What Do We Need to Understand to Improve Contact Lens Comfort?

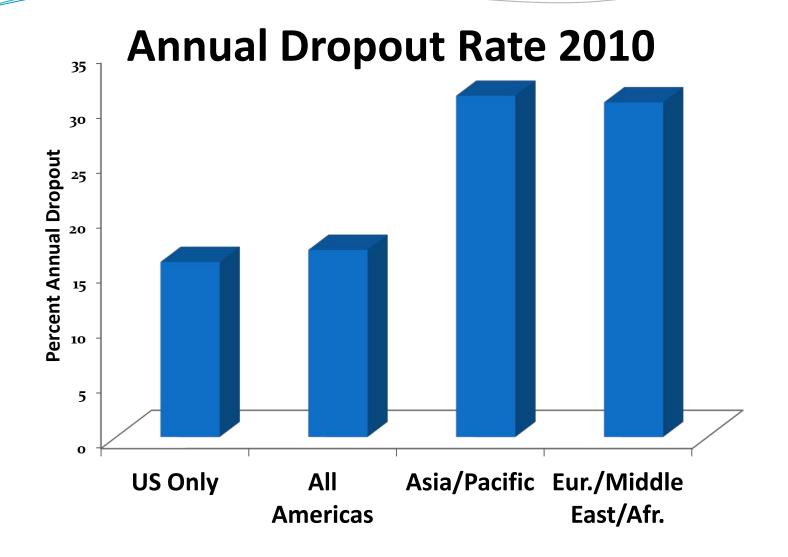
Ralph P. Stone, PhD R.P. Stone Consulting, Inc

Disclosure

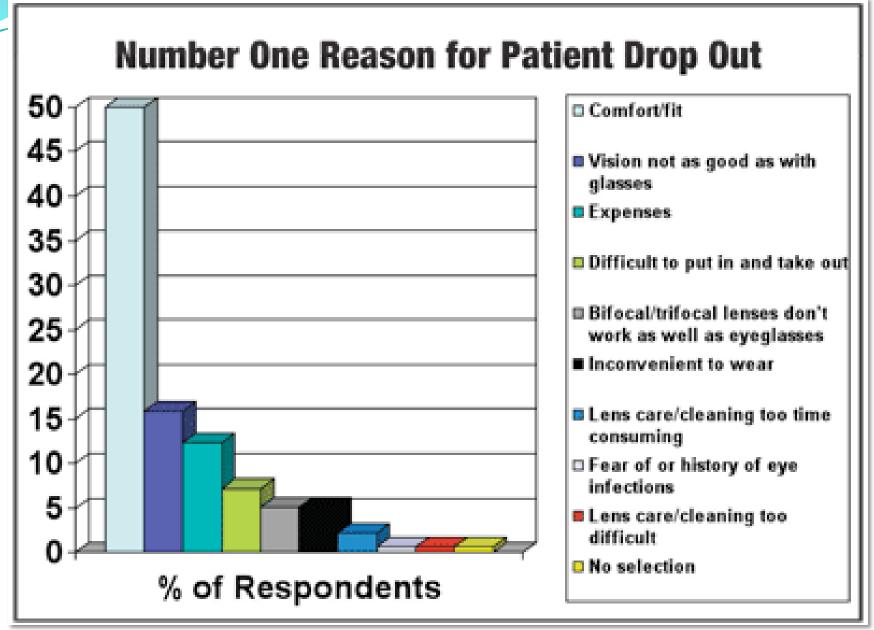
- Retired from Alcon Laboratories but have no stock or options from Alcon, or stock or options in Novartis.
- Consultant to Alcon Laboratories
- Consultant to NavaBay Pharmaceuticals
- Previously employed by Bausch and Lomb, Wesley-Jessen and Paco Pharmaceutical Services
- Hold Stock in Merck

What is our experience with comfort during Contact Lens wear?

