



Evaluation of Pain-Relieving Effect of Menthol, Diclofenac and Benzocaine Patches in Orthodontic Patients - *In Vivo* Study

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Abstract

Aims and objectives: The Purpose of this study was to evaluate the efficacy of benzocaine, menthol and diclofenac mucoadhesive patches in pain control caused by separation of teeth during orthodontic treatment by means of visual analog scale and numeric rating scale.

Materials and methods: Split mouth technique with 60 samples from Department of Orthodontics and Dentofacial Orthopaedics, PMS college of dental science and research, Trivandrum for orthodontic treatment were included in the study. The patient with consent was considered for the study. Elastomeric separators were placed mesial and distal to first maxillary molars in one quadrants and the placebo patches were placed on the other quadrant. The medication patch and the placebo patch were distributed among the three groups of 20 patients each. For both of their first maxillary molars, the patients were given Visual Analogue Scales (VAS) and Numerical Rating Scales (NRS). The Mann-Whitney U test and Krausal test analyses were done after data collection. The patient recorded readings every six hours beginning 30 minutes after the patch insertion. The mucoadhesive drug and placebo patch was replaced after 48 hours and every six hours, the reading was remarked, and the final marking was conducted at 72nd hour and mucoadhesive patch was replaced.

Results: There was statistically significant reduction in pain due when mucoadhesive drug patch was compared with the placebo patch. It was seen that benzocaine was most effective at 6th, 48th, 72nd hour, followed by diclofenac which was effective at 6th, 48th, 72nd hour and menthol effective at 6th, 12th, 18th, 48th 72nd hour. On overall comparison of three patches it was observed that benzocaine was significantly effective in relieving pain caused due to separators.

Conclusion: It can be concluded from the study that drug patches were effective in reducing pain caused by elastomeric separators as compared to the placebo patch. The use of benzocaine patches was most effective followed by diclofenac mucoadhesive patch and menthol.

Keywords: Menthol; Diclofenac; Benzocaine; Patients

Introduction

One of the main concerns of orthodontic treatment is the pain associated with the tooth movement. This pain is one of the reasons of patients not participating in orthodontic treatment process and is discouraging [1]. About 77% to 95% of orthodontic patients have reported some degree of pain and discomfort [2]. Orthodontic treatment-related pain will be initiated after four hours, reaches its peak after 12-72 hours and decrease to its baseline values after 7 days [3].

Various degrees of pain are experienced by the patients undergoing orthodontic treatment after placing interproximal separators and activation of appliances, within the first 4 days [4]. The discomfort experienced by patients due to separator placement is often described by them as a feeling of pressure, tension, soreness, or severe. This discomfort can be assessed with the help of rating scaling which evaluates the amount of pain experienced by the patient. So, for assessing pain several scales can be used, the Visual Analogue Scales (VAS) and Numerical rating scales (NRS) [5] are a few among those. Analgesics are largely prescribed for the patients with pain

undergoing orthodontic tooth movement. The drugs which are available for pain belong to two major groups: non-narcotic analgesics (e.g., NSAIDs) and opioids (or narcotics). The most commonly used NSAIDs in dentistry are aspirin, ibuprofen, and paracetamol, all of which are available as ‘over-the-counter’ medications.

Benzocaine is a local anesthetic drug used in dentistry and other minor surgeries. It does not effect on tooth movement and causes minimal systemic side effects. In some studies, benzocaine has been applied for relieving orthodontic treatment pain and reducing mucosal irritation [6]. Menthol, from mint (*Mentha piperita*), is a local anesthetic agent used as menthol patch and gel in treating painful conditions such as allodynia, migraine, musculoskeletal pain, neuropathy, and sports injuries.

The mucoadhesive patches are significantly more effective and are better tolerated than the oral route, as they are said to have direct access to the systemic circulation through the jugular vein bypassing the first pass hepatic metabolism causing high bioavailability. The efficacy of benzocaine, meloxicam and diclofenac mucoadhesive patches are evaluated. This study is being conducted to evaluate the efficacy of these mucoadhesive patch on pain induced by the separator.

