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Original Article

Split-mouth clinical trial evaluating pain perception in orthodontic patients using four types of separators: An *in vivo* study

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ABSTRACT

Objectives: The objectives needs to include the study aims to evaluate the pain associated with four different types of separators at 4 hours, 24 hours, and on the 5th day, and to compare the pain levels among the four types.

Materials and Methods: Four different types of separators were placed in each quadrant of 54 patients receiving fixed orthodontic treatment, and each quadrant was divided into four groups. In group I, kesling separators were placed, while groups II, III, and IV were given elastomeric, brass wire, and kansal separators, respectively. Pain perception was evaluated after 4 hours, 24 hours, and on the 5th day using the numerical pain rating scale (NPRS). The NPRS is a 0–10 scale where patients verbally rate their pain, with 0 being no pain and 10 being the worst pain.

Results: Kansal separators consistently produced the highest pain scores across all time intervals, while kesling separators resulted in the least discomfort. At 4 hours post-placement, the highest mean pain score was observed in the kansal group (7.52 ± 1.57) and the lowest in the kesling group (6.69 ± 1.31), with a statistically significant difference (P = 0.028). At 24 hours, pain remained highest for kansal separators (7.24 ± 1.63), though the differences were not statistically significant (P = 0.152). By the 5th day, overall pain levels had decreased, but kansal separators still recorded the highest pain (6.91 ± 1.54), while kesling recorded the lowest (6.00 ± 1.08), showing a significant difference (P = 0.012).

Conclusion: The type of separator has a significant impact on pain perception. Rigid separators, such as kansal and brass wire, induced higher pain, especially in the initial hours, while flexible separators, such as kesling, caused minimal discomfort. kesling separators may be preferred in patients with low pain tolerance to improve comfort and compliance.

Keywords: Brass wire separators, Elastomeric separators, Kansal separators, Kesling separators, Numerical pain rating scale

INTRODUCTION

Orthodontic treatment often begins with the placement of separators to create interproximal space for band placement. These separators, while essential, are often associated with varying degrees of pain and discomfort, which can influence patient compliance and satisfaction. Understanding the extent of pain associated with different types of separators is crucial for improving patient experience and tailoring pain management strategies. The extent of separation depends on the magnitude of the force, its duration, and the adaptability of the periodontal ligament. The extent and severity of pain experienced by patients vary based on individual pain

threshold, the magnitude and duration of force applied, and psychological factors.[1] Separation is a procedure done in orthodontic treatment that involves forcing or wedging teeth apart, generally for a week, to gently loosen the tight interproximal contacts between teeth to provide space for the fitting of orthodontic bands.[2] Understanding the impact of separator selection on both treatment efficiency and patient comfort is essential in orthodontic practice. The ideal separator should give rapid and good separation without causing the patient discomfort or pain, thereby making the fitting of the band to the tooth.[3]

The history of orthodontic separation dates back to the early 20th century, with Angle first advocating the use of brass wire ligatures to achieve space creation.[4] Several types of separators are commonly used, including elastomeric rings, spring separators, and brass wire separators. Several types of separators are commonly used, including elastomeric rings, spring separators, brass wire, and kesling separators. Each type differs in force application, duration of effectiveness, and comfort. Studies such as those by Asiry *et al*.[5] and Eslamian *et al*.[6] reported that peak pain typically occurs within 24 hours after separator placement, with rigid separators often causing greater discomfort than flexible ones.

Each type differs in force application, duration of effectiveness, and comfort. Despite their clinical utility, a systematic evaluation of pain perception caused by these separators *in vivo* is lacking in the literature. Hence, the present study was conducted to evaluate pain perception using different types of orthodontic separators, with a focus on patients' perception of pain and discomfort.

MATERIAL AND METHODS

The study is a non-randomized, split-mouth clinical trial conducted *in vivo* to evaluate pain perception associated with four different types of orthodontic separators placed in different quadrants of the same patient. This study was approved by the Institutional Health Ethical Committee and Institutional Research and Development Committee of Saraswati Dental College and Hospital, Lucknow.

