

# AN INVESTIGATIONAL LUBRICANT EYEDROP COMPARED WITH CARBOXYMETHYLCELLULOSE 0.5% IN PATIENTS AFTER LASIK SURGERY : RANDOMIZED 90-DAY TRIAL

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## PURPOSE

Postoperative signs and symptoms of dryness are common following laser in-situ keratomileusis (LASIK) surgery. This study compared the safety and efficacy of an investigational unit dose lubricant eye drop containing both Carboxymethylcellulose and Hyaluronic Acid (CMC-HA) with 0.5% Carboxymethylcellulose alone (CMC) in subjects following LASIK for myopia or hyperopia.

## METHODS

This prospective, multicenter, double-masked, randomized, 2-arm, parallel group study enrolled patients following successful LASIK surgery for myopia or hyperopia. 148 patients were recruited at 14 sites in Canada and Australia. Patients were randomized 1:1 to either CMC-HA or CMC (Refresh Plus, Allergan) for 3 months following LASIK surgery. Patients were administered the Ocular Surface Disease Index (OSDI), acceptability surveys, and were evaluated for corneal staining, tear break-up time (TBUT), and the Schirmer test at screening (prior to surgery) and at 1 week, and 1, 2, and 3 months post-op.

## RESULTS

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Dry eye signs and symptoms generally peaked at 1 week post-operatively and improved thereafter. Mean OSDI scores 3 months following LASIK were similar between treatments ( $p=0.775$ ) and had returned to the normal range. Notably, uncorrected visual acuity mean change from baseline for CMC-HA was better at all visits compared to CMC and the difference between treatments was significant at 1 month ( $p=0.013$ ). Corneal staining, Schirmer test, TBUT, and survey results were comparable. Safety assessment was acceptable in both groups but fewer subjects reported at least one ocular adverse event in the CMC-HA group (6 subjects) than for CMC (12 subjects).

## CONCLUSIONS

CMC-HA drops were as effective in treating post-surgical dryness as CMC alone in patients completing LASIK, with an incremental benefit to vision. While both eye drops were safe and well tolerated with no treatment-related serious adverse events, the overall safety profile favored the new CMC-HA eye drop.