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.

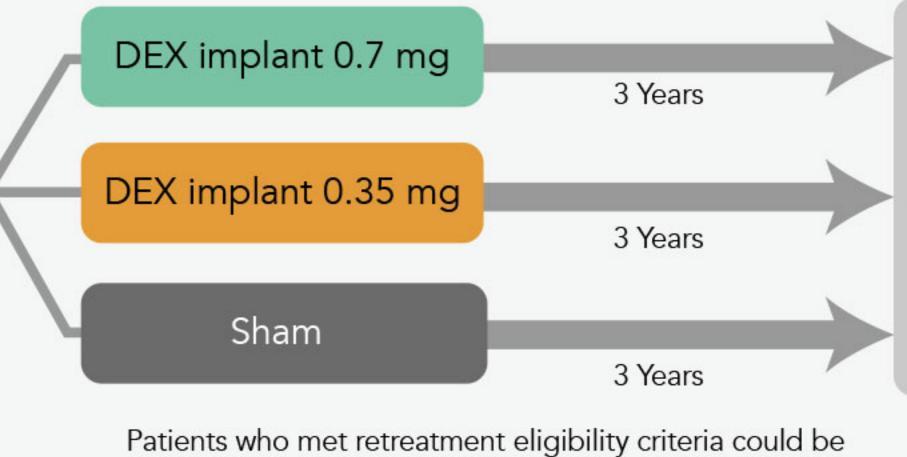
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The objective of this trial was to evaluate the safety and efficacy of dexamethasone intravitreal implant (DEX implant) 0.7 and 0.35 mg in the treatment of patients with DME.



Two randomized, multicenter, masked, sham-controlled, phase III clinical trials were conducted with identical protocols

Patients (n=1048) with DME, best-corrected visual acuity (BCVA) of 20/50 to 20/200 Snellen equivalent, and central retinal thickness (CRT) of ≥300 µm by optical coherence tomography.



retreated no more often than every 6 months.

efficacy endpoint for the United States Food and Drug Administration was achievement of ≥15-letter improvement in BCVA from baseline at study end. Safety measures included adverse events and intraocular pressure (IOP).

