

## **EFFICACY OF FLUOCINOLONE ACETONIDE IN THE TREATMENT OF ORAL LICHEN PLANUS : A 5 - YEAR FOLLOW UP STUDY**

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### **ABSTRACT**

Thirteen patients with atrophic or erosive oral lichen planus (OLP) failed to respond to other medications were selected for the treatment with fluocinolone acetonide 0.1% in orabase (FAO). The drug was applied to the lesions four times daily in the first month, after which the application frequency was gradually reduced. Examinations of the oral mucosa were carried out at 2 weeks, 1 month, 6 months, 1 year, 3 years and 5 years after starting the treatment. At one month, the lesions were satisfactorily in remission in 11 of the 13 patients, but at 5 years, only one patient was completely in remission. Acute pseudomembranous candidiasis was frequently complicated during the FAO treatment, but was effectively treated with topical antifungal agent in every instances. This study shows that FAO is a useful drug for the short term treatment of refractory OLP but is ineffective for the long term treatment, although serious long term side-effect is negligible.

**Key words :** fluocinolone acetonide, oral lichen planus

## INTRODUCTION

Lichen planus is a common chronic inflammatory disease of skin and oral mucosa with unknown etiology<sup>1</sup>. In non-erosive oral lichen planus (OLP), patients often complain of roughness of the oral mucosa or burning sensation with hot or spicy food. In erosive type, OLP may interfere with speaking, eating and swallowing which makes the patients suffer most. Various treatments for the disease have been tried, but complete cure is rather rare. Vitamin A analogues can eliminate the white lesions of OLP but rapid recurrence is noted after discontinuation of the drug<sup>2</sup>. Human interferon- $\beta$  has been reported to have high therapeutic efficacy but needs advanced genetic engineering for its synthesis<sup>3</sup>. Antifungal agent and cryosurgery have also been tried in the treatment of OLP<sup>4-5</sup>. Cyclosporin has recently been reported to be beneficial in the treatment of several mucocutaneous disorders but it does not seem to be reliably effective in severe OLP<sup>6-7</sup>. Furthermore, it is rather expensive and has some serious side effects<sup>8</sup>. Therefore, both systemic and topical corticosteroids have been widely used to alleviate pain and inflammation in OLP. In this study, a new preparation of topical steroid, fluocinolone acetonide 0.1% in orabase (FAO), was assessed for its efficacy and safety in the treatment of refractory cases of OLP.

## PATIENTS AND METHODS

Thirteen patients with atrophic or erosive OLP who had failed to respond to other medications and had no serious systemic diseases were selected. The number of female patients was greater than males (10 vs 3), and the age range was 30-79 years with a

mean of 48 years. The duration of disease varied from 364 months. Lesions were found most in buccal mucosa followed by mucobuccal fold, lip, palate, gingiva and tongue, respectively (Table 1). The diagnosis was confirmed by tissue biopsy. In addition, candida staining was performed in all cases before and during treatment. Patients were asked to stop any medications for the treatment of OLP at least 2 weeks before the commencement of FAO.

The lesions were scored 0-5 according to the following criteria.

- 5 = white striae with erosive area larger than 1 x 1 cm<sup>2</sup> with severe symptoms
- 4 = white striae with erosive area smaller than 1 x 1 cm<sup>2</sup> with moderate symptoms
- 3 = white striae with erythematous area larger than 1 x 1 cm<sup>2</sup> with mild symptoms
- 2 = white striae with erythematous area smaller than 1 x 1 cm<sup>2</sup> with mild symptoms
- 1 = very mild white striae without symptoms
- 0 = normal mucosa without symptoms

The criteria for cure or remission were the absences of erythematous or inflammatory area, white striae and symptoms, i.e. a score of 0 or 1. Score 2 represented partial remission and scores 3-5 represented no response to treatment. FAO 0.1% was prepared in the Pharmacological Department. Patients were advised to apply the drug to the lesions four times daily during the first month. When the lesions had responded to the treatment (score 2), the application was reduced to three times daily and gradually to twice (score 1) and once (score 0) daily, and finally stopped. One year after beginning the treatment,



the patients were advised to apply either FAO or fluocinolone acetonide 0.1 % in solution (FAS) topically to the lesions when they recurred as the above criteria. Evaluations by oral examinations together with photographs were performed at 2 weeks, 1 month, 6 months, 1 year, 3 years and 5 years after starting treatment respectively.

