

INTRODUCTION

- In the VEGA-1 Phase 2 presbyopia trial, 0.75% phentolamine ophthalmic solution (POS) in combination with low dose pilocarpine met its primary endpoint by improving distance-corrected near visual acuity (DCNVA) by 3 lines (61% vs 28% with placebo; p=0.004)
- Key secondary endpoints were met, including POS monotherapy improving DCNVA by 3 lines and preserving the pupillary response in different light conditions in presbyopia patients
- Maintenance of pupillary light reflex is important for normal daily vision function

METHODS

- Randomized, double-masked, placebo-controlled, multi-center, Phase 2 clinical trial
- N=147; 1:1 POS or Placebo for ~4 evening doses
- Primary Endpoint: % of patients with ≥15 letters (3 lines) binocular photopic DCNVA improvement on an ETDRS chart (POS vs placebo)
- Secondary Endpoints including mean photopic, mesopic pupil diameter by timepoint, and ≥10 or ≥15 () DCNVA letters (POS vs placebo)

DEMOGRAPHICS AND BASELINE CHARACTERISTICS	
Age, years, Mean (SD)	53 (5.0)
Female, n (%)	108 (72.0)
Race: White, n (%)	134 (89)
Photopic Pupil Diameter Mean (mm)	4.3
Mesopic Pupil Diameter Mean (mm)	5.1
Photopic DCNVA Mean Letters read-Binocular (Snellen Equiv.)	46 (20/63)

Disclosures

Each author is a medical advisor (JP), consultant (MB LH), or employee (RP, DC) of the study sponsor, Ocuphire Pharma, Inc. (Farmington Hills, MI).

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VEGA-1 Phase 2 Trial: Phentolamine Ophthalmic Solution Maintains Pupillary Light Reflex with Improved Distance-Corrected Near Visual Acuity in Presbyopes

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A single dose of POS reduced pupil diameter by ~1-1.5mm compared to placebo at all time points (12 to 18 hours post-dose) in both lighting conditions. The pupillary light reflex was maintained

