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RESEARCH ARTICLE

EVALUATION OF THE SAFETY AND EFFICACY OF TWO ELASTOMERIC SEPARATORS IN ORTHODONTICS - A COMPARATIVE STUDY.

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5. Senior Lecturer, Orthodontics and Dentofacial Orthopedics, Farooqia Dental College and Hospital, Mysuru... Manuscript Info Abstract Manuscript History: AIM: The elastomeric separators used in orthodontic practice to create a space between adjacent teeth to aid in the accurate placement of orthodontic Received: 14 January 2016 bands especially for molars, undoubtedly have several advantages over other Final Accepted: 19 February 2016 types of separators, but their iatrogenic potential is overlooked. The aim of Published Online: March 2016 this study is to compare two latex free elastomeric separators differing in their design for perception of pain and discomfort, their dislodgement and Key words: subsequent gingival displacement. Separators, Elastomers, MATERIALS AND METHOD: 60 patients, 26 males and 34 females had two different types of latex free elastomeric separators, type S and type T, **Orthodontic Pain.** placed randomly in right and left quadrants. The subjects recorded their pain and discomfort on visual analogue scale at 6 time intervals and were *Corresponding Author examined for the number of separators lost on 3rd and 5th day. **RESULTS:**This study shows that the loss of "type S" separators is Dr. Vikram Kumar Jain S significantly higher than the "type T" separators. This study confirms the drjainvikram@gmail.com peak pain levels to be on 2^{nd} day for both type of separators but the intensity of pain due to type T separators were significantly lesser than type S separators at all intervals of time. Subgingival displacement of type S separators was seen in eight patients whereas type T separators were retained well in all the subjects. CONCLUSION: Latex free elastomeric separators having knobs on either side of each ring that extend beyond the interproximal area out past the gingiva proved to be safe and effective for tooth separation with lower pain

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Introduction:-

Separators are usually placed prior to banding to gain space, reduce the pain and discomfort of banding, prevent injury to both hard and soft tissues and ensure that a band fits the tooth.¹ Different types of separators are available and they vary in the amount of pain they cause during separation, the effectiveness in separating teeth and maintenance of the separation gained.¹⁻⁵

and discomfort.

Many studies regarding the separation effect of elastomeric separators have been undertaken, and few have evaluated the patients' perception of the pain and discomfort related to the same.⁶⁻⁹

Currently, elastomeric modules are the separators of choice as they are easily placed and removed but they can loosen and fall out during eating or brushing and the loss is generally unnoticed by the patient. On several occasions, the patient returns to the office without the elastic separators. In most cases, the separators need to be placed again leading to an extra visit to the orthodontic office for band placement.

The ideal separator should be safely secured between the teeth, giving rapid and good separation without causing much discomfort or pain to the patient, thereby making the fitting of the band to the tooth easy. Of clinical interest is what occurs if the elastomeric separator becomes lost into the gingiva before its intended removal.¹⁰

An experimental study investigated the histopathology of periodontal lesions induced by elastics placed in the gingival sulcus of monkeys.¹¹After 2 to 4 weeks, the inflammation extended to the attached gingiva, and there were bleeding on probing, pockets of 5 to 8 mm, tooth extrusion, and horizontal and vertical bone loss. Even though this event is well reported in the literature, invasion of the periodontal space by rubber separators is not an uncommon finding.

Unsupported elastomeric separators creeping into gingival sulcus have been reported frequently in the literature.¹²⁻¹⁷ Reports citing orthodontic elastic separators as a major iatrogenic cause for loss of periodontal bone support dates back to more than 140 years. Since, serious periodontal problems can arise due to wedging of separators into interproximal spaces, radio-opaque and brightly colored separators are recommended.¹⁸

As the placement of elastomeric separator is routinely done in orthodontic practice, its iatrogenic potential should not be overlooked. Therefore, the aim of this study is to compare two latex free elastomeric separators for their dislodgement before banding and subsequent subgingival displacement of the separators and determining patient's perception of pain and discomfort following separator placement.

