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COMPARISON OF ANESTHETIC GEL AND ANTI-INFLAMMATORY GEL IN PAIN MANAGEMENT DURING INITIAL ALIGNMENT OF FIXED ORTHODONTICS.

Anum Mahmood[1], Imtaz Ahmed[2], Sadia Rizwan[3], Sadaf Zehra[4], Arslan Ali[5], Wajid Ali Rajpar[6]

ABSTRACT

BACKGROUND: The pain is a usual part of the fixed orthodontic treatment and ranks amongst its most common side effects. In the management of this discomfort, a range of strategies have been employed in the clinical practices including NSAIDs and topical anesthetics etc. **OBJECTIVE:** To determine the therapeutic effectiveness of anesthetic gel versus anti-inflammatory gel in the pain management during the initial phases of alignment of fixed orthodontics**. METHODS:** A randomized clinical trial was conducted in the Orthodontics Department at DIKIOHS over six months from October 2024 to March 2025. Patients aged 17–35 years undergoing fixed orthodontic treatment of either gender were enrolled. The oral cavity each participant was divided: a 5% anesthetic gel was applied twice daily to the left side, and an anti-inflammatory gel to the right side, during the initial alignment phase. Pain intensity was recorded using the Visual Analogue Scale (VAS) on days 15 and 30. Data were analyzed using SPSS version 26. **RESULTS:** A total of 32 patients (mean age 19.0 ± 5.47 years; 56.3% female) were enrolled. Mean VAS pain scores differed between gels at day 15, with significantly lower the pain scores on the anti-inflammatory side (2.90 ± 1.61) compared to the anesthetic side (3.65 ± 1.58), (p=0.053). By day 30, pain scores were nearly identical (1.96 ± 1.25 vs. 1.93 ± 1.11; p=0.941). Additionally, gender-based comparisons showed slightly higher pain in females at both time points. Overall, pain decreased significantly over time for both gels and genders, with no statistically significant difference (p>0.05). **CONCLUSION:** Both anesthetic and anti-inflammatory gels observed to be effective in reducing orthodontic pain during the initial alignment phase, with pain progressively declining over time for both, showing greater pain reduction with the anti-inflammatory gel on day 15, suggesting the anti-inflammatory gel may offer earlier pain relief.

KEY WORDS: Orthodontic pain, Anesthetic gel, Anti-inflammatory gel, fixed appliances, VAS

1. FCPS resident, Dept of orthodontics, DUHS Karachi.
2. Dean of Dentistry, HOD Orthodontics department, DUHS Karachi.
3. Associate Professor, Orthodontics department, DUHS Karachi.
4. Fcps resident, Department of orthodontics, DUHS Karachi.
5. Assistant professor, Oral biology department, BADC Larkana.
6. Assistant Professor of Oral Medicine BADC Larkana.

Corresponding Author: **DR. ANUM MAHMOOD,** FCPS resident, Dept of orthodontics, DUHS Karachi. **Email:** anumahmood91@gmail.com

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INTRODUCTION

Malocclusion, a frequently seen dental condition, arises in children from inherited genetic influences and environmental exposures during growth, including issues with tooth replacement, detrimental oral behaviors, illnesses, gum disease, or trauma occurring after development.[1] The fixed orthodontic appliances are frequently

applied to manage the malocclusion and improve the both dental function and its related aesthetics.[2,3] The movements of the teeth resulting from concentrating applied forces mechanically, activating remodeling indoors the periodontal ligament and alveolar bone surrounding. Though, such practice frequently causes the different levels of the pain and discomfort, posing anxieties for the individuals and potentially influencing their adherence to the management.[2] Pain experienced in orthodontic care arises from multiple factors, including variations in personal sensitivity, the nature and strength of applied forces, and psychological influences. Research identifies several primary elements affecting how patients perceive discomfort with fixed devices, such as the schedule of appliance adjustments, the time elapsed after appliance placement, and external triggers like eating or shifts in temperature.[2,3,4] It may during orthodontic treatment is additionally triggered by activation of sensory fibers within the supporting periodontal structures and the ensuing inflammatory reaction. Multiple strategies have been suggested to alleviate pain from orthodontic treatment, including the use of non-steroidal anti-inflammatory drugs (NSAIDs), chewing aids like gum or bite wafers, topical or local anesthetics, transcutaneous electrical nerve stimulation, low-intensity laser therapy, and vibration-based stimulation.[5-7]