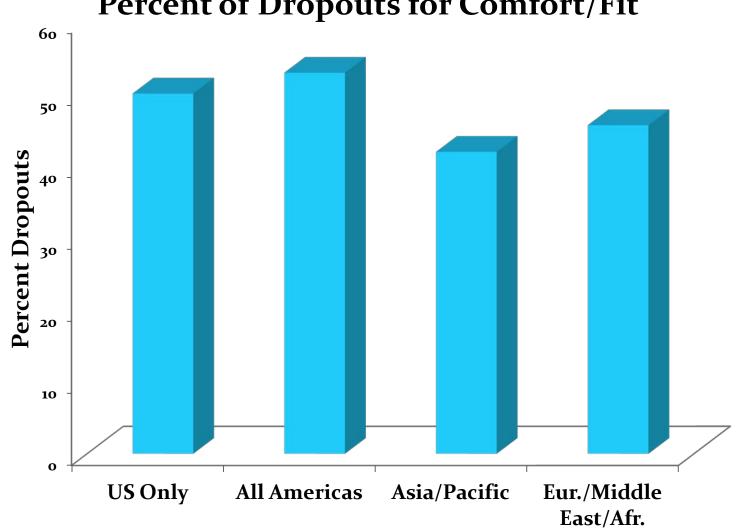
2010



Rumpakis JMB. New data on contact lens dropouts: an international perspective. Rev Optom. 2010 Jan;147(1):37-42.



Rumpakis JMB. New data on contact lens dropouts: an international perspective. Rev Optom. 2010 Jan;147(1):37-42.



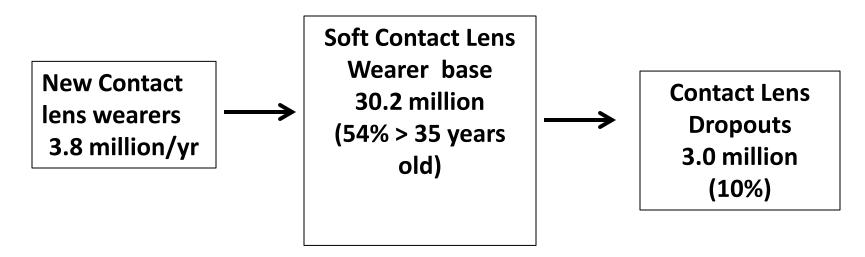
Percent of Dropouts for Comfort/Fit

Rumpakis JMB. New data on contact lens dropouts: an international perspective. Rev Optom. 2010 Jan;147(1):37-42.

What is our experience with comfort during Contact Lens wear?

2004

Estimated Rate of US Contact Lens Dropouts-2004



Growth of Contact Lens Wearers 2.7% (not counting refits)

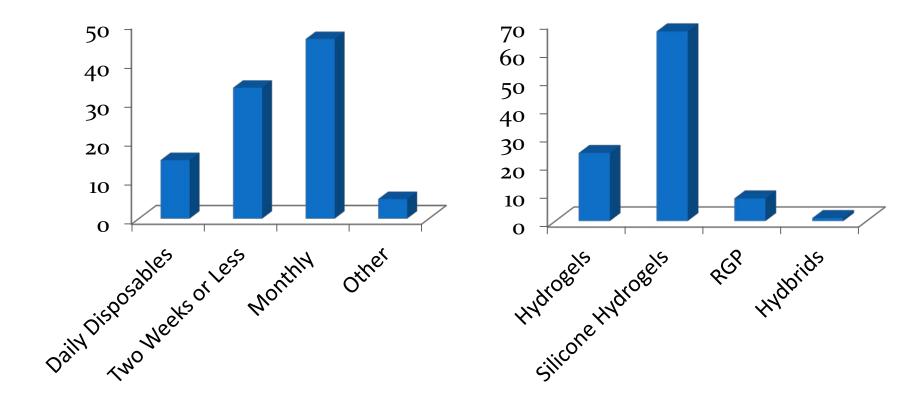
Who are our patients and what do they wear?

