ABSTRACT

Pain is defined as an unpleasant emotional experience usually initiated by a noxious stimulus and transmitted over a specialized neural network to the central nervous system where it is interpreted as such. Pain is an important reason that refrain patients from seeking orthodontic care. So the control of pain during orthodontic treatment is important to both orthodontists and patients. Pain is common after the placement of separators and it increases to a significant level of discomfort at 4 and 24 hours after insertion of separators. Systemic effects of NSAIDs have been reported due to administration of oral drugs. In this study, use of Diclofenac mouthwash to alleviate orthodontic pain has been hypothesized to overcome those systemic effects. Thus the purpose of this prospective clinical study was, to assess the effectiveness of Diclofenac mouthwash in reducing the incidence and severity of pain after orthodontic separator placement. The purpose of this prospective clinical study is, to assess the effectiveness of Diclofenac mouthwash in reducing the incidence and severity of pain after orthodontic separator placement. To know the efficacy of Diclofenac in controlling pain associated with orthodontic separator placement. To determine the difference in control of pain between Diclofenac and the placebo in each patient. A total of 30 patients with age between 15-25 years were included in this randomized, single blind, placebo controlled, and prospective study. Patient’s mouth was divided to 3 different quadrants. On the 1st day a statistically significant difference was observed between the control and Diclofenac group(p=0.0006) & control and placebo group(p=0.00018) where as a non-significant difference was observed between placebo and diclofenac group(p=0.6325). On the 2nd day a statistically significant difference was observed between the control and Diclofenac group(p=0.0001) & control and placebo group(p=0.0002) where as a non-significant difference was observed between placebo and diclofenac group(p=0.4870). On the 3rd day a statistically significant difference was observed between the control and Diclofenac group(p=0.0001) & control and placebo group(p=0.0009) where as a non-significant difference was observed between placebo and diclofenac group(p=0.1240). Diclofenac mouthwash...
wash found to be significantly effective in reduction of incidence and severity of pain after orthodontic separator placement. It was found to be significantly more effective in controlling the pain after separator placement. When compared to the placebo. This approach to managing pain during orthodontic treatment warrants further investigation with larger sample size and contribution of gender and age to the same.

INTRODUCTION
The concept of pain has evolved from that of a one dimensional sensation to that of a multidimensional experience encompassing sensory, discriminate, cognitive, motivational & affective qualities. It is a more or less localized sensation of discomfort, distress, or agony resulting from the stimulation of specialized nerve endings. It serves as a protective mechanism insofar as it induces the sufferer to remove or withdraw from the source (Dorland’s Illustrated Medical Dictionary). The control of pain during orthodontic treatment is of vital interest to both clinicians and patients. Research indicates that patients rank pain as the worst aspect of orthodontic treatment and the foremost reason for wanting to discontinue treatment. When compared with the pain associated with other dental procedures, both the incidence and severity of orthodontic pain is perceived to be greater. The orthodontist should inform the patient about this common side-effect of treatment, especially before inserting an appliance that will cause discomfort. It is also recognized that insertion of a new orthodontic appliance may diminish cooperation by causing considerable discomfort, such as unpleasing tactile sensations, feeling of constraints in the oral cavity, stretching of the soft tissues, pressure on the mucosa, displacement of the tongue, soreness of the teeth and pain. The amount of the initial pain and discomfort experienced may predict acceptance of the appliance and treatment in general. Therefore, control of pain during orthodontic treatment is important to both orthodontist and their patients. There exist differences among patients in the pain perceived dependent on factors such as individual pain threshold, the magnitude of the force applied, age, gender, cultural differences, previous pain experienced and present emotional state and stress. It is clear from the existing literature that all orthodontic procedures such as separator placement, archwire placement and activations, application of orthopaedic forces and debonding produce pain in patients. It is also clear that fixed appliances produce more pain than removable or functional appliances and there exists little correlation between applied force magnitude and pain experienced.
The two most important parts of orthodontic pain — its duration and intensity are often ignored. It is reported that orthodontic procedures will reduce the proprioceptive and discriminating abilities of the patients for up to 4 days, which result in lowering of the pain threshold and disruption of normal mechanisms associated with proprioception input from nerve endings in the periodontal ligament resulting in an inflammatory response mediated by cytokines and prostaglandin. At the same time, there will be pressure, ischemia, inflammation, and edema in the PDL space. Therefore, it is clear that all orthodontic procedures will create tension and compression zones in the PDL space resulting in a painful experience for the patients.

Orthodontic patient experience varying degrees of pain during treatment. First time an orthodontic patient perceives pain is during the initial procedure of placement of separators which may create a sense of fear among them. After separator placement pain increases to peak level at approximately 24 hours. Despite great concern expressed by orthodontists and their patients, there is still no standard of care for controlling orthodontic discomfort. Many orthodontists advise their patients to take analgesics “as needed” for post-operative pain.

