Comparison of the efficacy of 0.3% hypromellose (Lumecare®) and 0.03% sodium hyaluronate (Hylo-Fresh®) in the management of mild dry eye disease.

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Introduction

Management of dry eye has conventionally been achieved by use of lubricant eye drops to provide temporary symptomatic relief.1-3 These artificial tears contain electrolytes, mainly sodium chloride, to attain proper tonicity, polymers to enhance viscosity and preservatives to maintain the sterility of the preparation.4 Sodium hyaluronate is a mucopolysachharide compound5 found naturally in connective tissues and the aqueous and vitreous humour of the eye. Its structure characteristic makes it highly moisturising; it can retain up to 1000 times its weight of water and also absorb moisture from the atmosphere. Furthermore, its residency time on the ocular surface is significantly higher than other artificial tears because of its non-Newtonian properties.6 For these reasons, sodium hyaluronate is considered to be one of the more effective artificial tears.

Previous studies comparing the efficacies of sodium hyaluronate and other tear lubricants in dry eye therapy have shown conflicting results, some reporting superior effectiveness; others to the contrary.6-11 One explanation may be the different criteria employed for defining dry eye in these various studies. Unfortunately, this incompatibility also makes comparisons between the studies difficult.

Aim

The purpose of this clinical study was to compare the efficacy of 0.3% hypromellose (Lumecare®) and 0.03% sodium hyaluronate (Hylo-Fresh®) in the management of mild dry eye disease.

The efficacies of the test solutions were assessed by symptomatology (OSDI), measures of tear dynamics (tear break up time (TBUT)) and ocular surface staining (corneal and conjunctival).

Methodology

Study design

The study was two-armed, parallel and randomised in design.

Subjects

Potential subjects were screened for dry eye disease. The inclusion criteria were positive symptoms (≥13 - ≤32 using OSDI) and a non-invasive tear break up time (NITBUT) < 10 seconds. This was to ensure inclusion of mild-moderate dry eye sufferers only. Exclusion criteria required no contact lens wear and no ocular surface disorders or systemic conditions likely to affect the tear film. Patients taking medications that could influence the tear film were excluded from the study. Twenty patients were recruited and randomly allocated into one of two groups. Group A (n = 10; 39.8±14.8 years; 4F 6M) was treated for 2 weeks with a 0.03% sodium hyaluronate (Hylo-Fresh®) therapy while group B (n = 10; 43.4±15.3 years; 5F 5M) was treated with 0.3% hypromellose (Lumecare®) in the same period. Each group was instructed to instill the test therapy into both eyes, 4 times daily for the study duration. However, only the 'worst' eye, based on the inclusion test results, was assessed after therapy in each patient. If no 'worst' eye was evident, the right eye was used or comparison purposes. All parameters were measured at baseline and at 14±1 days after the initial use of each of the drops.

Investigations

Symptoms

For symptom assessment, the OSDI symptom questionnaire was used.12 It consists of 12 questions that rates the frequency of symptoms, task-related limitations due to ocular discomfort, and environmental irritants. For each item, the range of patient responses are from 'none of the time' to 'all of the time,' corresponding to a numerical 0-to-4 scale. The values are then summed, and the calculated OSDI score ranges from 0 to 100 with cut-off values for mild (13-22), moderate (23-32), and severe (33-100) dry eye.

FTBUT

TBUT was measured by instilling 2% sodium fluorescein solution and calculating the average of three consecutive breakup times, manually determined with a stopwatch.

Ocular Surface staining (corneal and conjunctival)

Ocular surface staining was assessed using sodium fluorescein, and the Oxford grading system employed to grade the staining on the ocular surface.[13]

Statistical Analysis

Using SPSS Version 21 (SPSS, Inc), all the data were tested for normality using a Shapiro–Wilk test. Data for all parameters were found not to be of Gaussian distribution, so nonparametric tests were used to test for significant differences from baseline to 14 days (Mann-Whitney U test).

