ISRCTN14364515

Title	Comparative Performance and Acceptance Validation Study of CooperVision New Multifocal Contact Lenses
Study Ref:	CV 17-81/OTGi 17-88, EC 18/LO/0162
Objective	The objectives of this dispensing study were to: i. Verify the overall vision satisfaction and visual performance achieved with CooperVision Inc. multifocal (CVI MF) contact lenses fitted following the optimized fitting guide when worn on a daily disposable basis and to compare these with 1-DAY ACUVUE® MOIST Multifocal (1DAVM) contact lenses; ii. Determine the number of contact lenses needed to attain the final contact lens with CooperVision Inc. multifocal (CVI MF) contact lenses fitted following the optimized fitting guide compared to 1-DAY ACUVUE® MOIST Multifocal (1DAVM) contact lenses.
Study Population	Fifty participants completed the study. All participants were presbyopic habitual daily wear multifocal soft contact lens wearers: i. In the Low Add; 11 participants between the ages of 44 and 51 years with reading additions between +0.75D (n=0), +1.00 (n=5) and +1.25D (n=6) completed the study; ii. In the Mid Add: 19 participants between the ages of 46 and 55 years with reading additions of +1.50D (n=3) and +1.75D (n=16) completed the study; iii. In the High Add: 20 participants between the ages of 52 and 80 years with reading additions of +2.00D (n=11), +2.25D (n=8) and +2.50D (n=1) completed the study.
Results	For the primary endpoints: i. The mean overall vision satisfaction for the overall population after one week of wear was equivalent for the two contact lenses (control 76.6 ± 21.3 and test 77.7 ± 20.3, p = 0.818). ii. The overall number of necessary modifications per participants were the same for the two study contact lenses: 10 out of 50 or 20% of the participants. The number of changes per eye was 13% for the test contact lens and 11% for the control contact lens (p = 0.864).
Adverse Events	There was one non-serious, non-ocular, non-device related AE
Conclusions	The study supported the hypotheses tested showing that: i. the test and control contact lenses achieved a similar good level of overall visual acceptance; ii. the number of contact lenses needing to be changed to arrive to the dispensed contact lens was less than 15% for both the test and control contact lenses, confirming the suitability of the fitting guide developed for the test contact lenses. Further, the contact lens fit was good for the two contact lenses and no adverse effects on the ocular tissues were recorded