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INVESTIGATING THE IMPACT OF 2% TOPICAL LIDOCAINE GEL ON DISCOMFORT AND PAIN ATTRIBUTED TO THE PLACEMENT OF ORTHODONTIC ELASTOMERIC SEPARATORS

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ABSTRACT

Orthodontic pain and discomfort can have a negative impact on a patient's compliance and can occasionally lead to poor cooperation, disinterest, hampered treatment outcomes, and even treatment termination. The purpose of this study was to compare the extent to which lidocaine 2% topical anesthetic gel in comparison to Vaseline placebo can reduce pain and discomfort that results from the initial placement of orthodontic elastomeric separators. This split mouth study design encompassed 30 patients presenting with Malocclusion, requiring fixed orthodontic treatment were included in this study who received 2% lidocaine in form of gel on one side of the mouth and placebo gel composed of Vaseline on other side of the mouth**.** Participants were asked to rate their pain on a visual analogue scale (VAS) immediately following the placement of the separator. The participant's responses were collected every 5 minutes following the insertion of the separator for a total of 15 minutes. The mean age of the study groups was 17.53 ± 2.03 years. The pain score was not statistically significant immediately or after 5 minutes of separator placement. However, it was significantly reduced at 10 and 15 minutes in the study group on one side of the patients compared to the other side as treated control [15.8±8.9 vs. 27.60±16.91; p=0.001 at 10 minutes, 5.23±3.82 vs. 11.07±8.93; p=0.002 at 15 minutes]. This study demonstrated that lidocaine could effectively reduce discomfort or pain caused by the first placement of the orthodontic elastomeric separators. This therapy may be beneficial for people with a low pain threshold, as well as anxious adults and children.

Keywords: 2% Topical Lidocaine Gel, Pain and Discomfort, Orthodontic Elastomeric Separators.

1. INTRODUCTION:

pain is a subjective reaction that is frequently brought on by unpleasant stimuli, such as orthodontic treatment (1, 2). The literature now in publication makes it abundantly evident that every orthodontic technique, including the insertion and activation of separators, the application of orthopedic forces, the usage of elastics, and debonding procedures, causes pain and discomfort (3). Following the placement of the appliance, patients frequently report feeling pressure, tightness, soreness in their teeth, and pain (2, 3). Numerous techniques for treating orthodontic pain have been documented in the literature. These include applying topical analgesic gels, chewing gum or bite wafers, transcutaneous electrical nerve stimulation, low-level laser therapy, vibratory stimulation, and oral administration of non-steroidal anti-inflammatory drugs (4, 5). However, each of these techniques has limitations.

In fixed orthodontic mechanotherapy, creating space mesially and distally to the teeth, which are to be banded, forms the initial step in patient's management. It is well established that placement of separator which can be elastomeric, brass wire, spring type, steel, and latex separators causes pain and discomfort almost in all the patients (5, 6). The pain and discomfort start within four hours of separator placement which increases over the next 24 hours with a peak level at day 2 and decreases to pre-placement level within 7days (3). Based on clinical experience, the placement of orthodontic separators in some patients can cause immediate initial pressure, leading to discomfort and pain. The patients' degree of initial and delayed responses to the uncomfortable and painful orthodontic procedures can be attributed to several factors, such as age, gender, and pain threshold, which can affect the patient's motivation for orthodontic treatment (3). Therefore, some orthodontic patients do need special consideration, making it imperative to find a method that decreases the patients' initial discomfort and pain during the separator placement visit to ensure good compliance in future orthodontic visits. The use of topical lignocaine anesthetics gel has been found to be effective in various orthodontic procedures for relieving discomfort and pain. The results of one of the studies suggest the potential usefulness of topical anesthetic gel when performing orthodontic procedures such as, band placement and cementation, band and bracket removal, and arch wire ligation (7). There are few studies conducted in international setting which has assessed the effects of topical lidocaine/prilocaine anesthetic gel from the initial placement of orthodontic elastomeric separator. The results of one study show, significantly lower overall mean of discomfort/pain score with the topical anesthetic (3.96 ± 5.70 SD) than with the placebo (12.77 ± 12.91) (1).

Our population's pain tolerance and threshold may vary due to differences in ethnicity and psychosocial backgrounds. Following a comprehensive literature search, and to the best of the author's knowledge, no study has been undertaken in the local population of Sindh, Pakistan. The findings of this study will assist us in encouraging the patient by eliminating pain associated with the insertion of an elastomeric separator, which will lead to improved patient management seeking fixed orthodontics.

