Visual Effects of Additional Short-Wave Filtering in Patients with Clear IOLs

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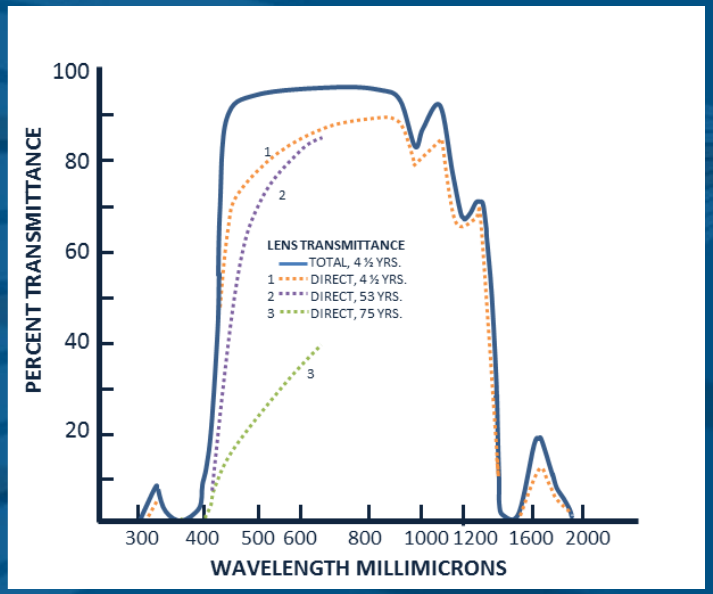
Introduction

Background

- The natural crystalline lens in the eye has two principal optical properties:
  - Focusses light to fovea
  - Spectral transmission-filtering of short wavelengths (**see figure below**)[1]
- Light energy transmission increases significantly following cataract extraction and intraocular lens (IOL) implantation
- Conventional IOLs tend to provide ultraviolet light filtration, but allow transmission of blue light which scatters inside the eye, thereby producing glare and reduction in image quality
- Prior studies on Blue Light Filtration (BLF) have demonstrated benefits between individuals or between eyes of an individual, but the true benefit of within-eye differences has not been demonstrated



1. Boettner, EA, Wolter JR. Transmission of the ocular media. *Invest Ophthalmol*. 1962;1:776-783.

Introduction (cont'd)

Purpose

- Evaluate within-eye visual benefit of BLF among pseudophakic eyes previously implanted with IOLs largely transparent to visible wavelengths

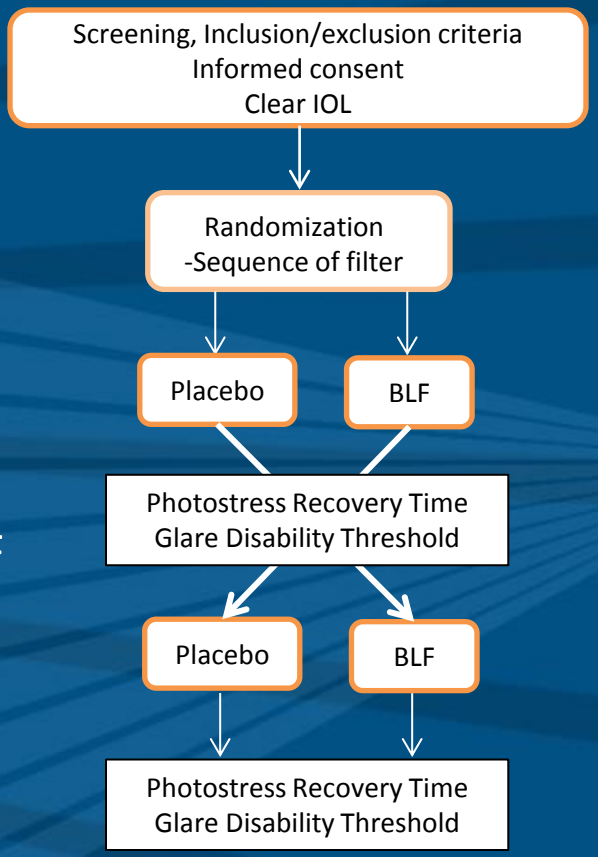
Specific Goals

- Primary
  - Measure photostress recovery time with addition of BLF vs a placebo (clear) filter among pseudophakes with IOLs that have no blue light filtration
- Secondary
  - Measure disability glare threshold with addition of BLF vs a placebo filter among pseudophakes with IOLs that have no blue light filtration