2011

2011 Distribution of Lenses and Wear Schedules

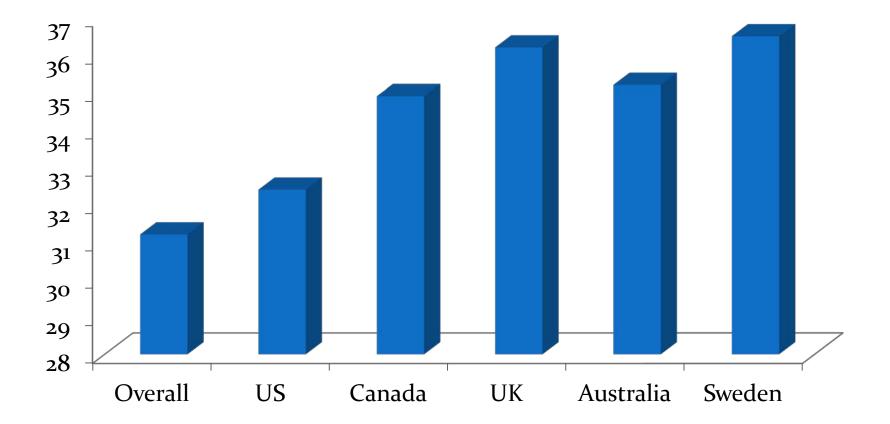
Percent of Wearers

Type of materials fitted



Nichols J, Contact Lenses 2011. Contact Lens Spectrum 1/20/2012; Article ID=106550

Average Age of Fits of Contact Lenses



What have been the approaches to improving comfort?

- Materials design and mechanical properties
- Contact Lens fit
- Cleaning
- Disposability
- Surface/Lens Treatments
- Care Systems

In order to design a product, there must be a way to measure the outcome of the design.

How have we been measuring comfort and are there better ways?

Comfort Scales

- Simple 0-5, 0-50, 0-100
- Anchored with intermediate points defined

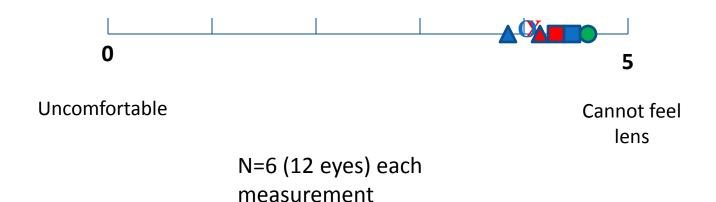
Simple Comfort Scales

Measured at instant in time





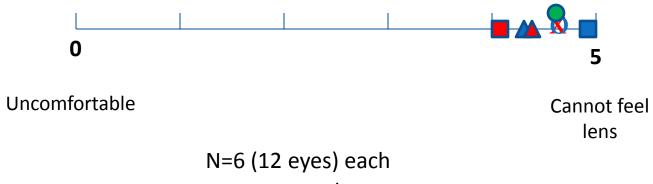
Measured at instant in time (I min)



Tranoudis I, Efron N. In Eye Performance of soft contact Lenses made from different materials. CL & Anterior Eye 2004; 27:133-148.



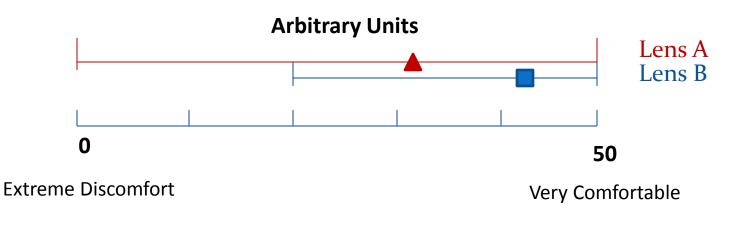
Measured at instant in time (6hrs)



measurement

Tranoudis I, Efron N. In Eye Performance of soft contact Lenses made from different materials. CL & Anterior Eye 2004; 27:133-148.

Simple Comfort Scales

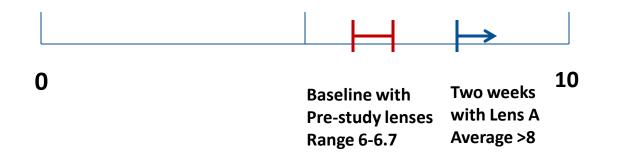


N=6 (12 eyes)

Morgan PB, Efron N, et al. Hydrogel Contact Lens Dehydration in Controlled Environmental Conditions . Eye& CL 2004; 30(2): 99-102.

