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An Effective Way of Reducing Traumatic Ulcer In Early Phase of Orthodontic Treatment - A Single Blind Randomized Controlled Trial.

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Abstract

Aims: To temporarily cover the brackets with flowable composite to reduce the mucosal irritation in the early phase of orthodontic treatment and to check its feasibility.

Settings and Design: It's a Split-Mouth design, single blinded randomized controlled trial where the investigator was blinded regarding the site of trial.

Methods and Material: Fifty patients with normal oral mucosa were selected for the trial and four standardized intraoral photographs were taken. The selected patients received metal brackets 0.022 slot MBT prescription and the brackets were shielded using flowable composite (soft flow) on the trial side of the oral cavity completing the baseline assessment (T0). Three days after delivering the shields (T1), the shields were removed and the patient's were allowed to rate their level of discomfort using a visual analog scale and then the mucosal assessment was done. Four days after removal of the shields (T2), the mucosal assessment and discomfort levels were recorded.

Statistical analysis used: Chi-square and Mann-Whitney U test was applied in the study.

Results: At T1, very high statistical significance was found in the terms of mucosal alterations (t-value -10.11111), while there was no statistically significant difference at T2 (t-value -1.26161). The patient's discomfort at T1 was 'U' value is -6.476 which is statistically highly significant while there was statistically no significance at T2.

Conclusions: The flowable composite shields can be used as a chair-side alternative to effectively reduce traumatic ulcerations, increasing the patient's compliance.

Keywords: Traumatic ulcers; Flowable Composite Shield; Bracket Irritation

Key message: The flowable composite (soft flow) is a chair-side and economically feasible option to reduce the traumatic ulcerations during the initial phase of orthodontic treatment.

Introduction

Orthodontic treatment has always been elective. The recent approach is more towards problem-oriented and patient-oriented approach. In this context, it is very crucial to consider the patient's comfort during the treatment. It is well documented that discomfort can negatively influence the desire to undergo treatment.[21-23, 25, 30]

Injury to the oral mucosa during orthodontic treatment is a common occurrence, and the irritations due to brackets on the labial or buccal mucosa are the most frequent patient's complaints. [1, 4, 20] Since early 1980's efforts have been made to reduce the patient's pain and discomfort level.[1, 3, 4] Topical application of 0.15% of benzydamine hydrochloride was used to relieve the discomfort in 1986 by Asher and Shaw but the active solution was ineffective in reducing the incidence, duration, and severity of soreness. [(3)] A new modification of an old remedy was used by adding benzocaine to a plain wax. This medicated wax slowly and continuously released benzocaine. [4] Hence, effectively reduced the pain associated with the mucosal irritation. This also inherited few drawbacks as the wax needs to be removed before each meal and the chances of accidental swallowing were high. [5]

Later, few authors like Pires et al (2015) attempted to overcome these disadvantages by replacing the conventional materials with a self-snapping flexible plastic shield which improved the texture perception of brackets without interfering with the biology of orthodontic tooth movement. [5, 24] The long-term follow-up period was unpredictable due to its interference with daily activities like brushing, consumption of large meal or ingesting carbonated drinks. The feasibility of these shields in a busy social life was still a concern.

With all the previous attempts, it had always been cumbersome to carry out daily activities. The aim and objective of this study was to assess the efficacy of flowable composite in temporarily covering the brackets to reduce the mucosal irritation. The feasibility of the material was also assessed for its practical applicability.

Null hypothesis

There is no difference in terms of visible mucosal alteration between with shield and without shield side of the mouth.

Research hypothesis

There is a difference in terms of visible mucosal alteration between with shield and without shield side of the mouth.

Subjects and Methods

The ethical clearance was obtained from the institutional review board before the start of trial. This study is a single blind, randomized controlled trial where the mucosal assessment rater was blinded regarding the trial side of the oral cavity. An investigator not involved in the study had randomly allocated the test and control groups following a lottery dip method. Fifty willing participants were selected from the subjects visiting the institute for orthodontic treatment. Patients were informed regarding the trial and consent regarding the same was obtained. Inclusion criteria were a) patient's with good general health and free of any systemic illness. b) Oral mucosa of normal soft tissue. c) No current or future use of any mouthwash solution. d) No history of recurrent mouth ulcers. e) No history of medications for illness. f) No history of chemotherapy or radiation. g) No history of previous orthodontic treatment. Exclusion criteria were a) History of Alcohol consumption or illicit drugs. b)History of smoking. c) History of the skin or systemic diseases with which oral lesions may be expected. d) Oral ulcerated lesions not located on the buccal mucosa (lesions on the tongue). e) Pregnant and lactating women. f) Patients with a known hypersensitivity to nickel or chromium ions.

