

## A comparative study of preserved and preservative-free hydroxypropyl methylcellulose-dextran-containing eyedrops in dry eye disease

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### ABSTRACT:

**Background:** Dry eye is a disorder of the tear film which occurs due to tear deficiency or excessive tear evaporation. The present study compared preserved and preservative-free hydroxypropyl methylcellulose-dextran-containing eyedrops.

**Materials & Methods:** 56 patients of dry eyes disease were divided into 2 groups of 28 each. Group I were prescribed dextran 70, 1 mg/ml and hypromellose, 3 mg/ml hydroxypropyl methylcellulose (HPMC) and group II 0.3 g HPMC and 0.1 g of dextran 70, with 0.01% benzalkonium chloride (BAK). The ocular surface disease index (OSDI) questionnaire, tear break up time (TBUT), corneal and conjunctival staining and Schirmer test were performed.

**Results:** The mean OSDI score at baseline was 42.6 and 39.4 and at 4 weeks was 32.7 and 28.1 in group I and II respectively, TBUT (sec) at baseline was 7.6 and 7.4 and at 4 weeks was 7.1 and 8.1 in group I and II respectively, conjunctival score at baseline was 6.78 and 7.32 and at 4 weeks was 5.30 and 5.4 in group I and II respectively, corneal score at baseline was 1.47 and 1.24 and at 4 weeks was 0.52 and 0.41 in group I and II respectively and schirmer test (mm) at baseline was 6.07 and 6.12 and at 4 weeks was 6.80 and 7.25 in group I and II respectively. The difference was significant ( $P < 0.05$ ).

**Conclusion:** Both preserved and preservative-free hydroxypropyl methylcellulose-dextran-containing eyedrops were effective in reducing symptoms of dry eyes disease.

**Key words:** Dry eyes, hydroxypropyl methylcellulose-dextran, Schirmer test.

### INTRODUCTION

Dry eye is a disorder of the tear film which occurs due to tear deficiency or excessive tear evaporation; it causes damage to the interpalpebral ocular surface and is associated with a variety of symptoms reflecting ocular discomfort.<sup>1</sup> Dry eye syndrome, also known as keratoconjunctivitis sicca (KCS), is a common condition reported by patients who seek ophthalmologic care and is characterized by inflammation of the ocular surface and lacrimal glands.<sup>2</sup> Dry eye symptoms may be a manifestation of a systemic disease, therefore timely detection may lead to recognition of a life-threatening condition.<sup>3</sup> Additionally, patients with dry eye are prone to potentially blinding infections, such as bacterial keratitis and also at an increased risk of complications following common procedures such as laser refractive surgery.<sup>4</sup>

Artificial tears are among the first line of therapy in management of DES.<sup>8</sup> They may be used along with other treatments such oral omega-3 essential fatty acid supplements, mucin secretagogues, short term steroids and daily cyclosporine A, to combat the inflammatory

nature of the disease.<sup>5</sup> Frequent eye care visits and different treatment options impose high costs to patients and health care systems. Due to their non-invasive nature and low side effect profile, artificial tears have remained the main stay of therapy for DES. Almost all tear substitutes rapidly replace the moisture layer of tears and quickly reduce the symptoms.<sup>6</sup>

Benzalkonium chloride (BAK) is a preservative frequently used in ophthalmic preparations. In patients with mild dry eye, benzalkonium chloride containing products may be well tolerated when used four to six times a day or less. Preservative free formulations are also indicated for those with a known history of allergy to preservatives and those who wear contact lenses.<sup>7</sup> The present study compared preserved and preservative-free hydroxypropyl methylcellulose-dextran-containing eyedrops.

### Materials & Methods

The present study comprised of 56 patients of dry eyes disease of both genders. All were informed and their written consent was obtained.