Material and Methodology

A sample size of 60 patients from the Department of Orthodontics and Dentofacial Orthopaedics, PMS College of dental science and research, Trivandrum, India for the orthodontic treatment was considered for the study.

Inclusion criteria

- 15 years or older
- Caries-free dentition with healthy periodontium.
- Presence of antagonist teeth in the opposite arch and absence of posterior open bite and interdental spaces.
- Mentally sound to answer the visual analog scale (VAS) score.

Exclusion criteria

- No use of analgesics and anti-inflammatory.
- If the elastomeric separators are removed during the study.
- Sensitivity or allergy to the patches.

Methodology

Patients were divided randomly into three groups 20 each, in which placebo patches and the drug patch will be placed randomly in both quadrant of maxillary arch in all the 3 groups.

- **Group A:** Benzocaine mucoadhesive patches
- **Group B:** Menthol mucoadhesive patches
- **Group C:** Diclofenac mucoadhesive patches

All the patches will be of 1 x 1cm² dimension. After inserting the separators, patches will be applied on the buccal attached gingivae and embrasure of both the first maxillary molars and the patient will be given both the scales Visual Analogue Scales, (VAS) as well as Numerical Rating Scale (NRS). Readings will be marked by the subject after every 6 hours. The subject will be asked to visit the department where the patch will be replaced and the reading will be marked at the 48th hour. The reading will be marked again every 6 hours and will be recalled on the 72nd hour for the final marking.

Results

The patient recorded readings every six hours beginning 30 minutes after the patch insertion. The mucoadhesive drug and placebo patch was replaced after 48hours and every six hours, the reading was remarked, and the final marking was conducted along with replacement of mucoadhesive patch at 72nd hour.

In our present study, the mean VAS and NRS scores for benzocaine and placebo for mucoadhesive patches were compared. The benzocaine mucoadhesive patch showed statistically significant reduced pain at the 6hour with the mean value of 2.45 ±1.33 and 2.45 ± 1.35, at 48th hour was 2.23 ± 0.64 and 2.10 ± 0.79 and at 72nd hour was 1.81 ± 0.55 and 1.78 ± 0.53, thus the 72ndhour having the lowest VAS and NAS score was noted. (Table 1 and Graph 1).

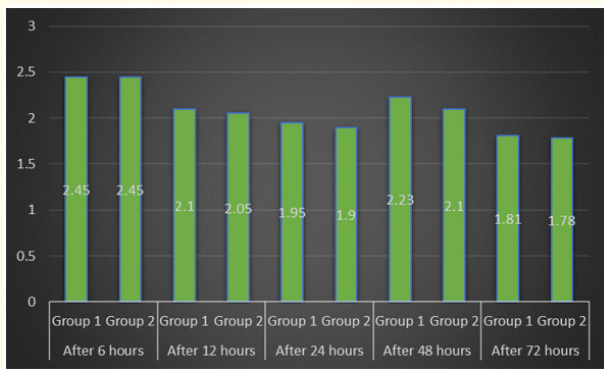
The mean VAS and NAS scores for menthol and placebo for mu-

S. No	TIME	Groups	Mean	SD	P value
1	After 6 hours	Group 1	2.45	1.33	0.829
		Group 2	2.45	1.35	
2	After 12 hours	Group 1	2.10	0.54	0.071
		Group 2	2.05	0.62	
3	After 24 hours	Group 1	1.95	0.47	0.241
		Group 2	1.90	0.47	
4	After 48 hours	Group 1	2.23	0.64	0.12
		Group 2	2.10	0.79	
5	After 72 hours	Group 1	1.81	0.55	0.002*
		Group 2	1.78	0.53	

Table 1: Efficacy of bezocaine patches and placebo patches at different time intervals using independent t test.

coadhesive patches were compared.The meloxicam mucoadhesive patch showed statistically significant reduced pain at the 6th hour with the mean value of 2.56 ±0.89 and 2.53 ± 0.97, at 48th hour was 3.44 ± 1.36 and 3.13 ± 1.51, at 72nd hour 5.52 ± 1.90 and 3.10 ± 1.21, thus the 6th hour having the lowest VAS and NAS score were noted (Table 2 and Graph 2).

