**Table S1. Hyperemia scores in response to CAC.** Table shows onset effects (S1A, 15 minutes after lens insertion) and duration effects (12 hours after lens insertion).

**Table S1A.**

| onset | **Study 1 4483** |  |  |  | **Study 2**  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Post-CACTime point** | **Control (N=121)** | **Test (N=119)** | **Test-control** | **p-value** | **Control (N=125)** | **Test (N=123)** | **difference** | **p‑value** |
| **7 minutes** |  |  |  |  |  |  |  |  |
| n | 112 | 113 |  |  | 121 | 116 |  |  |
| Mean (SD) | 1.56 (0.63) | 1.15 (0.63) | –0.41 | < 0.001 | 2.09 ( 0.72)  | 1.51 ( 0.79)  | -0.58  | <0.001 |
| **15 minutes** |  |  |  |  |  |  |  |  |
| n | 112 | 113 |  |  | 121 | 116 |  |  |
| Mean (SD) | 1.67 ( 0.75) | 1.34 ( 0.69) | –0.33 | 0.001 | 2.30 ( 0.71) | 1.81 ( 0.79) | -0.49 | <0.001 |
| **20 minutes** |  |  |  |  |  |  |  |  |
| n | 112 | 113 |  |  | 121 | 116 |  |  |
| Mean (SD) | 1.65 ( 0.81) | 1.35 ( 0.77) | –0.30 | 0.004 | 2.30(0.69) | 1.76(0.83) | -0.54 | <0.001 |

**Table S1B.**

| Duration  | **Study 1 4483** |  |  |  | **Study 2**  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Post-CACTime point** | **Control (N=121)** | **Test (N=119)** | **Test-control** | **p-value** | **Control (N=125)** | **Test (N=123)** | **difference** | **p‑value** |
| **7 minutes** |  |  |  |  |  |  |  |  |
| n | 119 | 117 |  |  | 124 | 121 |  |  |
| Mean (SD) | 1.51 (0.79) | 1.27 (0.77) | -0.24 | 0.018 | 1.83(0.749) | 1.38(0.755) | -0.446 | <0.001 |
| **15 minutes** |  |  |  |  |  |  |  |  |
| n | 119 | 117 |  |  | 124 | 121 |  |  |
| Mean (SD) | 1.60 ( 0.81) | 1.45 (0.83) | -0.15 | 0.155 | 2.02(0.722) | 1.72(0.774) | -0.301 | 0.002 |
| **20 minutes** |  |  |  |  |  |  |  |  |
| n | 119 | 117 |  |  | 124 | 121 |  |  |
| Mean (SD) | 1.62 (0.86) | 1.53 (0.77) | -0.30 | 0.004 | 2.00(0.738) | 1.71(0.821) | -0.293 | 0.004 |

**Table S2. Summary of ocular adverse events.** Unit of measure (N) is eyes tested. Table shows number of events, not subjects; for example in Study 2 increased tearing occurred in 1 subject, in both eyes so is listed as 2 events.

|  | Study 1  | Study 2  |
| --- | --- | --- |
| Adverse Event | Control (N=121) | Test(N=119) | Total(N=240) | Control (N=125) | Test (N=123) | Total(N=248) |
|  |  |  |  |  |  |  |
| All events | 3 | 10 | 13 | 3 | 8 | 11 |
| eye irritation | 0 | 2 | 2 | 1 | 1 | 2 |
| eye pain | 0 | 0 | 0 | 1 | 2 | 3 |
| increased tearing | 0 | 0 | 0 | 0 | 2 | 2 |
| mydriasis | 0 | 4 | 4 | 1 | 1 | 2 |
| dry eye | 0 | 2 | 2 | 0 | 0 | 0 |
| decreased acuity | 1 | 0 | 1 | 0 | 0 | 0 |
| trichaisis | 1 | 0 | 1 | 0 | 0 | 0 |
| lens complication1 | 1 | 2 | 3 | 0 | 2 | 2 |
| 1. Lens complications include events such as lens inversion or other irritation upon insertion.  |

**Table S3. Snellen Best-Corrected Visual Acuity: Baseline, Pre- and Post-CAC.** Unit of measure forthis assessment is the eye. Subject acuity was measured at the start of each visit, including screening (Visit 1), initial and confirmation CAC screening (Visits 2 and 3), included here as baseline.

|  |  |  |
| --- | --- | --- |
|  | **Study 1** | **Study 2** |
|  | **ControlN=121** | **TestN=119** | **TotalN=240** | **ControlN=125** | **TestN=123** | **TotalN=248** |
| *Baseline* |
| **Visit 1** |  |  |  |  |  |  |
| 20/20 or better | 102 | 102 | 202 | 79 | 81 | 160 |
| 20/25-20/30 | 19 | 17 | 38 | 45 | 42 | 87 |
| 20/40 or worse | 0 | 0 | 0 | 1 | 0 | 1 |
| **Visit 2** |  |  |  |  |  |  |
| 20/20 or better | 106 | 105 | 211 | 102 | 97 | 199 |
| 20/25-20/30 | 15 | 14 | 29 | 22 | 25 | 47 |
| 20/40 or worse | 0 | 0 | 0 | 1 | 1 | 2 |
| **Visit 3** |  |  |  |  |  |  |
| 20/20 or better | 105 | 106 | 211 | 94 | 98 | 192 |
| 20/25-20/30 | 16 | 13 | 29 | 30 | 24 | 54 |
| 20/40 or worse | 0 | 0 | 0 | 1 | 1 | 2 |
| *with allergen challenge* |
| **Visit 4** pre-CAC1 |  |  |  |  |  |  |
| 20/20 or better | 112 | 110 | 222 | 103 | 97 | 200 |
| 20/25-20/30 | 8 | 9 | 17 | 21 | 26 | 47 |
| 20/40 or worse | 1 | 0 | 1 | 1 | 0 | 1 |
| **Visit 4** post-CAC |  |  |  |  |  |  |
| 20/20 or better | 107 | 104 | 211 | 96 | 95 | 191 |
| 20/25-20/30 | 13 | 14 | 27 | 28 | 26 | 54 |
| 20/40 or worse | 0 | 0 | 0 | 0 | 0 | 0 |
| **Visit 5** pre-CAC2 |  |  |  |  |  |  |
| 20/20 or better | 100 | 102 | 202 | 90 | 89 | 179 |
| 20/25-20/30 | 13 | 11 | 24 | 31 | 26 | 57 |
| 20/40 or worse | 0 | 0 | 0 | 1 | 1 | 2 |
| **Visit 5** post-CAC |  |  |  |  |  |  |
| 20/20 or better | 107 | 104 | 211 | 90 | 96 | 186 |
| 20/25-20/30 | 6 | 8 | 8 | 28 | 18 | 46 |
| 20/40 or worse | 0 | 1 | 1 | 2 | 1 | 3 |
| 1. This measure is made 15 minutes after lens insertion. 2. This measure is made 12 hours after lens insertion. |