

## Introduction

More and more contact-lens users are demanding solutions for the discomfort caused when wearing their lenses.

This lack of comfort is due, on one hand, to the ease with which current contact lenses dry out, and on the other, to the increasing number of users who work in air conditioned environments with a very low level of humidity.

Both factors increase tear evaporation resulting in uncomfortable contact lenses, especially at night after being worn all day.

The solution to the problem is the incorporation of a wetting agent capable of maintaining the moisture level in the lens. However, current wetting agents (hpmc, hec, php, pva, etc.) though they do retain water, the effect does not last because they do not remain in the eye for long. The goal, therefore, is to find a wetting agent that lasts for a long time (long-lasting effect).

To prevent stress and the deterioration in tear quality caused by the use of soft contact lenses in these dry environments, we have developed a formula that creates film between the lens and the tear coating that is completely compatible with the eye and able to stabilize the tear even in unfavorable situations (dry environments, smoky environments, etc.).

Sodium hyaluronate is the active ingredient in the formula that achieves two effects: improved tear quality and wetting properties, and extending duration of the effect through its interaction with the corneal epithelium.

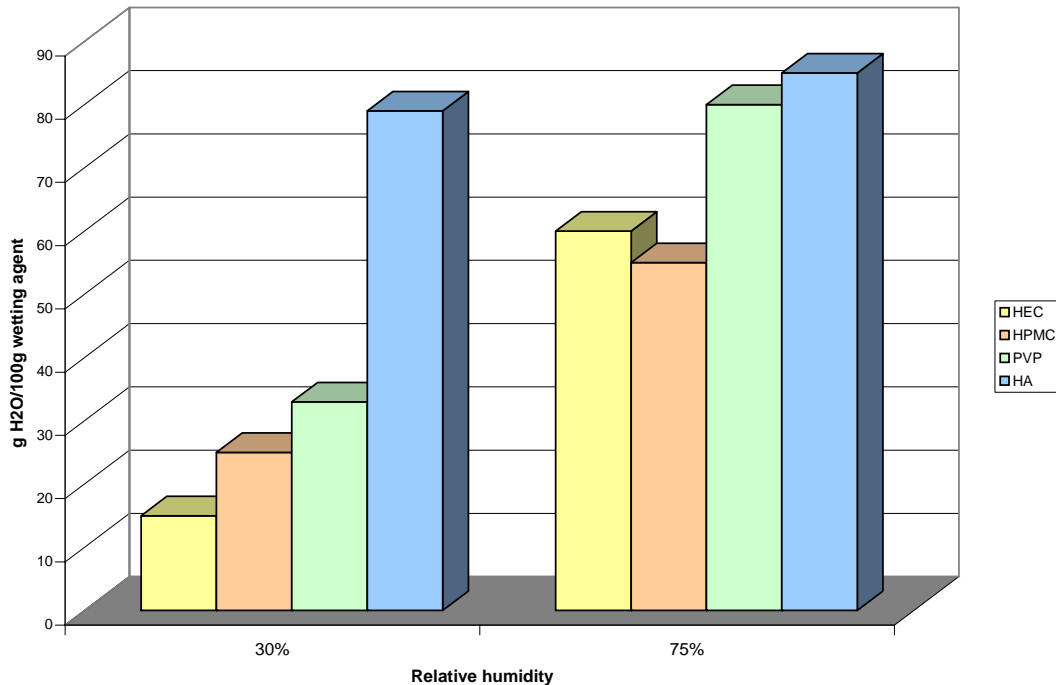
## Wetting. Sodium hyaluronate versus other wetting agents

We ran a study to compare the wetting capacity of sodium hyaluronate with respect to three widely-used synthetic wetting agents used in contact lens maintenance products.

The study was carried out in both a humid atmosphere (RH 75%) and a dry atmosphere (RH 30%). The graph below compares the grams of water that the different wetting agents can absorb in the two types of atmosphere (humid and dry).



Figure I. Comparison of wetting agents



Observe that all of the wetting agents perform very well in high ambient humidity (RH 75%) because they all absorb 50 grams. However, in dry environments (RH 30%), only sodium hyaluronate performed effectively.

A wetting agent is not really necessary in a moist atmosphere (RH 75%) because there is no significant tear evaporation. When ambient humidity is low, i.e. in the air conditioned environments common today, tear evaporation increases considerably and the use of a wetting agent is recommended. These studies showed that only sodium hyaluronate performs effectively in this conditions.

#### **Dua Elite. Clinical study and long-lasting effect**

Sodium hyaluronate is also a natural product that is totally biocompatible. This characteristic clearly distinguishes it from the other wetting agents, which, as mentioned before, are synthetic.

To demonstrate the wetting properties and long-lasting effect of the product, a clinical study was done by the Universidad Europea de Madrid (UEM).

