

# MANUSCRIPT

## TITLE:

The efficacy of commercially available mouth ulcer film in denture induced mucosal injuries - an in-vivo study.

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## **Abstract**

**OBJECTIVES.** To compare and evaluate the pain and healing of denture induced ulcers protected with mouth ulcer film and without films. **MATERIALS &METHODS.** 15 patients having a minimum of two bilateral traumatic ulcers were selected. In each patient, smaller lesion (control lesion) was allocated to routine treatment (without film), whereas the larger lesion (study lesion) was treated by usual protocol plus application of mouth ulcer film (with film). By using intraoral camera the photographs of each lesions were captured and measured in Photoshop software. Pain was evaluated by a 10-point VAS. The patients were instructed to apply the film on the ulcers 3 times daily until the lesion completely heals. All the subjects will be recalled on 3, 5 and 7 days for evaluation of pain level and healing process. **RESULTS.** In denture induced ulcers protected with mouth ulcer film, a statistical significant reduction was observed for pain score ( $p = 0.000$ ) and ulcer size ( $p = 0.000$ ). **CONCLUSION.** Denture induced mucosal injuries treated with mouth ulcer film significantly promoted the rate of healing, as well as decreased the accompanying pain

**Keywords:** Complete denture, Mucosal lesions, Adhesive films.

## INTRODUCTION

Denture induced mucosal injuries following the insertion of complete dentures may occur in any of the supporting tissues in contact with the base and borders of the dentures.

Acute and chronic irritation from ill-fitting dentures may injure the oral mucosa.<sup>1,2-6</sup> Many factors can cause mucosal irritation and, ultimately, tissue ulcerations.<sup>7</sup> As age increases, the oral mucosa becomes more vulnerable to mechanical damage and demonstrates a significantly lower tolerance to injury<sup>7</sup> and delays the healing resulting in extending of the discomfort for the patient.

Application of the topical medicaments is the routine protocol. Disadvantages of these topical applications have an unpleasant smell, taste and difficulty in ease of use. They also tend to get washed away resulting in decreased efficacy of medicament.

Recently, Oral strip technology is gaining much attention. With this technology, a mouth ulcer film was introduced in which thin films are prepared using hydrophilic polymers. These polymers slowly dissolve in the mouth after application over ulcer, releasing its active ingredients to reduce oral inflammation. They also protect the ulcer from the physical disturbance there by decreasing the discomfort.

Hence, the purpose of this study was to evaluate the efficacy of commercially available MOUTH ULCER FILM on pain and healing of denture induced mucosal injuries and to compare it with routine protocol.

## MATERIALS AND METHODS

15 patients of age 45yrs to 65yrs who have received new complete dentures from the Department of Prosthodontics and complaining pain & discomfort, in their routine first post

insertion visit to Out Patient Department of Prosthodontics J.S.S Dental College and Hospital, were considered for the study.

**MATERIALS:** ANABEL MOUTH ULCER FILM – group pharmaceuticals ltd.

### **Objectives**

1. To evaluate the pain and healing of unprotected denture induced ulcers.
2. To evaluate the pain and healing of denture induced ulcers protected with mouth ulcer film.
3. To compare the pain and healing of ulcers with mouth ulcer film and unprotected denture induced ulcers.

### **PATIENT SELECTION CRITERIA:**

#### **Inclusion criteria:**

- Patients having new complete dentures with pain and discomfort with minimum of two or more bilateral traumatic ulcers
- Patient having physical and psychological ability for acceptance of attending follow up examinations.
- Age group 45-65years.
- Patients with good general health and nourishment.

#### **Exclusion criteria:**

- Patients with known hypersensitivity to one or more of the ingredients of mouth ulcer film.
- Patients receiving topical or systemic corticosteroids and systemic disease.

### **METHODOLOGY**

The subjects having a minimum of two bilateral traumatic ulcers with a separation of minimum 1 inch were selected.

**Grouping was done as follows: Group A** (control group) Denture induced ulcers without film. **Group B** (study group) Denture induced ulcers treated with mouth ulcer film.

