

Regener-Eyes LITE: 10 Day Study Report

Introduction:

This is a short term, anecdotal, evaluation of the Regener-Eyes LITE as it impacts dry eye. The sample size is small (n =5) and the time frame of the evaluation is also short duration. This is not a blind study, rather designed to obtain private practitioner's view of the efficiency, practical usability in daily practice, and subjective patient acceptance of the drug.

Method:

The patients were evaluated before being placed on the medication (see criteria evaluation form attached), and again at 10 days, then at 20 days (this term has not been reached at this time). We designed the evaluation for both objective evaluation of the ocular surface as well as for subjective evaluation by the patients. All of the patient's current routines (lubricants, hot compresses, etc.) for maintenance were left in place as to not disturb the baseline performance.

Results:

The subjecting ratings and the tear break up time (TBUT) for the Day 1 and Day 10 are presented graphically in Figure 1. Data from the fifth (5th) patient is yet available.

All parameters, either subjectively, and objectively, were observed or reported at the 10 day phase. Many of these subjective symptoms significantly reduced, as is reflected in the graphs. Generalized staining was observed, and corneal changes remained stable or improved. Most significantly is the TBUT. The time for tear break up radically improved. This is in my estimation the biggest reason for patients increased comfort and satisfaction of their eyes while on the medication, with one subject reporting decreased blinking rate. The quality of life was also improved while on the medication, with all reporting subjects desirous of remaining on the medication in the future.

Patient comments reported:

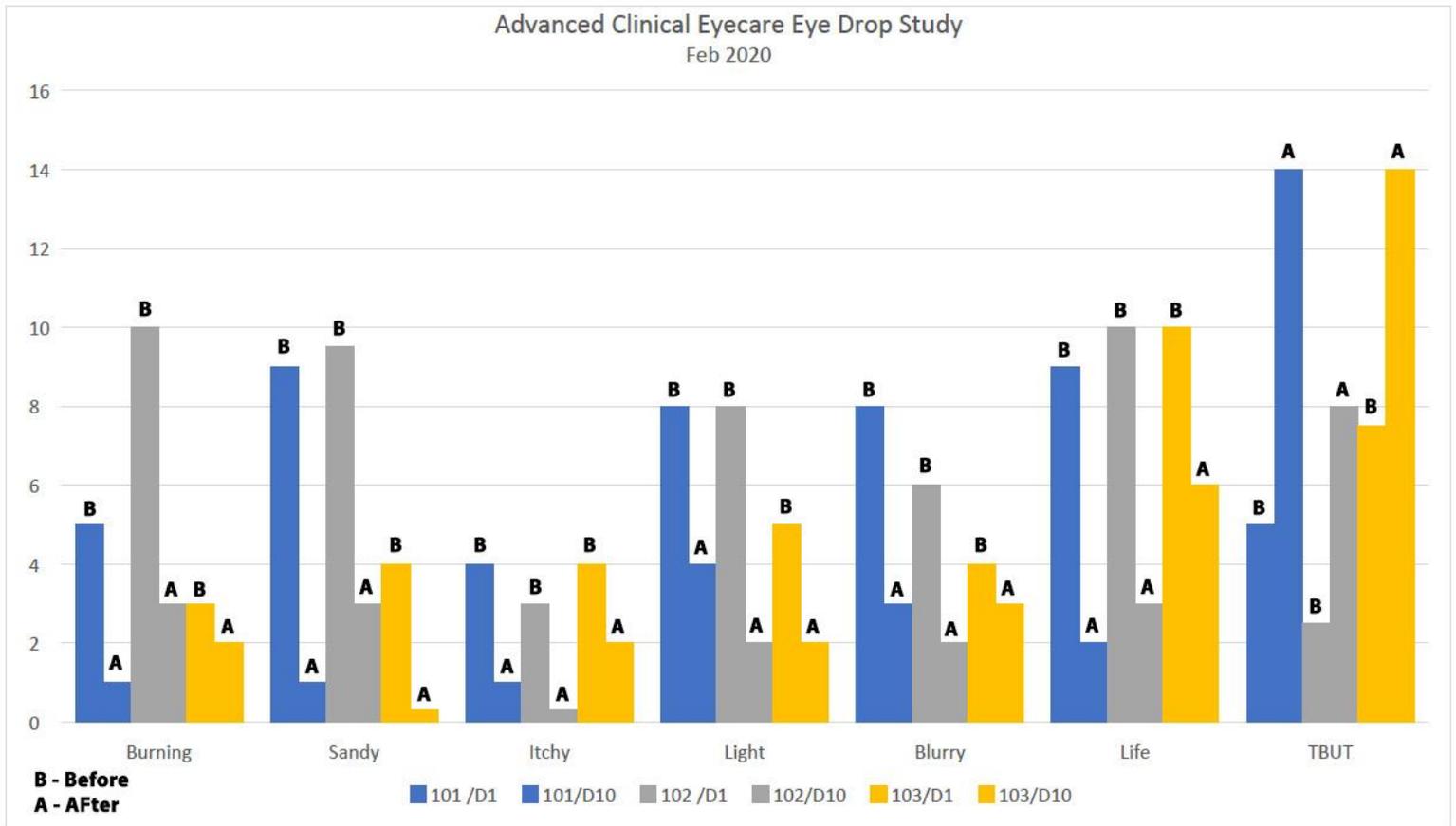
1. Amazing improvement.
2. Reduced blinking frequency in 3 to 4 days.
3. I didn't even think of my eyes all day.
4. Wonderful, instant help.
5. Smoother feeling.

Discussion:

As a primary provider, I find it difficult to get excited about new products; this is one of the exceptions. I will use this as soon as it becomes available and feel this is a product that is

patient friendly, and consistently provides provider confidence in the product with objective observation.

Bottle volume provided in the final product should take into consideration, most patients will miss or spill a few drops every week. Patients in this study did comment about missing drops and most wondered if they would have enough medication to finish the 20 day period, let alone a 30 day supply. Should these be dispensed, and the patient is to consistently run out before the end of the month it would reduce the satisfaction, by the patients, of the product. This is especially important, as I feel that t.i.d. dosing may be appropriate for most of these patients in the initial period.



10 Day Study, before and after for 3 patients, using Regener-Eyes® LITE. Shows significant improvements of the symptoms of dry eyes as well dramatic tear break up time (TBUT) and quality of life.