Results

- No significant difference between the groups (Sodium Hyaluronate (SH) and Hypromellose (H)) was found at baseline ($p > 0.05$) for any of the test parameters.
- Results can be seen in Table 1 below.

Group	OSDI (Ave±SD)	FTBUT (Ave±SD)	Corneal stain (Ave±SD)	Conjunctival stain (Ave±SD)
A (Sodium Hyaluronate)				
Pre	22.56±7.05	7.00±1.59	2.10±0.87	1.40±1.17
Post	17.36±7.99	9.95±3.03	1.90±0.73	1.10±0.73
P value	*p=0.009*	*p=0.008*	*p=0.157*	*p=0.180*
B (Hypromellose)				
Pre	23.65±7.35	6.40±1.66	2.60±0.96	1.6±0.51
Post	22.9±8.73	8.00±1.76	1.70±0.67	0.8±0.78
P value	*p=0.646*	*p=0.109*	*p=0.064*	*p=0.038*

Table 1. Mean results for each test parameter for both Sodium Hyaluronate and Hypromellose groups pre and post therapy

- Over the 14 day test period, a significant reduction in symptoms for the SH group was found (p=0.009) but not in the H group (p=0.686). For the SH group, 9 of 10 participants reported a reduction in symptoms compared with 6 of 10 in the H group (Figure 1).
- There was a significant improvement in FTBUT in the SH group (p=0.008) but not in the H group (p=0.109) (Figure 2).
- No significant difference was found in either group for corneal staining pre and post treatment (Figure 3).
- A significant improvement in conjunctival staining was found for the H group (p=0.038) but not for the SH group (p=0.180) (Figure 4).

