

# Prospective Double-Masked, Controlled Trial of blink Tears for Dry-Eye Disease

*E. D. Donnenfeld; M. B. McDonald;  
H. D. Perry; G. D'Aversa; R. Solomon*

# Objective

To evaluate the efficacy of a novel formulation artificial tear, blink Tears (AMO), for the treatment of mild-to-moderate dry eye disease.

# Methods

- 110 subjects were enrolled at one site in the U.S.
- Randomized, two-arm, double-masked, parallel-group study design

# Methods

- Patients randomized to the new tear (blink Tears, AMO) or HP-guar tear (Systane, Alcon)
- Dosed QID
  - 30 days
- At baseline, prior to instillation, patients completed subjective questionnaires rating the following: (1= very poor to 10=excellent):
  - eye comfort level
  - quality of vision
  - severity of symptoms
- Same questionnaires were completed at Days 7, 14, 21 and 30

# Results

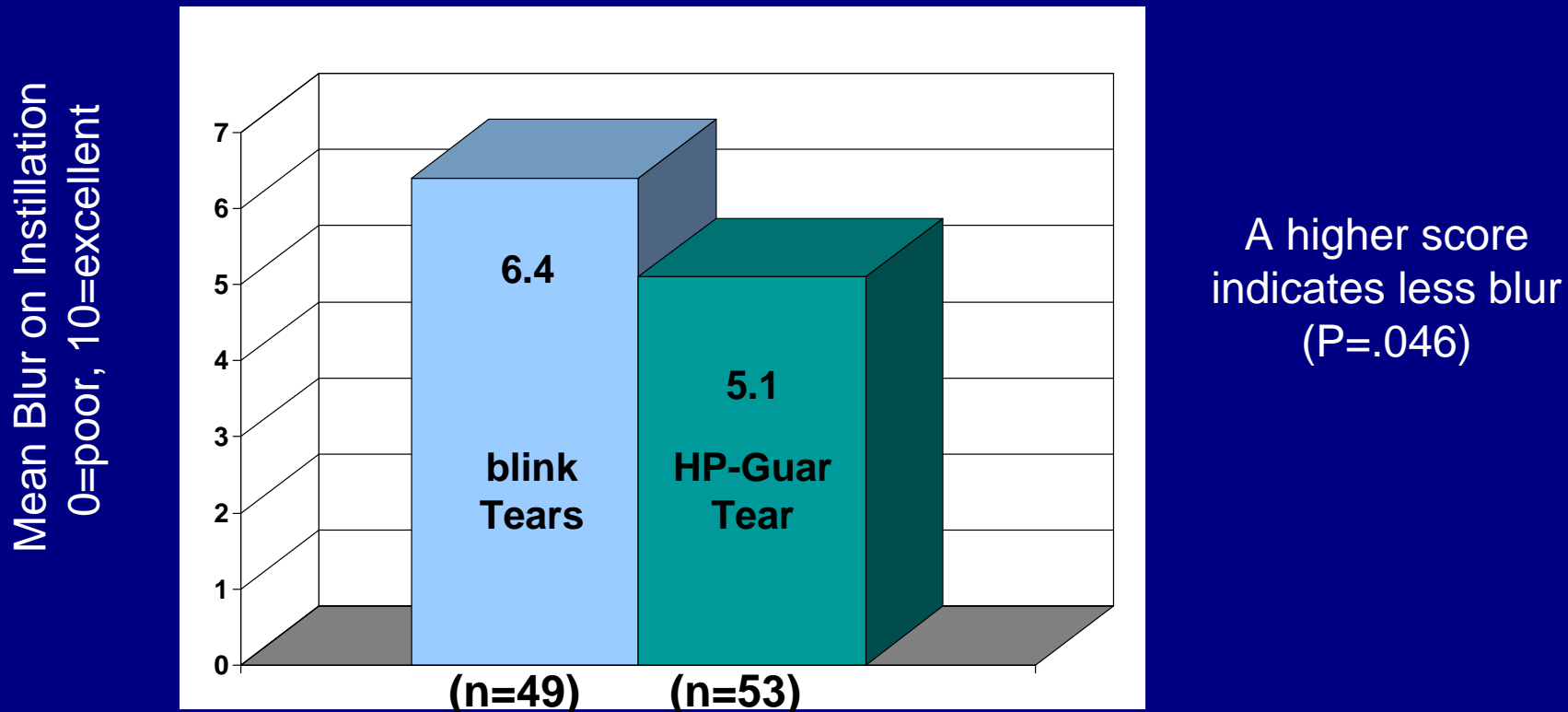
- Mean age of subjects in the per-protocol population for the test group was  $44.6 \pm 13.22$  years (range: 25 – 77), and  $41.4 \pm 13.08$  years (range: 19 – 78) for the control group
- Proportion of males to females in the test group (blink Tears, AMO) was 20.5%: 79.6% and in the control group (Systane, Alcon) 25.9%: 74.1%
- No statistical difference in mean age and proportion of males to females between the test and control groups ( $p=0.220$  and  $p=0.508$ , respectively)