Drugs like Ibuprofen have been studied at length for treating patients with postoperative pain after dental procedures. Ibuprofen has been shown clinically to decrease patients’ perception of pain after undergoing oral surgery procedures. Ibuprofen has also been shown to be superior to acetaminophen in decreasing postoperative oral surgery pain. In a series of studies evaluating ibuprofen with the use of dental pain models, 400 mg of ibuprofen was consistently more effective. The most common side effect of ibuprofen is gastrointestinal intolerance, skin rashes, headache.

Thus recent line of NSAID research has focused on the development of daily topical administration forms such as gels, toothpaste and mouthwash (rinses) as many of the compounds they are readily absorbed through gingival tissues and can easily penetrate into oral and gingival tissues. Diclofenac is a powerful anti-inflammatory and analgesic drug that is well suited for local use in the oral cavity.

The purpose of this study is to assess the effectiveness of diclofenac mouthwash in reducing the severity of pain after orthodontic separator placement in patients.
AIM
The purpose of this prospective clinical study is, to assess the effectiveness of Diclofenac mouthwash in reducing the incidence and severity of pain after orthodontic separator placement.

OBJECTIVES
• To know the efficacy of Diclofenac in controlling pain associated with orthodontic separator placement.
• To determine the difference in control of pain between Diclofenac and the placebo in each patient.

METHODOLOGY
Study Sample:
The study sample consisted of 30 subjects aged between 15-25 years, randomly selected among the patients seeking orthodontic treatment at the Department of Orthodontics and Dentofacial Orthopaedics, KLE-VK Institute of Dental Sciences, Nehru Nagar, Belgaum. Informed written consent was obtained from these patients. The approval of the study was taken from the ethical committee of the Institute.

Inclusion Criteria:
1. Patients between the age group of 15-25 years.
2. Patients who do not require prophylactic antibiotic coverage.
3. Patients who are not currently on antibiotic or analgesic.

Exclusion Criteria:
1. Patients with systemic disorders.
2. Patients who are on medication for systemic disorders.
3. Patients allergic to Diclofenac.
4. Patients with missing 2nd premolar or 1st molar.

Quadrant Allocation:
First permanent molar region of the first, second & third quadrants of all the 30 patients were chosen for the study. First Quadrant was treated as a control group and no intervention was
carried out. Second Quadrant was treated as an experimental group and Third Quadrant was treated as a Placebo group.

PROCEDURE

On the first visit, elastomeric separators were placed mesial and distal to the 1st molar in the first quadrant (control site) for all the subjects and were handed over Wong baker faces pain rating scale chart. The subjects were explained how to mark on the chart according to the pain intensity. The subjects were asked to mark the level of pain on the chart after 1 hour of separator placement, and daily in the morning, afternoon & night consecutively at a fixed interval time for the next 3 days from the day of placement of separators. Subjects were recalled on the 4th day elastomeric separators in the first quadrant were removed and patients were called after a wash period of 3 days i.e on the 7th day. On the next visit, new separators were placed mesial and distal to the 1st molar in the second quadrant (Experimental site). The subjects were handed over Wong baker faces pain rating scale chart. Commercially available Diclofenac mouth wash was given as analgesic, and were asked to rinse 15 ml of solution for 2 minutes every morning, afternoon & night for three days consecutively. The subjects were asked to mark the level of pain on the chart for the next 3 days from the day of placement of separators, after 1 hour of taking solution daily at fixed interval of time and asked to mark. Subjects were recalled on 3rd day after the placement of elastomeric separators in the second quadrant and the separators were removed. Following this subjects were given a wash period of 3 days. New separators were placed mesial and distal to the 1st molar in the third quadrant (Placebo site), on the 13th day i.e after the wash period. The patients were handed over Wong baker faces pain rating scale chart. Placebo in diluted form of (1:4) mouth wash in same Diclofenac bottle is given and subjects were asked to rinse 15 ml of the mouth wash for 2 minutes every morning, afternoon & night for three days consecutively. The subjects were asked to mark the level of pain on the chart for the next 3 days from the day of placement of separators, after 1 hour of taking solution daily at fixed interval of time and were asked to mark.
RESULTS

The mean pain scores for control group on the first day was 2.33±0.81, second day was 2.11±0.96 and on third day was 1.31±0.77.

The mean pain score for Placebo group on first day was 1.73±0.72, second day was 1.22±0.75 and on third day was 0.71±0.51.

The mean pain score for Diclofenac group on first day was 1.64±0.61, second day was 1.08±0.65 and on third day was 0.44±0.47.
Table 1: Pair wise comparison of three groups (control, Diclofenac, placebo) with respect to pain scores at 1st day, 2nd day and 3rd day treatment time by Duncans multiple posthoc procedure.

