



## A comparison of tissue conditioner alone versus tissue conditioner with chx for treatment of the denture stomatitis in older adults

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### ABSTRACT

**Objectives:** Denture stomatitis (DS) is a multifactorial common disorder of removable denture wearers. Incorporation of antimicrobial agents in the lining materials may be an effective treatment for this condition. The purpose of this study is to compare of tissue conditioner alone versus tissue conditioner with CHX for treatment of the DS.

**Materials and Methods:** Thirty six denture-wearing patients suffering from different stages of DS were investigated this clinical trial. Patients were assessed clinically and then randomly divided to two groups: test (TC containing CHX) and control (same TC without CHX) Clinical effectiveness of each treatment was measured using clinical indexes consist of lesion size, color of lesion and sore mouth on day0, day 1, day 3 and day 7.

**Results:** Findings showed that both treatments resulted in decreasing the lesion size with statistically significant differences between control and test groups. The percentage of the patient with pink lesions increased and the number of patients with ruby and red lesion decreased over treatment period with statistically significant differences between groups. Both treatments led to decrease of the pain without any statistically significant difference between groups.

**Conclusions:** It was concluded that of TC alone and TC with CHX are an treatment for DS. It seems that adding CHX to T.C has a statistically significant positive effect on lesion size and color compared to T.C alone.

**Keywords:** CHX, Denture stomatitis, Tissue conditioner.

### Introduction

Denture stomatitis (DS) is a multifactorial common disorder of removable denture wearers, characterized by: erythematous spongy burning strawberry like of the oral mucosal areas covered by the denture [1, 2]. This condition that usually happens in the

upper jaw. DS can be graded according to the appearance of clinical severity. Most of the times stomatitis is primarily discovered during examination by clinicians and patients don't have any complain [3, 4]. Associations of DS have been reported with mucosal trauma due to ill fit denture,

increasing age of the patients, increased age of dentures, systemic conditions, bacterial and fungal infection, allergy, and poor denture hygiene and etc. [3, 5-11].

The first suggested treatment for this condition is removal of the denture as long as possible and definitely overnight. But most of the times patients because of such problem like their social state cannot put away their denture easily, therefore for the prosthodontics treatment and management of traumatized oral mucosa, denture lining materials, which include tissue conditioners and soft denture liners, are widely used [12-14]. The mechanical properties and viscoelasticity of these materials produce a cushion effect that improves chewing and distribution of the occlusal forces on the supporting tissues [15]. Different disinfecting agents, such as sodium hypochlorite and chlorhexidine and different antifungal drugs such as amphotericin B, Itraconazole, fluconazole and nystatin used for eliminate denture plaque and control fungal colonization on the fitting surface of denture and basal seat tissue [16-19].

Against rapid healing in bacterial stomatitis, the rapid recurrence of DS that can occur after stopping antifungal treatment likely reflects recontamination by residual yeast that are present on the denture surfaces and which are relatively unaffected or resistant to the treatment. One of the main advantages of CHX, besides being a powerful antimicrobial, is its ability to attach to a wide variety of substrates such as oral mucosa, lining material and denture based acryl while maintaining its antibacterial activity. It is then slowly released, leading to persistence of effective concentrations. Therefore CHX can decrease secondary and recurrent infection rate [20-22].

Lining materials are easily degradable and suitable to microbial colonization. Therefore, some authors have suggested the incorporation of antimicrobial agents in the lining materials to extend their clinical longevity and prevent microorganism proliferation. The incorporation of antimicrobial agent and therapeutic effect of lining materials has been shown to be effective and viable by both in vitro and in vivo studies. But there isn't such combination in market as a commercial product so there is a need for reproduce able and usage method to provide this antimicrobial denture lining in clinic by clinicians [21, 23-25].

The purpose of this study is to evaluate the effect of a tissue conditioner (TC) containing CHX as an antimicrobial agent against same tissue conditioner with-

out CHX. The null hypothesis was that tissue conditioner containing CHX would accelerate DS.

