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An Evalution of the incidence of mucosal lesion and the level of comfort during orthodontic treatment with and without the use of bracket shield And in-vivo Randdomized study

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Abstract

Objective: To evaluate and compare shielded bracket and unshielded bracket for the incidence of mucosal alteration and increased comfort perception in orthodontic patient during orthodontic treatment.

Materials and method: 45 Adolescent patients undergoing fixed appliance treatment at the Department of Orthodontics of KD Dental College Mathura were recruited for this study. Customized bracket shields were placed on trial side and the non-shielded on contra lateral side which served as the control. Comparisons regarding mucosa and discomfort assessments were made between the shielded and no shielded sides at T1 and T2 using the Mann-Whitney U test.

Result: The comfort level was statistically higher at T1on the shielded side, whereas no difference was observed at T2.

Conclusion: Patients experienced less discomfort on the sides where the brackets were shielded. The outcome after removal of the shields must be interpreted with caution but suggests that the mucosa becomes adapted to the presence of the brackets after only 4 days or less.

Keywords: Orthodontic, Visual Analogue Scale

Introduction

Orthodontic treatment increases the risk of mucosal lesion 1,2, in the first 2 to 3 week after bracket placement3. Epithelial alterations may vary from minor wounds to large ulcerated areas and are considered quite uncomfortable.Because of the scarcity and un-pharmaceutical options and systemic drug release issues, patients are normally given wax to cover the protuberant parts of bracketshowever, the wax needs to be removed before each meal, as it may be accidentally swallowed. And also can interfere with wire slot frictional forces if worn for long time. The purpose of this study is to evaluate and compare shielded bracket and unshielded bracket for the incidence of mucosal alteration and comfort perception in orthodontic patient during orthodontic treatment.

Materials And Method

The present study was undertaken at the Department of Orthodontics and Dentofacial Orthopaedics, K.D. Dental College, Mathura. This study was conducted on 45 participants to evaluate and compare shielded brackets and unshielded brackets for the incidence of mucosal alteration and comfort perception in orthodontic patient during orthodontic treatment.

Inclusion Criteria

- Any patient undergoing fixed Orthodontic treatment
- The patient should have normal soft tissues
- Should be nonsmoking
- No current use of alcohol or illicit drugs
- No history of recurrent mouth ulcers,
- No diagnosed systemic diseases and
- No current or past history of chemotherapy or radiation.

Informed consents were acquired from each and every patient interested and involved in the trial.

Materials used

1. 0.017 x 0.025'' in Stainless Steel wire
2. . 022 in Slot Brackets
3. Acrylic
4. Modelling wax
5. Trimmer
6. Burs
7. Ligature wire 0.009 in

Method

In this split-mouth design, customized bracket shields were placed on trial side and the non-shielded on contra lateral side which served as the control. Shield were constructed for maxillary brackets except for molars. Also extra shield were constructed, if they needed replacement in case of misplacement while eating or brushing. Insert a 0.017 X 0.025-in steel wire into the 0.022 X 0.028-in slot of all maxillary brackets and tie it with elastomeric ligatures. Fill all the undercuts with modelling wax. 1-mm-thick polymethyl methacrylate was placed over the bracket-wire-ligature-wax set and retentive sites of the brackets(figure 1). Any unnecessary material was trimmed and polished with stone burs for a fine acceptable finish. The same bracket-wire- ligature-wax sets were used to fabricate all shield units to be used in the trial, including those as refills.

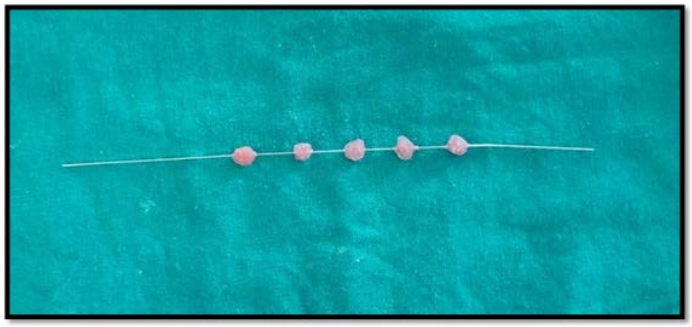


Figure 1: Shows a shields fabrication

The constructed shields were placed on one quadrant of maxillary arch and the other was left without shields to be used as control side. The patients were then recalled after 3 Days (figure 2).