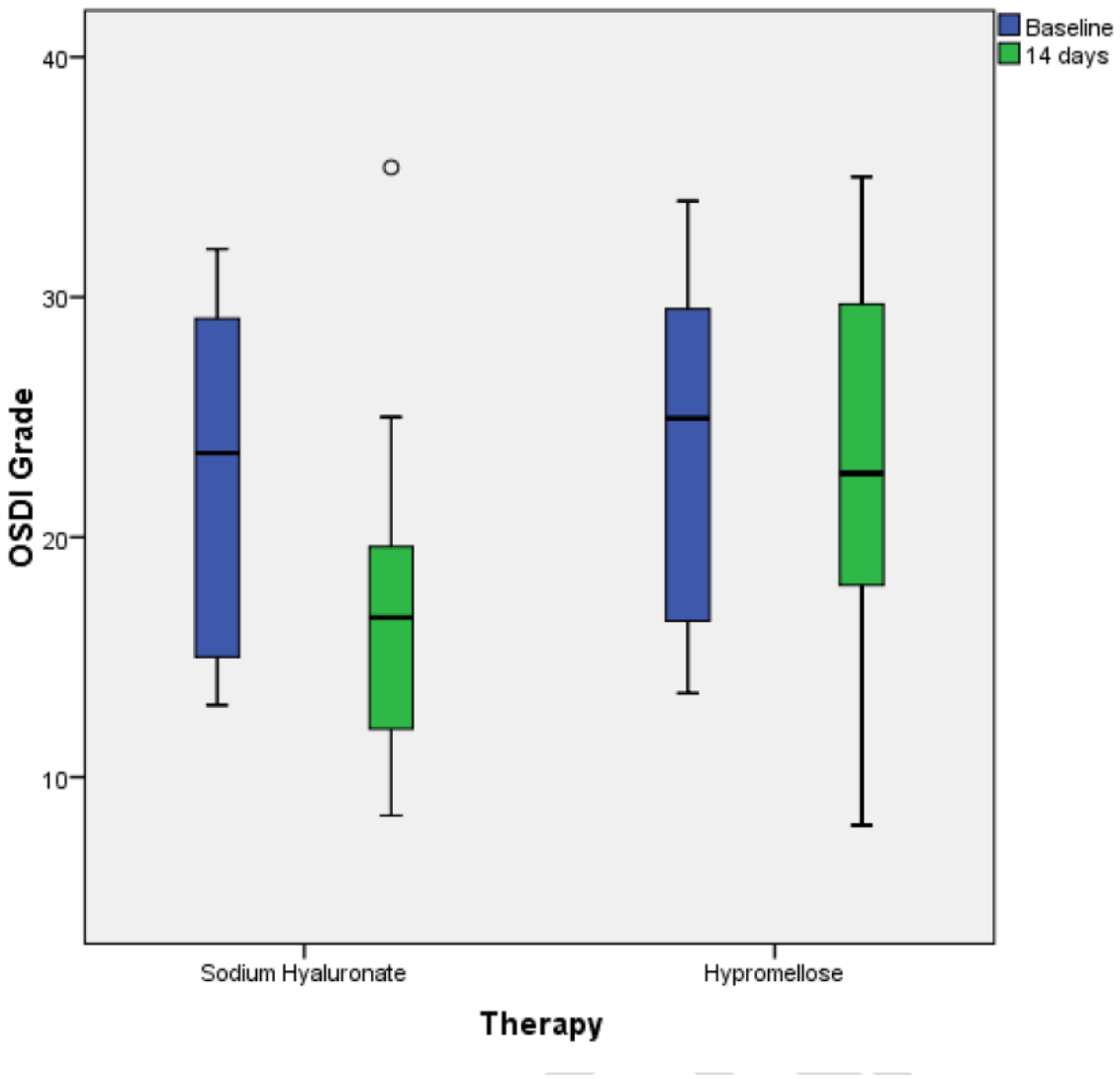

Figure 1. Subjective symptoms measured with OSDI at baseline (pre dose) and at 14±1 day post dose for sodium hyaluronate (Hylo-Fresh®) and hypromellose (Lumecare®). Box and whisker plots

are used to illustrate the data. The whiskers are lines that extend to the highest and lowest values. The line across each box indicates the median value. The blue box represents baseline data; the green box 14-day data. A significant reduction in symptoms was found with in the SH group (p=0.009) but not in the H group (p=0.646).