The use of anesthetic gels in the fixed orthodontics has been investigated to alleviate pain linked with the appliance activation and the separator placement. Studies indicated that the topical anesthetics can significantly decrease the pain perception, while their effectiveness is different.[8,9] Additionally in approaches for managing orthodontic pain vary widely, with (NSAIDs) remaining the most commonly used agents for pain relief. Tooth movement during orthodontic treatment triggers inflammation in the periodontal tissues and responses in the dental pulp, leading to the release of numerous biochemical mediators responsible for pain perception.[10,11] NSAIDs alleviate symptoms by inhibiting arachidonic acid conversion in the prostaglandin synthesis pathway, thereby decreasing prostaglandin levels, which are key mediators of the inflammatory reaction following orthodontic forces.[10,12] According to one study, benzocaine gel was found to reduce pain perception compared with a placebo gel.[8] Conversely, another investigation reported that naproxen gel demonstrated significantly greater analgesic efficacy than placebo at all evaluated time points.[13] However, there is insufficient comparative clinical evidence evaluating the effectiveness of anesthetic gels versus anti-inflammatory gels. This study, therefore, aims to assess their therapeutic benefits for pain management during the initial alignment phase of fixed orthodontic treatment**.**

MATERIAL AND METHODS

This randomized clinical trial was conducted in the Department of Orthodontics at DIKIOHS over a six-month period following approval from the Institutional Review Board (IRB) from October 2024 to March 2025. A total of 32 patients who met the inclusion criteria were recruited using a non-probability consecutive sampling technique. This study included male and female patients aged 17–35 years undergoing fixed orthodontic treatment, with healthy periodontal tissues and intact dentition (no carious teeth, fractured roots, or erupting third molars). All the patients if they had craniofacial abnormalities, temporomandibular joint dysfunction, hypertension, or were on regular medications such as those used for arthritis or migraine were excluded. Written informed consent was obtained from all participants prior to enrollment. Each participant's oral cavity was divided into left and right sides. The left side was assigned to receive a 5% anesthetic gel, and the right side was assigned to receive an anti-inflammatory gel. Both gels were

applied by the patients twice daily throughout the initial alignment phase of fixed orthodontic treatment. Patients were instructed on standardized application procedures to ensure compliance. The sample size of 32 patients were based on a one-sample t-test, using a mean and standard deviation for the pain index (PI) of 0.29 ± 0.04 on the anesthetic side at time point T3, derived from a prior reference study. With the test power of 99% CL, the required sample size was calculated 32. Outcome of the study in terms of effective changes in pain intensity, was evaluated by using the VAS at the two attempts: one on day 15 and 2nd on day 30 following the starting of the alignment phase of fixed orthodontic treatment among cases. The scores of the pain were measured separately for the left side of the mouth, where anesthetic gel was applied, and right side of the mouth, where the applied the anti-inflammatory gel, to assess the direct comparison in terms of effectiveness of each gel in reducing the treatment related pain during the immediate and delayed phases of the alignment. All the information was entered and analyzed via SPSS version 26. The mean VAS scores were compared between the sides of the month in each case applying the paired t-test, taking a p-value of <0.05 as statistically significant.