Materials and methods:-

The study sample consisted of 60 patients [26 males (mean age of 20.2years) and 34 females (mean age of 20.6years)] who required orthodontic treatment from Farooqia dental college and hospital, Mysuru participated in this study (Table 1). Informed consent was obtained from all subjects participated in this study.

The subjects included had no previous history of orthodontic treatment, extraction, had no proximal caries or restorations in posterior teeth with good interproximal contacts. The interproximal contact point characteristics of all the first permanent molars in all patients were checked with dental floss prior to separators placement.

The separators used were

- 1. Latex free Single separators (Ortho Organizers) were referred as **Type S (Figure 1)**
- 2. Latex free Safety separators (Ortho Organizers) were referred as **Type T** (Figure 2)

Four Separators of each type were placed randomly by coin toss method in the left and right quadrants of upper and lower 1st molars to avoid bias (Figure 3 and 4). All separators were placed by a single investigator.

Each subject rated their pain/discomfort on left and right side separately on Discomfort Index Card having Visual Analogue Scale of 100mm at 6 different time intervals that is immediately before placement, 1hr after placement, 4hrs after placement, 24hrs after placement, 48hrs after placement and 72hrs after placement.

The discomfort index card consisted of 6 separate visual analogue scales (VAS), each being 10cm in length, the extremes of which are taken to represent the limits of the pain experience; one end is therefore defined with appropriate verbal descriptors such as "no pain" and "worst pain". The VAS was scored by measuring in millimeters from the left hand end of the line to the vertical mark.

All patients were reviewed on the 3^{rd} and the 5^{th} day, the number and each type of separators lost were recorded. The remaining separators were removed on 5^{th} day using an explorer and the interdental sulcus was thoroughly examined for the presence of any dislodged separators.

The data collected was subjected to statistical analysis with paired t test using SPSS software.

Figure 1: Type S separators

Figure 2: Type T separators





Figure 3: Type S separators placed mesial and distal to left upper and lower 1stmolar



Figure 4: Type T separators placed mesial and distal to right upper and lower 1stmolar



Results:-

Table	1. Δσε	and	Gender	distribution	oft	he d	white	samnle
Table	I: Age	anu	Genuer	aistribution	UI L	псз	scuuy	sample

	N	Mean	Std. Deviation	Std. Error	
М	26	20.2308	2.12241	.41624	
F	34	20.5882	2.11943	.36348	
Total	60	20.4333	2.11024	.27243	

Table 1 represents the descriptive characteristics of the patients involved in this study.

Table 2: Comparison of type S and type T separators lost on day 3 andday 5

Separators Lost		Mean	Ν	Std. Deviation	Std. Error Mean	P value
Day 3	Type S	.5667	60	.62073	.08014	00000
	Туре Т	.0000	60	.00000	.00000	.00000
Day 5	Type S	1.60000	60	.71781	.09791	00000
	Туре Т	.0333	60	.18102	.02337	.00000

Table 2 shows that the loss of type S separators was significantly higher than the type T separators on 3^{rd} day and on 5^{th} day.





Graph 1 represents the variation in pain perception with time measured with both types of separators. Type S separators induced mild pain after 1 hour whereas type T separators induced pain after 4 hours of insertion. The pain gradually increased with both the separators and peaked on day 2 (24 hours). The pain started to subside on the 3^{rd} day and by day 4, pain was completely absent with type T separators whereas mild pain persisted with type S separators.

	Pai			
	Mean	Std. Deviation	Std. Error Mean	P value
After 1 hour	10.40000	7.36736	.95112	.000
After 4 hours	19.50000	6.61662	.85420	.000
After 24 hours	32.76667	6.10464	.78811	.000
After 48 hours	30.03333	10.80014	1.39429	.000
After 72 hours	18.90000	6.36383	.82157	.000

 Table 3: Correlation of pain between type S and type T separators at different intervals of time after

 placement of separators

Table 3 shows that the pain/discomfort was significantly lesser with type T separators compared to type S separators

at all the time intervals.

