

EFFICACY OF DICLOFENAC AND RUTA GRAVEOLENS IN THE CONTROL OF ORTHODONTIC SEPARATOR PAIN: A RANDOMIZED COMPARATIVE TRIAL

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ABSTRACT

The objective of the present investigation is to evaluate patients pain perception and discomfort, the duration of pain and the level of self medication over time during tooth separation, and the effectiveness of diclofenac and ruta in orthodontic separators. **Objective:** The main aim of this study was to compare the efficacy of diclofenac and ruta graveolens in the control of orthodontic pain and to ascertain the pain relief by ruta graveolens comparison with diclofenac during orthodontic separation. **Material and method:** 30 cases of orthodontic separator pain were selected and diclofenac and ruta graveolens were prescribed for these cases and follow up was every 2nd hours, 6th hours,

1st day, 2nd days, 3rd days, 5th days and 7th days. **Results:** Over a period of 7 days, there was significant reduction in orthodontic separator pain in both groups. ANOVA repeated measures also showed significant difference $P = 0.001$. **Conclusion:** There is significant reduction in orthodontic separator pain both groups (diclofenac and ruta graveolens) in orthodontic separator pain cases. The results suggested that diclofenac and ruta graveolens has beneficial pain reliever effective and warrants future investigation.

KEYWORDS: Diclofenac, ruta graveolens, Homoeopathy, orthodontic separator pain.

INTRODUCTION

At the very beginning of dental therapy the separation of teeth is needed for banding of the molars. Teeth normally maintain a tight inter proximal contact point. The contact point of posterior teeth is almost three times tighter than that of anterior teeth, so more force is

required to place molar bands. Furthermore, tighter contact point exists at the distal aspect of these teeth compared with the mesial aspect. Therefore, their separation is required for the placement of orthodontic bands.^[1,2] Orthodontic separators are devices that when inserted between adjacent teeth exhibit an increase in compressive force after insertion between adjacent teeth in the oral environment. The separator, after insertion, exerts sufficient force on the adjacent teeth to push the teeth apart.^[1] The separator is inserted so that it can force or wedge the teeth apart, and it is left in place long enough for initial tooth movement to occur. Thus banding can be performed by the next patient visit. Separators often cause pain and discomfort. The separators cause high levels of discomfort at 4 and 24 h after placement, and that the discomfort is significantly reduced by analgesics.



Figure 1: Separators for braces.

Graber^[3] reconstructed the duration of separation as a matter of personal preference. Begg^[4] first described separating springs. According to Begg separating springs should be left in position for several days to allow sufficient time for separation of the teeth, but not long enough to allow the teeth to separate so much that the springs fall out. During separation the plastic elastics were the least painful, and the latex elastics were the most painful. The brass and plastic separators left the teeth, the least sensitive to band seating pressure, and the latex elastics left the teeth, the most sensitive. After 3 days of separation, there was a noticeable decrease in tooth sensitivity, regardless of the type of separator. The elastics were more painful than the springs, but the difference was not significant. After placement, the pain gradually increased with both separators, peaking on the second day, gradually subsiding on the third day, and almost gone on day 5. The separation effect of two types of separators was

considered clinically equivalent. Molar band fitting should be done at least 5 days after placing the separators.^[5]

Types of separators^[6-11]

Brass separator, Elastic ring separator, Spring clip separator, C separation maintainers (TP ortho.), Dumbell separators (Maxian separators), Niti spring separators, Kansal separators. The ideal separators should give rapid and adequate separation without causing the patient discomfort or pain. They should also be easy to clean and remain in place till the bands are placed. Separators are usually placed for a few days to a week. Due to the occlusal interferences, they inevitably cause discomfort that can last the whole week.^[12] 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.^[13] Hence, the control of pain during orthodontic treatment is important to both orthodontist and patients. Pain is the major cause for discontinuing orthodontic therapy.^[14] Pain is usually as a result of pressure, ischemia, inflammation, and oedema occurring in periodontal ligament due to the exerted orthodontic forces.^[14-18] Separators, arch wires, bands, and other fixed appliances produce pressure, tension, soreness, and pain in patients.^[19] Bondemark^[20] et al. evaluated that pain perception to two types of separators, and found that there were no differences in pain effect of both types of separators.