Clinical Data for Lens A

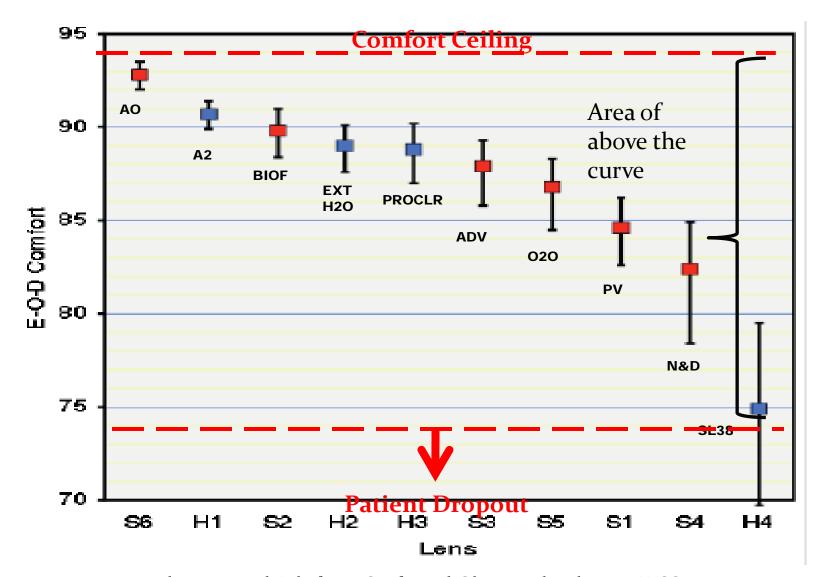
N=50 patients, 2weeks of wear



- At baseline 32% found lenses comfortable at the end of the day.
- After 2 weeks with lens A, 91.5% found the lens to be comfortable

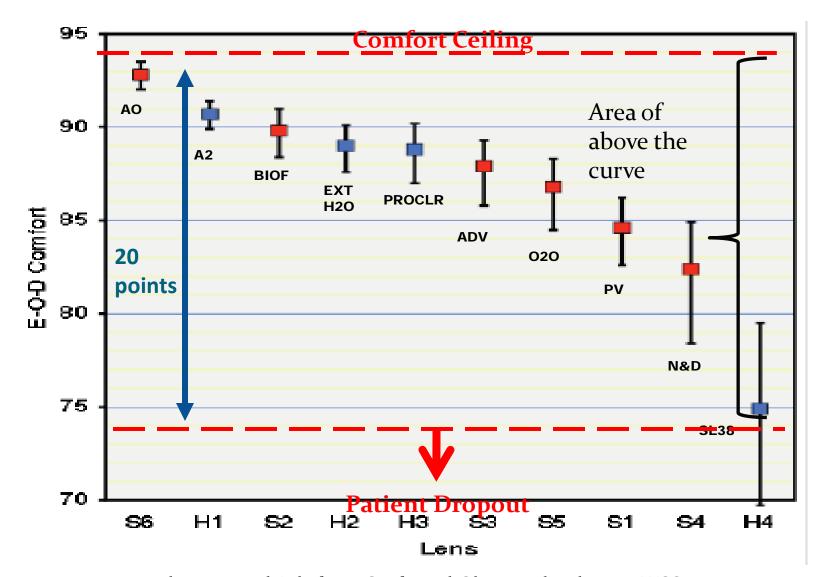
Hall B, Can a Dry Eye Test Predict Soft Contact Lens Use? Contact Lens Spectrum August 2002

Interpreting Comfort Data from Contact Lens Wearers



Brennan et al, Dryness and End-of –Day Comfort with Silicone Hydrogel Lenses; TFOS 2007

Interpreting Comfort Data from Contact Lens Wearers



Brennan et al, Dryness and End-of –Day Comfort with Silicone Hydrogel Lenses; TFOS 2007