## RESULTS

After the first 2 weeks, 9 out of 13 cases (69.23%) remitted while after 1 month, 11 cases (84.61%) re-mitted. After 5 years, however, only one case (7.69%) was completely in re-mission, whose oral mucosa had become normal without any symptoms (Table 2). The lesions before and after treatment were illustrated for clinical comparison as shown in Figure 1-6. Acute pseudomembranous candidiasis was frequently found 5 out of 13 cases (38.46%) during the first 2-6 months after beginning treatment but was completely cured by miconazole gel in all cases.

## DISCUSSION

Both systemic and topical corticosteroids have been widely used in the treatment of OLP for alleviating pain and inflammation<sup>9-11</sup>. Steroids used topically or by local injection are often more effective and safer than systemic steroids<sup>12-13</sup>. It was shown in previous study that fluocinolone acetonide cream did not result in significant differences in blood pressure and synacthen test before and after treatment<sup>14</sup>. Moreover, our recent study indicated no

permanent adrenal suppression after treatment with FAO for 6 months<sup>15</sup>. This present study showed that only one case of OLP out of 13 cases was still in complete remission after 5 years follow-up. It is not known whether the remission of lesions in this case occurred as a consequence of the drug or did it occur spontaneously. The lesions in this case had persisted for longer than 34 months before treatment with FAO without remission. Even though the FAO may not help curing the disease, it may help reducing pain. Nine patients dropped out during the follow up period. It was ascertained through telephone communication that most of them had had only partial remission with mild symptoms. Only two cases had shown no response to the treatment while most patients responded very well after one month. Acute pseudomembranous candidiasis occurred as a complication of the treatment was common but could readily be cured with topical miconazole in all cases.

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**Table 1** Sex, age, site and duration of disease in OLP patients.

No	Sex	Age(years)	Sites of the lesions*	Duration (months)
1	M	79	B, M	56
2	F	53	P	35
3	F	50	B, T	34
4	F	32	B, L	36
5	F	56	B, L	34
6	F	38	B, M, G	42
7	F	52	G	6
8	M	67	B, L	24
9	F	39	B	6
10	F	30	P	4
11	F	33	L	64
12	M	36	B, M	3
13	F	57	B, M	60
Total = 13	F:M = 10:3	Mean± SD = 47.85±14.84	B = 9    P = 2 M = 4    G = 2 L = 4    T = 1	range = 3-64 months

\* B = buccal mucosa, G = gingiva, L = lip,  
M = mucobuccal fold, P = palate, T = tongue

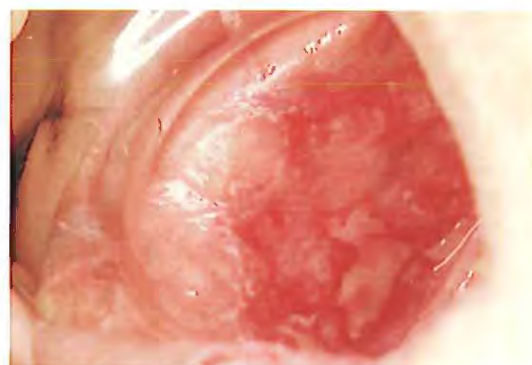
**Table 2** Result of the FAO treatment at 2 weeks, 1 month, 6 months, 1 year, 3 years and 5 years in 13 OLP patients.

Duration of treatment	Number of patients			
	remission	partial remission	no response	dropped out
2 weeks	9	2	-	2
1 month	11	2	-	-
6 months	9	2	-	2
1 year	2	3	-	8
3 years	2	2	-	9
5 years	1	1	2	9





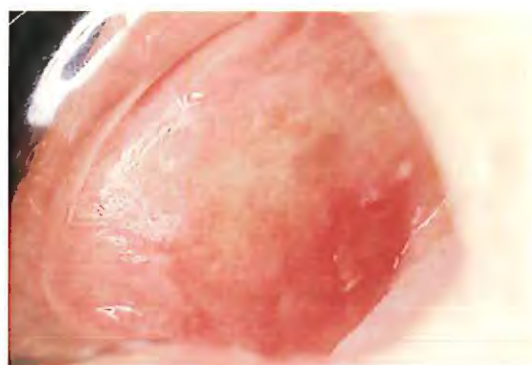
**Figure 1** Case 1 patient with erosive lichen planus on right buccal mucosa before treatment with FAO.



**Figure 4** Case 2 patient with erosive lichen planus on right buccal mucosa before treatment with FAO.



**Figure 2** Case 1, one month after treatment with FAO.



**Figure 5** One month after treatment with FAO in case 2, the buccal mucosa showed good response to the treatment.



**Figure 3** Case 1, five years after the start of treatment, there was neither white striae nor erythematous area.



**Figure 6** Case 2, one year after treatment with FAO. The mucosa appeared to be normal.

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