## Materials and Methods

The study protocol was approved by the Ethics Committee of the Dental Research Center of Tehran University of Medical Sciences, and the patients signed an informed consent forms. Thirty six denture-wearing patients suffering from different stages of DS were investigated in a single-blind randomized controlled clinical trial.

The inclusion criteria were older adults of both sexes using superior complete removable acrylic denture and presenting DS. Exclusion criteria were cognitive decline or dementia, and recent use of antibiotics and/or antifungals (in the past 2 months). None of the participants had history of radiotherapy because of head and neck cancer [26].

At the initial visit, 36 patients were assessed clinically and then randomly divided to two groups: test (TC containing CHX) and control (same TC without CHX). Both groups received TC in viscogel type (VG; Dentsply, Weybridge, UK), inside their ill fit dentures. The TC were prepared and placed according to the manufacturer's instructions (5g / 3ml powder / liquid ratio). The tissue surfaces of the dentures were adjusted before the placement of the TC and then, any possible traumatic area of the relined dentures was checked and polished. The experimental TC with CHX was prepared as follows. 1 cc CHX solution (2% by w/v) was first incorporated into the monomer liquid of the TC in 1:2 ratios, which was then mixed with the polymer powder at the ratio recommended by the manufacturer. TC in both groups repeated in 3rd day [27]. The effectiveness of treatment were clinically evaluated using clinical indexes consist of lesion size, color of lesion and sore mouth on day 0, 1, 3 and 7.

## Evaluation indexes

**1-lesion size:** in each appointment lesion area were measured by intra oral scaled caliper in  $\pm 0.01$ mm accurate and reported in  $\text{mm}^2$ .

**2-color of lesion:** the colors were assessed in 3 predetermined grades as followed: ruby, red and pink.

**3-sore mouth:** patients were instructed to quantify their pain level in the examination days by means of a visual analogue scale (VAS). The visual analogue scale consists of a 10 cm line anchored at one end by the la-

bel 'No pain' and at the other end 'Worst possible pain. The patient marks on the line the spot for the pain intensity which is then measured. Patients that marked between 7 to 10 on VAS line classified in positive group as group with severe sore mouth, and patients that marked between 0-7 classified in moderate group and patients with no pain were called negative group.

### Statistical analysis

Sample size was predicated based one Cochran formula for comparing the two means. Based on the results of five test and five control and a significance level of  $\alpha = 1\%$  and  $\beta = 5\%$ , a total sample size of at least 36 patients (18 control and 18 test) would be required. Statistical analysis was performed using a software program (SPSS, v.20.0 for Windows, IBM, Chicago, IL., USA). Mann whitney u test was used for statistical analysis.

### Results

Thirty six patients entered the trial. Table 1 show the summary statistics for lesion size on day 0, 1,3 and 7 in

the control (TC without CHX) and test (TC containing CHX) groups. Findings showed that both treatments resulted in decreasing the lesion size. There were statistically significant differences in decreasing the lesion size between control and test groups at 3th day.

Table 2 show the summary statistics for lesion color on day 0, 1,3 and 7 in the control (TC without CHX) and test (TC containing CHX) groups. Results showed that the percentage of the patient with pink lesions increased and the number of patients with red lesion decreased more. According statistical analysis there is a significant difference between test and control groups in favor of test group at 3th day. It means TC containing CHX increased the lesion color.

Table 3 show the summary statistics for pain on day 0, 1,3 and 7 in the control (TC without CHX) and test (TC containing CHX) groups. Both treatments led to decrease of the pain. However during treatment period statistical analysis don't show any significant difference between test and control groups. So seems that adding CHX to T.C has no effect on sore mouth than use T.C alone.

Group		0 Day	1th Day	3th Day	7th Day
Test	Mean (mm <sup>2</sup> )	199.42	143.19	103.83	83.56
	N	18	18	18	18
	Std. Deviation	212.28	200.38	146.04	140.39
Control	Mean (mm <sup>2</sup> )	187.75	171.42	162.69	110.78
	N	18	18	18	18
	Std. Deviation	164.09	157.12	154.54	109.27
P value		0.563	0.085	0.025	0.202

**Table 1.** The mean± standard deviation (SD) values for lesion size on day 0, 1,3 and 7 in the control (TC without CHX) and test (TC containing CHX) groups.

