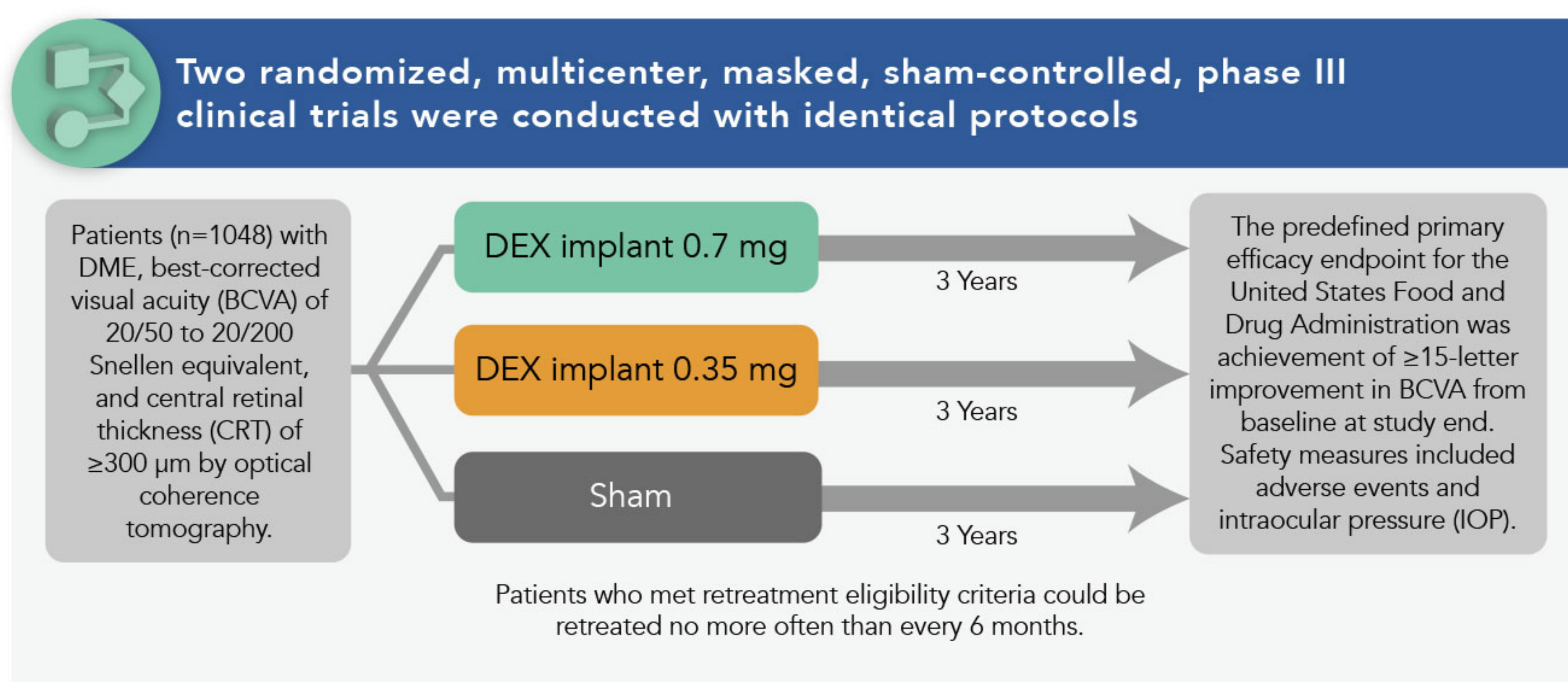


Three-year, randomized, sham-controlled trial of dexamethasone intravitreal implant in patients with diabetic macular edema (DME)