<table>
<thead>
<tr>
<th>Treatment Group</th>
<th>Control</th>
<th>Diclofenac</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st day</td>
<td>Mean</td>
<td>2.3333</td>
<td>1.6444</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>-</td>
<td>0.0006*</td>
</tr>
<tr>
<td></td>
<td>Diclofenac</td>
<td>0.0006*</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Placebo</td>
<td>0.0018*</td>
<td>0.6325</td>
</tr>
<tr>
<td>2nd day</td>
<td>Mean</td>
<td>2.1111</td>
<td>1.0788</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>-</td>
<td>0.0001*</td>
</tr>
<tr>
<td></td>
<td>Diclofenac</td>
<td>0.0001*</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Placebo</td>
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<tr>
<td>3rd day</td>
<td>Mean</td>
<td>1.3111</td>
<td>0.4444</td>
</tr>
<tr>
<td></td>
<td>Control</td>
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<tr>
<td></td>
<td>Diclofenac</td>
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<td>-</td>
</tr>
<tr>
<td></td>
<td>Placebo</td>
<td>0.0009*</td>
<td>0.1240</td>
</tr>
</tbody>
</table>

*p<0.05

Table 1 shows the Pair wise comparison of three groups (control, Diclofenac, placebo) with respect to pain scores at 1st day, 2nd day and 3rd day treatment time was done using Duncans multiple posthoc procedure.

On the 1st day a statistically significant difference was observed between the control and Diclofenac group (p=0.0006) & control and placebo group (p=0.00018) whereas a non-significant difference was observed between placebo and diclofenac group (p=0.6325).

On the 2nd day a statistically significant difference was observed between the control and Diclofenac group (p=0.0001) & control and placebo group (p=0.0002) whereas a non-significant difference was observed between placebo and diclofenac group (p=0.4870).

On the 3rd day a statistically significant difference was observed between the control and Diclofenac group (p=0.0001) & control and placebo group (p=0.0009) whereas a non-significant difference was observed between placebo and diclofenac group (p=0.1240).

**DISCUSSION**

Patients may experience a considerable amount of discomfort from orthodontic treatment, such as feelings of tension, pressure, soreness of teeth, and even pain. Discomfort caused by orthodontic appliances may significantly affect patients’ compliance with treatment. Pain, associated complaints, functional, and esthetic impairment are the primary reasons for poor cooperation, and are also sometimes the reasons for patients desire to discontinue treatment.

Burstone (1962) classified a painful response to orthodontic mechanics in two ways:
1) Depending on the relationship of force application with pain.
2) According to the time of onset.

Various approaches have been used to measure and evaluate pain perception in orthodontic patients. The methods adopted vary from traditional surveys with pretested questionnaires, rating with VAS (Linacre, 1998). Most of the studies have a VAS, which is designed to present the respondent with a rating scale with minimum constraints.

Two advantages of VAS
1. It provides freedom to choose the exact intensity of pain.
2. It gives maximum opportunity for expression in an individual personal response style.

Lars et al conducted a number of studies on springs and elastomers which are often used as separators for creating orthodontic band space. However, there are few studies that have thoroughly investigated the moving teeth effect of different separators or how the patient has perceived the effect of different separators.

Perception of discomfort in patients undergoing orthodontic treatment, including 7 days of separation by elastomeric separators was evaluated by Ngan et al. He reported that patients experience significant levels of discomfort at 4 and 24 hours after insertion of separators and placement of archwires. Furthermore, Jones and Chan showed that patients who underwent orthodontic tooth movement experienced more pain 24 hours after initial archwire placement than 24 hours after tooth extraction.

In Orthodontic separation creating space mesially and distally to teeth, which are to be banded, forms the initial step in fixed orthodontic mechanotherapy. Placement of orthodontic separators (brass wire, elastomeric, spring type steel separators, and latex elastics) results in a painful experience for almost all patients.

In this present study the readings based on VAS score (average) was 2.33 on the first day for control group and reduced significantly to 2.11 on the second day and 1.31 on third day. Ngan et al reported that patients experience significant levels of discomfort within 4 and 24 hours after insertion of separators and placement or arch wires. In a study, the level of prostaglandins was found to increase and peak at 2, 6 and 24 hours and decrease in 7 to 14 days after the application of orthodontic forces. This could be the possible reason why there is decrease in pain on subsequent days even without any medication.

Bondemark et al 2004 has also addressed this issue. They evaluated and compared the separation effect and patient perception of pain and discomfort to two types of orthodontic separators (elastomeric and spring type) but found no statistically significant difference.
between the discomforts caused by the two types of separators. They reported that the worst pain was experienced at day 2 and subsided almost completely by day 5.33.

