

Title

Toric Contact Lens Digital Performance and
Comfort Study

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Statistical Plan

The outcome measures for the two contact lens designs were first analyzed using the Grizzle model. The data were tested for the presence of a carry-over effect by examining the average of outcomes in the two periods within subjects between the two sequences of randomization, that is, sphere then toric / toric then sphere. Independent paired T-test or Mann-Whitney test, as appropriate, was carried out to ensure there were no carry-over or period effects at the alpha level of 0.10.¹⁹ The differences in outcome measures between lens designs were examined using a linear mixed model, with fixed factors of sequence and contact lens design to obtain unbiased effect sizes. Estimated means, standard errors and medians and interquartile ranges were reported for each lens design. Estimated means, standard errors, and 95% confidence intervals of the differences between lens designs were also reported. In the presence of any carry-over effects, hypothesis tests were conducted on period one only. Significance was defined as P values of 0.05 or less.