After obtaining consent from the patient, following protocol was followed.

- In each patient,
  - The ulcer lesion with greatest dimension received the film treatment in addition to usual care (study group), and
  - The lesion with smaller dimension acted as a control lesion by receiving usual care.
- On the first visit of the patients, information was collected regarding pain intensity of both the lesions by asking the patient to fill out a 10-point visual analogue scale.
- 10-point VAS is a subjective measure of pain, where no pain is defined as 0 and intolerable pain as 10.
- The greatest measurement of each ulcer lesion was measured to evaluate healing process.
- By using an intraoral video camera the photographs of each lesions were captured. (figure 1).



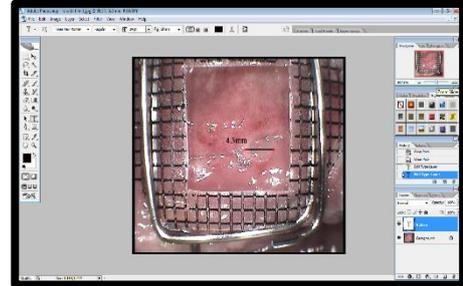
**Fig: 1**

- A distance of 2cm between the lens and lesion was standardized by using a jig made of stainless steel wire. It was removed from the camera in between uses for sterilization. (figure 2).



**Fig: 2**

- A millimeter calibrated grid was inserted into the jig while capturing the picture to standardize the measurement for image analysis of the ulcer lesion.
- Image analysis; image files were opened in Photoshop software and with the measuring tool, the greatest dimension of the lesion was measured and always use the same method to measure the lesion. (figure 3).



**Fig: 3**

- Pressure indicator paste was used to evaluate the accuracy of tissue contact and locate the denture areas causing pressure at the time of denture placement, and any parts of the dentures causing tissue irritation and ulcerations was corrected using a tungsten carbide bur and then the denture was finished and polished.
- The first film was applied on the ulcer and patients were instructed how to correctly self -apply the remaining films.
- According to the manufacturers instructions place the film on the lesion 3 times per day. Patients were monitored until complete healing of all ulcers and the subject was informed not to put the film on the other ulcer.
- During the night, patients were instructed to immerse the dentures in water after cleaning procedures and not to take any other medication for the ulcers.
- All the patients were recalled on 3, 5 and 7 days after the first visit. At each visit, the subjects were asked to complete the same pain and discomfort scale, and the greatest dimension was again measured using the same procedure as described.

The results were tabulated and statistically analyzed and compared.

## Data Analysis

Dependent variable: size of the ulcer in millimeters

Table:1 – shows descriptive statistics of ulcer size in group A (unprotected denture induced ulcers).

Group	N	MEAN	Std. deviation
Group A day 0	15	3.07	0.51
Group A day 3	15	2.68	0.45
Group A day 5	15	2.22	0.33
Group A day 7	15	1.58	0.22

Group	N	MEAN	Std. deviation
Group B day 0	15	4.79	0.60
Group B day 3	15	3.56	0.61
Group B day 5	15	2.70	0.38
Group B day 7	15	1.48	0.27

Table:2 – shows descriptive statistics of ulcer size in group B (denture induced ulcers protected with film).

Dependent variable: pain score in VAS of 1-10 points

Table: 3 - shows descriptive statistics of pain score in Group A (unprotected denture induced ulcers).

Group	N	MEAN	Std. deviation
Group A day 0	15	9.06	0.45
Group A day 3	15	7.26	0.88
Group A day 5	15	6.20	0.86
Group A day 7	15	4.93	0.88

Group	N	MEAN	Std. deviation
Group B day 0	15	10.00	0.00
Group B day 3	15	4.40	0.50
Group B day 5	15	2.86	0.63
Group B day 7	15	1.46	0.99

Table: 4 – shows descriptive statistics of pain score in Group B (denture induced ulcers protected with mouth ulcer film).

## Results

It has been observed that there was reduced pain perception and decrease in size of the ulcer in both the groups but the percentage decrease in size and in pain score of the ulcer treated with film was significantly greater than the control lesions without the films. (P = 0.000).