2. METHODOLOGY

Involvement of Participants: This study comprised of 30 patients who had received 2% lidocaine in form of gel on one side of the mouth i.e. study group and the same patients received placebo gel composed of Vaseline on other side of the mouth.] The authors of this research collected and checked the content's accuracy. To collect thorough information through surveys and share drafts for feedback to ensure appropriate presentation. Transparency and consent, particularly for sensitive information, were critical throughout the process. This collaborative approach not only enriches the article but also fosters trust and ethical standards in medical research and publication.

Study Design, Setting and Duration:

This study was Experimental -Split Mouth Design, conducted at Department of Orthodontics Institute of Dentistry, Liaquat University Medical & Health Sciences Jamshoro/Hyderabad followed for

duration of six months i.e., 02-08-2021 to 02-02-2022.

Population and Sampling:

Using Open Epi online software, the sample size of 30 patients was determined based on the prior study statistics: Study Group: Mean pain score: 3.96 ± 5.70 SD; Control Group: 12.77 ± 12.91)1 with 80% power of the study and a 95% confidence interval. The Non-Probability Consecutive Sampling Technique was used to choose the samples.

Inclusion Criteria:

- Patients presenting with Malocclusion, requiring fixed orthodontic treatment, of either gender between the age of 14-22 years
- Presence of healthy gingival tissues (was assessed clinically using gingival index)
- Tight contact between posterior teeth (was assessed by passing dental floss)
- Complete intact posterior occlusion (was assessed on clinical examination)
- Intact maxillary dentition except for the third molars (was assessed on Clinical examination)
- No Pain at the onset of study (neither dental nor gingival)

Exclusion Criteria:

- Existence of inflamed gingival tissues and periodontal disease
- Missing posterior teeth
- Spacing between the posterior dentition
- Retained deciduous posterior teeth
- Interproximal carious lesion or restoration between the first molar and second premolar
- Subjects with systemic disease and or taking systemic analgesics.

Data Collection Procedure:

Patients who met the criteria for inclusion and needed orthodontic treatment at the Department of Orthodontics, LUMHS Jamshoro/Hyderabad, were enrolled in the study. Each research participant was given a thorough explanation of the study at the time of recruiting, and both written and verbal informed consent were obtained from each subject's parents.

The single population used in this study was split up into the following groups.

Study Group: The participants who had received 2% lidocaine in form of gel on one side of the mouth.

Control Group: The same participants who had received placebo gel composed of Vaseline on other side of the mouth.

The efficacy of topical 2% lidocaine gel was evaluated by comparing it to placebo gel in a split mouth design, which minimized individual differences in pain experience while also allowing investigators to compare the study and control groups in the same patient. The order in which study and control agents were placed, as well as which side of the dental arch was treated first, was randomized between subsequent patients.

Operative Procedure:

The gingival tissues of the first molars and second premolars on both sides of the maxillary arch were initially dried using gauze and an air-water syringe. The topical anesthetic gel would next be applied to one side of the arch, around the gingival margins, and into the crevices of the first and second premolar teeth, immediately before the elastomeric separator was placed. The topical anesthetic gel dispensing process is non-invasive and painless because it is delivered directly to soft tissues.

On the contralateral side, placebo Vaseline was applied to the gingival margins of the first molar and

second premolar. The sides on which the materials were delivered were randomly alternated such that if the initial participants received topical anesthetic gel on the right side, the following person would receive it on the left side, and so on. Thus, at the conclusion of the trial, half of the participants would be given topical anesthetic gel on the right side and the other half on the left side. After 2 minutes of applying the agents to both sides, the orthodontic elastomeric separator was put between the first molar and second premolar on both sides.

Assessment:

The participants were asked to immediately report the degree of pain after the placement of separator, on a visual analogue scale (VAS). The participants were first familiarized with 100-mm VAS for pain measurement in a scripted presentation. The overall mean pain score of participants was measured by using a 100-mm horizontal non-graded VAS, with the left endpoint marked as "0 mm, no discomfort/pain," and the right endpoint marked "100 mm, worst possible discomfort/pain." The participant's responses were recorded every 5 minutes after the placement of separator for a total period of 15 minutes.

Statistical Analysis:

The data was analyzed using computer software" Statistical Package for Social Science, SPSS Version 23.0" (IBM Corp, Armonk NY USA). While the mean and standard deviation were computed for the quantitative data, such as age, years of education, and VAS, the qualitative variables, such as gender, occupation, and ethnicity, were reported as frequency and %. The independent t test was used to compare the mean VAS score between the groups.

Effect modifiers like age, ethnicity, gender, occupation, years of education was controlled through stratification. The *P* value equal to or less than.05 was considered statistically significant.

