ISRCTN12460884 Basic Results

Title	Evaluation of Rexon-Eye Efficacy in Symptomatic Contact Lens Wearers and Dry Eye Sufferers
Objectives	The primary objective of the study was to quantify the effect of using Rexon-Eye in symptomatic contact lens (CL) wearers and dry eye (DE) sufferers on (i) Symptomatology; a. CLDEQ-8 score for the contact lens wearing group; b. OSDI score for the non-contact lens wearing dry eye sufferers' group; (ii) ocular tissue anomalies, and (iii) tear volume.
Study Design:	The study was a non-dispensing (in the office use only), bilateral (Rexon-Eye applied to both eyes), double masked (participant and investigator), randomized (treatment application for test-instrument active and control-instrument inactive) study design.
Device Regimen:	The test application: one 20-minute session per week for a four-week period. The control application: one 20-minute session per week for four weeks in the sham manner, inactive (i.e the instrument output being set to '0').
Hypothesis	The primary hypotheses to be tested were that Rexon-Eye treatment: i. decreases symptomatology; ii. decreases ocular tissue anomalies; iii. increases tear volume.
Visit Schedule:	6 visits over a 4-month period for the CL group (total 11.25 h) and for the DE group (total 8.25 h).
Number of Subjects	54 (41F; 13M), average age: 38.4 ± 13.3 years. [30 symptomatic CL wearers, 24 non-contact lens DE sufferers]
Study Period	23 April 2018 to 29 October 2018
Results	1. The CLDEQ8 comparison between baseline (BL) and the three-month (3M) revealed no difference between the control and test groups (p >0.1). 2. The OSDI comparison between BL and 3M revealed no difference between the control and test groups (p >0.1). 3. Conjunctival Staining clinical rating comparison between BL and 3M revealed no difference between the control and test groups (p >0.1). 4. Tear Volume comparison between BL and 3M revealed no difference between the control and test groups (p >0.1). 5. The NIBUT comparison between BL and 3M revealed no difference between the control and test groups (p >0.1). 6. For subjective comfort ratings the profile and amplitude of the improvement were near identical for the test and control groups. 7. For oxford score, the mean and median staining were very similar at BL and 3M for both the test and control groups.
Adverse Events (AE)	There were 26 non-serious AE involving 13 subjects (24.1%); • 12 were ocular AE (9 events were device related); 14 were non-ocular AE, non-device related. All AE were resolved prior to study exit.
Conclusions	The study assessed the effect of Rexon-Eye treatment, used as per manufacturer's instruction, on symptomatology (CDEQ8 & OSDI as applicable), ocular tissue anomalies and tear film kinetics. The results of the study did not reveal any significant improvement in symptoms, ocular surface anomalies or tear volume and tear film kinetics.