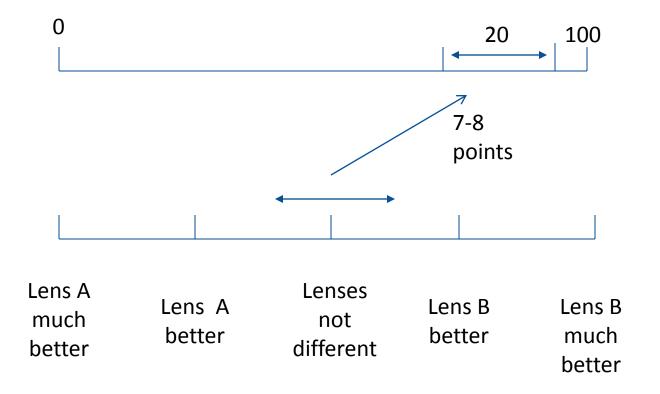
What is the minimum difference we can detect with these scales?

0 100

What is the minimum difference we can detect with these scales?

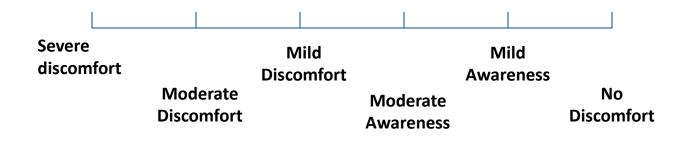


What is the minimum difference we can detect with these scales?



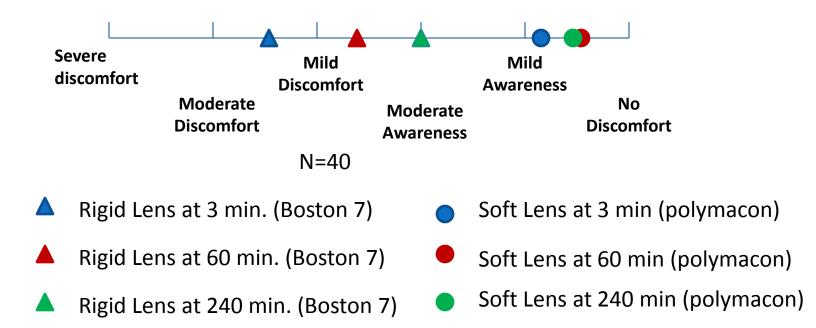
Papas EB, Keay L, Golebiowski B. Estimating a Just-Noticeable Difference for Ocular Comfort in Contact Lens Wearers. IOVS 2011; 52(7): 4390-4394

Anchored Comfort Scales



Dumbleton K, Simpson T, Sorbara L, et al. Ocular Comfort Measurements of Neophyte Contact Lens Wearers. IOVS 1996; 37(3):S72

Anchored Comfort Scales



Dumbleton K, Simpson T, Sorbara L, et al. Ocular Comfort Measurements of Neophyte Contact Lens Wearers. IOVS 1996; 37(3):S72

How have we been measuring comfort and are there better ways?

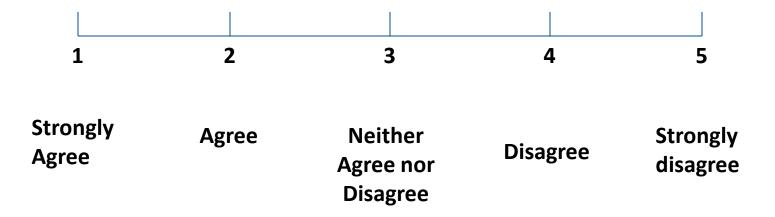
Comfort Scales

- Simple 0-5, 0-50, 0-100
- Anchored with intermediate points defined
- Multiple Scales
 - Scales to measure a variety of comfort Attributes

