focus of this study.

Formulation and delivery also matter for clinical effect. A 2023 pediatric trial tested a 10% lidocaine/10% prilocaine gel and reported better pain control and parent satisfaction with no adverse events [11]. Another 2024 clinical trial investigated microneedle patches delivering EMLA cream and showed superior comfort compared with conventional injection anesthesia [12]. These findings support the safety and utility of amide-amide topical combinations in oral settings.

Despite the availability of several pain-control methods, there is a lack of direct comparisons between 5% EMLA cream and 20% benzocaine gel for immediate pain during elastomeric separator placement. Immediate pain refers to pain reported in the first few minutes after placement. Addressing this pain is critical for patient comfort and building trust at the first orthodontic visit.

The present study was designed to address this gap. Using a quasi-experimental study design, we examined EMLA and benzocaine in reducing pain at multiple intervals (2, 4, 6, 8, and 10 minutes) following separator placement. We expected that EMLA would produce a greater reduction in immediate pain compared to benzocaine. Findings from this study may help clinicians choose an optimal topical anesthetic and improve patient experience at the start of orthodontic treatment.

## MATERIALS AND METHODS

This was a quasi-experimental non randomized controlled study. It was conducted in the Department of Orthodontics, Bacha Khan College of Dentistry, Mardan. The duration of the study was six months after approval of the synopsis by the institutional review board (IRB).

Ethical clearance was obtained from the IRB of Bacha Khan College of Dentistry, Mardan before data collection. Written informed consent was taken from all participants. Patient confidentiality was maintained by coding the data and storing it securely [13]. The study followed TREND guidelines for non-randomized research [14].

Sample size was calculated using a significance level (α) of 0.05 and power of 80%. Based on expected pain reduction of 30% for EMLA and 10% for benzocaine, 30 patients were required per group. A total of 60 patients were included using consecutive non-probability sampling.

The inclusion criteria for this study were patients aged between 16 and 35 years who required orthodontic treatment, had a permanent dentition except for the third molars, exhibited a healthy periodontium, and presented with tight interproximal contacts as confirmed with dental floss. The exclusion criteria included patients taking systemic medications or analgesics, those who were pregnant or lactating, individuals with a known allergy to local anesthetics, and those with loose interproximal contacts. Participants were non-randomly assigned to Groups. To maintain partial blinding, the anesthetic agents were placed in containers labeled "Type A" and "Type B" by a supervisor

who was not involved in outcome assessment. The operator applying VAS and placing separators was kept unaware of the anesthetic used.

Before separator placement, cotton rolls were placed, and the gingiva was dried to ensure isolation. Participants closed their eyes during application. The assigned topical anesthetic (EMLA or benzocaine) was applied with a cotton pellet to the buccal and palatal gingiva of the upper first molars and to the separators. On the opposite side, placebo petroleum jelly was applied in the same way. After two minutes, separators (Ormco, USA) were placed using separating pliers.

Pain intensity was measured using a 100-mm Visual Analogue Scale (VAS), which is a validated tool for pain assessment [3]. Patients recorded their pain at 2, 4, 6, 8, and 10 minutes after separator placement on both the anesthetic and placebo sides. Although multiple paired comparisons were performed, these were planned comparisons at predefined clinically relevant time points. However, we acknowledge that multiple testing may increase the risk of type I error.

Data were analyzed using SPSS version 20.0. Mean and standard deviation were calculated for quantitative variables such as pain scores. Frequencies and percentages were calculated for qualitative variables such as gender. Age and gender distributions were comparable between the two groups at baseline, with no statistically significant differences observed. Therefore, additional multivariable adjustment was not performed. Paired t-tests were applied to compare mean pain scores between intervention and placebo sides. Chi-square test was used for categorical variables. A *p*-value of $<0.05$ was considered statistically significant.

## RESULTS

Sixty patients were enrolled in the study. All completed the study and were included in the analysis. The mean age of participants was 23.8 ± 4.2 years. There were 36 females (60%) and 24 males (40%). Because allocation was not randomized, baseline similarity cannot be guaranteed (Table 1).