Study Design

Cross-over Study Design

- 154 pseudophakes with no BLF IOL
  - Bilateral pseudophakia ≥ 3 mo post-op
  - Both eyes with BCVA of 20/40 or better
  - No ocular pathology/degeneration
  - Study eye was randomly selected
- Within-eye comparison of placebo vs BLF
  - Randomization of filter order: placebo vs BLF
- Sample size
  - Using a 0.35s standard deviation in within subject estimates[1], the sample size required to provide 80% power to detect a 20% difference would be 153



1. Hammond BR, Renzi LM, Sachak S, Brint SF. Contralateral comparison of blue-filtering and non-blue-filtering intraocular lenses: glare disability, heterochromatic contrast, and photostress recovery. *Clinical Ophthalmology.* 2010:4:1465-1473.

Study Measurements

Primary: Photostress Recovery Time (PRT)

- PRT is the time (seconds) for the eye to recover following a 5-second exposure to bright light

Secondary: Glare Disability Threshold (GDT)

- GDT is the intensity of background light (logμW/cm^2) required to mask visualization of a central target

Additional

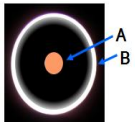
- Pupil size
- Visual acuity

Safety

- Incidence of adverse event(s) or medical device effect

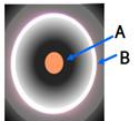
Data Analysis

- Comparisons between the 2 filters were performed using paired t-tests



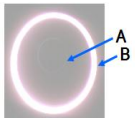
Subject saw:
A) A 3.1° diameter halogen-light disk as the target
B) An annulus from the xenon channel with:
- A shape that was 20° inner and 22° outer diameter
- An intensity that was too low to obscure the target

Technician increased glare intensity



Subject saw:
A) The same central 3.1° diameter disk but,
B) The brightness (ie, the glare) of the annulus was beginning to move toward obscuring the central target

Technician increased glare intensity



Subject saw:
A) No central 3.1° diameter disk, because
B) The glare from the annulus had obscured the central target. The intensity of the annulus of light at that point was defined as the glare disability value.

Schematics are not exact representations. They are for purposes of explanation only.

Methods

- Optical set up: 2-channel Maxwellian-view system
- Transmission spectrum with addition of BLF/placebo filter*
  - Addition of placebo filter does not alter the spectral transmission of the IOL (**Figure A**)
  - Addition of BLF provides progressive increase in transmission with increase in wavelengths (**Figure A**)
  - Similar transmission of no BLF IOL + BLF to AcrySof® IQ 21D IOL from 420-480 nm (**Figure B**)