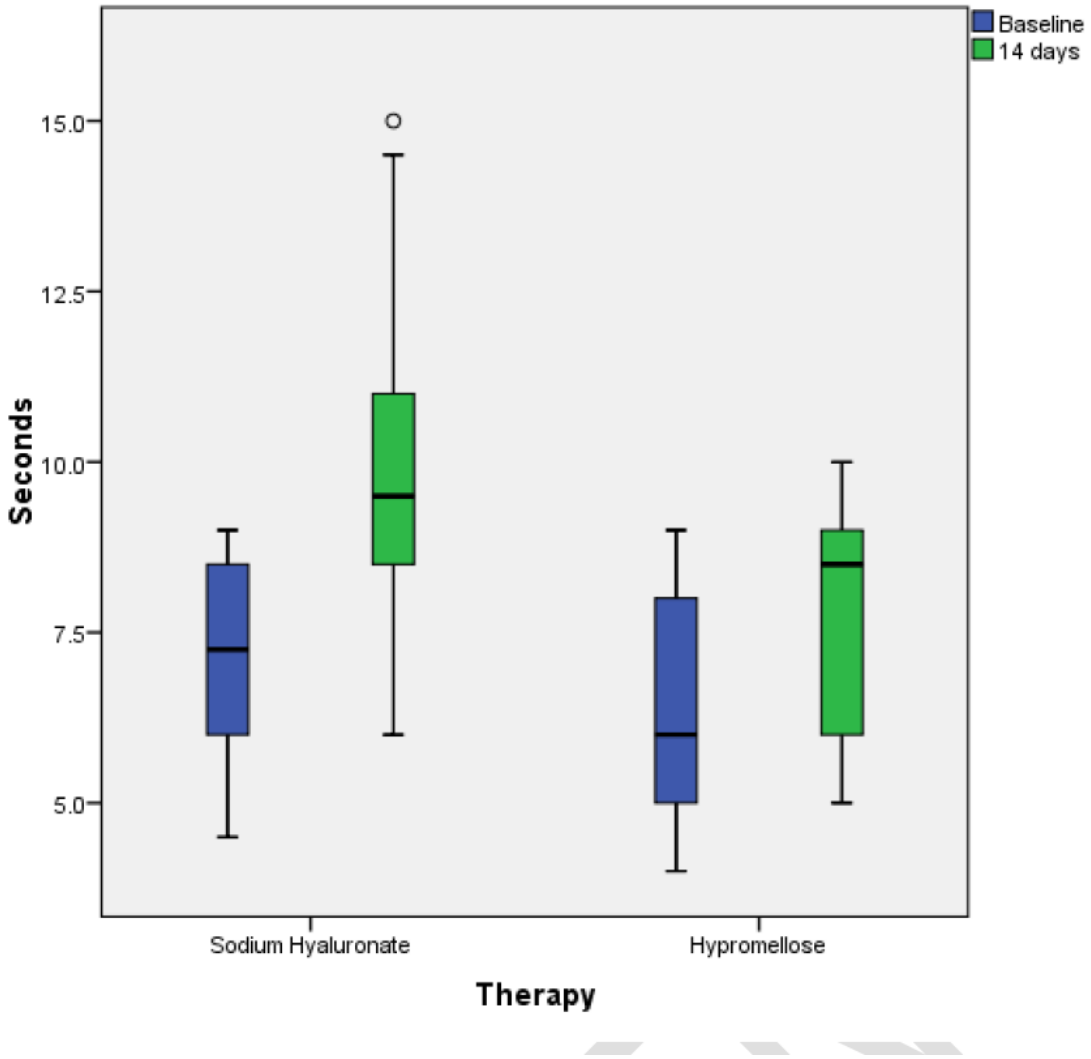

Figure 2. Fluorescein tear break up time (FTBUT) at baseline (pre dose) and at 14±1 day post dose for sodium hyaluronate (Hylo-Fresh®) and hypromellose (Lumecare®). Box and whisker plots are used to illustrate the data. The whiskers are lines that extend to the highest and lowest values. The line across each box indicates the median value. The blue box represents baseline data; the green box 14-day data. A significant improvement in FTBUT was found with in the SH group (p=0.008) but not in the H group (p=0.109)