		T-test for Equality of Mean			
		T	Df	Sig. (2- tailed)	Mean Difference
size of the ulcer	Day 0 – day 7	-12.080	28	.000	-1.820

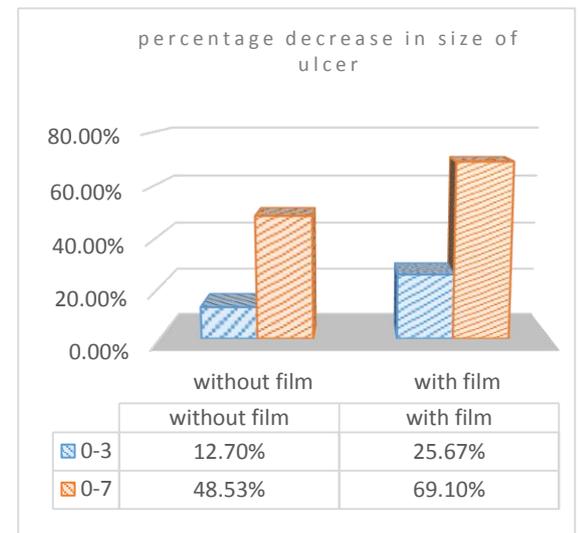
The above table shows a statistically highly significant relationship between Group A and Group B as p=0.000. Denture induced ulcers protected with mouth ulcer film had higher % decrease in ulcer size compared with unprotected denture induced ulcers from day 0 to day 7.

		T-test for Equality of Mean			
		T	Df	Sig. (2- tailed)	Mean Difference
Pain score	Day 0 – day 7	-13.762	28	.000	-4.40

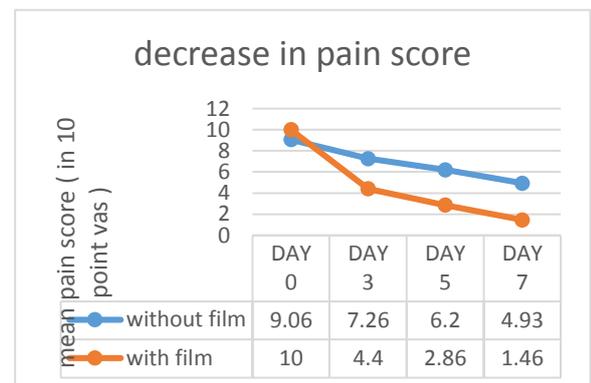
The above table shows a statistically highly significant relationship between Group A and Group B as p=0.000. Denture induced ulcers protected with mouth ulcer film had higher

% decrease in pain score compared with unprotected denture induced ulcers from day 0 to day 7.

The graph indicates percentage decrease in mean size of ulcer between unprotected denture induced ulcers and denture induced ulcers with mouth ulcer film on day 0 - day 3, day 0 - day 7. Group B has higher percentage difference (25.67% on day 0 - day 3, 69.1% on day 0 -day 7) compared to group A (12.7% on day 0 - day 3, 48.53% on day 0 -day 7).



The graph shows comparison of mean pain scores between unprotected denture induced ulcers and denture induced ulcers with mouth ulcer film on different follow up sessions (day 0, day 3, day 5, and day 7).



The graph indicates decrease in pain score in group B is higher than in group A at different follow up sessions (day 0, day 3, day 5, and day 7).