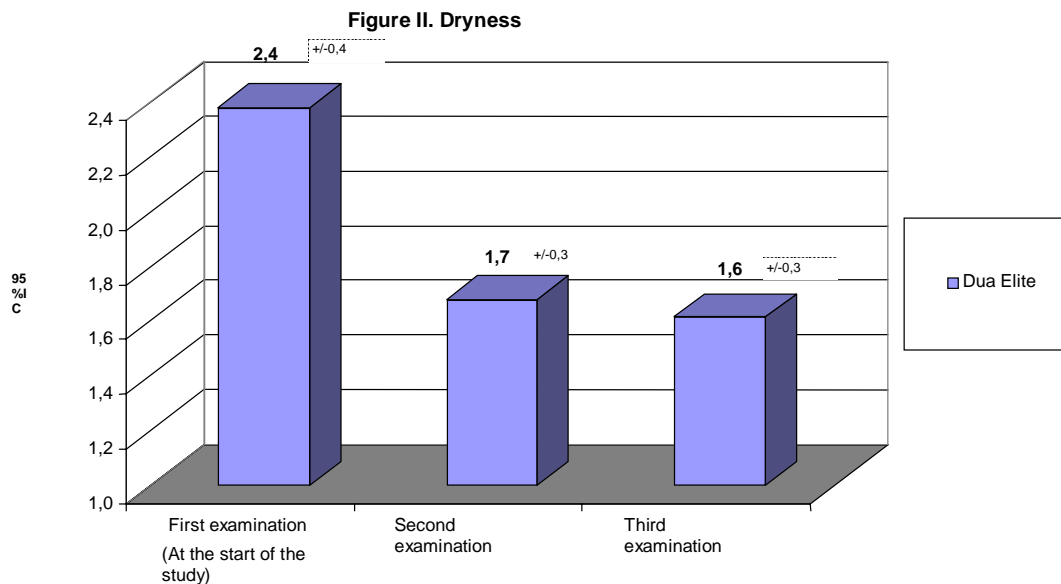
The study was multi-centric, random, and double-blind in cases and controls, which evaluated the safety and tolerance of an “all-in-one contact lens care solution with sodium hyaluronate as a wetting agent”.

To evaluate the safety and tolerance of the all-in-one solution being studied, a primary examination was done with contact lenses and the normal care system of each patient, and two later exams, one month and two months later, with the new care system that they were given with the sodium hyaluronate all-in-one solution.

To unify evaluation criteria, the “Efron Scale Grading for Contact Lens Complications” was used as the reference scale.

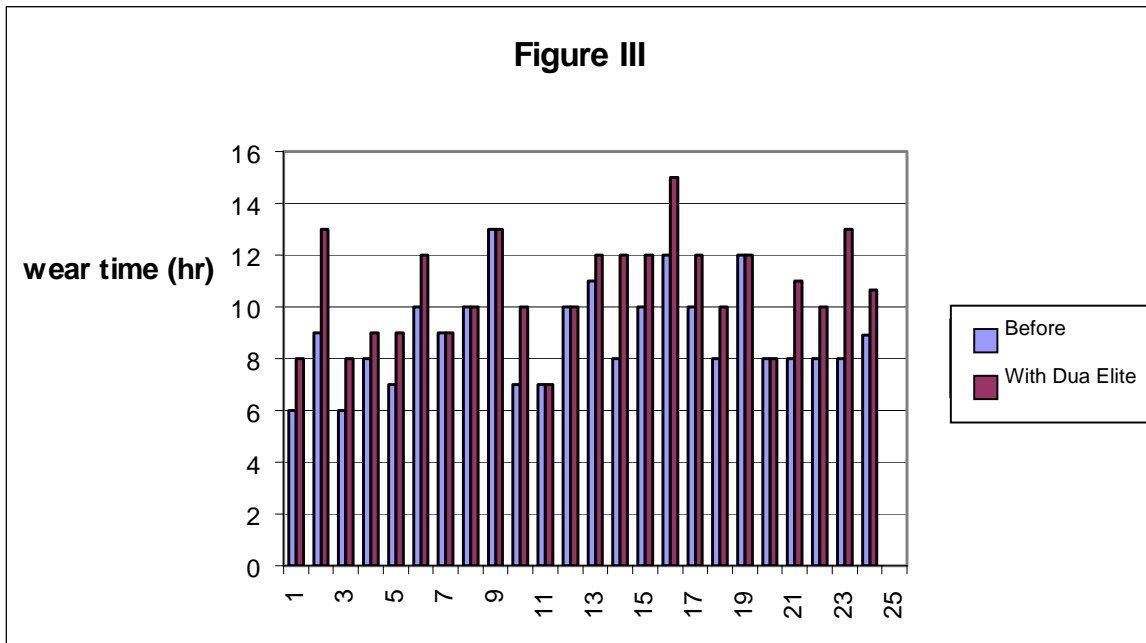
One of the most significant conclusions of the study was that the product really provides wetting action with an extended effect and this was demonstrated when evaluating the symptom of eye dryness.