Figure A

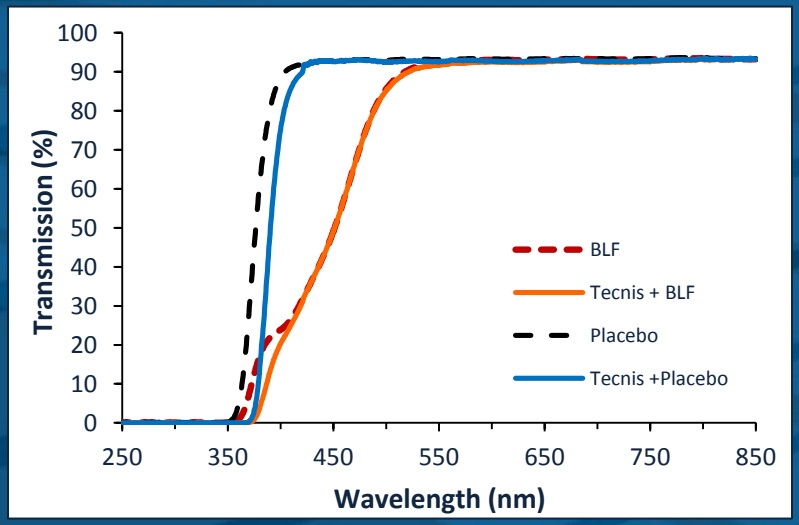
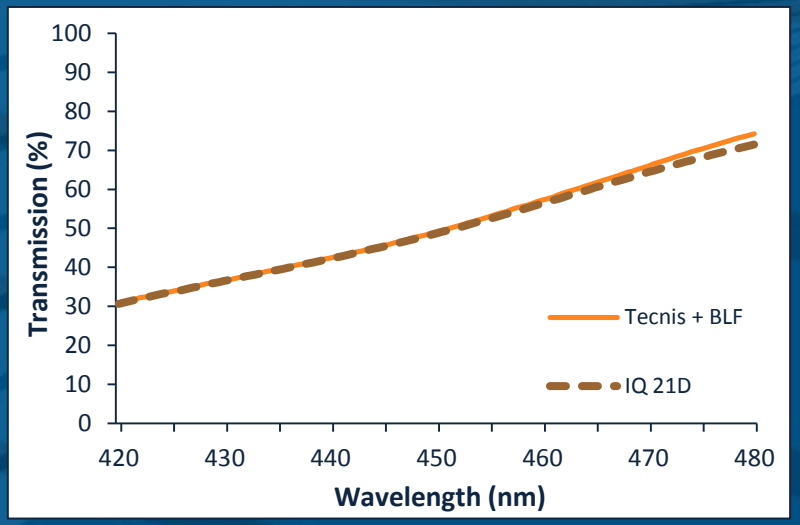


Figure B



*114 of the subjects had Tecnis IOL.

Results: Demographics

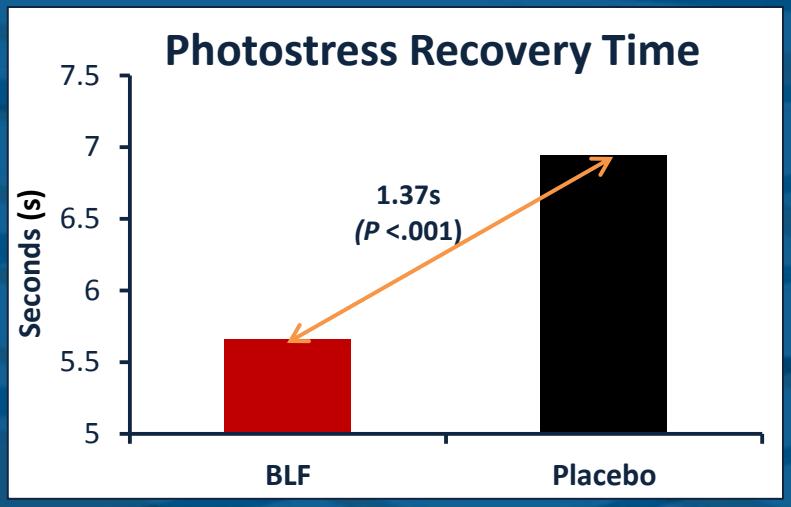
- Six clinical sites in US

Parameter	Total
Total Enrolled	158
Screen Failure	4 (2.5%)
Randomized & Completed	154 (97.5%)
Discontinued	0

Parameter	Total
Total Enrolled (N)	158
Gender	
Male	66 (41.8%)
Female	92 (58.2%)
Age (Years)	
Mean	69.9
SD	8.01
Median	70.0
(min, max)	(48, 88)
Race	
White	150 (94.9%)
African American	5 (3.2%)
Asian	1 (0.6%)
Pacific Islander	1 (0.6%)
Other	1 (0.6%)
Eye	
OD	76 (48.1%)
OS	79 (50.0%)
Missing	3 (1.9%)