## DISCUSSION

Wearing dentures improves quality of life and restores masticatory function in edentulous patients.<sup>9,3</sup> Mucosal injuries are most common denture-related lesions which develop within 1 to 2 days after insertion of new dentures or old worn out ill-fitting dentures.<sup>5,10,11</sup>

During the rehabilitation therapy denture placement must not be the final patient-clinician encounter when treating with complete dentures.<sup>12</sup> It was found in a study that approximately 85.8% of patients required adjustments in the first 24 hours after insertion.<sup>12</sup>

Mucosal injuries range in shape and size: from a diameter of 1–8 mm and as small round or oval areas or hyperaemic painful spots.<sup>4,13</sup> The prevalence of traumatic ulcers vary from 3.5% in the general elderly population to 16% in wearers of partial removable dental prostheses and 25% in wearers of complete dentures.<sup>14,15</sup> Percentages increased to 92% when edentulous patients were fitted with a new prosthesis.<sup>16</sup>

The number of mandibular mucosal injuries were significantly higher than those of maxilla in all the post-insertion appointments. According to Kivoviks et al<sup>4</sup> dentists tend to extend flanges as much as possible to overcome the retention problem and that is why the highest frequency of injuries were seen in borders and flanges in the retromylohyoid area (48.6%), the buccal sulcus adjacent to the buccal shelf (9.8%), the retromolar pad (9.5%).

Mandibular denture has less support and stability compared to maxillary denture and a smaller denture-bearing area.<sup>17</sup> Presence of the tongue and greater movement range of mandibular denture make this situation more complicated.<sup>17</sup>

In addition to coexistence of nutritional deficiencies, various systemic diseases, use of medications, salivary changes, tobacco use, and poor oral hygiene, the elderly patients may further become more susceptible to these injuries<sup>18,14</sup> and in these circumstances mechanical irritations such as denture irregularities, sharp edges, pearls, fins, result in more severe and recurrent oral lesions.

The above-mentioned defects are usually due to clinical or laboratory errors during various stages of denture fabrication, including border molding, impression taking, and inadequate or insufficient polishing of the denture.<sup>4,19-23,24</sup>

By applying a pressure indicating paste and detection of overextended borders/flanges at delivery or post-insertion stages, mucosal injuries can be avoided and patient satisfaction achieved.

**Sequel of mucosal injuries :** Patient reports with symptoms and signs of trauma and mucosal inflammation, pain and discomfort, difficulty in wearing the dentures.

### **Healing<sup>25</sup>**

It is the response of the body or living tissues to restore the damage or injured tissue to its normal permanent structure. It is usually noted that the denture induced traumatic ulcer heals within 7 – 10 days without scar formation.

The process of healing involve the following phases: Inflammatory phase, Proliferative phase and Maturation phase.

## **FACTORS INFLUENCING WOUND HEALING**

### **LOCAL FACTORS**

The local factors effecting the healing process are:

Type, size & location, Adequacy of blood supply, Presence of infection, any Movement, etc.

### **SYSTEMIC FACTORS**

The following are the systemic factors effecting the healing process:

Circulatory status, Metabolic status like D.M., Vit C & zinc deficiency, Infection, etc.

### **Available medicaments for mouth ulcers**

Systemic medications and topical agents like corticosteroids, analgesics and antimicrobial mouth wash are used to treat the inflammation and pain associated with ulcers. These medications, which are supplied in a gel, cream or paste formulation, are applied three to four times a day, are usually symptomatic in treatment. However, these have an unpleasant smell, taste and difficulty in ease of use. They also tend to get washed away resulting in decreased efficacy of medicament.

Graser<sup>26</sup> compared the efficacy of three topical aesthetic gels in reducing denture soreness. He found that all three gels were equally effective and reduce perceived pain in one-third of subjects.

A study was done to determine the efficacy of a topical gel with triester glycerol oxide for treating ulcerations related to new complete dentures and compared with a placebo gel, which concluded that Clinically, TGO gel is not effective in the treatment of mucosal injuries occurring following placement of complete dentures<sup>7</sup>. Results indicated that because the ulcerations healed after adjusting the denture areas<sup>27</sup> most of the topical gels have psychological therapeutic effects.

To overcome the problems associated with the topical medicaments, films or patches which act as dressing for the mucosal injuries, to protect and hold the medicament for longer duration of time were introduced in the recent years.

Since the early 1980's, there has been renewed interest in the use of bioadhesive polymers to prolong contact time of the drug. These polymers<sup>28</sup> can be *Hydrophillic*, which

have carboxylic group and possess excellent mucoadhesive properties and *Hydrogels*, which swells in contact with water and adhere to the mucus membrane.