The subjective perception of pain is difficult to measure and there is a wide range of individual response even when similar forces are applied to teeth. These studies report that pain begins a few hours after application of an orthodontic force and lasts approximately 5 days. There is less unanimity about the question of how fast pain starts and whether or not the force magnitude, the sex and the age of the patient influences the outcome of pain reports.

NSAIDs are associated with many adverse effects like gastric irritability. Inhibition of PG synthesis diminishes the protective effect of PG on the gastric mucosa. This inhibition may lead to dyspepsia and more seriously to gastric bleeding. Ibuprofen was gastrointestinal intolerance. It has been reported that gastrointestinal side effects occur in up to 15% of patients taking ibuprofen. Long term use causes occult blood loss, thrombocytopenia, skin rashes, headache, dizziness, blurred vision, toxic amblyopia, fluid retention, and edema. Ibuprofen also reversibly alters platelet function and prolongs bleeding time. Moreover, an additional drug antacid is given to avoid gastric irritation caused by NSAIDs.

In the orthodontic patients if the drugs like (NSAIDs) are given during the 1st step i.e molar separation stage, patients get habitual to the drug and continue it for long term till the end of the treatment, which may last for 18 to 24 months and use it for psychological pain relief without knowing its long term side effect.

Hence in this study Diclofenac mouth has been used as it has topical and local effect at the area of pain and has no systemic effects. Topical NSAIDs are said to reduce pain in inflammatory pathway. It inhibits the action of cyclooxygenase, an enzyme vital to prostaglandins synthesis which makes them very useful in controlling pain and inflammation without adversely impacting immune system. NSAIDs such as diclofenac are excellent analgesic and are more effective than intramuscular morphine. When administrated topically as a mouthwash diclofenac is slowly absorbed through the oral mucosa and a very small amount of the drug gets into the systemic circulation. Therefore side effects resulting are very negligible.

In the Diclofenac group it was observed that the pain was reduced, by maximum of VAS score at 1.64 on the first day and reduced significantly to 1.08 on the second day and 0.44 on third day. From this it was evident that diclofenac mouth wash was potentially efficacious in reducing the pain. A Clinical study confirmed the efficacy, accessibility and safety of a
mouth was containing 0.074% Diclofenac in patients undergoing oral and periodontal surgery. The pain score was significantly lower in Diclofenac group.22

In the Placebo group it was observed that the pain was less than control group. But when compared to the diclofenac group it was reduced by 1.73 on the first day for control group and reduced significantly to 1.22 on the second day and 0.71 on third day. The possible explanation for the reduction in the pain could be due to previous course of Diclofenac which could have altered the pain threshold there by making the patient resistant to pain sensation. The second reason could be the patient perceived that he/she was under medication and hence did not feel the pain. Krishnan et al stated that the relationship between the psychological well-being of patients and orthodontic pain perception is proven beyond doubt.

Individual psychological susceptibility is likely to be a significant factor for the intensity of discomfort caused by physical effects of an appliance on oral tissues. Psychological research has shown that experience of pain and discomfort is influenced by personal values and expectations such as expectations of self-efficacy and treatment outcome.

Comparison of three groups (control, Diclofenac, placebo) with respect to pain scores at 1st day, 2nd day and 3rd day treatment time by one way ANOVA test, statistically significant differences were obtained between all the three groups. Pair wise comparison of pain was done between the three groups at 1st day, 2nd day and 3rd day by Duncans multiple posthoc analysis.

The result of the study, particularly in clinical terms demonstrated that diclofenac mouth wash is characterized by better efficacy in relieving pain consequent to the placement of separators.

Limitations of this study: The study requires more extensive research. Pain is a psychological aspect every human has their own pain threshold.

Never the less, with time the options for reducing pain to the patient have improved. The shift to bonding rather than banding of molars has helped in reducing the anxiety and the fear of pain in orthodontic patients, thereby, increasing the patient compliance. Similarly, Diclofenac mouthwash provides an added advantage of lesser side effect over the more commonly used oral administration of NSAIDs.
CONCLUSIONS

- Diclofenac mouth wash found to be significantly effective in reduction of incidence and severity of pain after orthodontic separator placement.
- Diclofenac was found to be significantly more effective in controlling the pain after separator placement, when compared to the placebo used in the study.
- The placebo group also showed a decrease in intensity of pain compared to the control group. The possible explanation could be due to previous course Diclofenac mouth wash which could have altered the pain threshold there by making the patient slightly resistant to pain sensation, and second reason is psychological adaptation to repetitive and familiar procedures tends to occur as a short term event.
- This approach to managing pain during orthodontic treatment warrants further investigation with larger sample size and contribution of gender and age and Psychology to the same.

BIBLIOGRAPHY