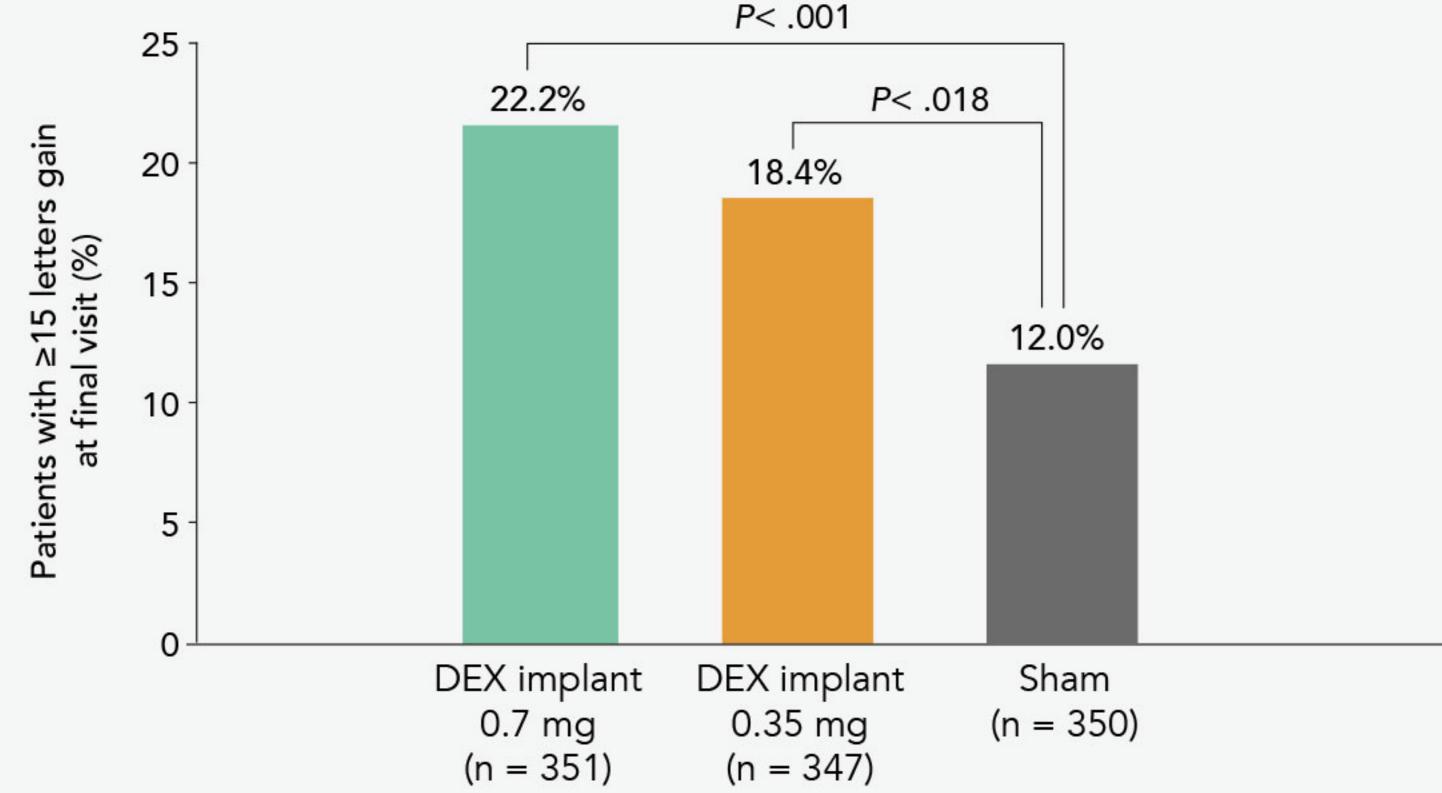
The predefined primary



edema with a mean of only 4 to 5 injections over 3 years

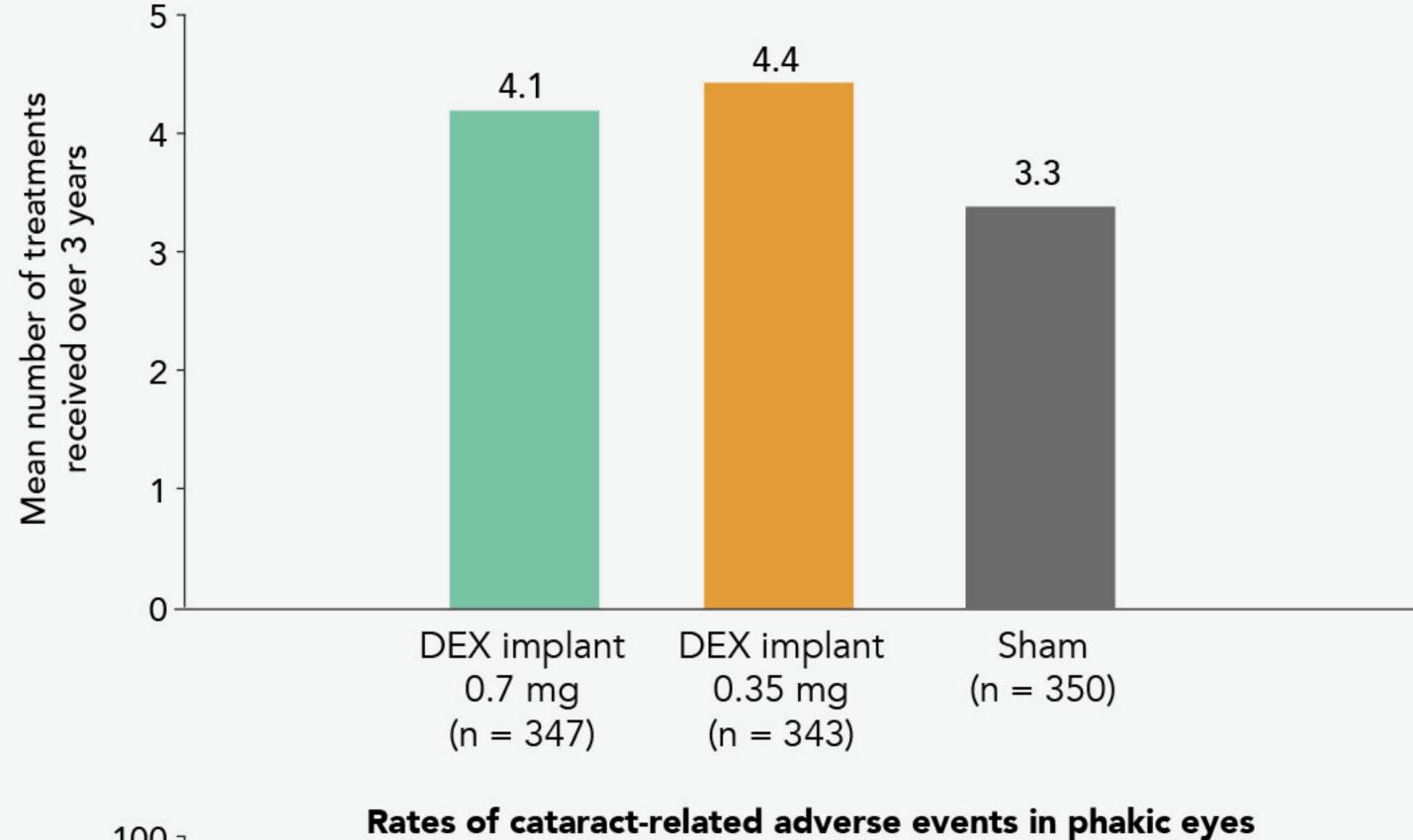
DEX implant provided long-term improvement in vision and macular