Several studies have been done on the efficacy of mucoadhesive patches on aphthous ulcers. A study reported that patients claimed reduced pain and healing time due to treatment with bioadhesive hydrogel patches, made of a pharmaceutical grade cellulose derivative, in the control of pain and as an aid to healing of aphthous ulcerations<sup>8</sup>

The present study was performed to analyse the efficacy of Mouth Ulcer Film with eugenol (active ingredient) for treating mucosal injuries following placement of complete dentures. The Mouth ulcer film contained Hydroxypropyl cellulose, Glycerol, Eugenol, Copovidone and Water.

Mouth ulcer film measured 20mm x 19mm, prepared using hydrophilic polymers which formed a barrier and dissolved in the mouth slowly after application, releasing its active ingredients.

The active ingredient in Mouth Ulcer Film is Eugenol which has analgesic, antiseptic, antimicrobial and anaesthetic effects that

- Relieves pain associated with ulcer,
- Prevents secondary infection,
- Promotes faster healing of ulcer.

In addition, the film forms a protective seal over the irritated and inflamed oral tissues, providing protection from further irritation caused by normal activities such as speaking and eating. It is therefore possible that part of the observed improved healing associated with the mouth ulcer film may have been due to the “bandage” effect of the film and not necessarily

attributable to its medicinal components. Such bandage would also protect against additional pain caused by mechanical irritation and possibly against infections.

The patients included in the study had a mean age of 55 years (45 to 65 years) with good general health, nourishment and having a minimum of two bilateral traumatic ulcers with a separation of minimum 1 inch.

According to the dimension of the lesion, grouping in the study was done. The lesion with the greatest dimension was used as treatment lesion and the lesion with smaller dimension as the control lesion in the same patient.

To accurately obtain the size of the lesion, an intraoral camera was used to capture the pictures of the lesions as the denture induced mucosal injuries have ill-defined borders. To maintain an uniform distance between the ulcer and the lens of the camera a distance standardization device made of orthodontic stainless steel wire was used, then the image files were opened in Photoshop software and with measuring tool, the greatest dimension of the ulcer was measured. Pain was evaluated by a 10-point visual analogue scale where no pain was defined as 0 and intolerable pain as 10, by the subjects.

Analysis of the results so received indicated that there was a decrease in ulcer size and pain score in both the treatments, with and without application of mouth ulcer film on denture induced lesions. It was found that local treatment, by application of a mouth ulcer film on denture-related oral ulcerations was associated with significantly higher rates of healing and faster decrease in pain level compared to usual care.

In this study, it was found that denture induced ulcers protected with mouth ulcer film attained 25% to 69% reductions in their greatest dimension from baseline to day 3 and 7 respectively, compared to 12% to 48% reduction in lesions without mouth ulcer film. The

participants reported significant improvement in pain level associated with 86% decrease of lesions treated with film and 56% decrease without mouth ulcer film.

Therefore, benefit of the mouth ulcer film was observed in both the rate of healing of the traumatic ulcer and in the associated pain, compared to the lesions without film.

The limitations of the study includes small sample size, which prevented more comprehensive subgroups analyses. This study was a nonrandomized clinical study. Future studies are needed to confirm these findings. Such studies should be conducted among many more individuals.

## **CONCLUSION**

Within the limitations of this in vivo study the following conclusions were made from the data obtained:

- In Denture induced ulcers treated without mouth ulcer film, the mean pain score has reduced by 45.58% and size of the ulcer has decreased by 48.53%.
- In Denture induced ulcers treated with mouth ulcer film, the mean pain score has reduced by 86% and size of the ulcer has decreased by 69.1%.
- Among the denture induced ulcers treated without and with mouth ulcer films the percentage decrease in both pain score and ulcer size are greater in the lesions treated with mouth ulcer films.

Hence, it can be concluded that denture induced mucosal injuries treated with mouth ulcer film significantly promoted the rate of healing, as well as decreased the accompanying pain.

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