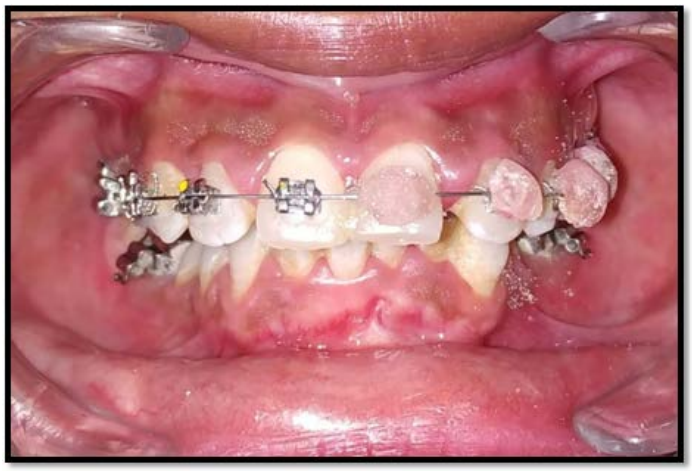


Figure 2: Shows a patient wearing the shields

The patients were provided with Visual Analogue Scale (VAS) to assess the amount of pain experienced on the trail as well as the control side (figure 3).

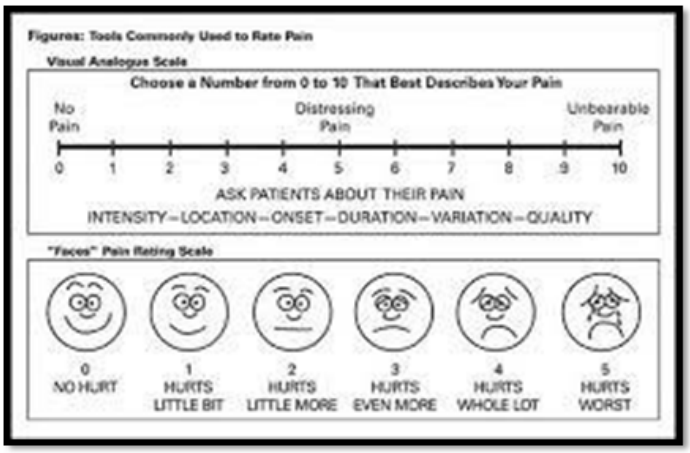


Figure 3: Visual Analogue Scale

Mucosal changes were recorded on day 1(T0), day 3 (T1) and after day 4 (T2) (figure 4 ,Figure 5. figure 6 and figure 7).

Figure 4: Mucosal changes on trial side (T1)

Figure 5:Mucosal changes on the control side (T1)

Four days after removal of the shields (T2), the same process was repeated (Figure 6 and 7).

Figure 6: Mucosal changes on trial side (T2)

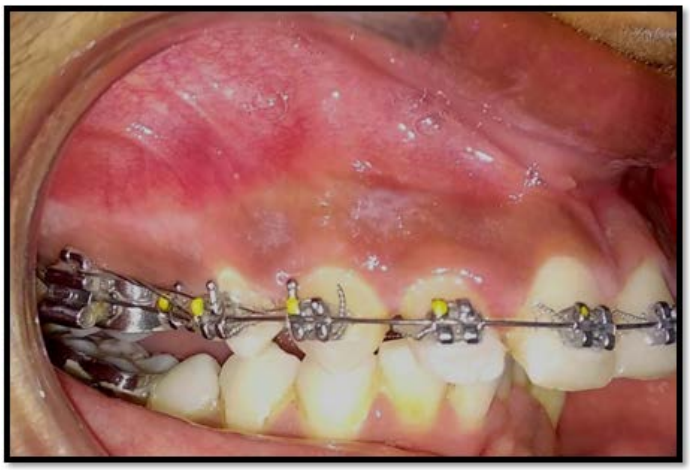


Figure 7: Mucosal changes on the control side (T2)

Assessment of outcomes

The assessments of outcomes were done on the basis of: severity of mucosal alterations, level of discomfort felt on both sides.

Types of assessments

Mucosal assessment at: T0, T1,T2

Discomfort felt at : T0, T1, T2

Statistical Analysis

Comparisons regarding mucosa and discomfort assessments were made between the shielded and no shielded sides at T1 and T2 using the Mann- Whitney U test.

Discussion

Oral mucosa is thin membrane causing any vesicles and bullae to break rapidly into ulcers. These ulcers are easily traumatized from teeth and food particles, and they become secondarily infected by the oral flora[7]. Orthodontic treatment carries with it the risks of tissue damage, treatment failure and increased predisposition to dental disorders[6].

The use of shield over the bracket may significantly reduce trauma and discomfort. Rubber tubing on the unsupported arch wire also reduces the risk of iatrogenic damage[2].This study seems to be the first to evaluate the in-vivo effectiveness of a customized bracket shield in preventing or reducing soft tissue trauma. Patients' perceptions of comfort when wearing these shields were also evaluated.

Although the outliers in both groups were not correlated with the higher frequency of shield failure, we cannot guarantee that all patients followed all instructions as recommended. This limitation has also been encountered in other clinical trials that relied on patient compliance and has been stated to hinder life saving conclusions in the medical field[9].