RESULTS

Overall 32 patients were studied with an overall mean age of 19.0 ± 5.47 years. Out of all participants, 56.3% (18 patients) were female, while 43.8% (14 patients) were male, showing a slightly higher proportion of female patients. Table: 1

In this study mean pain scores were measured by the Visual Analogue Scale (VAS) showed a difference between the two gels at day 15, with lower pain on the right side treated with anti-inflammatory gel (2.90 ± 1.61) compared to the left side treated with anesthetic gel (3.65 ± 1.58), though the difference was not statistically significant (p = 0.053), while by the day 30, pain scores were nearly identical between the right side (1.96 ± 1.25) and left side (1.93 ± 1.11), with no significant difference (p = 0.941) as shown in table: 2

According to the gender-based comparison of mean pain scores was slightly higher in females than males, though differences were not statistically significant. After 15 days, pain on the right side (anti-inflammatory gel) was 2.55 ± 1.44 for males and 3.17 ± 1.72 for females ($p = 0.289$). At 30 days, scores reduced to 2.08 ± 1.39 in males and 1.86 ± 1.16 in females ($p = 0.632$), while on the left side (anesthetic gel), pain after 15 days was 3.20 ± 1.80 for males and 4.00 ± 1.33 for females ($p = 0.159$), and by 30 days, scores were nearly equal (1.95 ± 1.13 in males vs. 1.92 ± 1.12 in females, $p = 0.945$). However, the pain was decreased over time for both genders, without significant difference, as shown in table: 3

Table: 1. Mean age and gender distribution of the patients n=32

Variables		Frequency	Percent
Gender	**Females**	18	56.3
	Males	14	43.8
	Total	32	100.0
Age	**Mean ±SD**	19.0±5.471 years	

Table: 2. Mean pain score (VAS) comparison according to types of gels n=32

Variables	Site of mouth	N	Pain score (VAS)		p-value
			Mean	Std. Deviation	
Pain score after 15 days	Right site	32	2.90	1.607	0.053
	Left site	32	3.65	1.580	
Pain score after 30 days	Right site	32	1.96	1.246	0.941
	Left site	32	1.93	1.105	

Right side = Anti-inflammatory gel. **Left side** = Anesthetic gel

Table: 3. Mean pain score (VAS) comparison according gender n=32

Variables	Site of mouth	N	Pain score (VAS)		p-value
			Mean	Std. Deviation	
pain score after 15 days at right side	Male	14	2.55	1.439	0.289
	Female	18	3.17	1.718	
pain score after 30 days at right side	Male	14	2.08	1.385	0.632
	Female	18	1.86	1.159	
pain score after 15 days at left side	Male	14	3.20	1.803	0.159
	Female	18	4.00	1.331	
Pain score after 30 days at left side	Male	14	1.95	1.130	0.945
	Female	18	1.92	1.118	

Right side = Anti-inflammatory gel. **Left side** = Anesthetic gel

DISCUSSION

Although orthodontics has progressed with modern innovations, pain remains unavoidable and challenging for patients during treatment. Studies indicate that procedures such as placing separators, initiating archwires, and subsequent adjustments are primary triggers of orthodontic discomfort.[14] However this study assessed the effectiveness of anesthetic and anti-inflammatory gels in reducing pain during the initial alignment phase of fixed orthodontic treatment in 32 patients (mean age 19.0 ± 5.47 years), with a slight female predominance (56.3% vs. 43.8%). These findings are consistent with the study by Keppler FL et al[15] where the mean patient age was 17.04 ± 5.4 years, and females constituted the majority (73.4% vs. 26.6% males). However, our findings differ from those of Pattanaik S et al[16] who reported a higher mean age of 32.4 ± 7.2 years but a comparable gender distribution, with 64.8% females and 35.2% males. The variation in mean age across studies may be attributed to differences in the sample size of the study, sample selection criteria and treatment populations, while the consistent female predominance could reflect the greater likelihood of females seeking orthodontic treatment for aesthetic concerns.