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

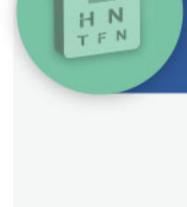




Mean number of treatments received over 3 years



Rates of cataract-related adverse events in phakic eyes (%) 75 67.9% 64.1% 50 20.4% 25 0 DEX implant DEX implant Sham 0.35 mg 0.7 mg Greater BCVA improvement in both dexamethasone implant groups

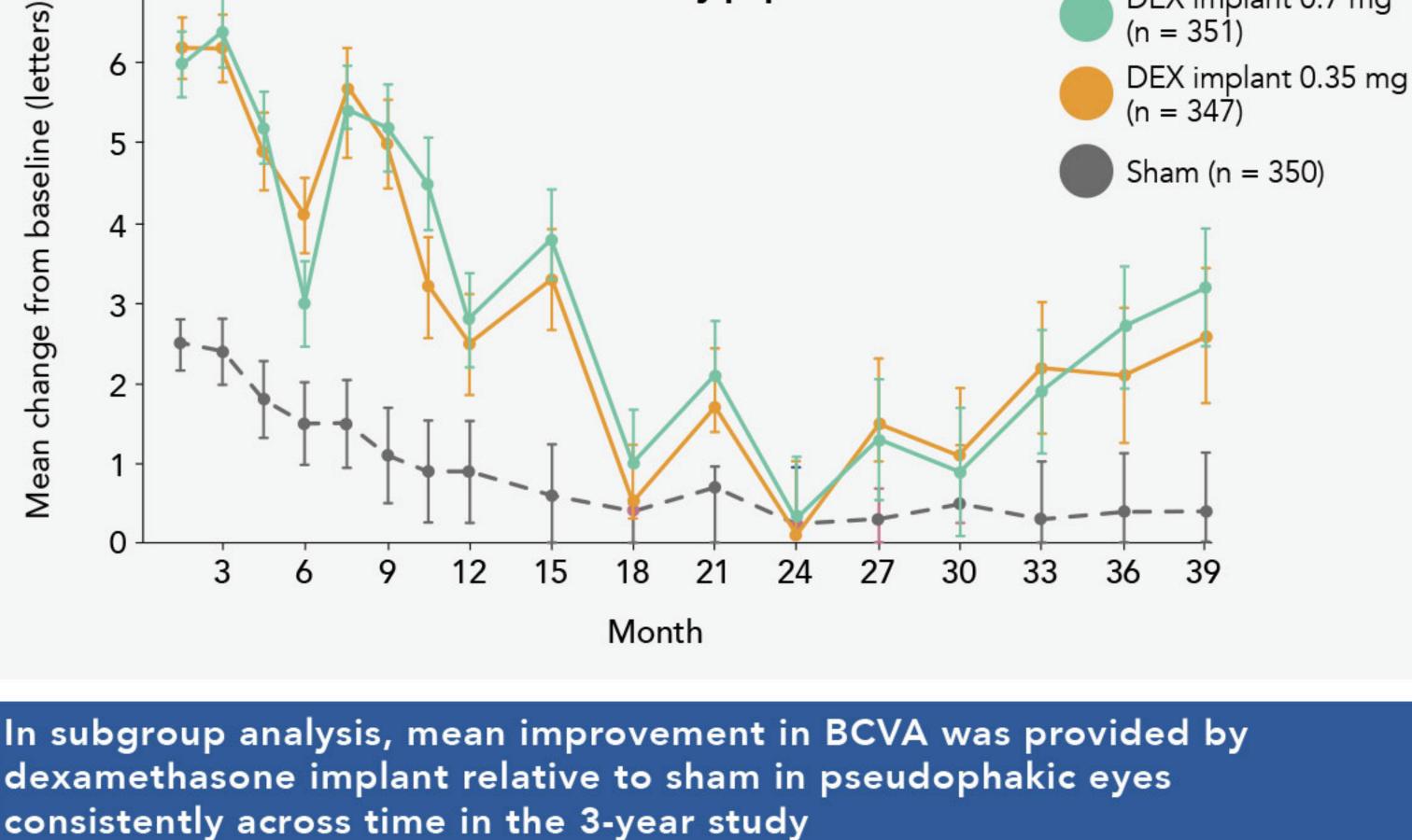


15 months

100

Mean change in best-corrected visual acuity in the total study population DEX implant 0.7 mg