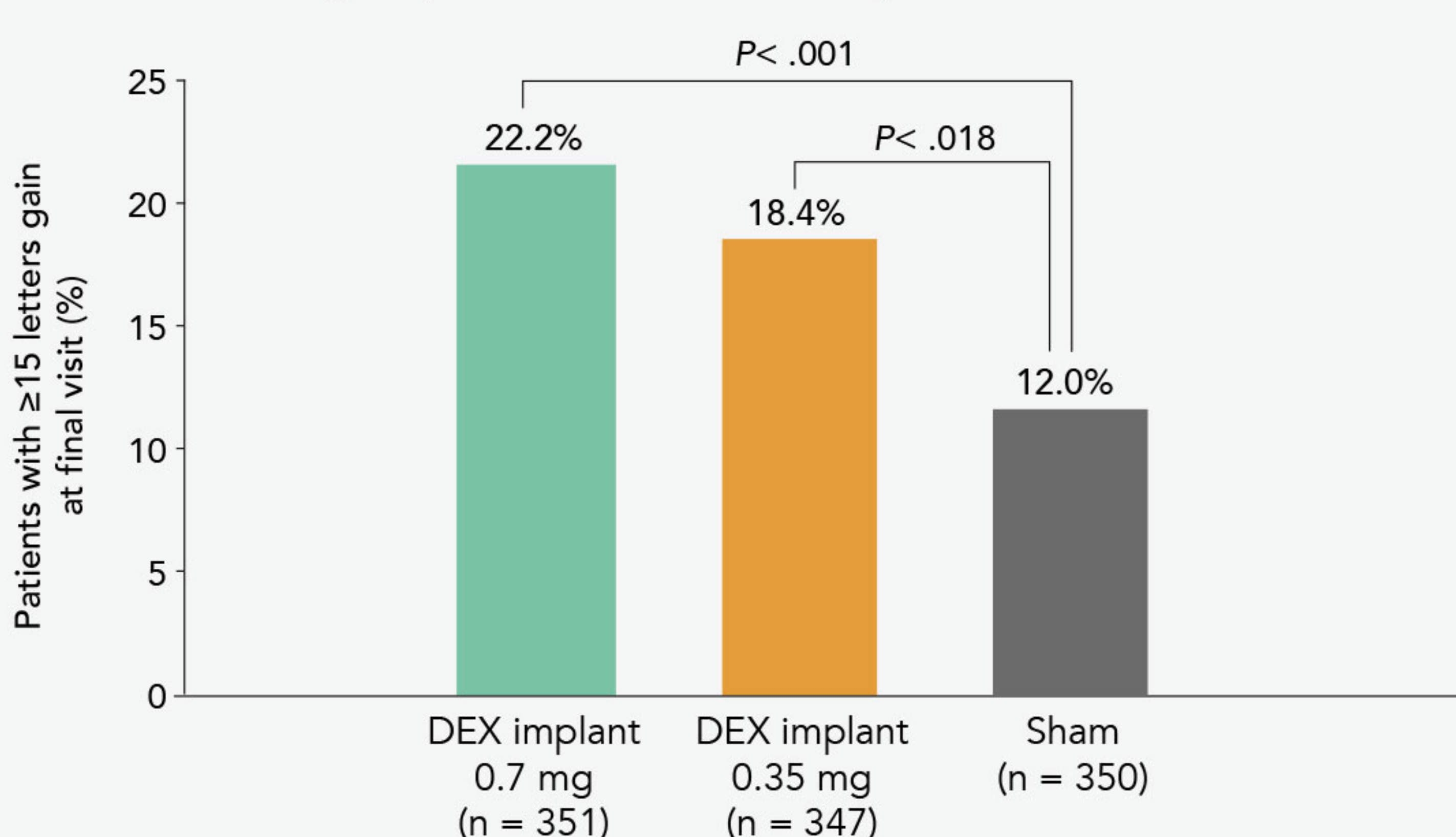
Boyer DS, Yoon YH, Belfort, Jr R, et al. *Ophthalmology*. 2014;121:1904-1914.
doi: <http://dx.doi.org/10.1016/j.ophtha.2014.04.024>

The objective of this trial was to evaluate the safety and efficacy of dexamethasone intravitreal implant (DEX implant) 0.7 and 0.35 mg in the treatment of patients with DME.