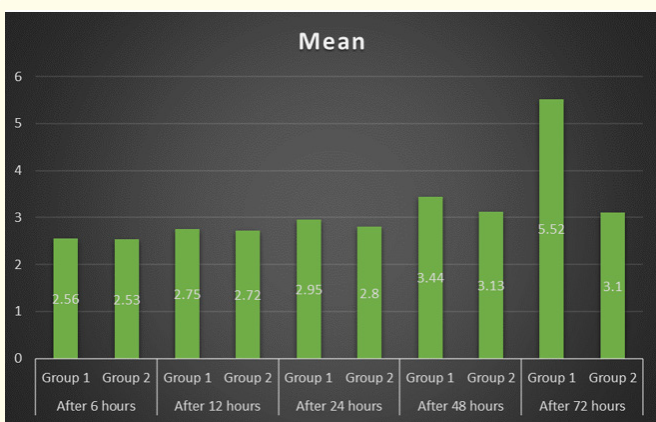
When compared to the placebo mucoadhesive patch, the Diclof-



Graph 1: Graphs showing Efficacy of bezocaine patches and placebo patches at different time intervals using independent t test.

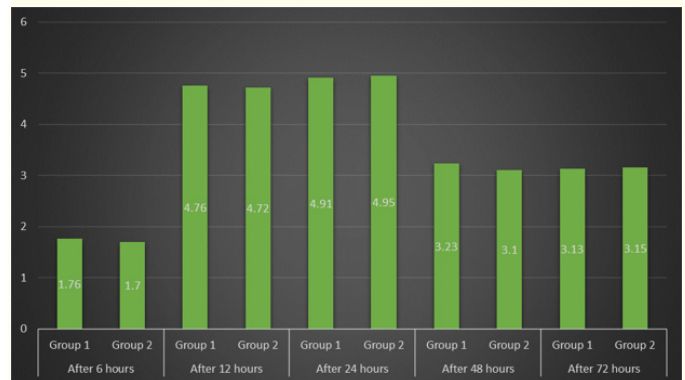
S. No	Time	Groups	Mean	SD	P value
1	After 6hours	Group 1	2.56	0.89	0.003*
		Group 2	2.53	0.97	
2	After 12hours	Group 1	2.75	0.36	0.23
		Group 2	2.72	0.56	
3	After 24hours	Group 1	2.95	0.98	0.46
		Group 2	2.80	0.10	
4	After 48hours	Group 1	3.44	1.36	0.78
		Group 2	3.13	1.51	
5	After 72hours	Group 1	5.52	1.90	0.82
		Group 2	3.10	1.21	

Table 2: Efficacy of menthol and placebo patches at different time intervals using independent t test.



Graph 2: Graphs showing Efficacy of menthol and placebo patches at different time intervals using independent t test.

enac mucoadhesive patch showed statistically significant reduced pain(VAS and NAS score) at the 6th hour with the mean value of 1.76 ± 1.23 and 1.70 ± 1.26 , at 12th hour 4.76 ± 1.13 and 4.72 ± 1.11 , at 18th hour was 4.91 ± 0.96 and 4.95 ± 1.05 , at 48th hour was 3.23 ± 0.69 and 3.10 ± 0.79 and 72nd hour was 3.13 ± 0.55 and 3.15 ± 0.58 , with the 6th hour having the lowest VAS and NAS score (Table 3 and Graph 3).



