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Quantum molecular resonance electrotherapy (Rexon-Eye) for recalcitrant dry eye in an Asian population

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Objectives: To assess the safety, efficacy, patients' satisfaction and acceptability of Rexon-Eye electrotherapy in treating Asian severe dry eye disease (DED) patients.

Methods: Prospective parallel-arm pilot study recruiting 40 DED Chinese patients with >moderate recalcitrant DED (Contact Lens Research Unit [CCLRU] > grade 2). Subjects were randomized into 2 groups, undergoing four weekly treatment sessions each: group 1 received full treatment power; group 2 received control treatment (power 1 treatment). Non-invasive tear break-up time (NIBUT), cornea fluorescein staining graded via CCLRU and Schirmer's I test were compared pre- and 2 months post-treatment. The SPEED and QUEST questionnaires that evaluated subjective symptoms and treatment satisfaction, respectively, at baseline and 2 weeks post-treatment were carried out. Tear cytokine levels in both groups were examined at 2 weeks post-treatment.

Results: The amount of improvement in post-treatment corneal staining in the inferior corneal zone was significant in Group 1 (p = 0.038) but not in Group 2 (p = 0.832). Group 1 eyes with worse baseline staining (total score >9.8) had a significantly greater reduction of corneal staining than those with better baseline staining (-11.7 ± 1.98 vs. -4.6 ± 2.89, $p < 0.001$). There were no other significant differences in NIBUT, Schirmer's 1 and cornea fluorescein staining grading within or between the groups.: Group 1 (n = 24) had improved subjective dryness scores compared to Group 2 (n = 16) (SPEED score: 6.38 + 4.16 vs. 10.0 + 6.36, p = 0.04). No significant differences were seen in 11 tear cytokine levels at 2 weeks post-treatment between the 2 groups.

Conclusion: In Asian DED patients treated with Rexon-Eye, inferior cornea staining showed significant improvement compared to placebo, and eyes with greater cornea staining at baseline achieved a greater improvement in staining. There were no other significant improvements in NIBUT and Schirmer's 1. Rexon-Eye also improved subjective DED scores in 41.7% of eyes without any adverse effects.

KEYWORDS

tear disorder, ocular disease, dry eye, therapeutics, clinical trial