Figure 1: VEGA-1 Study Design

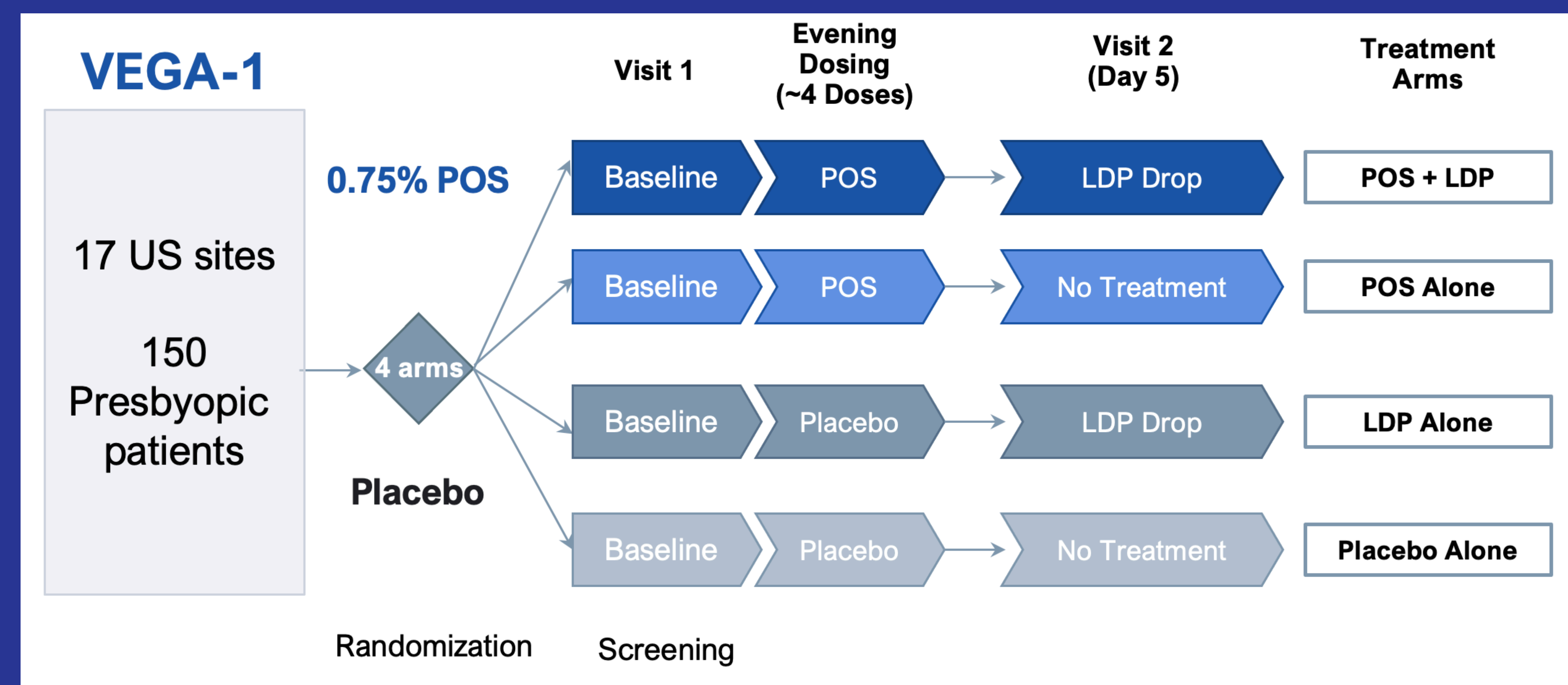
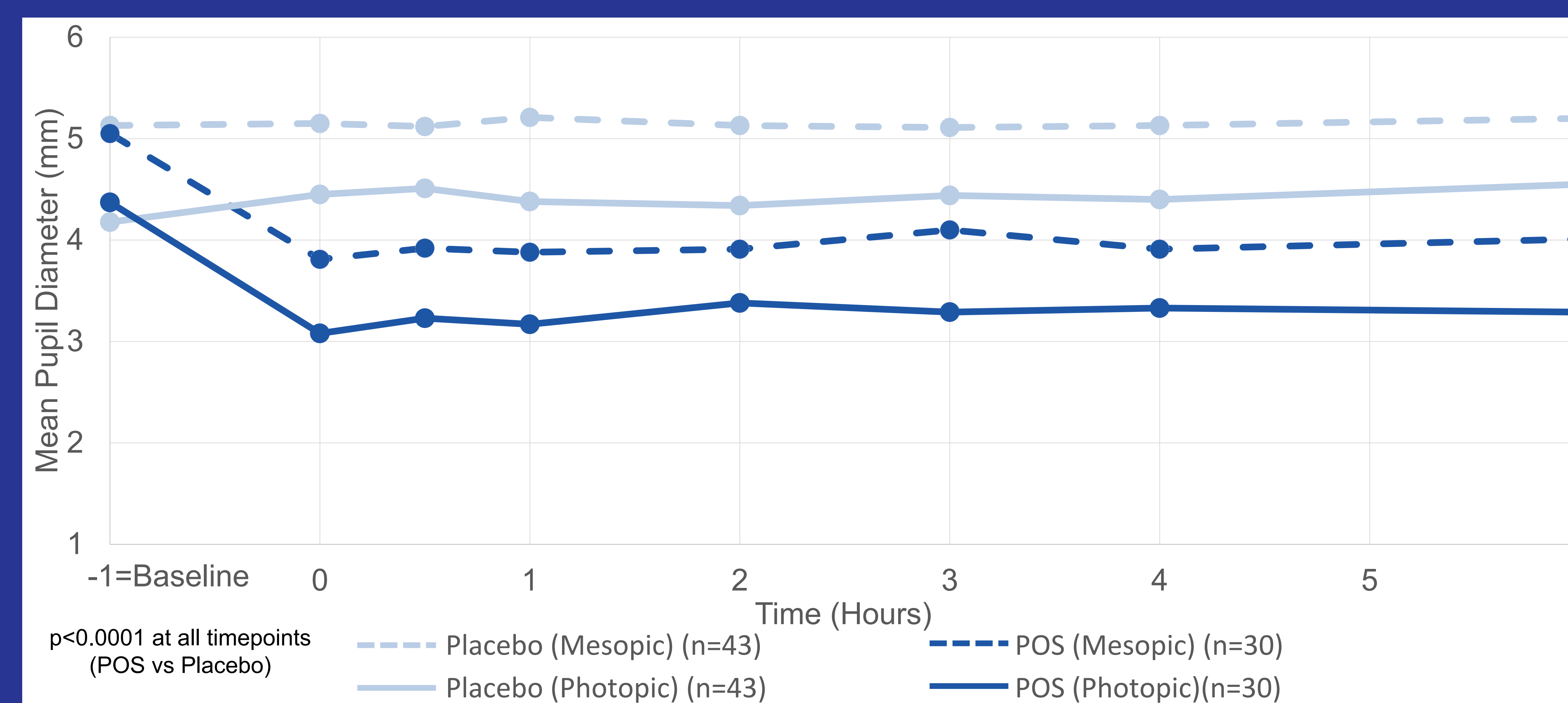