2 RESULTS:

These 30 patients were referred to as study groups because they were given 2% lidocaine in the form of gel on one side of their mouths, while Vaseline-based placebo gel was applied to the other. The average age of the patients was 17.53±2.03 years. Similarly mean years of education is also reported in table 1. There were 17(56.67%) male and 13(43.33%) female (figure-1) Ethnicity of the patients were Sindhis and Urdu speaking as shown in figure 2. Almost 71% of the patients were student 13.3% were employed and 10% were un-employed (figure-3). Comparison of mean pain score by VAS overtime and groups has been reported in table 2. Mean pain score was not statistically significant at immediate and after 5 minutes of the placement of separator however it was significantly reduced at 10 and 15 minutes in study group one side as compared to other side of the same patients as treated control group [15.8±8.9 vs. 27.60±16.91; p=0.001 at 10 minutes, 5.23±3.82 vs. 11.07±8.93; p=0.002 at 15 minutes] respectively. Stratification was performed as per effect modifiers and presented in table 3 to table 7.

TABLE 1: Descriptive Statistics of Age and Years of Education of the Patients N=30

Statistics	Age (Year)	Years of education
Mean	17.53	10.23
Std. Deviation	2.030	2.635
Median	17.50	9.00
Interquartile Range	4	5

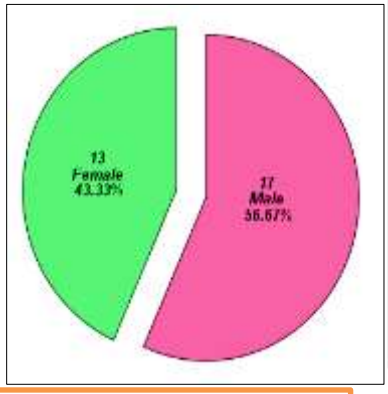

Figure 1: Gender Distribution (*N=30*)

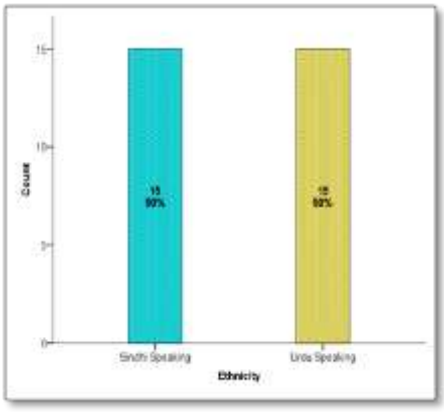

Figure 2: Ethnicity Of the Patients (*N=30*)

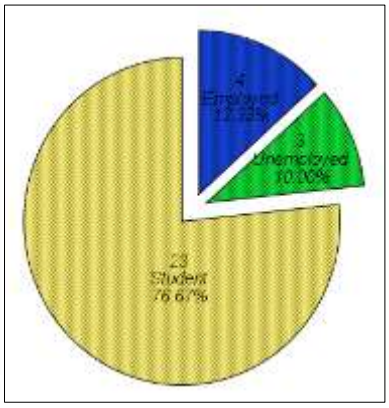

Figure 3: Occupational Status (*N=30*)

TABLE 2: Effect of 2% Topical Lidocaine Gel, In Term of Reducing the Pain Overtime

	Study Group		Control		
VAS after the Placement of Separator	2% lidocaine in form of gel on one side of the mouth		Placebo gel composed of Vaseline on other side of the mouth		**P-Value**
	Mean	Std. Deviation	Mean	Std. Deviation	
Immediately	58.33	10.85	64.00	13.54	0.079
5 Minutes	51.00	6.07	51.50	14.21	0.860
10 Minutes	15.80	8.90	27.60	16.92	0.001
15 Minutes	5.23	3.82	11.07	8.93	0.002

Study Group: The participants were receiving 2% lidocaine in form of gel on one side of the mouth.

Control Group: The same participants were receiving placebo gel composed of Vaseline on other side of the mouth.