**Table 1. Baseline characteristics of participants**

| Variable | Group A (EMLA) (n=30) | Group B (Benzocaine) (n=30) | p-value |
|---|---|---|---|
| Age (years, mean ± SD) | 23.6 ± 4.1 | 24.0 ± 4.3 | 0.72 |
| Gender (F/M) | 18/12 | 18/12 | 1.00 |

In Group A (EMLA), mean pain scores were significantly lower than placebo at all time intervals (2, 4, 6, 8, 10 minutes) ($p<0.05$). In Group B (benzocaine), pain reduction was significant at 2 and 4 minutes only ($p<0.05$) and not significant at 6, 8, and 10 minutes (Table 2).

**Table 2 Within-group comparison of mean pain scores (VAS, mm)**

| Time (min) | Group A: EMLA vs Placebo (p-value) | Group B: Benzocaine vs Placebo (p-value) |
|---|---|---|
| 2 | 0.001* | 0.01* |
| 4 | 0.002* | 0.02* |
| 6 | 0.004* | 0.07 |
| 8 | 0.003* | 0.11 |
| 10 | 0.001* | 0.13 |

*Significant at $p<0.05$

Direct comparison showed that Group A had significantly lower pain scores than Group B at all time intervals ($p<0.05$). EMLA showed lower pain scores at all time points in this non-randomized comparison (Table 3). A non-randomized design may allow residual confounding.

**Table 3 Inter-group comparison (EMLA vs Benzocaine) of mean pain scores**

| Time (min) | Mean Pain (EMLA) ± SD | Mean Pain (Benzocaine) ± SD | p-value |
|---|---|---|---|
| 2 | 1.8 ± 0.6 | 3.1 ± 0.7 | 0.001* |
| 4 | 2.0 ± 0.7 | 3.4 ± 0.8 | 0.001* |
| 6 | 2.1 ± 0.6 | 3.6 ± 0.9 | 0.001* |
| 8 | 2.3 ± 0.7 | 3.8 ± 1.0 | 0.001* |
| 10 | 2.4 ± 0.6 | 3.9 ± 1.0 | 0.001* |

*Significant at $p<0.05$

EMLA significantly reduced pain compared with placebo at every time point. Benzocaine reduced pain significantly only at 2 and 4 minutes. EMLA consistently outperformed benzocaine at all intervals. No adverse events were observed

## DISCUSSION

This study assessed the effect of 5% lidocaine/prilocaine cream (EMLA) and 20% benzocaine gel on immediate pain during elastomeric separator placement. Pain was recorded at short intervals, beginning 2 minutes after placement. Results showed that EMLA produced significantly lower pain scores than benzocaine at all time points. Benzocaine significantly reduced pain compared to placebo only at 2 and 4 minutes. These findings suggest that EMLA offers superior and sustained pain control in the first 10 minutes of separator placement.

Our findings are in line with research that shows topical anesthetics can lower pain from orthodontic procedures. Zakai et al. (2024) found that 2% lidocaine gel significantly reduced pain after separator placement at 10 and 15 minutes compared with placebo [9]. Our study adds to this by focusing on the first 2–10 minutes, the peak period of discomfort. By showing significant pain reduction even at 2 minutes, EMLA appears to act quickly and consistently.

A recent randomized split-mouth trial by Naik et al. (2024) compared 5% EMLA cream with 20% benzocaine gel during rubber-dam clamp placement and reported lower VAS scores with EMLA at 3 minutes [8]. This supports our result that EMLA provides stronger early pain suppression compared to benzocaine. Another clinical trial tested Oraqix, a gel containing lidocaine and prilocaine, for periodontal probing and found improved comfort with minimal systemic absorption [6]. Together, these results confirm that eutectic lidocaine-prilocaine formulations penetrate mucosa well and provide adequate local anesthesia for short procedures.

Our study also agrees with reports on benzocaine's limited duration. Benzocaine is an ester anesthetic with rapid onset but short action. This explains why its effect was significant only at the first two time intervals in our study. A trial comparing benzocaine with 8% lidocaine found no difference in pain reduction during inferior alveolar nerve block in children, suggesting both are adequate but may not provide profound anesthesia [7]. In our study, benzocaine did not maintain its effect beyond 4 minutes, highlighting its limitation for procedures causing prolonged pressure.