Figure 2: Pupil Diameter in Mesopic and Photopic Lighting Conditions



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RESULTS

Figure 3: Percent of Subjects With ≥ 15 and ≥ 10 Letters Improvement From Baseline in Photopic Binocular DCNVA at 0 Min for POS- and Placebo-Treated Subjects

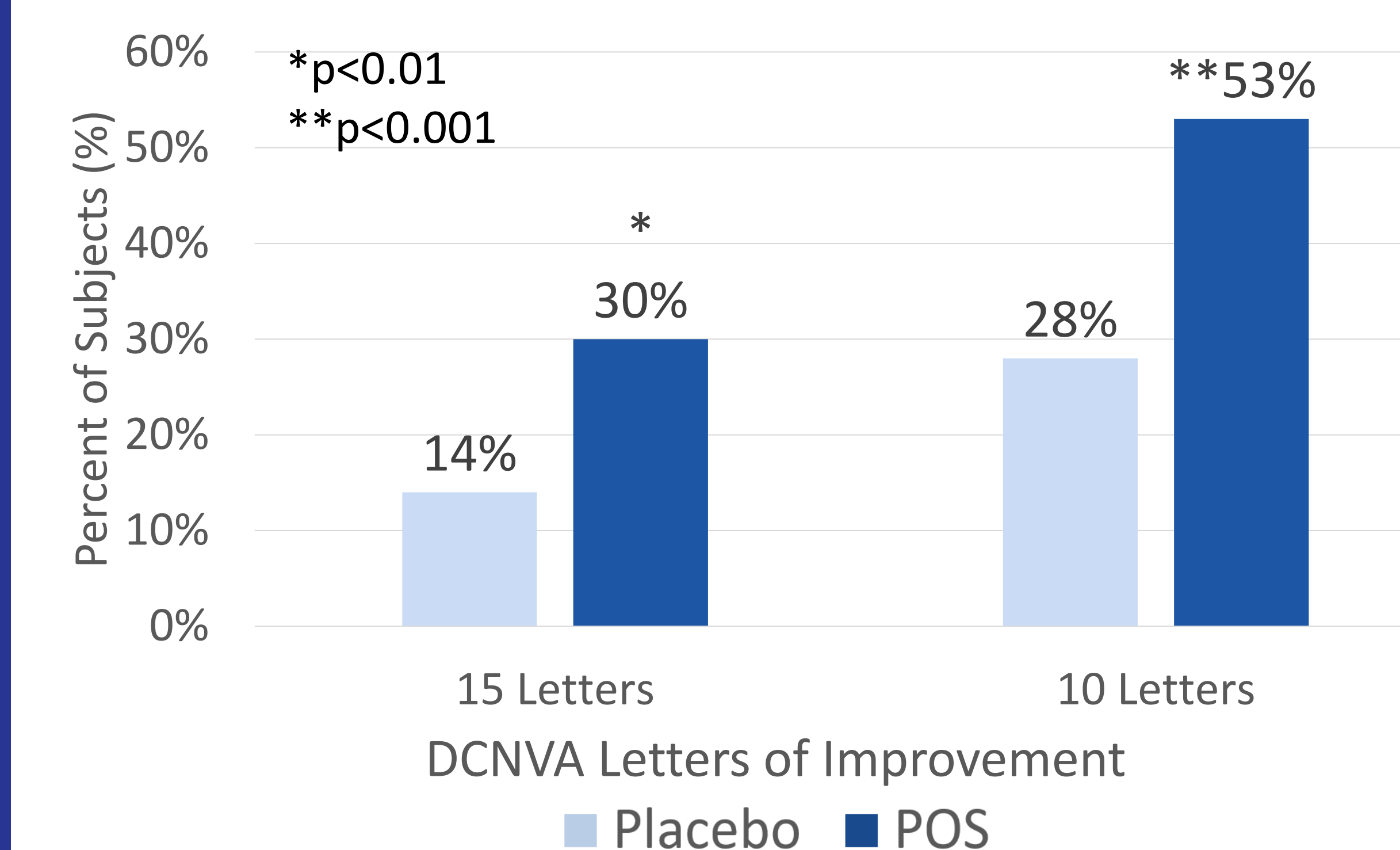


Figure 4: Distribution of Photopic Binocular DCNVA in POS-Treated Subjects at Baseline and 12 Hours post-dose