TABLE 3: Effect of 2% Topical Lidocaine Gel, In Term of Reducing the Pain Overtime Stratified by Age Groups

Age groups	**VAS**	**Study Group**		**Control**		**P-Value**
		2% lidocaine in form of gel on one side of the mouth		Placebo gel composed of Vaseline on other side of the mouth		
		Mean	Std. Deviation	Mean	Std. Deviation	
14-18 (**n=21**)	Immediately	56.67	9.13	60.50	13.56	0.293
	5 Minutes	52.38	6.25	49.75	15.60	0.479
	10 Minutes	12.33	4.29	30.35	18.37	0.0005
	15 Minutes	4.81	3.86	12.00	10.56	0.006
19-22 (**n=9**)	Immediately	62.22	13.94	71.00	11.01	0.144
	5 Minutes	47.78	4.41	55.00	10.80	0.079
	10 Minutes	23.89	11.67	22.10	12.61	0.753
	15 Minutes	6.22	3.77	9.20	3.97	0.113

TABLE 4: Effect Of 2% Topical Lidocaine Gel, In Term of Reducing the Pain Overtime Stratified by Gender

Gender	VAS	Study Group		Control		P-Value
		2% lidocaine in form of gel on one side of the mouth		Placebo gel composed of Vaseline on other side of the mouth		
		Mean	Std. Deviation	Mean	Std. Deviation	
Male (n=17)	Immediately	58.24	11.31	66.43	13.93	0.081
	5 Minutes	51.18	6.00	48.57	15.12	0.519
	10 Minutes	17.18	9.61	29.07	17.07	0.021
	15 Minutes	5.82	3.73	10.71	9.18	0.054
Female (n=13)	Immediately	58.46	10.68	61.88	13.28	0.460
	5 Minutes	50.77	6.41	54.06	13.32	0.422
	10 Minutes	14.00	7.88	26.31	17.23	.025
	15 Minutes	4.46	3.95	11.38	9.00	0.016

TABLE 5: Effect Of 2% Topical Lidocaine Gel, In Term of Reducing the Pain Overtime Stratified by Ethnicity

Ethnicity	VAS	Study Group		Control		P-Value
		2% lidocaine in form of gel on one side of the mouth		Placebo gel composed of Vaseline on other side of the mouth		
		Mean	Std. Deviation	Mean	Std. Deviation	
Sindhi (n=15)	Immediately	57.33	10.33	64.62	15.06	0.413
	5 Minutes	49.33	5.94	55.00	15.28	0.195
	10 Minutes	18.27	10.96	29.31	19.40	0.070
	15 Minutes	4.47	3.60	13.38	9.76	0.003
Urdu (n=15)	Immediately	59.33	11.63	63.53	12.72	0.340
	5 Minutes	52.67	5.94	48.82	13.17	0.307
	10 Minutes	13.33	5.56	26.29	15.24	0.004
	15 Minutes	6.00	4.00	9.29	8.09	0.164

TABLE 6: Effect of 2% Topical Lidocaine Gel, In Term of Reducing the Pain Overtime Stratified by Employment Status

Employment	VAS	Study Group		Control		P-Value
		2% lidocaine in form of gel on one side of the mouth		Placebo gel composed of Vaseline on other side of the mouth		
		Mean	Std. Deviation	Mean	Std. Deviation	
Employed (n=4)	Immediately	52.50	5.00	64.44	15.09	0.158
	5 Minutes	47.50	5.00	51.11	11.67	0.571
	10 Minutes	15.00	5.77	31.00	18.95	0.134
	15 Minutes	2.25	4.50	9.33	5.07	0.036
Un-employed (n=3)	Immediately	70.00	17.32	75.00	7.07	0.735
	5 Minutes	50.00	.00	50.00	14.14	0.999
	10 Minutes	26.67	5.77	17.50	3.54	0.146
	15 Minutes	8.67	.58	8.50	.71	0.789
Student (n=23)	Immediately	57.83	9.98	62.63	13.27	0.188
	5 Minutes	51.74	6.50	51.84	15.92	0.978
	10 Minutes	14.52	8.89	27.05	16.83	0.004
	15 Minutes	5.30	3.636	12.16	10.658	0.006

TABLE 7: Effect Of 2% Topical Lidocaine Gel, In Term of Reducing the Pain Overtime Stratified by Years of Education

YEARS OF EDUCATION	VAS	Study Group		Control		P-Value
		2% lidocaine in form of gel on one side of the mouth		Placebo gel composed of Vaseline on other side of the mouth		
		Mean	Std. Deviation	Mean	Std. Deviation	
≤10 Years (n=22)	Immediately	56.36	9.02	60.50	13.56	0.247
	5 Minutes	51.82	6.64	49.75	15.60	0.573
	10 Minutes	12.45	4.23	30.35	18.37	0.0005
	15 Minutes	4.82	3.76	12.00	10.56	0.005
>10 Years (n=8)	Immediately	63.75	14.08	71.00	11.01	0.237
	5 Minutes	48.75	3.54	55.00	10.80	0.138
	10 Minutes	25.00	11.95	22.10	12.61	0.627
	15 Minutes	6.38	4.00	9.20	3.97	0.154

