OBJECTIVE: To assess QOL as measured by patient-reported outcomes (PRO) within the iStent inject pivotal trial.

DESIGN: Randomized controlled trial analysis of secondary outcomes.

METHODS: The Vision Function Questionnaire (VFQ-25) and Ocular Surface Disease Index (OSDI©) questionnaire were administered at baseline, months 1, 6, 12, and 24. PRO responders were defined as patients reaching improvement based on minimally important differences.

RESULTS: 505 patients were randomized (N = 386 iStent inject, N = 119 surgery alone). The iStent inject group exhibited a greater percentage of PRO responders across all follow-up visits over 24 months, averaging 58.0% vs. 45.8%; P < 0.05) higher for the ODSI. Driving (49.0% vs. 28.8%; P < 0.05).

CONCLUSIONS: Exploratory analysis suggests that by reducing medication dependence, implantation with the micro-scale iStent inject device with cataract surgery may improve QOL vs. cataract surgery alone over 24 months with improvements influenced by ocular symptoms and vision related activities.

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