The study was conducted on 54 participants seeking fixed orthodontic treatment, aged between 17 and 28 years, with no previous history of orthodontic treatment. The study design and participant flow are illustrated in Figure 1. The study included participants who met the following inclusion criteria: Absence of systemic illness, willingness to participate, no prior history of orthodontic treatment, fully erupted permanent first and second molars and second premolars, no caries or restorations on the proximal surfaces of these teeth, and good gingival and periodontal health. Exclusion criteria included the presence of systemic disease, poor oral hygiene, and any signs of gingival or periodontal pathology.

Out of 97 participants who fulfilled and willing the inclusion criteria given below, only 54 participants who gave their consent to participate in the study were selected. The sample size was calculated using G power software (version 3.1), keeping the standard values of alpha error at 0.05 and power of the study at 90% and effect size at 0.25, and the minimum sample size of the study is 52.

Statistical analysis was performed using the statistical package for the social sciences software version 26.0 statistical analysis software. Descriptive statistics, including mean and standard deviation, were used to summarize pain perception scores for each separator group at 4 hours, 24 hours, and on the 5th day. One-way analysis of variance (ANOVA) was applied to compare mean pain scores among the four groups. Where statistically significant differences were found, tukey's honestly significant difference *post hoc* test was used for

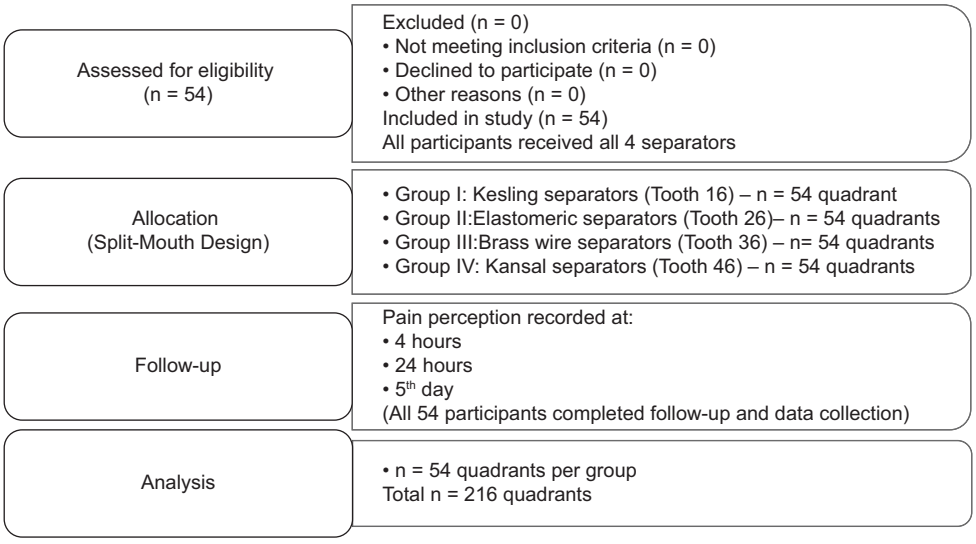

Figure 1: Consort-style flowchart showing participant enrollment, allocation of quadrants to the four separator groups, follow-up, and analysis.

pairwise comparisons. $P < 0.05$ was considered statistically significant.

Each participant's mouth was divided into four quadrants, with each type of separator placed in a fixed, non-randomized order to maintain consistency. Group allocation for the four separators in different quadrants is summarized in Table 1. All separators were placed simultaneously during the same clinical appointment to standardize the timing of force application. Participants were guided on how to independently assess pain in each quadrant by gently biting or pressing the specific area, aided by a quadrant-specific chart to localize discomfort. Figures 2 and 3 illustrate the placement of kesling and elastomeric separators in the maxillary right and left quadrants, respectively, and brass wire and kansal separators in the mandibular left and right quadrants, respectively. Pain perception was measured using the numerical pain rating scale (NPRS), a validated patient-reported scale ranging from 0 (no pain) to 10 (worst possible pain). Participants recorded their pain scores for each quadrant at 4 hours, 24 hours, and on the 5th day after separator placement. A follow-up visit was scheduled on the 6th day to remove the separators, which were kept for 5 days as peak pain occurs around day 2 and reduces after day 3, ensuring optimal space creation with minimal discomfort. All data related to pain perception and discomfort were documented on a standardized data sheet.