Out of 60 patients, type S separator was found embedded in gingiva in 8 (eight) patients which is insignificant relative to the total number of lost type S separators but is significant when compared to type T separators which showed less dislodgement.

Discussion:-

For many patients placement of separators marks the start of their orthodontic treatment, which they have been usually told will be free of pain and discomfort.⁹Many studies have evaluated the pain response of patients undergoing orthodontic treatment following separator placement. Ngan and coworkers⁶ reported that pain and discomfort started at 4 hours and increased over the next 24 hours after the insertion of separators. Bondemark and coworkers⁷ reported that the worst pain with separators was experienced at day 2, which subsided almost completely by day 5.

In this study, the visual analogue scale (VAS) was used to assess pain/discomfort intensity, since it is one of the most commonly used pain assessment tool and is easy to score. The VAS is also a valid and reliable method of measuring discrete pain, being able to discriminate between small changes in pain intensity. It has also been found that the VAS is a useful tool when patients have to discriminate between pain/discomfort in the posterior and anterior teeth.¹⁹Hence, in this study the patients had no problem in discriminating between pain/discomfort in right and left quadrants when two different separators were placed on the right and left side.

It was found that mild to moderate pain was associated with both types of orthodontic separators. Type T separators were less painful than the type S separators. The pain was percieved to be worst during day 2 and had subsided completely by 3^{rd} day with type T separators. Thus, according to this study, it seems advisable to perform band fitting on 3^{rd} day after inserting the type T separators.

Although the space gained after separator placement was not directly measured in this study, it was assumed from previous studies that elastomeric separators produce sufficient separation.^{1-5,19} Provided they stay in place, elastomeric separators produce more tooth separation than any other type of separators. From the standpoint of patients comfort, they must be maintained for atleast 3 days prior to attempt of banding the tooth which is enough time to promote separation between the teeth.

A gradual reduction of contact point tightness often permits separator loss before the banding appointment. This can occur during eating or brushing and results in rebounding of teeth and return to the initial contact point thickness.¹⁹ It was found in this study that the number of type S separators were dislodged significantly by 3^{rd} day and 5^{th} day when compared to type T separators.

On the other hand, a separator is lost when the space gained is wide enough so that during mastication, the occlusal part of the elastomeric ring is compressed below the contact point and gets embedded into the gingival sulcus.¹⁹ Such elastomeric separators may cause a localized periodontitis, particularly when they are displaced interproximally and bacteremia which contraindicate their use in patients with systemic disorders.²⁰ Thus, Patients who present with missing separators at the banding appointment must be asked if they actually viewed the separator and if not, interdental region must be carefully inspected. A shorter time of rubber separators in the mouth could be a better measure to prevent accidents reported in the literature¹¹⁻¹⁶

In this study, one type S elastomeric separators were found embedded subgingivally in eight patients at the end of the study $period(5^{th} day)$. Although insignificant, their iatrogenic potential should not be overlooked considering their potency of causing severe periodontal destruction in otherwise healthy individuals leading to irreversible loss of supporting tissues and permanent damage as reported in the literature

Conclusion:-

The elastomeric separators were found to be painful regardless of the type, but type T separators caused significantly less amount of pain and discomfort.

Type S separators were lost more than type T separators, thereby the use of type S separators may lead to an extra visit of a patient to the orthodontic clinic for reinsertion of separators to gain space for band placement.

Also, type S separators were found to be iatrogenic to induce localized periodontitis(trauma) due to subgingival displacement. This study serves to highlight the importance of vigilance in ensuring the separators are removed or accounted for once they have served their purpose.

Latex free elastomeric separators having knobs on either side of each ring that extend beyond the interproximal area out past the gingiva proved to be safe and effective for tooth separation with lower pain and discomfort to the patient.

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