Results: Photostress Recovery Time

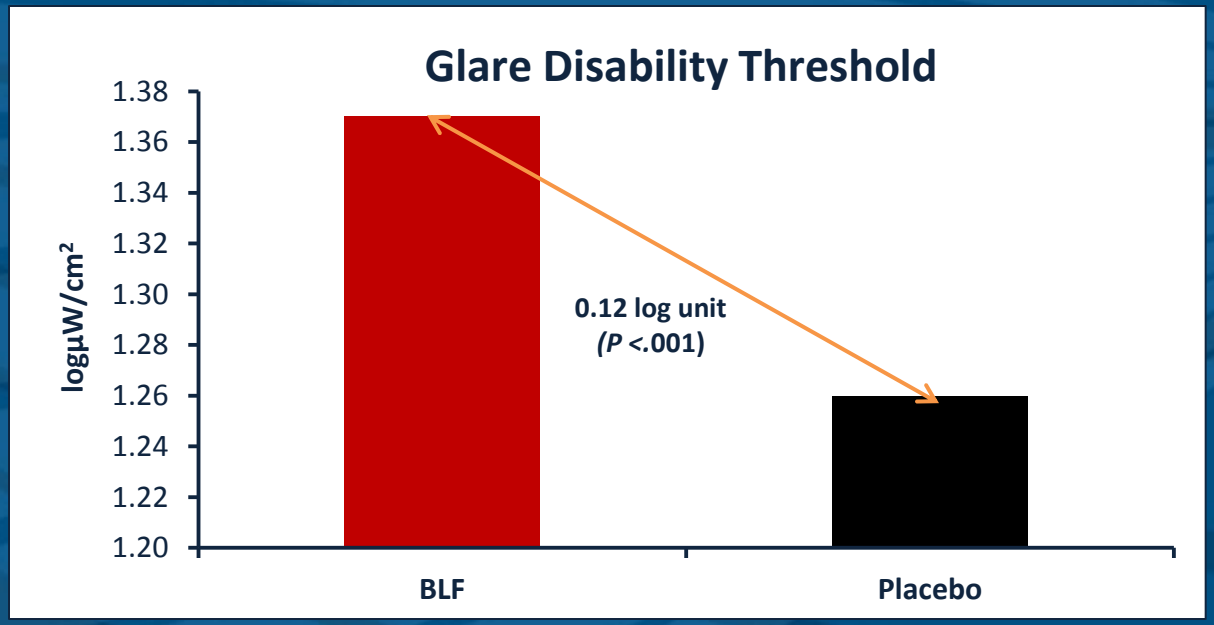
- The addition of BLF provided faster photostress recovery time compared to placebo filter *(P* <.001) among pseudophakes with IOLs that are largely transparent to visible light



Parameter	Difference in PRT (BLF – placebo)
N	144
Mean (SD)	-1.37 s (4.32)
95% CI	-0.66 to -2.08 s

Results: Glare Disability Threshold

- The addition of BLF provided greater glare disability threshold compared to placebo filter *(P* <.001) among pseudophakes with IOLs that are largely transparent to visible light



Results: Visual Acuity & Pupil Size

- Visual acuity and pupil size were similar with BLF and placebo filter

Parameter	BLF	Placebo
CVA (logMAR): Mean ± SD	0.05 ± 0.11	0.05 ± 0.10
Pupil Size (mm): Mean ± SD	3.54 ± 0.80	3.52 ± 0.79

- No adverse event or medical device defect was reported in the study

Discussion & Conclusions

Key Finding

- The addition of BLF provided faster photostress recovery and greater threshold to disability glare compared to a placebo filter *(P* <.001)

Real-world Applications

- Analogous situations could occur under bright midday sunlight or when a driver is looking into oncoming headlights. By filtering the blue light, the visual performance maybe improved

Additional studies would be required to demonstrate direct functional benefit of BLF.