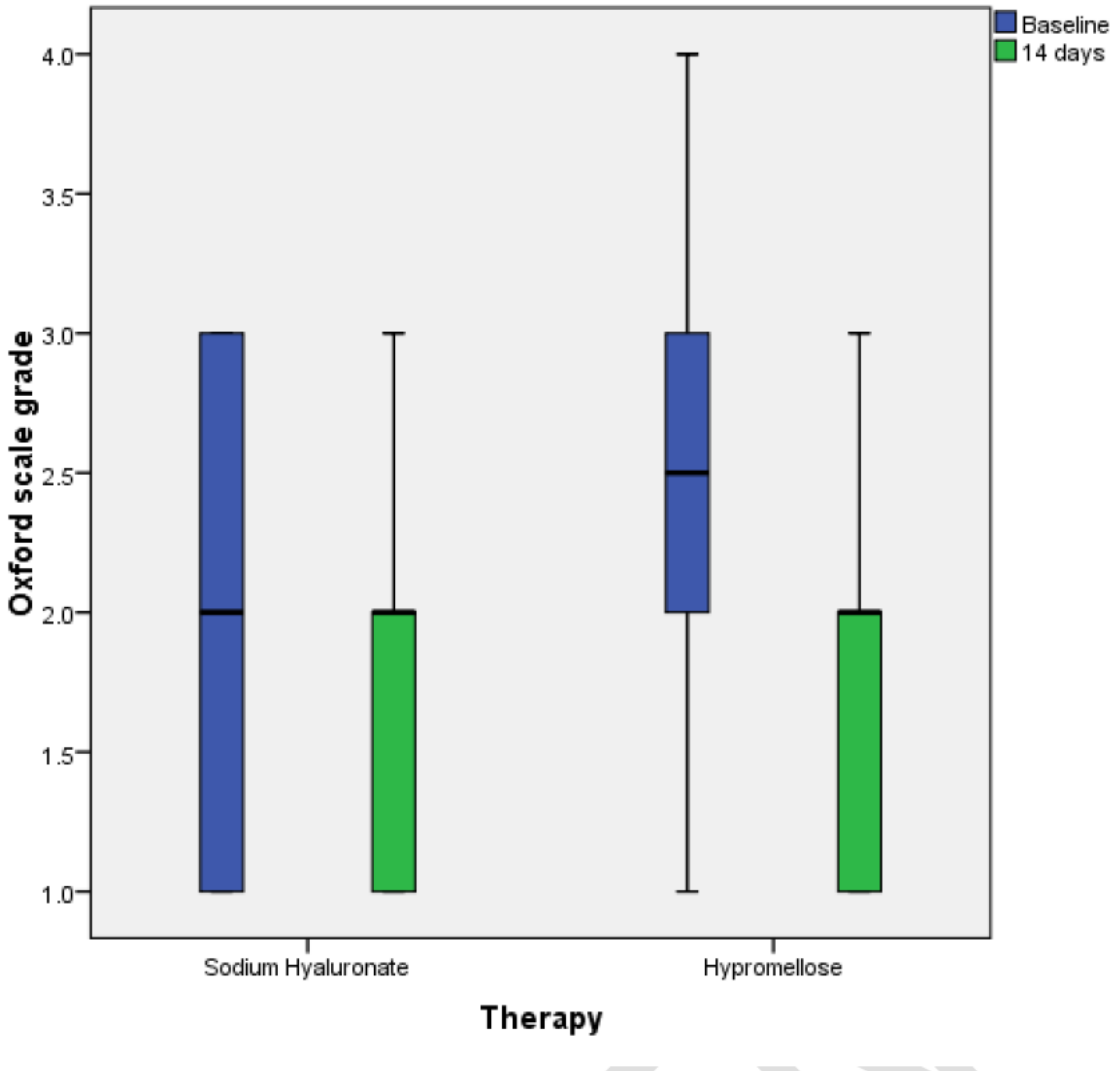

Figure 3. Corneal staining at baseline (pre dose) and at 14±1 day post dose for sodium hyaluronate (Hylo-Fresh®) and hypromellose (Lumecare®). Box and whisker plots are used to illustrate the data. The whiskers are lines that extend to the highest and lowest values. The line across each box indicates the median value. The blue box represents baseline data; the green box 14-day data. No significant difference was found post treatment with either therapy.