compared with sham at most timepoints was seen during the first

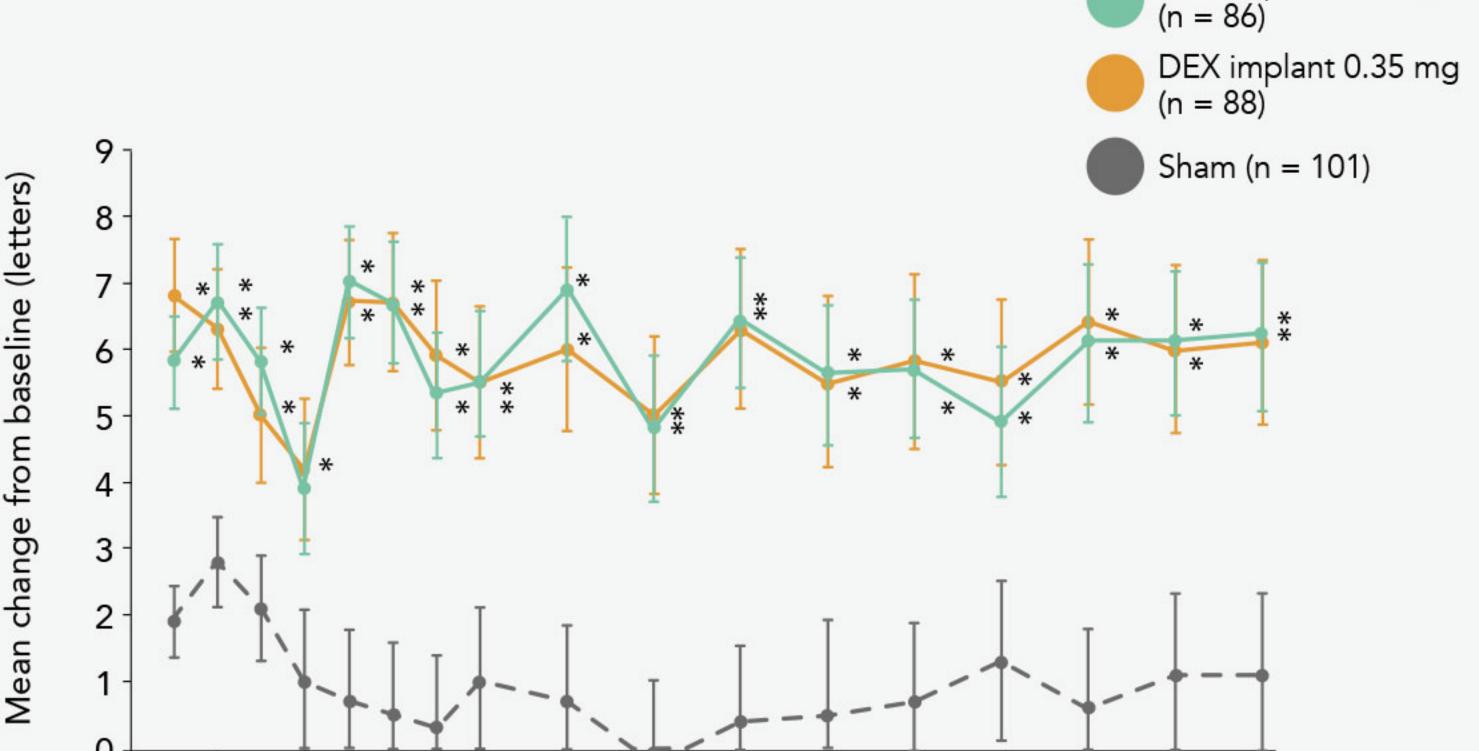




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HN

Mean change in BCVA in the subgroup of patients with psuedo phakic study eyes at baseline DEX implant 0.7 mg



0

30

33



3

missing values).

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.

15

9

18

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

Month