In this study, mean pain scores measured using the Visual Analogue Scale (VAS) demonstrated a difference between the two gels at day 15, with lower pain reported on the side treated with anti-inflammatory gel (2.90 ± 1.61) compared to the anesthetic gel side (3.65 ± 1.58), although this difference was not statistically significant (p=0.053), while by the day 30, pain scores were nearly identical between the anti-inflammatory side (1.96 ± 1.25) and the anesthetic side (1.93 ± 1.11; p=0.941), suggesting both gels were equally effective in reducing discomfort over time. These findings align with the results of Eslamian L et al[17] who compared benzocaine and ketoprofen gels in orthodontic patients and found ketoprofen to provide the greatest pain reduction versus placebo, benzocaine to show moderate efficacy, and peak pain occurring two hours' post-force application before subsiding by day seven. In aligns to present study Zakai AM et al[8] stated that lidocaine significantly decreases the pain during initial separator placement, specifically promoting the cases with lower pain severity and those

feeling the anxiety. Supporting to our findings, Al-Melh MA et al[18] demonstrated that the anesthetic gels can effectively decrease the early pain linked to the orthodontic procedures and alos decease the requirements for systemic analgesics. Consistently, Vettorello I et al[19] reported that the level of pain was consistently deceased on the treated side where plant-based gel was applied, starting from the first application and keep on until elastic removal p = <0.05. Conversely, they found higher reports of burning sensations on the site of experiment, with the 20% of individuals describing the CV gel as possess unpleasant tastes, and they generally observed that intraoral CV application possesses notable analgesic potential for separator induced pain. Moreover, Long H et al[20] observed that the NSAIDs are widely recognized based on the effectiveness in relief of pain, while their potential effects on orthodontic tooth movement remain controversial, demanding further search into alternative modality. In the study by Javed A et al[21] demonstrated that while NSAIDs effectively reduce pain, uncertainty regarding their impact on tooth movement emphasizes the requirement for additional studies exploring harmless, effective strategies for the pain management. Overall studies suggested that both anesthetic and anti-inflammatory gels are effective in controlling orthodontic pain, particularly during the early treatment phase, though the magnitude and duration of their effects are different. Particularly, there is very limited studies specifically evaluating anti-inflammatory gels, with most existing literature highlighting the need for future large-scale studies. Though the present study adds novelty by directly comparing anesthetic and anti-inflammatory gels; however, it possesses many limitations, like very limited sample size and the application of both gels within the same individuals, divided by the oral sides, which may have influenced the effectiveness. Hence, further larger-scale studies with randomized patient allocation into separate treatment groups are advised to validate our findings and contribute new insights to orthodontic clinical practice.

CONCLUSION

In the conclusion both anesthetic and anti-inflammatory gels were effective in reducing orthodontic pain during the initial alignment phase, with a progressive decline in pain scores over time for both interventions. On the 15th day, pain reduction was greater with the anti-inflammatory gel (right side) compared to the anesthetic gel (left side), whereas by the 30th day, pain scores were nearly identical on both sides, suggesting that the anti-inflammatory gel may provide earlier relief in pain. Generally, either gel can be used as a simple, non-invasive adjunct for managing discomfort associated with fixed orthodontic therapy, improving patient tolerance and adherence to treatment. Due to the limited sample size, these findings cannot be considered definitive; therefore, larger multicenter randomized trials are recommended to validate the outcomes and determine whether patient-specific factors influence gel effectiveness.

ETHICS APPROVAL: The ERC gave ethical review approval. **IRB-3698/DUHS/APPROVAL/2024/338 DATED: 29/10/2024.**

CONSENT TO PARTICIPATE: written and verbal consent was taken from subjects and next of kin.

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AUTHORS' CONTRIBUTIONS:

All persons who meet authorship criteria are listed as authors, and all authors certify that they have participated in the work to take public responsibility of this manuscript. All authors read and approved the final manuscript.

CONFLICT OF INTEREST: No competing interest declared.

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