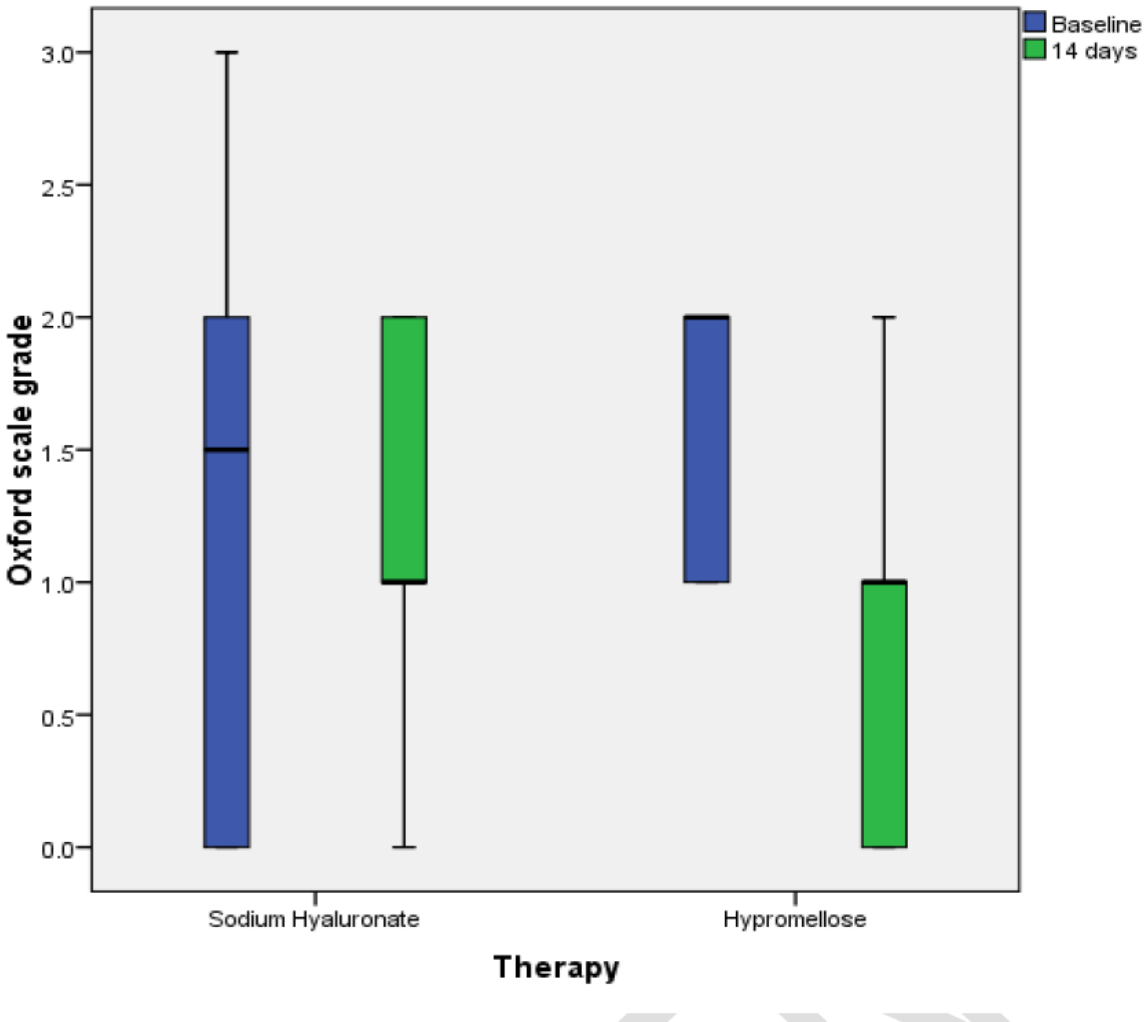

Figure 4. Conjunctival staining at baseline (pre dose) and at 14±1 day post dose for sodium hyaluronate (Hylo-Fresh®) and hypromellose (Lumecare®). Box and whisker plots are used to illustrate the data. The whiskers are lines that extend to the highest and lowest values. The line across each box indicates the median value. The blue box represents baseline data; the green box 14-day data. No significant difference was found post treatment in the SH group (p=0.180). However, a significant reduction in conjunctival staining was found in the H group (p=0.038).

Summary

The overall results of this clinical study indicate that a significant reduction in symptoms, corneal staining and a significant improvement in tear break up time in the sodium hyaluronate group were found from baseline to 14 days. The sodium hyaluronate group was shown to perform best in relation to these clinical test parameters. No significant effect was seen for these parameters in the hypromellose group. However, a significant reduction in conjunctival staining was found in the hypromellose group (p=0.038) where no reduction was found with the sodium hyaluronate (p=0.180).

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