# Results

- No statistically significant differences in corneal/conjunctival staining and tear film break-up time (TBUT) between test and control groups
- End-of-day vision quality was comparable between the two groups

# Results

Significantly less blur on instillation with blink Tears reported on day 30 ( $p=0.046$ )

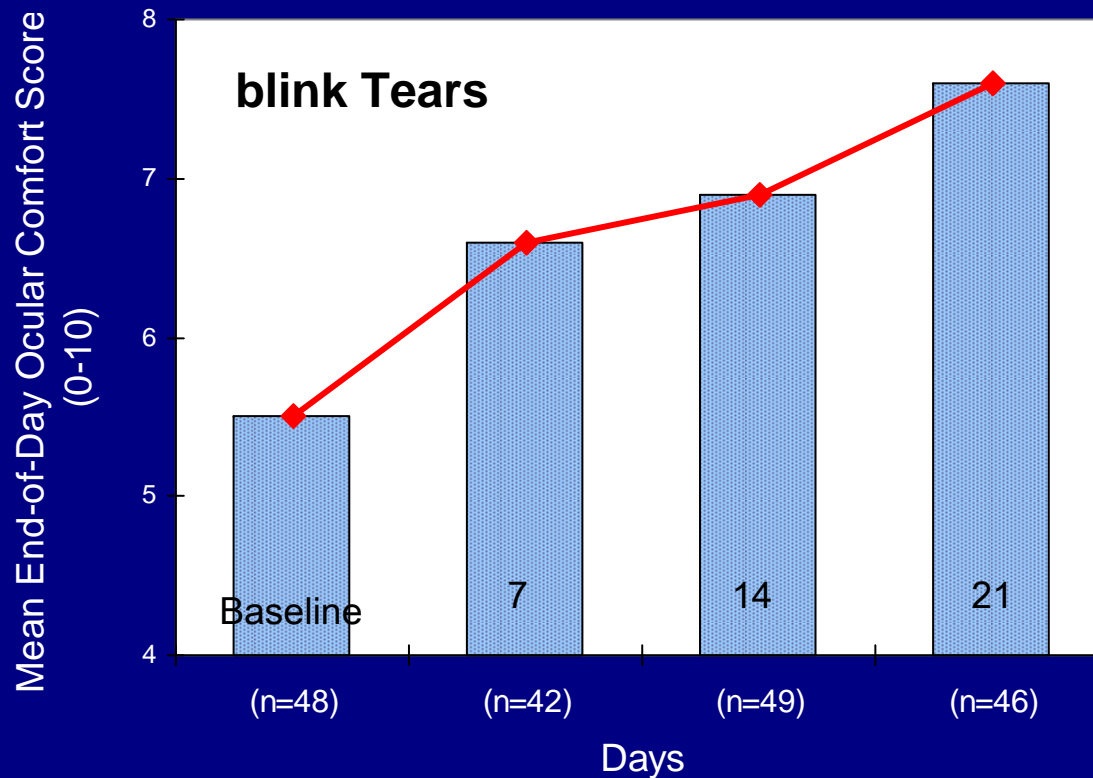


Significantly less blur vs control drops

Data reflect patient responses at Day 30.