Demographic data such as name, age, gender etc. was recorded. Patients were divided into 2 groups of 28 each. Group I were prescribed dextran 70, 1 mg/ml and hypromellose, 3 mg/ml hydroxypropyl methylcellulose (HPMC) and group II 0.3 g HPMC and 0.1 g of dextran 70, with 0.01% benzalkonium chloride (BAK). The ocular surface disease index (OSDI) questionnaire, tear break up time (TBUT), corneal and conjunctival staining and Schirmer test, were performed. Results thus obtained were subjected to statistical analysis. P value less than 0.05 was considered significant.

### Results

**Table I Distribution of patients**

Groups	Group I	Group II
Drug	Hydroxypropyl methylcellulose	Benzalkonium chloride
M:F	15:13	12:16

Table I shows that group I had 15 males and 13 females and group II had 12 males and 16 females.

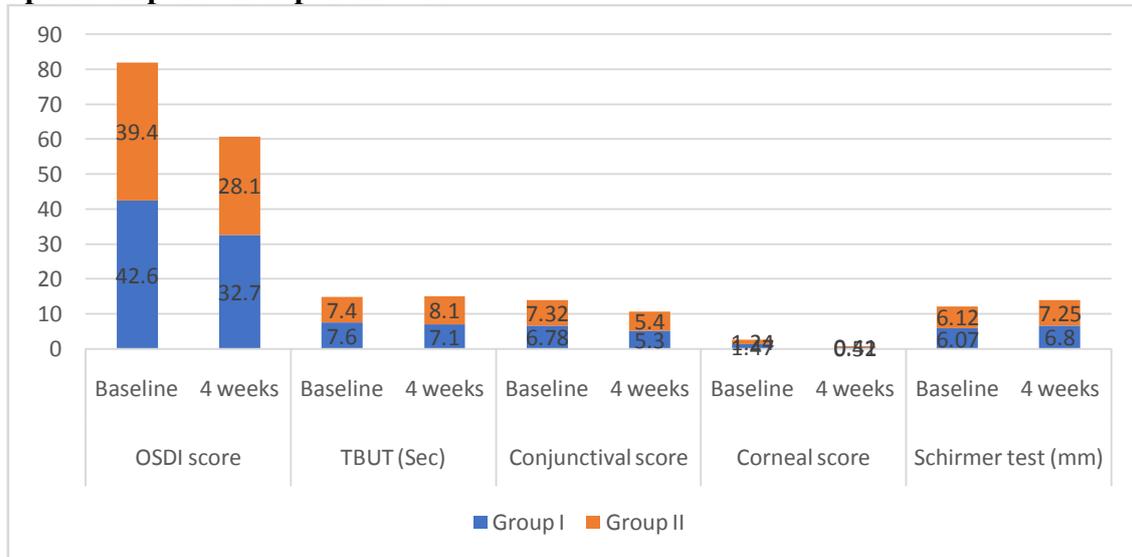
**Table II Comparison of parameters**

Parameters	Variables	Group I	Group II	P value
OSDI score	Baseline	42.6	39.4	0.04
	4 weeks	32.7	28.1	
TBUT (Sec)	Baseline	7.6	7.4	0.03
	4 weeks	7.1	8.1	
Conjunctival score	Baseline	6.78	7.32	0.01
	4 weeks	5.30	5.4	
Corneal score	Baseline	1.47	1.24	0.02
	4 weeks	0.52	0.41	
Schirmer test (mm)	Baseline	6.07	6.12	0.02
	4 weeks	6.80	7.25	

Table II, graph I shows that mean OSDI score at baseline was 42.6 and 39.4 and at 4 weeks was 32.7 and 28.1 in group I and II respectively, TBUT (sec) at baseline was 7.6 and 7.4 and at 4 weeks was 7.1 and 8.1 in group I and II respectively, conjunctival score at baseline was 6.78 and 7.32 and at 4 weeks was 5.30 and 5.4 in group I and II respectively, corneal score at baseline was 1.47 and 1.24 and at 4 weeks was 0.52 and 0.41 in group I and II respectively

and schirmer test (mm) at baseline was 6.07 and 6.12 and at 4 weeks was 6.80 and 7.25 in group I and II respectively. The difference was significant ( $P < 0.05$ ).