MATERIAL AND METHODS

Sample size

The sample consisted of 30 cases of orthodontic separator pain visited to dental department, Out Patient Department (O.P.D) and peripheral centers of Sri Ganganagar Homoeopathic Medical College, Hospital and Research center, Sri Ganganagar, Rajasthan, India.

Type of Study

This was comparison study of *diclofenac* and *ruta graveolens* in orthodontic separator pain patients with 2nd hours, 6th hours, 1st day, 2nd day, 3rd day, 5th day, 7th day follow up and comparison before, after with *diclofenac* and *ruta graveolens*.

Inclusion Criteria

- Both sexes and aged between 20 to 35 years.
- Cases of orthodontic separator pain.

- Cases with non extraction treatment plan having proper contacts mesial and distal to permanent first mola.
- Currently not taking any NSAIDs.
- Cases not taking antibiotics.

Exclusion criteria

- Allergic to herbal medicines/ diclofenac.
- Pregnancy.
- Patients consuming analgesics/NSAIDS.
- Patients consuming anti inflammatory medications.
- Cases having a history of pulmonary tuberculosis, chronic illness, ESRD.

Method

30 patients (diclofenac group 15 patients and ruta graveolens group 15 patients) were enrolled by simple random method. Diagnoses of the cases were made based on relevant clinical history obtained during the first visit according to current dental diagnosis and treatment guidelines. Thirty potency of ruta graveolens and diclofenac sodium were prescribed for the above cases and was followed for a period of 2 hours, 6 hours, 1 day, 2nd day, 3rd day, 5th day, 7th day. Each selected case was recorded on the standardized case record with a special attachment evolved particularly for this study. Before placement of elastomeric separators which was administered in the dental O.P.D and 1 dose six hours after the placement. A set of 7 printed pages of visual analogue scale (VAS) along with instruction of how to record pain response (including hindi language) was given to patients. Visual analogue scale was a 10 cm scale with millimeter calibration to record their pain at 2 hours, 6 hours, 1 day, 2nd day, 3rd day, 5rd day and 7th day intervals. Patients were asked to mark the appropriate response they felt on biting and chewing. Patients were instructed to call the consultant orthodontist if he/she felt the unbearable pain so that necessary analgesic treatment can be administered to the patient.

Remedy used

30 dilution of homoeopathic remedy ruta graveolens brought from homoeopathy pharmacy, Sri Ganganagar, Rajasthan, India. Ruta 30 potency was given twice daily for a period of study and diclofenac twice in a day. Follow up was watched and analyzed as per criteria set

up in each case according to standard guideline of homoeopathy using the symptomatology of the patient.

Follow up and symptomatic assessment

Each follow up was taken on special follow up sheet of examination. Each case was evaluated by the orthodontist, homoeopathic physician. Baseline investigations done in each case were fasting and post prandial blood sugar, glycosylated haemoglobin, urine examination, serum creatinine, lipid profile, electrocardiogram, ultra sound abdomen and ophthalmic check up. Each follow up was of 2 hours, 6 hours, 1 day, 2nd day, 3rd day, 5th day, 7th day and assessed according to the guidelines given in standardized case record follow up sheet.

Statistical Analysis

The collected data was analyzed by mean, standard deviation, chi square tests, P value and repeated measure ANOVA.

Research hypothesis

There is a significant decrease in orthodontic separator pain before and after diclofenac and ruta graveolens.

Null Hypothesis

There is no significant decrease in orthodontic separator pain before and after diclofenac and ruta graveolens.