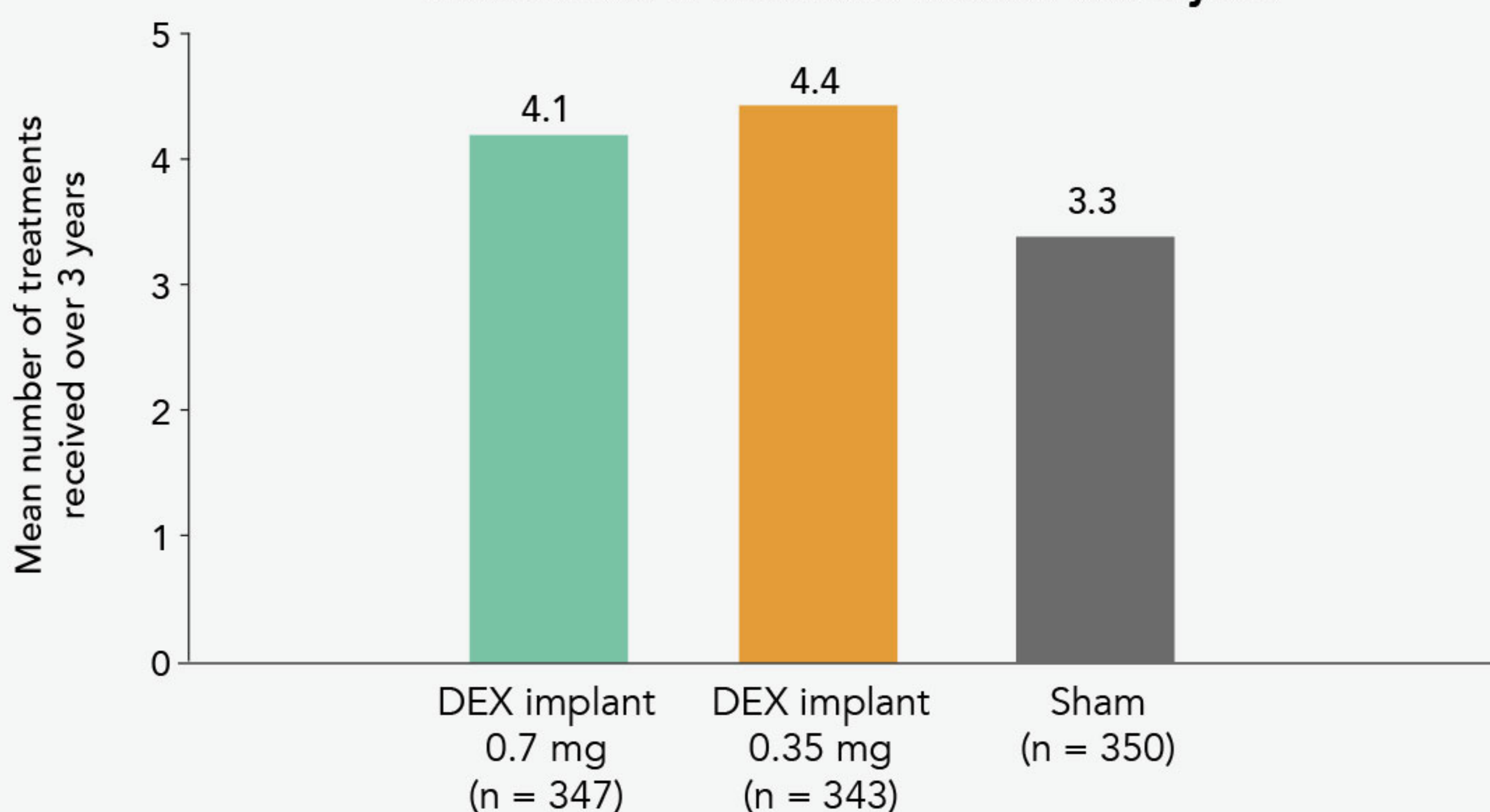


DEX implant provided long-term improvement in vision and macular edema with a mean of only 4 to 5 injections over 3 years