The second assumption is that the mucosa response to trauma may be related to either the bracket or the patient, or a combination of both. In other words, the surface and the profile of the brackets used in the trial might not be rough enough to induce the formation of mouth ulcers during the observation period. Alternatively, patients with no history of recurrent mouth ulcers may already be less susceptible to bracket-induced soft tissue trauma. Since the recurrence of aphthous ulceration is not significantly altered by the orthodontic treatment, as reported by Kvam et al,[2]one can imply that non susceptible subjects are less likely to be affected. If valid, this assumption restricts the extrapolation of our data to a specific population. Our methodology opens a new horizon to study the benefit from shielding the brackets in susceptible patients, not to mention the possibility of testing new materials that could enhance soft issue comfort, especially during trauma-prone orthodontic mechanics or in the presence of full-blown lesions. Although studies aimed at determining the onset time of traumatic ulcers are scarce, clinical orthodontic experience shows that these lesions tend to have a sudden onset. In addition, Budtz-Jorgensen8stated that traumatic ulcers(sore spots) most commonly develop within 1 to 2 days after the insertion of new dentures.The same was observed by Asher and Shaw,3 who reported soreness in 89% of the patients, but it was not severe. The split-mouth design of this trial might have enhanced the perception of the unshielded brackets, thereby increasing the appreciation for the shields. A placebo effect was also observed by Asher and Shaw, when a minor statistically insignificant analgesic effect was reported not only by most patients using an active agent, but also by a group using a placebo analgesic. The increased comfort perception with the shields is analogous to that observed with Invisalignaligners.9It should be advantageous to combine the perception of smoothness from wearing the shields with the movement precision achieved with fixed appliances. Another aspect is whether these shields would be a feasible option in a busy orthodontic practice. In our study, 57% of the patients needed to replace between 0 and 3 shields (Graph 1) within 3 days.Because the ultimate long-term goal is that orthodontic companies provide their own refills of shields, this does not seem to be unpractical or economically burdensome. Also,

orthodontists can choose to shield only brackets that are prone to cause injury or close to an ulcer. This would greatly reduce the compliance requirements, since fewer shields would be necessary.There are 4 laboratory studies: one raised a red flag regarding the environmental degradation of vinyl acetate,9two evaluated its oral mutagenic potential10-11and another assessed the likelihood of this material to cause developmental toxicity in rodents.11It was found that vinyl acetate is degradable in different environments but surprisingly less degradable than other polymers. Also, its carcinogenic potential was found to be low or even negligible as long as exposed cells are capable of maintaining the intracellular homeostasis via detoxification by aldehyde dehydrogenase.10Vinyl acetate was not uniquely toxic to rodent embryos. None of these studies, however, was conducted in humans undergoing dental procedures or exposed to a dental appliance containing the material.

Limitations

An intention to treat analysis could have been performed for the noncompliant participants excluded at T1. However, since they did not wear any of their shields, and the clinical and statistical differences in terms of mucosal and discomfort assessments were virtually nonexistent at T1, the inclusion of these patients in a split-mouth design would have no benefit.

Results

From 90 patients seeking orthodontic treatment between June and October 2018, 45 did not meet the inclusion criteria when examined at T0 between October 2018.The breakdown of the exclusion reasons was as follows: (1) 3 patients were smokers and were receiving prescription medication, (2) 2 had partially erupted permanent first molars and a missing lateral incisor, (3) another were using a mouthwash, (4) 9 were using or had recently used prescription medications, (5) 1 had partially erupted permanent first molars and a mouth ulcer, (6) 2 had at least 1 mouth ulcer, (7) 5 had a strong demarcation of the linea alba with or without a mouth ulcer, (8) 3 had already received orthodontic treatment, (9) 5 either reported or were in doubt about a history of recurrent mouth ulcers, (10) 2 had posterior crossbite, and (11) rest were not interested in participating in the trial.

No patient confirmed a history of either alcohol or illicit drug abuse of the 45 who fulfilled the inclusion criteria, were assigned and requested to provide written informed consent. It was decided to select more patients than what had been estimated by the sample size calculation.

A total of 45 patients participated in the study who were assessed at all 3 time points (T0, T1, and T2). The data pertaining to the patients were stored and analyzed for the relevant time points in which they participated.

All subjects examined at T0 met the baseline requirement of no mucosal alteration before the trial. No trauma during bracket placement was reported by the orthodontists, and all patients committed to wearing the shields at all times from T0 to T2 and replacing them when necessary. Baseline information regarding age, sex, and side of the mouth where the shields were assigned was recorded. In this split-mouth study, the oral mucosa on both sides had to be normal for the trial. Consequently, both sides of the mouth of each participant were considered highly comparable. The Mann-Whitney U test was performed to compare the shielded and non shielded sides at T1 and T2. A lower median score was obtained on the shielded side when assessing the mucosa at T1, but the difference was not statistically significant (Table I). At T2, a much less apparent difference was observed between the 2groups.