RESULTS

Orthodontic separators pain patients were in the male 15(50.00%) and 15 (50.00%) patients were females out of 30 cases (Table 1). In comparison research *diclofenac and ruta* was prescribed to the patients according to the totality of symptoms and similarity. Post hoc comparison indicated that there was no difference between the two group at 2 h ($P= 0.7542$), 6 h ($P= 0.1094$), 1 day ($P= 0.7175$), 2 day ($P= 0.7775$), 3 day ($P= 0.5895$), 5 day ($P= 0.4514$) and 7 days though the visual analogue scale pain was higher in ruta group than diclofenac group table 3. Mean visual analogue scale pain score at different time intervals after separator placement in diclofenac and ruta group in figure 1. There was a statically significant effect of time on visual analogue scale pain soccer ($F= 213.79$, $P= 0.0001$), but there was no significant interaction between time and group ($F= 196.35$, $P= 0.101$). Between subjects,

there was statistically no significant ($F = 187.69$, $P = 0.07$), difference of visual analogue scale pain in between the group (table 3).

Table 1: Baseline Characteristics

(A) Distribution of cases according to age group.

Age Group	No. of Cases	Percentage (%)
30-40	10	33.33
40-50	11	36.66
50-60	5	16.66
60-65	4	13.33
Total	30	100

(B) Distributions of cases according to gender.

Gender	No. of Cases	Percentage (%)
Male	15	50
Female	15	50
Total	30	100

(C) Chi square tests.

χ^2	df	P
0.26	1	0.014

(D) Comparison of mean age in diclofenac and ruta.

Age	Diclofenac (n=15)	Ruta (n=15)
Mean	39.81	40.7
SD	4.26	4.3
Mean difference	0.89	
P	0.7	

S D: Standard deviator.

Table 2: Repeated measure ANOVA.

Time Point	VAS pain, mean (SD) Diclofenac (n=15)	Ruta (n=15)	Mean difference (95% CI)	P value
2 h	7.733	7.800	- 0.06 (-0.36-0.498)	0.7542
6 h	9.266	9.600	- 0.33 (0.079 – 0.746)	0.1094
1 st day	6.466	6.533	- 0.06 (0.412 – 0.545)	0.7175
2 nd day	5.466	5.533	- 0.06 (- 0.412 – 0.545)	0.7775
3 rd day	4.600	4.733	- 0.13 (- 0.367 – 0.633)	0.5895
5 th day	3.800	4.000	- 0.20 (- 0.335 – 0.736)	0.4514
7 th day	0.00	0.00	0.00	0.000

VAS: Visual analogue scale, SD: Standard deviator, CI: confidence interval.

Table 3: Repeated measure ANOVA.

	Source	Type III SS	df	M S	F	Significant
Within subjects effects	Time	485.1	6	80.86	213.79	0.0001
	Time X Group	504.91	6	84.15	196.35	0.101
Between subjects effects	Group	1069.65	1	82.281	187.69	0.07

SS: Sum of Squares MS: Mean Square.

DISCUSSION

Orthodontic separators are devices to force or wedge the teeth apart, so that the teeth are slightly separated by the appointment at which bands are to be flitted. Separation can be painful, particularly for anterior teeth and the necessity for separation must be considered a disadvantage of banding and its absence an advantage of bonding. Pain experienced during orthodontic treatment is not trifling and needs to be taken care of from the 1st appointment with the dental doctor. Although wide ranges of pt. response are present pain and discomfort is generally experienced, which may instill a negative approach towards the treatment or in very few cases may lead to discontinuation.

Justyna kolodziejslea found that oral administration of diclofenac significantly reduced pain scores as compared to post separator placement and control group, also the peak plasma level concentration of diclofenac in blood reaches in one hour hence, administration of diclofenac one hour before placement of separators was decided for the study. So many studies that have been conducted to compare the efficacy of various non steroid anti inflammatory drugs showed that diclofenac is consistent in reducing the pain scores when compared to control (placebo) groups. Diclofenac has proved to be better than ibuprofen and placebo groups. Whereas another study suggested that diclofenac and paracetamol were at par to placebo groups. Gastric irritation is a common side effect possible with consumption of non steroid anti inflammatory drugs such as diclofenac, although single dose administering clinically does not produce the aforementioned symptom; however, the potential of side effect still cannot be find out. Homoeopathic medications have no side effects.