Figure II shows the average of the values obtained by exploration of the symptom of eye dryness with a slit lamp. The dryness symptom was observed to decrease significantly in the second and third examinations with respect to the first one.



In addition to the clinical study, a test was done consisting of determining the hours in the day per day that twenty-three users wore their lenses comfortably. Figure III shows the values of the hours of daily wear before and after the use of the all-in-one solution with sodium hyaluronate. These are the average values for each patient taken over two weeks of use.





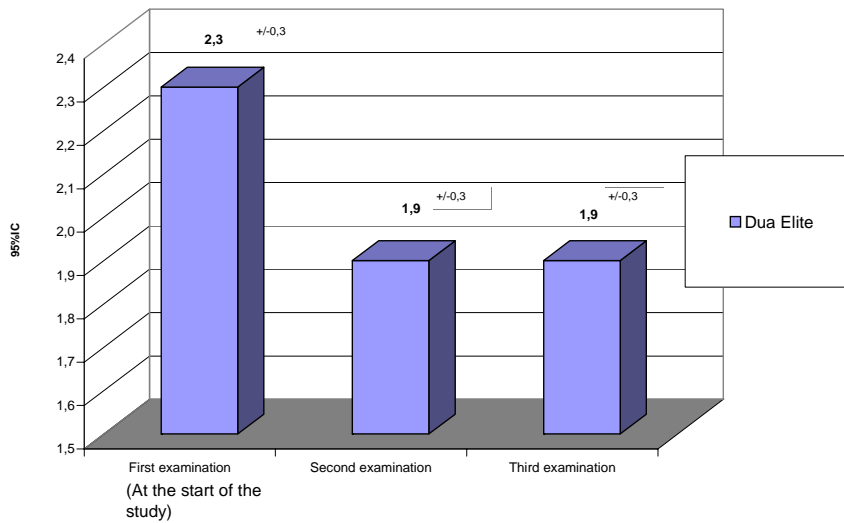
The study shows that the number of hours of wear per day increased significantly, generating an average increase of three hours of daily wear.

**Dua Elite. Cleaning ability**

In the clinical study by the UEM, the condition of the contact lenses of the patients was examined, and it was found that Dua Elite kept lenses cleaner than the contact lenses before the start of the study. Figure IV shows the degree of dirtiness of the lenses at the start of the study and a month and two months after using Dua Elite.



Figure IV. Dirtiness



### Dua Elite. Disinfecting capacity

The Dua Elite all-in-one solution with sodium hyaluronate guarantees the disinfection of lenses overnight.

The product is effective against all of the microorganisms specified in the ISO standard 14729. The following table shows the D values for each of the microorganisms obtained after six hours. According to the standard, the D value must be greater than or equal to 3 for the bacteria pseudomona aeruginosa, staphylococcus aureus, and serratia marcescens, and greater than or equal to 1 for fusarium solanii and candida albicans.

microorganism	time	reduction	D value*
S Aureus	4 hours	$> 10^4$	$> 4$
Ps Aeruginosa	4 hours	$> 10^5$	$> 5$
S. Marcescens	6 hours	$> 10^4$	$> 4$
F. solanii	6 hours	$10^{1,7}$	1,7
C. Albicans	2 hours	$10^2$	2



**References:**

Balazs, E.A.

“Physical chemistry of hyaluronic acid”

*Fed Proc* 1958; 17: 1086

Bio sodium hyaluronate. Technical Information. Shiseido. “Water uptake of moisturizers” & “Moisture retention of moisturizers”.

Goa , K.L.; Benfield, P.

“Hyaluronic acid. A review of its pharmacology and use as a surgical aid in ophthalmology, and its therapeutic potential in joint disease and wound healing”

*Drugs* 1994; 47, 3: 536

Mengher, L.S.; Pandher, K.S.; Bron, A. J.; Davey, C. C.

“Effect of sodium hyaluronate 0.1% on break-up time (BUT) in patients with dry eyes”

*Brit J Ophthalmol* 1986; 70: 442

Polack, F. M.; McNiece, M. T.

“The treatment of dry eye with Nahyaluronate”

*Cornea* 1982; 1: 133

Saettone, M. F.; Chetoni, P.; Torracca, M.T.; Bergalassi, S.; Giannaccini, B.

“Evolution of muco-adhesive proprieties and in vivo activity of ophthalmic vehicles based on hyaluronic acid”

*Int J Pharm* 1989; 51: 203