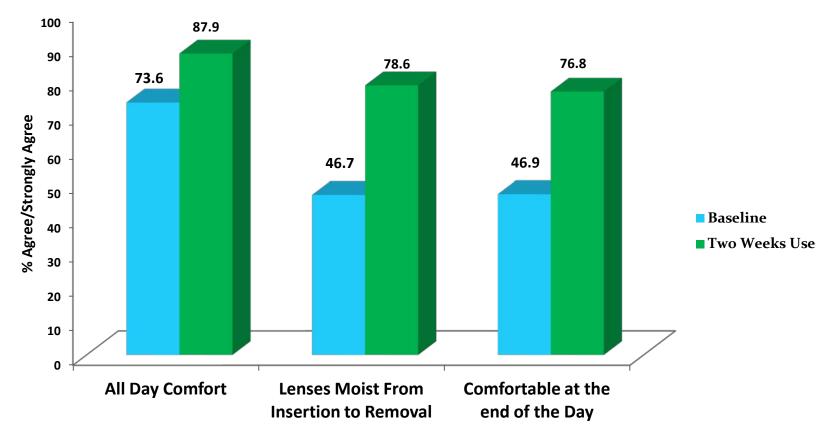
Use of Likert Scales

- Measures of responses to specific statements.
- Able to discriminate specific responses.
- Used to understand comfort and other lens wear responses over time.
- Examples
 - "My lenses feel comfortable all day."
 - "My lenses are moist feel moist from Insertion to Removal."
 - "My lenses are comfortable at the end of the day."
 - My lenses feel fresh
 - 1. Likert R, A Technique for the Measurement of Attitudes. Archives of Psychology 1932; 140: 1-55
 - 2. Garofalo R. Lemp J. Clinical Trial Experience with Opti-Free PureMoist MPDS. Contact Lens Spectrum Sept 2011;

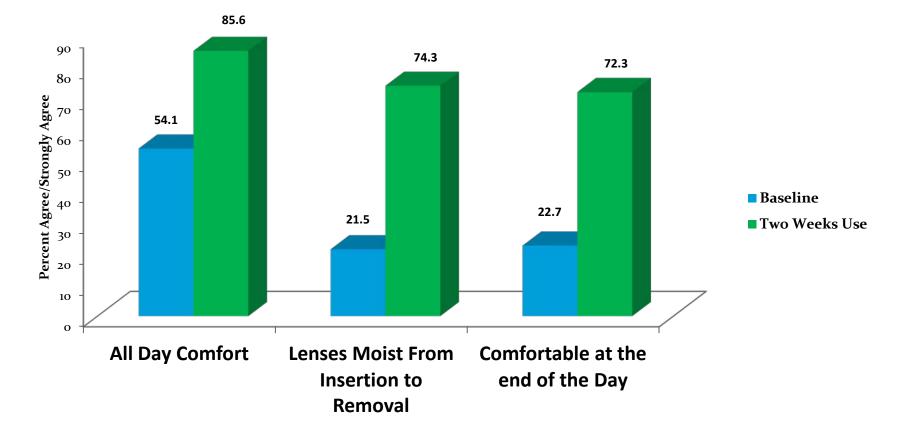
Likert Measurement Scale



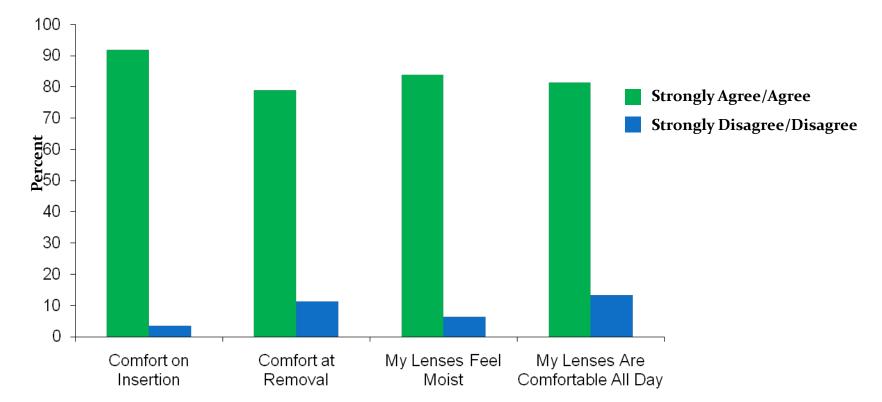
All Patients Uncontrolled Product Use N= 9,412