3 DISCUSSION:

A 2% lidocaine topical anesthetic gel has previously been tested for its effect on pain reduction during orthodontic operations. One study found that 2% lidocaine topical anesthetic gel could be effective for orthodontic operations including as band implantation and cementation, arch wire ligation, and band/bracket removal (8). Lidocaine, a topical anesthetic gel, had the benefit of being delivered directly into the gingival crevice. The suggested indication for use was linked to a reduction in pain during scaling in gingival pockets. The gel solidified at intraoral temperature and was therefore easily retained within the gingival fissure. Furthermore, the application process was reportedly simple and painless (9). Because lidocaine 2% gel has not yet been utilized for discomfort and pain reduction after initial elastomeric separator installation, extending its use to alleviate patients from the related experience of discomfort would be an intriguing effort.

In the present investigation, the average age of the study groups was 17.53±2.03. There were 17 (56.67%) men and 13 (43.33%) women. The Utomi and Odukoya study included 28 males and 36 females, with an average age of 17.58 ± 6.22 years (10).

The mean pain score was not statistically significant across groups at 5 minutes after separator placement, however it was significantly lower after 10 and 15 minutes in the study group compared to the control group [p=0.001 at 10 minutes, p=0.002 at 15 minutes]. The findings of this investigation were consistent with those of two prior studies that examined the anesthetic effects of two lidocaine/prilocaine compounds to benzocaine. Both investigations found that lidocaine/prilocaine compounds (EMLA® and Oraqix®) reduced pain much better than benzocaine within the first and second minutes of application (11-13).

Concerning the VAS results of Abu Al-Melh et al study [1], regardless of the sides the materials were applied to, it was shown that the Oraqix side reduced discomfort/pain earlier and significantly better than the Vaseline side. The significant difference in the percentage of pain reduction between both materials was evident from the fourth and sixth minutes onwards.

Some studies looked at pain from orthodontic tooth separation by registering pain responses on a VAS at three time points: T1 (before insertion of the tab), T2 (immediately after insertion), and T3 (24 h after insertion) (2, 14). In Abu Al-Melh study [1], the effect of the topical anesthetic lidocaine versus the placebo Vaseline® on discomfort or pain from the very beginning of the placement of the orthodontic elastomeric separators was analyzed. It would be interesting to monitor the effect of Oraqix® 24 h after insertion. However, this is difficult to achieve this as the duration of action of Oraqix® is about 20 min in a dry field. It has been reported by Friskopp and Huledal et al. (14) and Herdevall et al. (15), that there is a large safety margin regarding the systemic effects following the application of L/P topical anesthetic Oraqix®. The plasma profiles of lidocaine and prilocaine following a single dose of Oraqix® to adult patients with advanced periodontitis were low in

comparison to those reported to cause initial signs of CNS toxicity (15, 16). Adverse effects of methemoglobinemia after the use of topical L/P cream have been reported in infants and newborns.30 In the Al-Melh study, the sample comprised of only adults, and the L/P constituents of the CG used caused no reported local or systemic adverse reactions.

The results of this study showed that topical anesthesia could be a valuable tool in reducing pain and discomfort associated with several orthodontic procedures. The lidocaine/prilocaine topical anesthetic, Oraqix®, could be effective in relieving pain and discomfort related to the initial placement of orthodontic elastomeric separators. Based on clinical experience, the placement of orthodontic separators in some patients can cause immediate initial pressure, leading to discomfort and/or pain as soon as the separator is wedged between the teeth. The patients' degree of initial and delayed responses to the uncomfortable and painful orthodontic procedures can be attributed to several factors, including age, gender, and pain threshold, which can affect the patients' motivation for orthodontic treatment (16, 17). Therefore, some orthodontic patients do need special consideration, making it imperative to find a method that decreases the patients' initial discomfort and pain during the separator placement visit to ensure good compliance in the orthodontic visits. The use of topical anesthetics was found to be involved in various orthodontic procedures for relieving discomfort and pain.

CONCLUSION:

This study confirmed the effectiveness of a 2% lidocaine topical anesthetic gel, in reducing pain or discomfort following the initial placement of orthodontic elastomeric separators. Patients with low pain thresholds and anxious adults and kids may find this approach helpful.

Ethical Approval

The research project sought approval from the ethical review boards of LUMHS Jamshoro Research Ethics Committee (REC) on July 02, 2021 and CPSP Karachi before it was authorized to begin.

Data Availability:

The data to support the findings of this study can be provided by corresponding author upon request.

Author's Conflict of Interest

There is no conflict of interest between the authors.

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