Title: Toric Contact Lens Performance Study

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Statistical Analysis Plan:

The treatment effects on pre- specified outcomes that met the parametric assumptions were analyzed using the Grizzle model (Grizzle, 1965) for the two-period two-treatment crossover trial. First, the data were tested for the presence of a carry-over effect according to the sequence of randomization, that is, sphere or toric, during the first period at the critical level of 0.10. Then, the treatment effect was estimated using a linear mixed model in the presence of period and sequence effects to obtain unbiased effect sizes. For pre-specified outcomes that did not conform to non-parametric testing, Koch's approach using the Wilcoxon rank sum test was used. Treatment differences and 95% Confidence Intervals were estimated using the Hodges-Lehmann method. In the presence of any carry-over effects, hypothesis tests were conducted on period 1 only. Unadjusted p-values are reported and inferred using a specified critical region after adjusting for multiple testing. Summary measures of means and standard deviations are reported for variables conforming to parametric testing and median, 25th percentile, and 75th percentile were reported otherwise. A one-sample binomial test was used to test the hypothesis that the probability of subject preference to treatment lens and standard lenses are equally likely. The hypothesis that $H_0: \Delta=0$ $vs. H_1: \Delta \neq 0$ using a two-sided test with significance level $\alpha=0.05$ was tested, where Δ is the underlying benefit for treatment contact lenses versus spherical contact lenses in this cross-over design. To assess treatment differences in spatial frequency, a repeated measures model was used and tested for the interaction between spatial frequency and lens type. In the presence of a statistically significant interaction, follow Confidential -up testing with appropriate Type I error adjustment was used.