Group		0 Day			1th Day			3th Day			7th Day		
		Ruby	Red	Pink	Ruby	Red	Pink	Ruby	Red	Pink	Ruby	Red	Pink
Test	Count	8	10	0	1	12	5	1	5	12	1	2	15
	%	44.4	55.6	0	5.6	66.7	27.8	5.6	27.8	66.7	5.6	11.1	83.3
	within Group												
	% of Total	22.2	27.8	0	2.8	33.3	13.9	2.8	13.9	33.3	2.8	5.6	41.7
Control	Count	3	15	0	3	15	0	1	15	2	0	8	10
	%	16.7	83.3	0	16.7	83.3	0	5.6	83.3	11.1	0	44.4	55.6
	within Group												
	% of Total	8.3	41.3	0	8.3	41.7	0	2.8	41.7	5.6	0	22.2	27.8
P value		0.222			0.83			0.028			0.444		

Table 2. The Count, % within Group, % of Total for lesion color on day 0, 1,3 and 7 in the control (TC without CHX) and test (TC containing CHX) groups.

Group		0 Day			1th Day			3th Day			7th Day		
		No pain	Moderate	Severe									
Test	Count	14	0	4	15	3	0	16	2	0	17	1	0
	% within Group	77.8	0	22.2	83.3	16.7	0	88.9	11.1	0	94.4	5.6	0
	% of Total	38.9	0	11.1	41.7	8.3	0	44.4	5.6	0	47.2	2.8	0
Control	Count	14	2	2	15	3	0	14	3	0	18	0	0
	% within Group	77.8	11.1	11.1	83.3	16.7	0	83.3	16.7	0	100	0	0
	% of Total	38.9	5.6	5.6	41.7	8.3	0	41.7	8.3	0	50	0	0
P value		0.389			1			0.889			0.944		

Table 3. The Count, % within Group, % of Total for pain on day 0, 1,3 and 7 in the control (TC without CHX) and test (TC containing CHX) groups.

### Discussion

To our knowledge from indexed literature, this study is the first randomized controlled clinical trial to compare tissue conditioner alone versus tissue conditioner with CHX for treatment of the denture stomatitis (DS) using clinical and patient reported outcomes. The time of the different treatment of the DS ranged between 1-4 weeks [28, 29]. In our study, one week was enough to see effectiveness. However, further studies with more time of treatment with TC alone or TC with CHX are needed.

In our study, both treatments resulted in decreasing the lesion size with statistically significant differences between control and test groups.

So we conclude that CHX affect inflammatory component of lesion and accelerate their healing time. The diagram showed that the test group decrease the lesion size more rapidly and result in less final lesion size than control group. This result is consistent with some previous studies which demonstrate that TC alone led to healing but had greater resolution time [27, 30].

The percentage of the patient with pink lesions increased and the number of patients with red and ruby lesion decreased during treatment period. On 7th day, the test group had more pink lesion and less red lesion than control group. So this results showed that TC with CHX are more effective in eliminating palatal inflammation TC alone [27, 30]. Both treatments led to decrease of the pain without any statistical significant difference between test and control groups. So seems that adding CHX to T.C has no effect on sore mouth than use T.C alone. So, it can be concluded that TC with CHX can affect sign of the DS but did not affect symptoms.

The positive results in the control group could be explained by the Hawthorne effect, which was letting patients perform better oral hygiene. Also the application of TC along with other treatment, as the complementary practices for the prevention and treatment of denture stomatitis led to distribution of the occlusal forces on the supporting tissues. Several studies confirmed the etiologic role of trauma in DS and have advocated the construction of well-made dentures or relines to reduce denture trauma [12, 13, 31]. One study demonstrated that candida growth has been associated with soft liner which is a paradox [32] and must be investigated in future studies.

## Conclusion

It was concluded that of TC alone and TC with CHX are a treatment for DS. It seems that adding CHX to T.C has a statistically significant positive effect on lesion size and color compared to T.C alone.

## Conflict of Interest

There is no conflict of interest to declare.

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