### Graph I Comparison of parameters



### Discussion

The precorneal tear film is an essential component of the ocular surface and can be subdivided into an anterior lipid layer, a middle aqueous layer and an innermost mucin layer.<sup>8</sup> These layers are produced by the meibomian glands, the lacrimal gland and goblet cells of the conjunctiva, respectively.<sup>9</sup> The tear film lubricates the eye, maintains nutrition and oxygenation of ocular structures, acts as a refractive component and helps remove debris from the ocular surface.<sup>10</sup> In terms of tear production, dry eye can be divided into tear deficient and evaporative type. Dry eye syndrome is associated with a long list of causes which can be divided into primary and secondary.<sup>11</sup> Dry eye may develop secondary to inflammatory disease (e.g. vascular, allergic), environmental conditions (e.g. allergens, cigarette smoke, dry climate), hormonal imbalance (e.g. perimenopausal women and patients under hormone replacement therapy), and contact lens wear.<sup>12</sup> The present study compared preserved and preservative-free hydroxypropyl methylcellulose-dextran-containing eyedrops. In present study, group I had 15 males and 13 females and group II had 12 males and 16 females. Safardazeh et al<sup>13</sup> found that the mean of age of the participants in the Group A and B was  $44.08 \pm 6.29$  (range, 33-58 years) years and  $45.83 \pm 8.42$  (31-60 years), respectively. In comparing two groups before the intervention, the OSDI scores, the TBUT scores, the conjunctival and corneal staining scores and the Schirmer scores did not show statistically significant differences ( $p = 0.339$ ,  $p = 0.640$ ,  $p = 0.334$ ,  $p = 0.807$  and  $p = 0.676$ , respectively). After 4 weeks, the OSDI scores, conjunctival and corneal staining scores showed improvement in compare to those before the intervention ( $p < 0.001$ ). But, the differences for the Schirmer test score and TBUT score was not significant ( $p = 0.115$ ,  $p = 0.013$ , respectively).

In present study, mean OSDI score at baseline was 42.6 and 39.4 and at 4 weeks was 32.7 and 28.1 in group I and II respectively, TBUT (sec) at baseline was 7.6 and 7.4 and at 4 weeks was 7.1 and 8.1 in group I and II respectively, conjunctival score at baseline was 6.78 and 7.32 and at 4 weeks was 5.30 and 5.4 in group I and II respectively, corneal score at baseline was 1.47 and 1.24 and at 4 weeks was 0.52 and 0.41 in group I and II respectively and schirmer test (mm) at baseline was 6.07 and 6.12 and at 4 weeks was 6.80 and 7.25 in group I and II respectively. Prabhasawat et al<sup>14</sup> included 70 glaucoma patients with ocular surface disease Index (OSDI) score greater than 20 points and/or presence of ocular signs. Patients

were randomized to receive either preservative-free 0.3% HPMC/dextran (n = 35) or preservative-free 0.18% SH (n = 35). Treatment was 1 drop in each eye, 4 times a day. The groups were homogeneous at baseline. At day 28, both treatments showed significant improvements ( $P < 0.05$ ) in the mean OSDI score, lid skin and lid margin inflammation, conjunctival injection, and expressibility of meibomian glands, corneal staining score, fluorescein tear breakup time (FBUT), and Schirmer I test. However, the mean OSDI score, lid margin inflammation and conjunctival injection showed significant improvements ( $P < 0.05$ ) in the SH group at days 7 and 28, compared to the HPMC/dextran group. FBUT and the Schirmer I test also showed significant improvements ( $P < 0.05$ ) in the SH group compared to the HPMC/ dextran group, at day 28. No adverse reactions were observed in either group.

### Conclusion

Authors found that both preserved and preservative-free hydroxypropyl methylcellulose-dextran-containing eyedrops were effective in reducing symptoms of dry eyes disease.

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