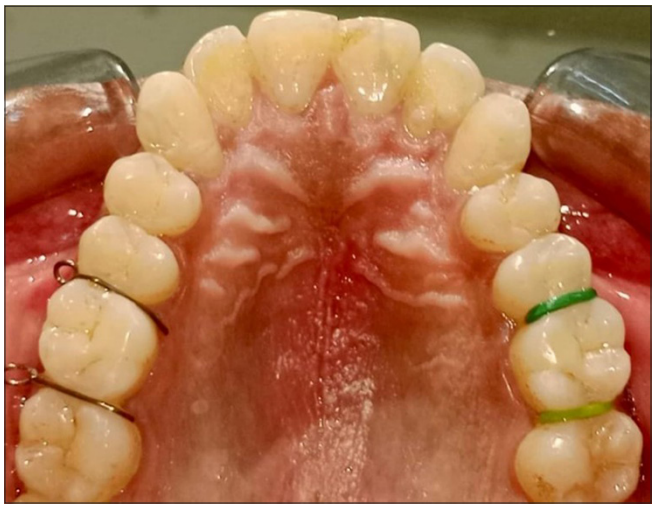

Figure 2: Intraoral photograph showing kesling separator placed in the maxillary right side and elastomeric separator placed in the maxillary left side.

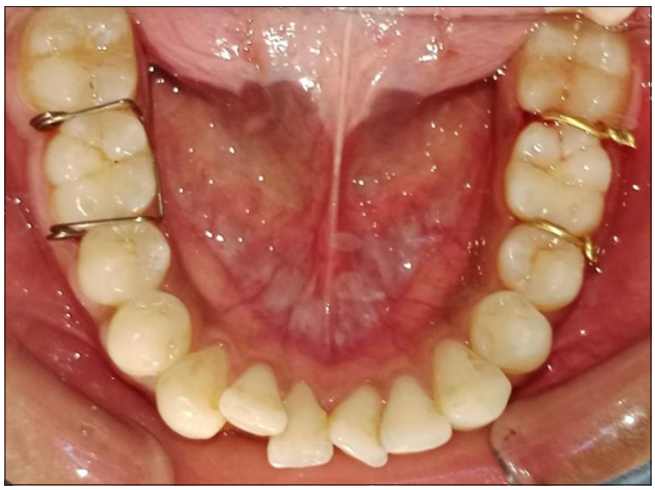

Figure 3: Intraoral photograph showing a brass wire placed on the mandibular left side and a kansal separator placed on the mandibular right side.

RESULTS

Table 2 reveals a comparative evaluation of pain perception scores recorded using the NPRS for the four separator groups: kesling (group I), elastomeric (group II), brass wire (group III), and kansal (group IV) at 4 hours, 24 hours, and on the 5th day following separator placement. At 4 hours, pain perception was highest in the kansal separator group and lowest in the kesling separator group. A similar pattern was observed on the 5th day, with kansal separators

Table 1: Group allocation of separators in different quadrants for each participant in a split-mouth study design.

Group	Tooth / quadrant	Type of Separator
Group 1	16 (first quadrant/upper right)	Kesling separators
Group 2	26 (second quadrant/upper left)	Elastomeric separators
Group 3	36 (third quadrant/lower left)	Brass wire
Group 4	46 (fourth quadrant/lower right)	Kansal separators

Table 2: Comparative evaluation of pain perception score using NPRS between 4 different separators at 4 hours.

Separators *n*=54/Group	Pain perception score using NPRS		
	At 4 hours	At 24 hours	At 5 days
	Mean±SD	Mean±SD	Mean±SD
Group I (Kesling separator)	6.69±1.31	6.67±1.28	6.00±1.08
Group II (Elastomeric separator)	6.93±1.62	6.63±1.68	6.30±1.68
Group III (Brass wire separator)	7.20±1.49	6.93±1.58	6.35±1.36
Group IV (Kansal separator)	7.52±1.57	7.24±1.63	6.91±1.54
Total	7.08±1.52	6.87±1.56	6.39±1.46
ANOVA "F" value	3.081	1.778	3.746
Significance "*P*" value	0.028 (S)	0.152 (NS)	0.012 (S)

NPRS: Numerical pain rating scale, SD: Standard deviation, ANOVA: Analysis of variance, F-value: from Analysis of Variance, P-value: Probability value indicating statistical significance, S:Significant, NS: Non-significant

continuing to show the highest pain scores and kesling the least. At 24 hours, the kansal separator again recorded the highest mean pain score, while the elastomeric separator group reported the lowest. Statistical analysis using one-way ANOVA revealed a significant difference in pain perception scores among the four groups at 4 hours ($P = 0.028$) and on the 5th day ($P = 0.012$). However, no statistically significant difference was observed at 24 hours ($P = 0.152$). *Post hoc* comparisons further confirmed that the pain associated with kansal separators was significantly greater than with kesling and elastomeric separators at the significant time points.