Graph 3: Graphs showing Efficacy of diclofenac and placebo patches at different time intervals using independent t test.

The three mucoadhesive patches, Benzocaine, Menthol, and Diclofenac, VAS and NAS scores had mean values of 2.23, 1.81, 3.44, and 3.13 at 48 and 72hours, respectively and 2.10, 1.78, 3.13, and 3.10 at 48 and 72hours respectively. It was found that Benzocaine (VAS and NAS score) was the most effective at reducing pain from elastomeric separators, followed by Diclofenac and Menthol.

Discussion

The present study was conducted to evaluate the patient’s pain perception with mucoadhesive patches due to elastomeric separators. 60 patients were included who decided to seek orthodontic treatment at the department of orthodontics and dentofacial orthopaedics. Following the patient’s consent, elastomeric separators were used to make room for the bands. Then, a mucoadhesive drug patch was placed on one side and a placebo mucoadhesive patch on the other side above the buccal mucosa of the maxillary 1st molar. The patient marked the first reading half an hour after patch placement, followed by every 6 hours. The patch was replaced on the 48th and 72nd hours, and readings were recorded. It was observed that the pain worsened on the first day and last until the fifth day after the separators were inserted.

A similar study was done by Ngan., *et al.* [5]. which was also associated with separator placement and concluded that pain increased over 24 hours and decreased within 7 days of insertion. The results obtained indicated that when VAS and NRS score of all the three mucoadhesive patches of benzocaine, menthol, and diclofenac were compared with placebo mucoadhesive patch there was significant effective in decreasing the pain caused by elastomeric separators. In 2020, Chandrashekar., *et al.* [8]. conducted a study, which gave resembling results when the mucoadhesive patches of meloxicam and diclofenac were compared to meloxicam and diclofenac tablets for reducing pain caused by an odontogenic tumor. Diclofenac mucoadhesive patches reduced pain more effectively than meloxicam patches ($p > 0.05$). When compared to meloxicam, diclofenac tablets showed a statistically significant reduction ($p > 0.05$).

In the present study the patches were most effective in reducing pain at some particular time. For benzocaine mucoadhesive patch it was effective at 6th, 48th and 72nd hour for menthol was effective at 6th, 48th and 72nd hour and for Diclofenac was effective at 6th, 12th, 18th, 48th and 72nd hour. There are few studies which gave similar result to this study like Eslamian L., *et al.* (2013) [9] 30 patients were studied. At 2, 18, 24, 48, and 72hours, there were significant differences in pain perception between groups. Pain perception did not differ between genders or jaws ($p > 0.05$). Only in the placebo group were significant negative correlations (r) found between pain perception scores and patient ages at 18 (-0.438), 24 (-0.526), 48 (-0.565), and 72h. (-0.458). The benzocaine 20% patches were found to significantly reduce post-separation orthodontic pain.

Annigeri., *et al.* in (2015) [10]. a similar study was done to assess the efficacy of Menthol mucoadhesive patches in the treatment of dental pain. The study included 55 patients of either gender who were suffering from dental pain. Menthol patches were applied to the site of the primary complaint for about 30 minutes, and pain levels were recorded. The pain started decreasing significantly from baseline to the score recorded after 30 minutes. The pain reduction was greatest in the first 20 minutes. There was a significant reduction in dental pain when using mucoadhesive patches with no side effects, and it was suggested that menthol administered in this mucoadhesive patch presented a potential therapeutic use as a strong analgesic. There is little research available that combines all three drugs, namely benzocaine, menthol, and diclofenac mucoadhesive patch. As a result, there is a need to investigate these drugs together.

Conclusion

- It was found that the benzocaine, menthol, and diclofenac mucoadhesive patches were significantly effective in reducing pain caused by elastomeric separators as compared to placebo.

- When all the three mucoadhesive drug patches were compared it was found that benzocaine was most effective in reducing pain caused by elastomeric separators.

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