

Title	Validation of CV Multifocal Daily Disposable Contact Lenses Performance in Multisite Study
Study Ref:	CV 18-56 / OTG-I ID18-43 / REC 20/LO/0633 / IRAS 281917
Objective	The objectives of this one-week dispensing clinical study were to compare Pluto contact lenses with Moist contact lenses for: <ul style="list-style-type: none"> <li>i. overall satisfaction;</li> <li>ii. visual performance;</li> <li>iii. the number of contact lenses needed for the final contact lens to be dispensed</li> </ul>
Study Population	One hundred and four participants completed the study without significant deviation making up the per protocol population. All participants were presbyopic habitual daily wear multifocal soft contact lens wearers. The participants were divided in three near addition groups: <ul style="list-style-type: none"> <li>i. 29 emerging presbyopes (low add: +0.75D to +1.25D);</li> <li>ii. 35 established presbyopes (mid add: +1.50D and +1.75D);</li> <li>iii. 40 advanced presbyopes (high add: +2.00D to +2.50D).</li> </ul>
Results	The primary and secondary endpoints results are as follows: <ul style="list-style-type: none"> <li>i. Pluto achieved good overall visual satisfaction, similar to Moist (; mean: Pluto 80.1pts, Moist 80.1pts; <math>p = 0.983</math>;</li> <li>ii. Based upon the multiple visual acuities measurements included in the study , Pluto achieved very good overall visual acuity, similar to Moist (mean: Pluto 0.026logMAR, Moist 0.034logMAR; <math>p = 0.225</math>);</li> <li>iii. Based upon the number of contact lens pairs needed to arrive to the contact lens being dispensed the ease of fit of Pluto was shown not to be inferior to that of Moist.</li> </ul>
Adverse Events	A total of seven adverse events were recorded during the study: five non-ocular and two ocular, one being study device related. None of the adverse events were serious
Conclusions	The study supported the hypotheses tested showing that: i. overall clinical acceptance of Pluto was not inferior to that of Moist; ii. overall clinical performance of Pluto was not inferior to that of Moist; iii. Ease of fit of Pluto was not inferior to that of Moist.