A 6-month, observational trial investigating with electronic monitoring the level of adherence and ocular surface health with latanoprost/timolol fixed versus latanoprost and timolol unfixed therapy in glaucoma

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Purpose: To investigate the impact of dosing upon the rate of adherence and ocular surface health comparing fixed versus concomitant unfixed treatment in glaucoma.

Methods: Prospective 6-month, parallel, observational study. We recruited well controlled patients with open-angle glaucoma, or ocular hypertension who received either unfixed therapy comprising Latanoprost once in the evening and Timolol twice daily, or Latanoprost/Timolol Fixed Combination therapy once in the evening. We investigated the level of adherence and selected signs of ocular surface disease (OSD) in the two groups at baseline and after 3 and 6 months of follow up. All eligible patients who consented were recruited and their adherence was monitored with the MEMS Caps device. Morning IOP control, rate of adherence (% of doses instilled) and signs of OSD were compared between groups.

Results: We enrolled 142 consecutive patients (71 in the fixed and 71 in the unfixed group). There were no baseline differences between the two groups with regard to age, sex, diagnosis, duration of therapy, visual acuity and corneal thickness. Patients in the unfixed group however demonstrated worse vertical cup-to-disc ratio (0.65 vs 0.58, p = 0.005) and worse mean visual field defect (5.9 vs 3.8 dB, p = 0.017) at baseline. Mean morning IOP was similar between groups at baseline, 1 and 3 months but the unfixed group demonstrated higher mean IOP at 6 months (16.6 vs 15.0 mmHg, p = 0.009). Adherence rate, was significantly better in the fixed combination group at 3 (75.6% vs 61.2%) and 6 months (73.0% vs 57.3%) of follow up (p = 0.001 for both comparisons). Signs of OSD (Break Up Time, Schirmer test, corneal and conjunctival staining) were significantly worse in the unfixed group at baseline and for every subsequent evaluation (p < 0.01 for all comparison).

Conclusions: This trial demonstrated significantly superior rate of adherence and ocular surface health in the fixed combination treatment group. Therefore we observed a negative impact upon adherence and ocular surface health from multiple dosing (three-times-daily) in patients with open-angle glaucoma, or ocular hypertension. This trial provides for the first time verification for the benefits accrued in terms of adherence and ocular surface health with fixed combination therapy in glaucoma.