Symptomatic Uncontrolled Product Use N= 4,611

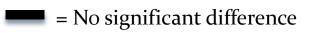


Asymptomatic SiHy Lens Wearers Comfort From Insertion To Removal



At the end of a 90 day clinical study when using test product Patients undecided are not included and data may not equal 100% Lenses replaced on manufacturer's recommended schedules

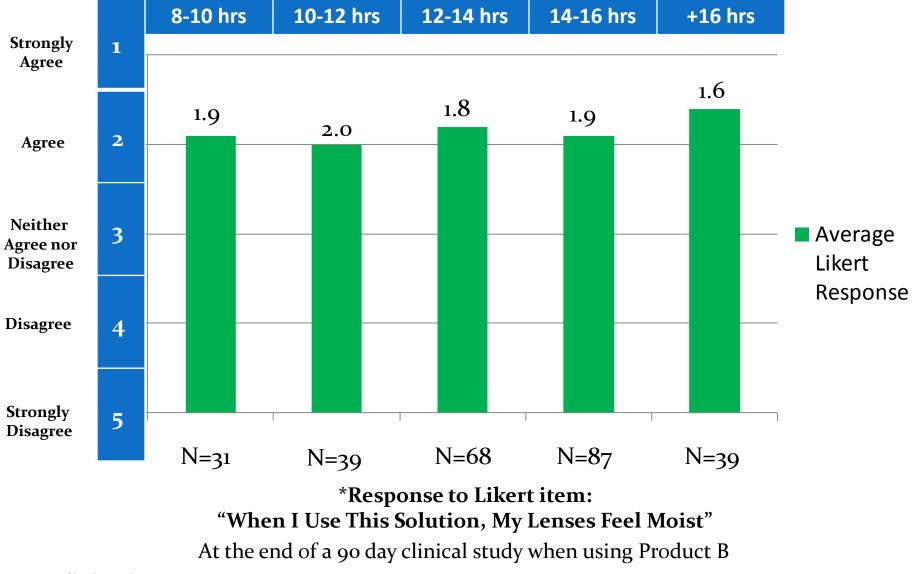
	Acumptomotio	Cumptomotio	Acumptomotio
	Asymptomatic	Symptomatic	Asymptomatic
Statement	Product A v.	Product A v.	Product B v.
	Control*	Control*	Control*
	2003	2004	2010
	N=352	N=362	N= 573
Enhances lens comfort/ comfortably wear lenses	_	+	+
Comfortable end of day /all day/long lasting		+	+
Feel moist		+	÷
Gentle on eyes	+	+	+
Vision clear end of day		+	+
Insertion comfort			+
Removal comfort			+
Feel fresh			+
Like handling			+



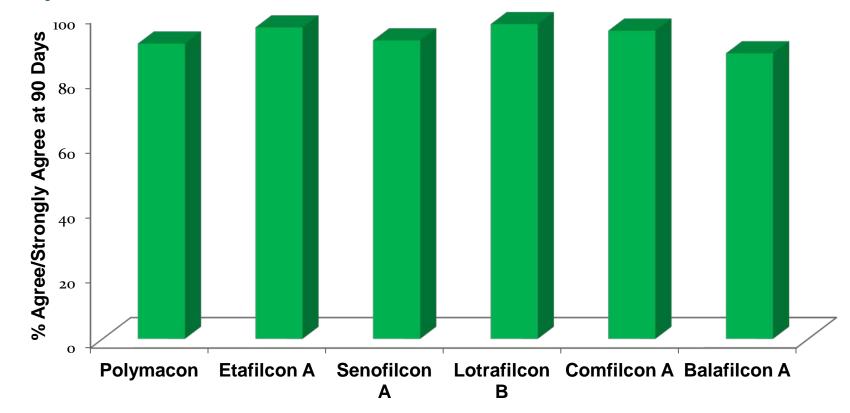


*Same control in all 3 studies

Lenses Feel Moist*



Agreement by lens to Likert Statement: "I can Comfortably wear my lenses." after 90 days



Leach NE, Paul M, Campbell R, et al. A New Multipurpose Disinfecting Solution Optimized for Silicone Hydrogel Lens Wearers, Posters AAO 2011

With better measurement systems and technologies, we are making progress providing better lens comfort.