The first orthodontic visit can be stressful. Pain during separator placement may create anxiety and reduce compliance with subsequent treatment steps. EMLA cream is easy to apply, well tolerated, and effective even in the first minutes after placement. Its ability to maintain lower pain scores throughout the observation period can improve patient experience and trust in treatment. This is especially relevant for adolescents who may be more sensitive to pain or anxious about dental procedures.

Topical anesthetics also avoid the disadvantages of systemic analgesics. NSAIDs have been widely used for orthodontic pain control but can cause gastrointestinal side effects and are contraindicated in certain patients [2]. EMLA offers a safe, non-invasive alternative that acts locally and does not require systemic absorption. It may also be useful for patients who refuse or cannot take oral medication.

The superior effect of EMLA can be explained by its pharmacologic properties. It is a eutectic mixture of lidocaine and prilocaine in equal concentrations, resulting in a lower melting point and enhanced penetration into keratinized and non-keratinized tissues [5]. This allows it to block sodium channels more effectively and provide deeper anesthesia than benzocaine, which acts only superficially. The cream formulation also maintains prolonged contact with gingival tissues, improving absorption.

Other pain-control methods have been studied for separator placement, including laser therapy, vibratory devices, and chewing adjuncts. A 2024 network meta-analysis concluded that low-level laser therapy and vibratory stimulation reduce pain during the first 24–48 hours of orthodontic treatment but are less practical for immediate chairside use [3]. Chewing gum and bite wafers can also reduce pain perception but require patient compliance after leaving the clinic [4]. In contrast, EMLA provides immediate relief with minimal patient effort, making it ideal for use at the first appointment.

No adverse events or allergic reactions were reported in our study. This aligns with large multicenter trials showing that lidocaine/prilocaine preparations are safe for use on oral mucosa [15]. Benzocaine, although safe for most patients, has been rarely associated with methemoglobinemia, especially in young children [16]. EMLA therefore represents a safe and effective option for a wider patient population when used in recommended quantities.

This study has several strengths. The split-mouth method allowed each patient to serve as their own control, improving internal validity. Pain was measured using a Visual Analogue Scale, a reliable and validated tool for pain assessment [17]. Recording pain at short intervals provided a detailed picture of immediate pain patterns.

Our study has some limitations. The sample size, though adequate for detecting differences, was limited to two centers in one region, which may affect generalizability. Pain perception is subjective and influenced by psychological and cultural factors. We did not evaluate anxiety levels, which could have influenced pain reporting. Although baseline characteristics were comparable, residual confounding cannot be completely excluded due to the non-randomized design. Also, the follow-up was limited to 10 minutes; longer monitoring could clarify whether EMLA continues to provide benefit after this period. Future studies could include larger multicenter samples and assess pain up to 24 hours after placement.

Research should explore combining topical anesthetics with non-drug measures such as vibration or pre-emptive chewing to maximize pain control. Studies could also compare different concentrations and formulations of lidocaine-prilocaine mixtures. Investigation of patient-reported outcomes such as anxiety reduction and treatment satisfaction would provide a more comprehensive view of the clinical benefit.

This study provides new evidence that EMLA is superior to benzocaine for controlling immediate pain during separator placement. It acts quickly, sustains its effect through the first 10 minutes, and is safe and easy to use. These findings can help orthodontists improve patient comfort and compliance at the start of treatment.

## CONCLUSION

In this non-randomized comparison, EMLA cream significantly reduced immediate pain during elastomeric separator placement compared to benzocaine gel. Its effect was consistent at all measured time intervals. Benzocaine was effective only in the first few minutes and lost significance after 4 minutes. Using EMLA may improve patient comfort, reduce anxiety, and enhance cooperation during the first orthodontic visit. We recommend its use as a simple and effective chairside method for pain management in clinical orthodontics.

## DECLARATIONS

This study was approved by the Institutional Review Board of Bacha Khan College of Dentistry (Ref. No:----------). Written informed consent was obtained from all participants. The study followed the principles of the Declaration of Helsinki.

**Conflict of Interest**
The authors declare no conflict of interest.

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**Authors' Contributions**

- **Principal Investigator:** Conceived the study, supervised data collection, and reviewed the manuscript.

- **Co-investigators:** Assisted in patient recruitment, data entry, and manuscript preparation.
- **Statistician:** Performed data analysis and interpretation.

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