Selected patients were initially examined to ensure that all have a normal oral mucosa before the trial and intraoral

photographs (1 side view of each cheek, 1 frontal view of each lip) were taken. After the initial procedures, the patients received metal brackets 0.022 slot MBT prescription and no complex mechanics was used during the trial. The brackets on the trial side of oral cavity were covered with flowable composite (soft flow, Dentos India Pvt Ltd). This was done using randomization. This step completed the baseline time point (T0). Three days after delivering the shields (T1 time interval), the shields were removed and patient's were allowed to rate their level of discomfort using a visual analogue scale. After this, a table containing a written description was used to assess the mucosal alterations (Table no.1) and rated by a rater who was blinded regarding the trial side. Four days after the removal of these shields (T2 time interval), the mucosal assessment and discomfort levels were recorded again.

Calibration of examiner

The clinical examinations for every subject were comprehensively carried out by one examiner. Examiner calibration was done by assessing few subjects oral cavity and that examiner was blinded with regard to the side of the mouth on which the bracket shields were applied. Intra examiner calibration was done to minimize the examiner variability. The results so obtained were subjected to kappa statistics. The kappa coefficient scores were 0.88 and 0.78, these values reflected high degree of conformity in observations.

Statistical analyses

Data obtained was compiled systematically in Microsoft Excel spread sheet and a master table was prepared. The data set was subdivided and distributed meaningfully. Statistical analyses were performed using a personal computer with Statistical Package for Social Sciences software (SPSS version 20, USA). Categorical data were compared using Chi square test and Mann-Whitney U test, while numerical data were compared using unpaired t-test.

Results

i) Assessment of mucosal alterations with shield and without shield (Table no.2)

The study revealed that there was statistically very highly significant difference of means of mucosal alterations with and without the shield at the time point of T (t-value was -10.11111, p value was < .00001).The result was significant at $p < .05$. While there was no statistically significant difference of means of mucosal assessment with and without the shield at T2 time point (The t-value is -1.26161, p-value is .105043).

ii) Assessment of patient's discomfort level on with shield and without shield. (Table no.3)

The mean rank of the patient's discomfort at T1 with shield and without shield was 50.5±145.05 and 'U' value was -6.476 which is statistically highly significant (0.0001) and T2 mucosal discomfort with shield and without shield was not statistically significant at P value < 0.05.

iii) Comparison of pain of the patient with shield and without shield at different point of time. (Table no.4)

It was found that there was statistically very highly significant difference of pain between with shield and without shield at T1 time ($X2=47.42$, $P<0.001$). There was no statistically significant difference of pain between with shield and without shield at the T2 time ($P>0.05$). Without the shield, there were only 4(8.0%) cases which had no pain in T1 time point, whereas in T2 time point there were 34(68.0%) cases with no pain. There was statistically very highly significant difference of categories of VAS score among time point of T1 and T2.

Discussion

Orthodontic treatment is often interpreted as a painful procedure[1, 6, 8-11, 13, 14, 27] and negatively impact the quality

of life.[31] Although the initial phase of treatment is stressful until the oral mucosa adapts to the orthodontic appliance, this can be avoided.

Literature dating back to 1980's where attempts were made to reduce the pain and discomfort through pharmacological ways[1, 3] or application of wax [4], but were not efficient to enhance patient's perception and had their own disadvantages.[5] A number of factors can influence treatment-related discomfort, including age, gender, pain thresholds, stress, current emotional state, cultural differences, social class and past pain experience. [19, 8,11, 28, 13]

In this study, a flowable composite is used which remains soft after polymerization and can be considered in reducing the initial mucosal alterations and discomfort during orthodontic treatment.

The flowable composite used in this study is available commercially under the name "Soft Flow" Dentos India Pvt Ltd. The company claims that the material is composed of dimetharcylate and silicon dioxide. It is available in various colors while clear was chosen for the study. It is currently used to reduce the mucosal irritation caused by temporary anchorage devices.

In the previous studies the stability of the shields used was challenging and interfered with the routine activities. The flowable composite shield used in this trial adequately retained on the irregular surface of the brackets. Taking advantage of this retentive ability, the need for patient's compliance was considered to be reduced which were a huge concern and also a reason for failure of follow up.