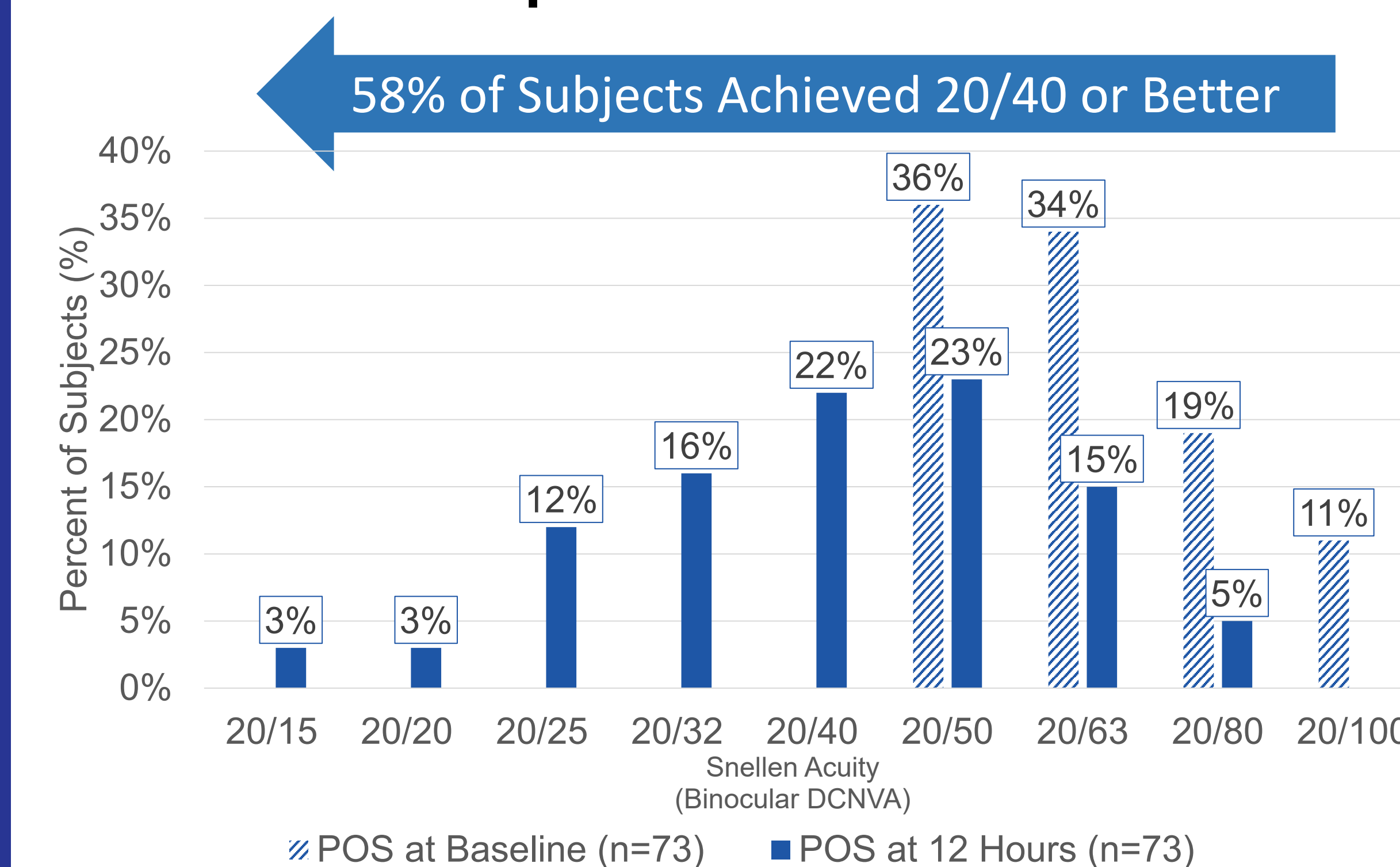


Figure 5: Percent of Subjects With ≥ 15 Letter Improvement From Baseline in Photopic Binocular DCNVA at 12 hours for POS- and Placebo-Treated Subjects By Baseline PD