Unshield Side						Shield Side						Intergroup comparison		
Median	Min.	Max.	Percentiles			N	Median	Min.	Max.	Percentiles			MD	P-value	Ns/S
			25th	50th (Median)	75th					25th	50th (Median)	75th			
0	0	3	0	0	0	45	0	0	2	0	0	0	0	1.000	NS
0	0	0	0	0	0	45	0	0	3	0	0	0	0	1.000	NS

Min-max, Minimum and maximum; MD, median of all differences.

Table 1: Mucosal assessment intergroup comparisons (Mann-Whitney U test)

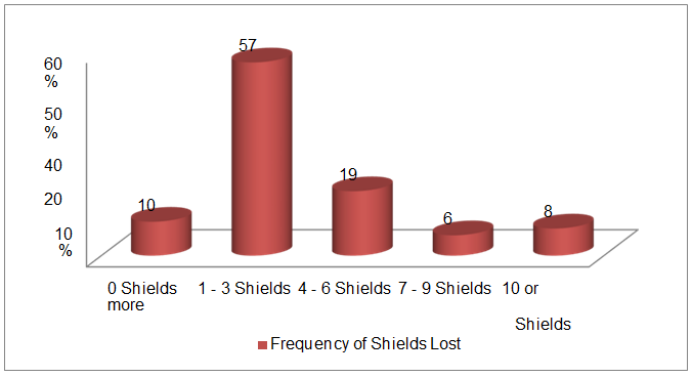
Unshield Side						Shield Side						Intergroup comparison		
Median	Min.	Max.	Percentiles			N	Median	Min.	Max.	Percentiles			MD	P-value	Ns/S
			25th	50th (Median)	75th					25th	50th (Median)	75th			
6	3	7	4.5	6	6	45	3	2	6	2	3	4	1	0.029	S
3	0	6	2	3	4	45	1	0	5	0	1	2	0	1.000	NS

Min-max, Minimum and maximum; MD, median of all differences.
*Statistically significant at P <=0.05.

Table 2: Discomfort assessment intergroup comparisons (Mann-Whitney U test)

The comfort level was statistically higher at T1on the shielded side, whereas no difference was observedat T2 (Table II).

Between T0 and T1, 10% of the patients did not need to replace their shields. One to 3 shields were replaced by 57% of the patients, whereas 19% replaced 4 to 6 shields. 6% replaced 7 to 9 shields, and 8% replaced10 or more. In most occasions, the shields fell off during either chewing or brushing but were not swallowed. No specific tooth was linked to a higher frequency of failure. The frequency of shield failure is illustrated in Graph1.



Graph 1: Frequency of shield replacements between T0 and T1.

Conclusion

The null hypothesis was partially rejected. Although it was not possible to observe a difference in terms of visible mucosal alterations 3 days after initiation of orthodontic treatment, patients experienced less discomfort on the sides where the brackets were shielded. The outcome after removal of the shields must be interpreted with caution but suggests that the mucosa becomes adapted to the presence of the brackets after only4 days or less.

These cases suggest cause- effect relationship between chronic traumatism and oral ulcer with mild dysplasia. Placement of metallic brackets in the buccal cavity induces cellular alerations. These alterations do not suggest malignancy.[12]

As reported by Keim[13] , ‘ pain management and even more important, pain prevention are given short shrift in many orthodontic training programs ’ . With increased apprehension from patients as well as parents and more application of common sense by orthodontists in managing these conditions, the need to streamline research in this area has become a necessity. This article has attempted to provide an overview of research developments in this field. Orthodontic researchers as well as clinicians are encouraged to give more attention to the topic and undertake more randomized clinical trials on this issue. This will help in arriving or formulating correct methods to measure, evaluate, and manage pain as well as the distress experienced by orthodontic patients. The research will help in improving not only the living standards of our patients but also the practice environment of every orthodontic clinician.

Metal brackets, stainless steel wires and metal and elasticties can induce cytomorphometric and cytomorphological changes to adjacent oral mucosa cells. This fact suggestsan adaptive response to the physical stimulus, whichis characterized by reactive

hyperparakeratosis of the epithelium but which regresses when the irritant stimulus is withdrawn.[48]

Considering all the esthetic, functional and oral health benefits that orthodontic treatment brings and the fact that the mucosa's adaptive response to the injury caused by these accessories is reversible, we believe that the benefits of this treatment outweigh the disadvantages of discomfort and possible lesion of the oral mucosa.

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