# Results

## Significant Improvement in Patient Comfort Over Time

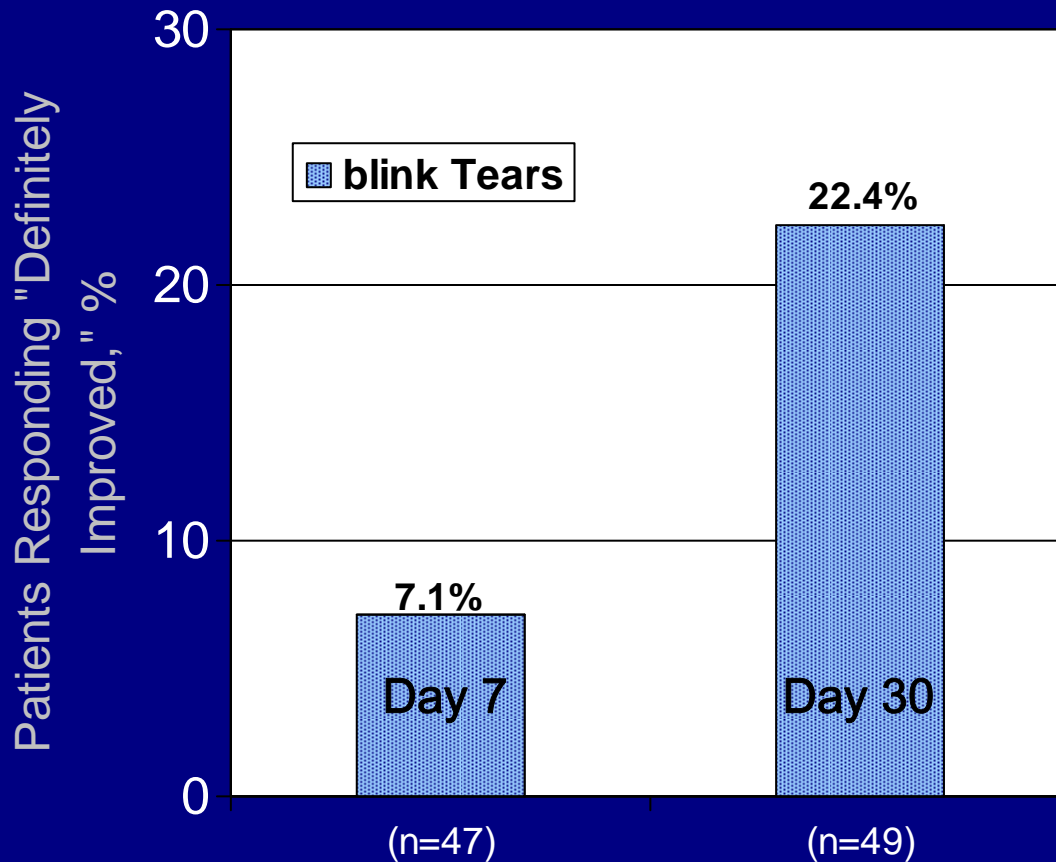


Statistically significant difference between Day 7 and Day 21 ( $P < .001$ )

Patient-reported ratings at indicated visit.

# Results

## Improved Vision Quality Over Time



Tear film stability supports vision quality with long-lasting moisture and comfort

Data reflect patient responses within first five minutes after eye-drop instillation.

# Conclusion

- Ocular **comfort and efficacy** of blink Tears (AMO) was comparable to HP-guar tear (Systane, Alcon) after 30 days of use for the treatment of mild-to-moderate dry eye
- Patients **with** blink Tears (AMO) compared to HP-guar tear (Systane, Alcon), were **more** satisfied with their vision and ocular comfort after instillation
- Patients experienced **significantly** less blurring on installation with blink Tears