A total 50 subjects were selected for the study. Age was stratified into two groups for data analysis into 15-19 years and 20-23 years. Majority of the subjects that is 38(76%) belong to the age group 15-19 years. The sex ratio of male to female was 1:1.8.

Previous studies stated that "Thickening of the epithelium and mucosal erosions are the most commonly described changes on oral mucosa caused due to friction-related micro trauma (contact irritation) by the orthodontic appliance, whereas more extensive ulcerations occur less frequently."[7, 16, 26]

Based on the observations made on the mucosal alterations in this study, it is revealed that the use of flowable composite shields significantly reduced the mucosal alterations and ulcerations (Table no.3). The presence of normal mucosa on the shielded side implied that, the flowable composite was efficient to avoid initial mucosal changes caused by an appliance in the early phase of orthodontic treatment than without shield. This also implied that the smooth soft polymerized composite surface can be better tolerated than an irregular metal bracket and non-susceptible subjects are less likely to be affected.

Kvam et al showed that among wearers of fixed orthodontic appliances, 75.8% of patients had small wounds, whereas only 2.5% had bad ulceration.[7]

According to Bergius et al, motivation is the willingness to endure pain during orthodontic treatment.[2] Therefore, appropriate measures taken to prevent traumatic ulcerations means preventing pain and increasing the patient's motivation. [13, 14, 17, 24, 30] Thus, the flowable composite material used in the study not only reduces the incidence of traumatic ulcerations but also alleviate pain and increase patient's perception towards the orthodontic treatment.

Kluemper et al stated that, increased friction between the tissues and the brackets results in oral lesions, which can induce varying levels of pain and discomfort in most of the subjects associated with orthodontic care.[4]

While Sampaio Mei et al observed in their study that, the cytomorphometric and cytomorphological changes on

adjacent oral mucosa cells are induced due to irritants like the metal brackets, stainless steel wires and metal and elastic ties. This indicates that the reactive hyperparakeratosis of the epithelium is an adaptive response to the physical stimulus, which regresses when the irritant stimulus is withdrawn.[18]

These results are in line with those of a study in which Pereira *et al*, who observed similar cellular changes on the oral mucosa due to friction between the oral mucosa and metal and ceramic brackets. They stated that the changes in the epithelial cells are part of an adaptive process that occurs on the oral mucosal epithelium (hyperplasia together with reactive hyperparakeratosis), following interaction with an irritant. This is also characterized with an increase in the number of surface and subsurface cells.[15]

These soft composite shields were dislodged from the bracket only in three cases (usually in the upper central incisors which can be assumed due to brushing activity). The material flows in-between the bracket wings and other areas which provides mechanical retention. This allows an orthodontist to routinely shield the brackets chair-side in the early phase of treatment. As the shield failure rate was negligible, the material used in the study seemed to be practical and economically less burdensome.

The oral hygiene of the patient was not affected due to the smooth surface of the shield. Since clear colour composite was used in the study, discoloration was seen after 3 days during time interval T1. Accidental swallow of the shield was not reported while consumption of meal which can be attributed to the interlocking of composite on the undercut and tie wings of a bracket.

The study revealed relatively a high statistical significance in the discomfort assessed on with shield and without shield side of mucosa at time interval T1 (table no.3). This highlights the point that the shields not only reduced the mucosal alterations but also enhanced patient's comfort after appliance placement. While no statistical significance at T2 which indicated that an adaptation to new appliance took place within the first seven days (1 week) after appliance insertion.

Pires et al also concluded in his study that the bracket shields can effectively reduce the patient's discomfort during the first three days of orthodontic treatment.[5]

Kvam *et al.* (1989) also observed no significant patient's discomfort due to mechanical irritation after 6 days.[7]

Scheurer et al. observed that the mean pain intensity score was less than 15 after the 5th day and concluded as very mild discomfort.[11]

The study also found that there was statistically very highly significant difference of pain between with shield and without the shield at T1 time (table no.4). With the shield, no pain cases were significantly more as compared to without shield cases. Without the shield, there were only 4(8.0%) cases which had no pain in mucosa on control side at the T1 time point, whereas in T2 time point there were 34(68.0%) cases had no pain. Thus overall pain and discomfort were reduced in time T2.