DISCUSSION

In this study, kansal separators produced the highest pain levels across all time points, while kesling separators were the most comfortable. Elastomeric separators resulted in moderate discomfort. Significant differences at 4 hours and day 5 indicate that the separator type directly affects the pain experience, while the non-significant variation at 24 hours likely reflects individual pain adaptation.

These findings align with those of Shivaprasad *et al*.,[3] who reported better tolerance with kesling separators after adjustment. The declining pain trend supports prior studies, which note peak discomfort within the first 24 hours. Consistent with Hoffman, brass wire separators caused soft-tissue irritation; however, Hoffman found elastomeric separators to be the most painful, unlike our results, where kansal separators ranked highest.[4]

Overall, rigid separators can induce more discomfort and may be less suitable for patients with sensitive skin. The split-mouth design minimized individual variability, strengthening internal comparisons. Clinically, kesling or elastomeric separators may be preferred in pain-sensitive patients to enhance comfort and compliance.

The findings of this study confirm that separator type significantly impacts pain perception. kesling separators consistently caused the least discomfort, in agreement with Kumar *et al*., who also noted reduced pain by day 5.[7] In contrast, kansal separators were the most painful throughout, likely due to their rigidity and force application.

The observed pain peak between 4 and 24 hours, followed by a gradual decline, is consistent with the findings of Asiry *et al*. and Eslamian et al., reinforcing the transient nature of separator-induced discomfort.[5,6]

Although early differences in pain were not statistically significant, the consistent trend of greater pain with rigid separators supports findings by Tripathi *et al*., Sabuncuoglu *et al*. who emphasized better patient tolerance with kesling separators.[8,9]

The significant difference observed at 24 hours highlights the impact of separator design during initial adjustment. In addition, findings from Oshomoji *et al*. suggest that higher separation force may correlate with increased discomfort, potentially explaining the consistent pain associated with kansal separators in our study.[10] Additionally, findings from Oshomoji *et al*. and Manandhar P suggest that higher separation force may correlate with increased discomfort.[10,11]

The intra-subject split-mouth design used here minimized individual variability, enhancing the reliability of comparisons. The use of the NPRS scale, validated by Iwasaki *et al*. and Polat and Karaman, ensured accurate and consistent pain reporting across quadrants.[12,13]

A key strength of this study is its intra-subject (split-mouth) design, wherein each participant received all four separator types in different quadrants. This approach minimized inter-individual variability and enhanced internal validity. The use of the NPRS, a validated and reliable tool, further ensured consistency in pain assessment.

However, certain limitations should be acknowledged. The relatively small sample size may affect the generalizability of results. Pain perception, being subjective, can vary with psychological state, individual pain thresholds, and unmonitored analgesic use, all of which were not controlled. Additionally, the study did not evaluate separator efficiency or dislodgement, both of which may impact pain perception. The short follow-up period may have also overlooked delayed discomfort.

These findings emphasize the need to prioritize patient comfort in orthodontic care. kesling separators, being better tolerated, are well-suited for pediatric or pain-sensitive patients. In contrast, kansal and brass wire separators, though effective, may cause more discomfort and should be used with caution. Future studies should explore separator efficiency, consider psychological factors, and include broader samples to support more personalized and comfortable treatment choices**.**

CONCLUSION

This study demonstrates that separator type significantly affects pain perception, with rigid separators causing more discomfort, especially in the early hours, and flexible ones like kesling being better tolerated. Pain levels declined over time, reflecting patient adaptation. NPRS shows more consistent and statistically significant differentiation between separator types. These findings highlight the importance of selecting separators that balance clinical effectiveness with patient comfort, promoting better compliance and individualized orthodontic care.

Ethical approval: The research/study approved by the Institutional Review Board at Saraswati Dental College and Hospital, Lucknow, number ST40R18042023D, dated May 16, 2023.

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