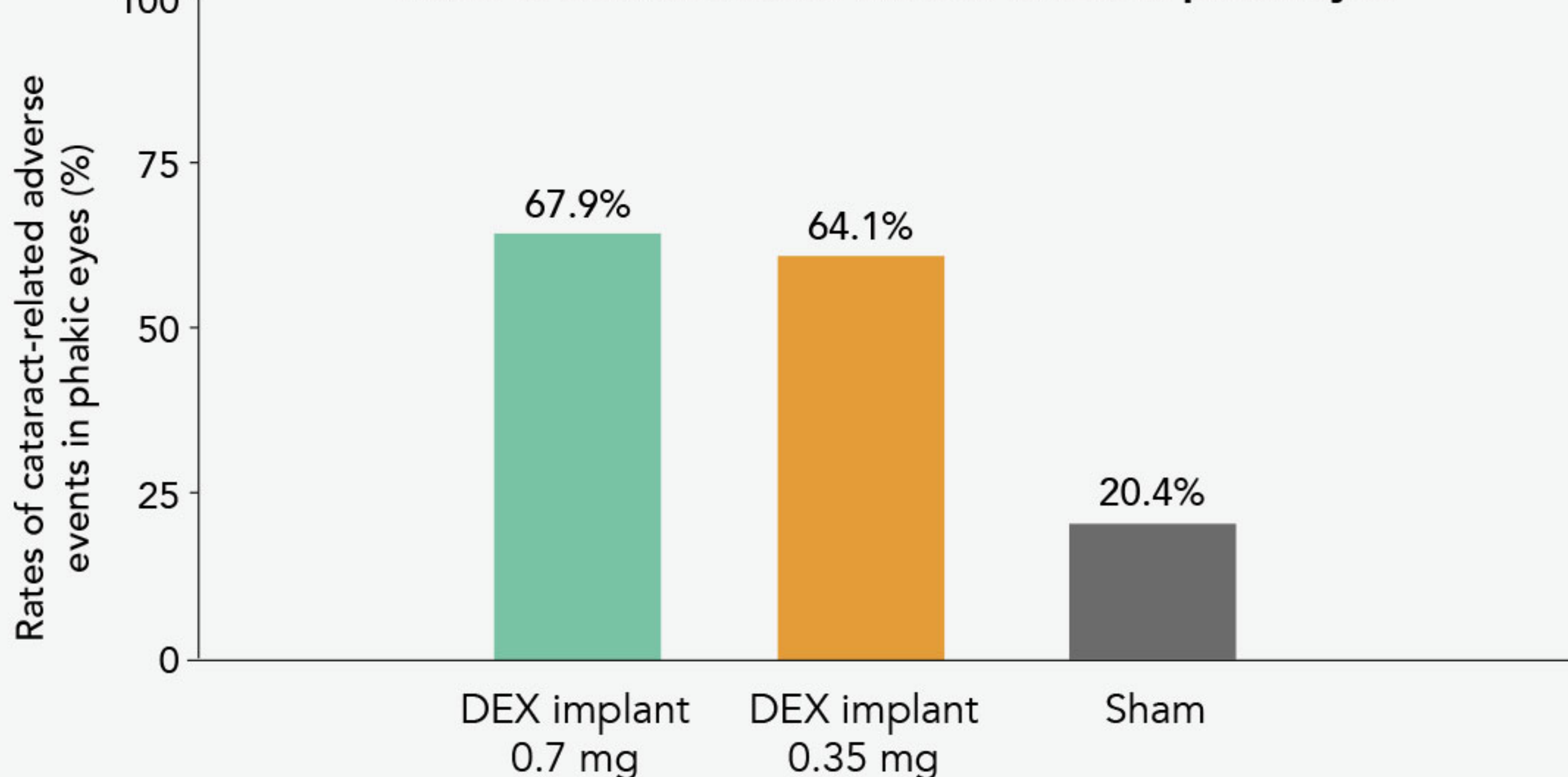
Percentage of patients with ≥ 15 -letter improvement in BCVA from baseline