Elastomeric modules work well in adolescent patients whose teeth are slightly mobile and free of restorations. Adult patients commonly have tight contacts and/or sharp amalgam fillings with broad contacts that prevent placement of elastomeric modules without distortion or breakage. The results of comparison study indicated that peak pain levels wee maximum

after twenty four hours of placement and the average scores during the first twenty four hours of placement indicated that diclofenac group was more effective than ruta. But here was no significant statistical difference present between the two groups in the first twenty four hours. Visual analogue scale pain score decreased after twenty four hours and but ruta group scores were lesser than that of diclofenac, which might be attributed to half life of diclofenac which is 1.7 to 2 hours and the drug is completely eliminate from the system in twenty four hours. After twenty four hours average ruta pain scores are lower than diclofenac group.

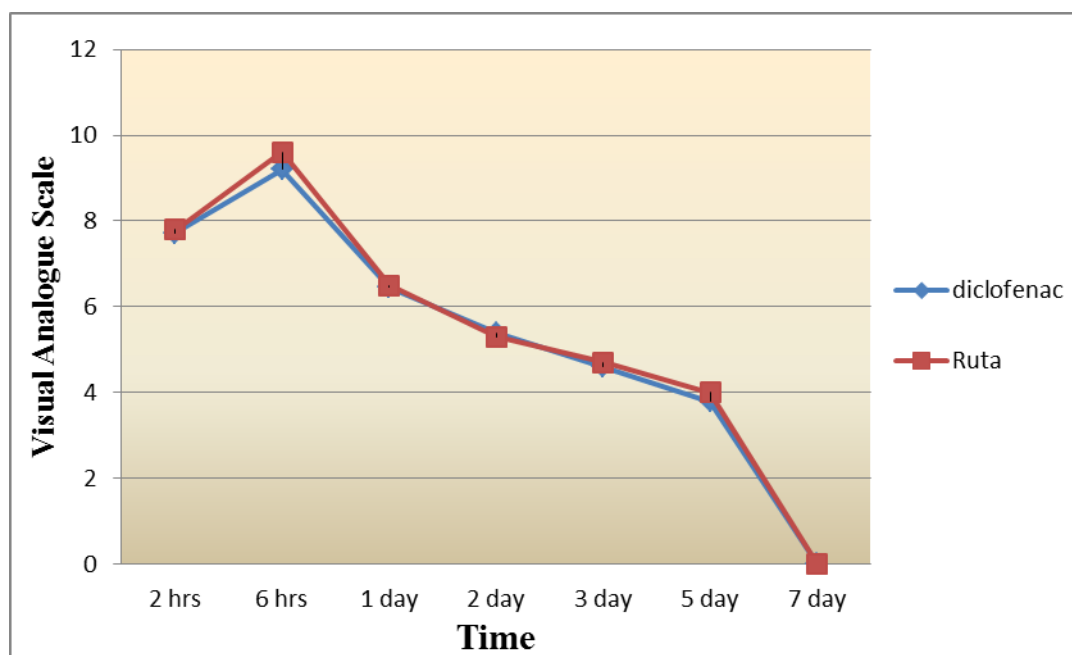


Figure 2: Mean visual analogue scale pain score at different time intervals after separator placement in diclofenac and ruta group.

CONCLUSION

The research showed that significant reduction in VAS score with diclofenac and ruta graveolens. Ruta plays an important role in the treatment of pain reduction. There was no side effective during the treatment and it can be concluded that diclofenac and ruta graveolens can be help the orthodontic separator pain patients to take a new lease on life.

During the comparison study it was observed that diclofenac ruta graveolens are effective and provide adequate analgesia with no statistically significant difference.

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Conflict of Interest

None declared.

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