Soltis et al explained this as a significant loss of proprioceptive ability 4 days after insertion of fixed appliances.[29]

Many authors shared the opinion that pain subsides and is negligible after 5 to 7 days of appliance placement (Soltis *et aI.*, 1971 [29]; Jones, 1984 [6];Kvam *et aI.*, 1987 [7]; Ngan *et al.*, 1989 [8], 1994; Brown and Moerenhout, 1991 ; Jones and Chan, 1992 [9]).

Hans sergl (1998) showed that an adaptation to the severity of pain and discomfort occurred during the first 3 to 5 days after placement of the appliance.[12]

There was no statistical significant difference in the perception of pain among both the gender and the age groups considered in this study.

Table no. 1: Scores to assess mucosal alterations

Score	Oral Mucosa Alteration Features
1	Presence of normal oral mucosa
2	Presence of reactive epithelial hyperkeratosis or erythema in response to the mechanical stimulus.
3	Presence of one or more traumatic ulcers ≤ 3mm and / or redness around the ulcer.
4	Combination of score 2 and 3
5	Presence of one or more traumatic ulcers ≥3mm and / or redness around the ulcer.
6	Combination of all the scores except score 1.

Table No. 2: Comparison of score for assessing the patient mucosal alteration with shield and without shield at different point of time.

Time point	With shield Mean± SD	Without shield Mean± SD	t-test value & p-value
T1	1±0	2.56±1.19	The t-value is -10.11111; p-value is < .00001. The result is significant at p < .05.
T2	1.42±1.06	1.7±1.4	The t-value is -1.26161; p-value is .105043. The result is not significant at p < .05.

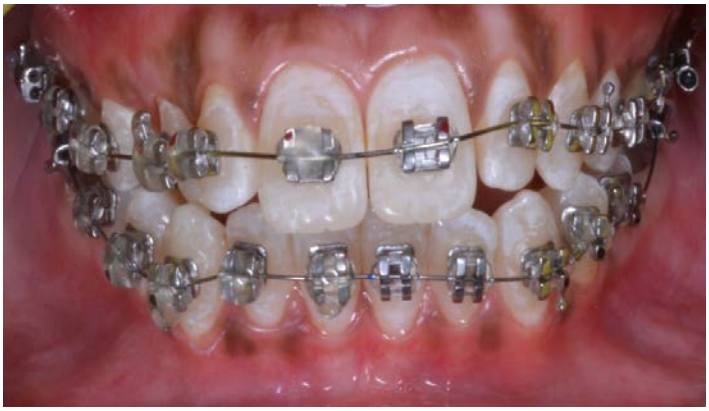
Table No. 3: Comparison of VAS scores for assessing the patient mucosal discomfort with shield and without shield.

Time point	With shield	Without shield	Mann-Whitney U Test & p-value
	Mean of ranks	Mean of ranks	
T1	69.3	31.7	Mean of ranks: 50.5; Standard Deviation: 145.0575. U-Score is -6.47674 & p-value is < .00001.
T2	47.72	53.28	Mean of ranks: 50.5;Standard Deviation: 145.0575 U-Score is -0.95479 & p-value is .34212. (The result is not significant at p < .05.)

Table No. 4: Comparison of pain of the patient with shield and without shield at different point of time.

Categories of pain	T1		T2	
	With shield	Without shield	With shield	Without shield
No pain	38	4	41	34
Mild pain	12	31	2	12
Moderate pain	0	13	6	3
Severe pain	0	2	1	1
Chi-square value & p-value	X^2=47.42; <0.0001		X^2=2.605; p>0.05	

Fig 1: application of soft flow on right side



Conclusion

1. Traumatic ulcerations in the initial phase of treatment were effectively reduced on the shielded side during the first 3 days. Evaluation of the results showed that the patients experienced less discomfort and pain at T1 time interval with the shields than without shields.

2. Pain, and discomfort on both with and without the shield were reduced in most of the cases after 7days of appliance placement (Time interval T2). Few patients showed severe ulcerations despite the use of shields which can be attributed to the inherent or confounding factors.

3. Taking advantage of the smoothness of the shields and less failure rate, it is of great benefit in non-susceptible subjects to deliberately reduce the chances of ulcerations and discomfort during the treatment.

4. Laboratory free procedure with less failure rate of these shields points out that the material (soft flow) is a feasible option for an orthodontist to use them in their routine practice.

Taken together, it can be concluded that the flowable composite (soft flow) is a chairside alternative to effectively reduce the traumatic ulcers in early phase of orthodontic treatment, increase patient compliance which in turn improves the treatment outcome.

Thus null hypothesis was rejected and research hypothesis was accepted.

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