Mean number of treatments received over 3 years

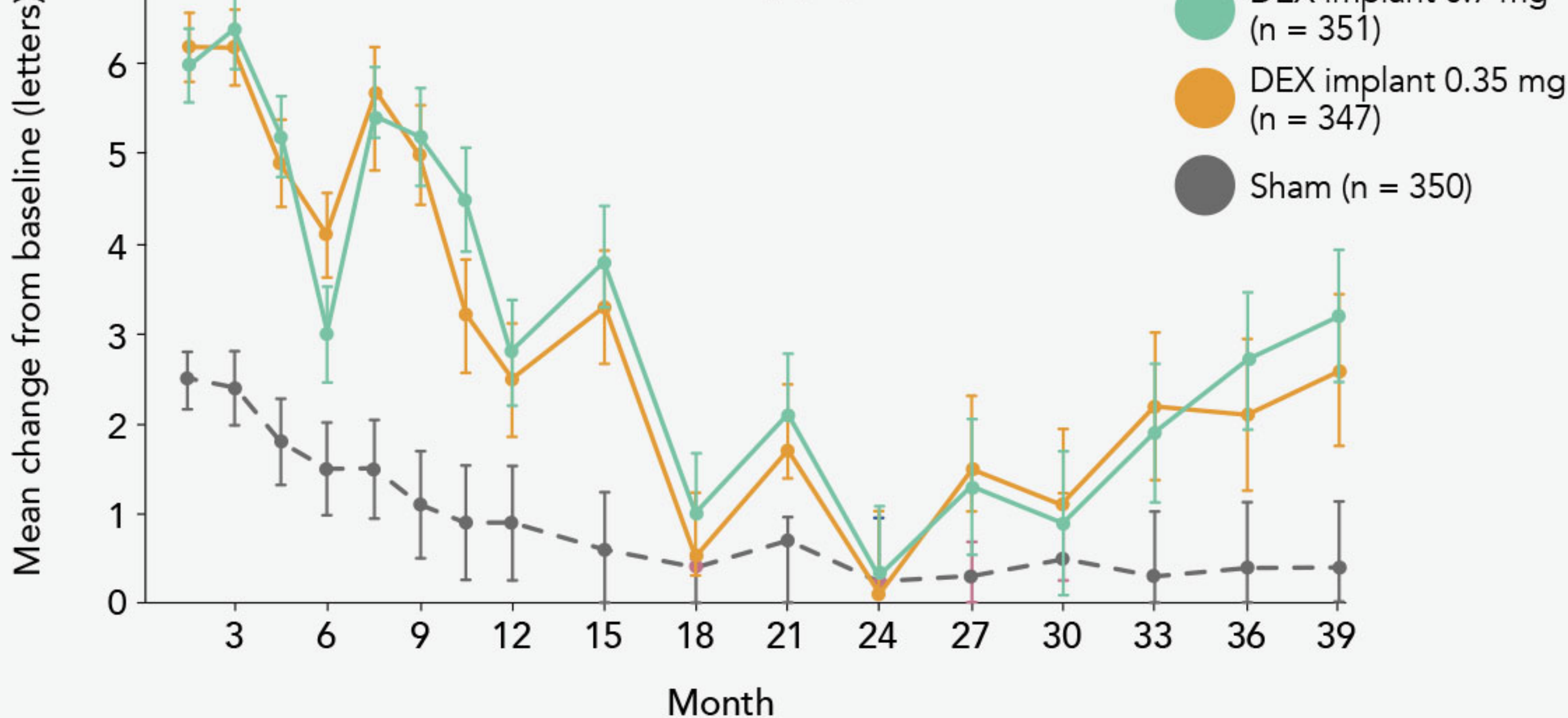


Rates of cataract-related adverse events in phakic eyes



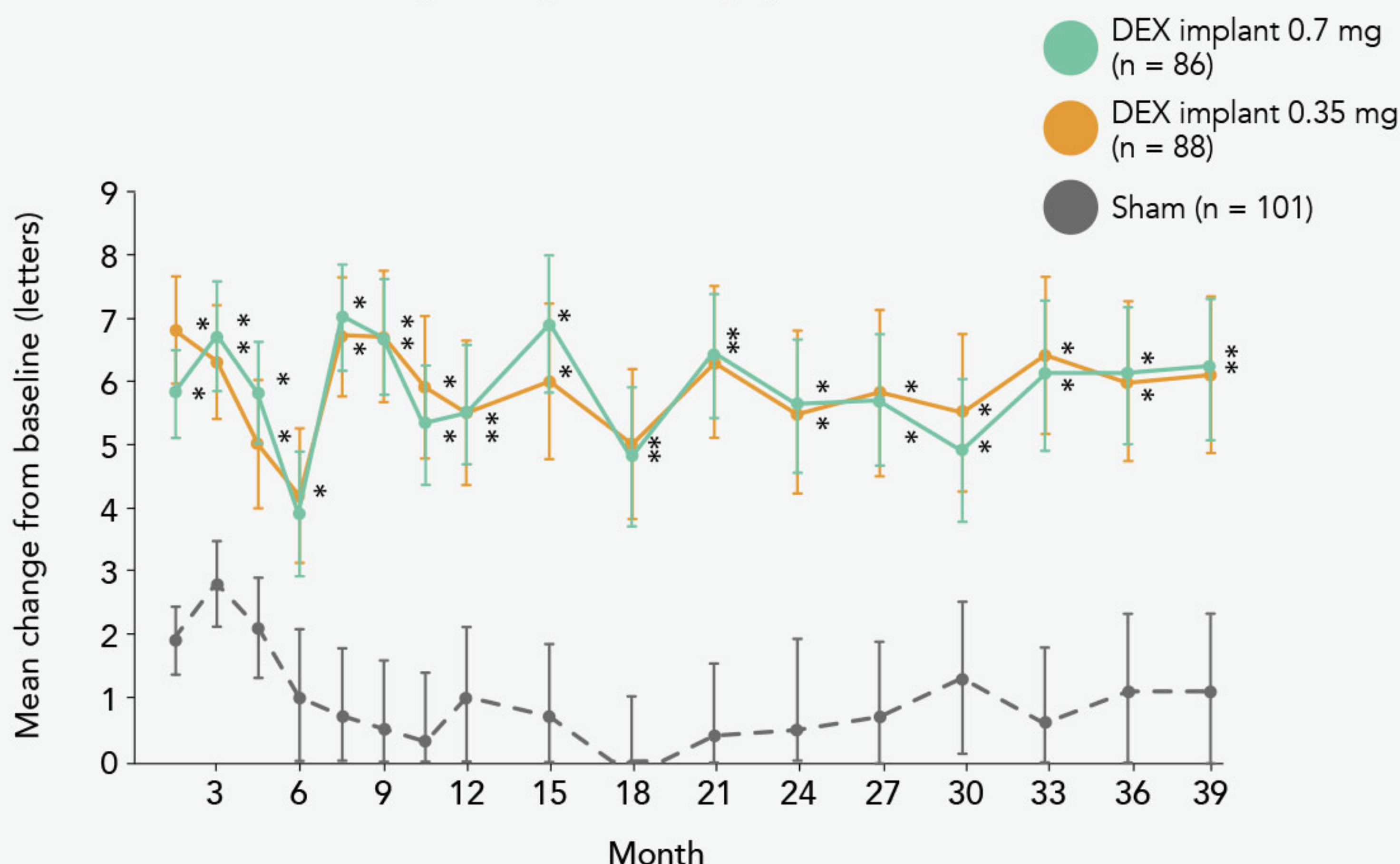
Greater BCVA improvement in both dexamethasone implant groups compared with sham at most timepoints was seen during the first 15 months

Mean change in best-corrected visual acuity in the total study population



In subgroup analysis, mean improvement in BCVA was provided by dexamethasone implant relative to sham in pseudophakic eyes consistently across time in the 3-year study

Mean change in BCVA in the subgroup of patients with pseudo phakic study eyes at baseline



* $P = 0.046$ versus sham (analysis of covariance in the intent-to-treat population with last-observation-carried-forward imputation of missing values).

Conclusions

The dexamethasone implant 0.7 mg and 0.35 mg met the primary efficacy endpoint for improvement in BCVA. The safety profile was acceptable and consistent with previous reports.