

# Ophthalmic Devices Panel meeting

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# Outline of talk

- Effects of Contact Lens Disinfecting Solutions on the Cornea
  - Solution Induced Corneal Staining (SICS)
  - Corneal Inflammatory Events and SICS
- Rub vs No Rub Efficacy
- Recommendations



# The IER Matrix Study

- Series of daily wear trials examining the performance of contact lenses and disinfecting solutions
  - 7 lens types tested to date
    - Mostly silicone hydrogels
    - Acuvue 2
  - 6 solution types tested to date
    - Multipurpose solutions including
      - 1 step Hydrogen peroxide
      - PHMB
      - polyquad/Aldox
- Approximately 40 patients in each lens/solution combination
  - 3 months duration
    - Visits at 2W, 1M, 3M
  - Lenses replaced 2W or monthly



# Rate of SICS in the IER Matrix Study

Lens/solution	CLEAR CARE® - H <sub>2</sub> O <sub>2</sub>	AQuify® MPS - PHMB	OPTI-FREE Express® - polyquad/Aldox	OPTI-FREE RepleniSH® - polyquad/Aldox
ACUVUE® ADVANCE™	0.0%	0.9%	0.0%	0.0%
ACUVUE® OASYS™	0.9%	2.5%	6.2%	7.1%
O <sub>2</sub> OPTIX™	0.5%	3.2%	5.9%	6.7%
Purevision®	0.9%	23.2%	11.3%	14.2%
NIGHT & DAY™	1.7%	0.9%	7.2%	6.7%

Carnt *et al.*, Contact Lens Spectrum, 2007 and [www.ier.org.au](http://www.ier.org.au) (also under peer review)  
 Coloring represents lower, inner two, and upper quartiles of overall rate = 4.7%

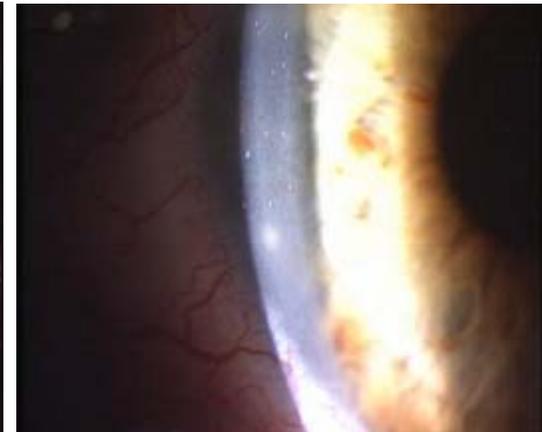
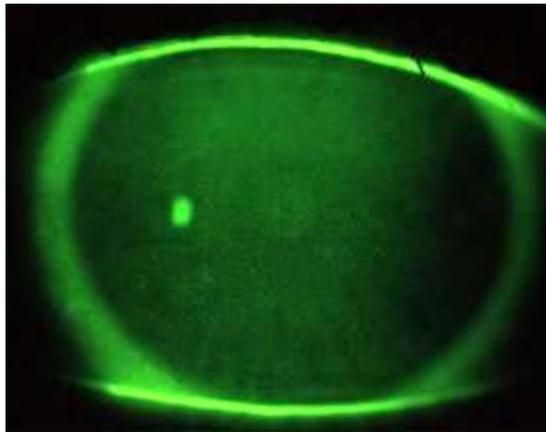
# The IER staining grid

- Two hour exposure to silicone hydrogel lens/solution combinations does not always predict three-month clinical findings
- A relatively poorer performance of e.g. OPTI-FREE Express with Acuvue Oasys, and PureVision lenses compared with two hours of wear.



# Toxic Staining is associated with corneal inflammation

Type of CIE	Toxic Staining Group	Unaffected Control Group	p-Value	Odds Ratio	95% CI
Any Infiltrate	6.7% (9/134)	2.3% (24/1049)	0.008	3.08	1.4 - 6.8
Asymptomatic	6% (8/133)	1.2% (12/1037)	0.001	5.47	2.2 - 13.6
Symptomatic	0.8% (1/126)	1.3% (13/1338)	1.00	0.63	0.08 - 4.9



Carnt *et al.*, *Optometry & Vision Science*. 84:309-15, 2007



# 3M data versus earlier times

Visit	Type of CIE	SICS Group	Unaffected Control Group	p-Value	Odds Ratio	95% CI
3M	Asymptomatic	11.4% (5/44)	4.4% (33/745)	<b>0.042</b>	2.8	1.0 – 7.4
1M	Asymptomatic	7.3% (4/55)	4.6% (34/734)	0.380	1.6	0.6 – 4.7
2W	Asymptomatic	9.3% (4/43)	4.6% (34/746)	0.166	2.1	0.7 – 6.3

- At least 3M wear needed to demonstrate association between SICS and asymptomatic corneal infiltrative events



# Risk factors associated with corneal inflammation in DW

- Multivariate Logistic Regression
- Pre-event factors

<i>Factor</i>	<i>Referent (1.0)</i>	<i>Odds Ratio</i>	<i>p value</i>	<i>95% CI</i>	
				<i>Lower</i>	<i>Upper</i>
Use of multipurpose solution (MPS)	Hydrogen Peroxide	10.3	0.025	1.3	79.1

- Multivariate Logistic Regression
- **After removal of eyes with SICS**

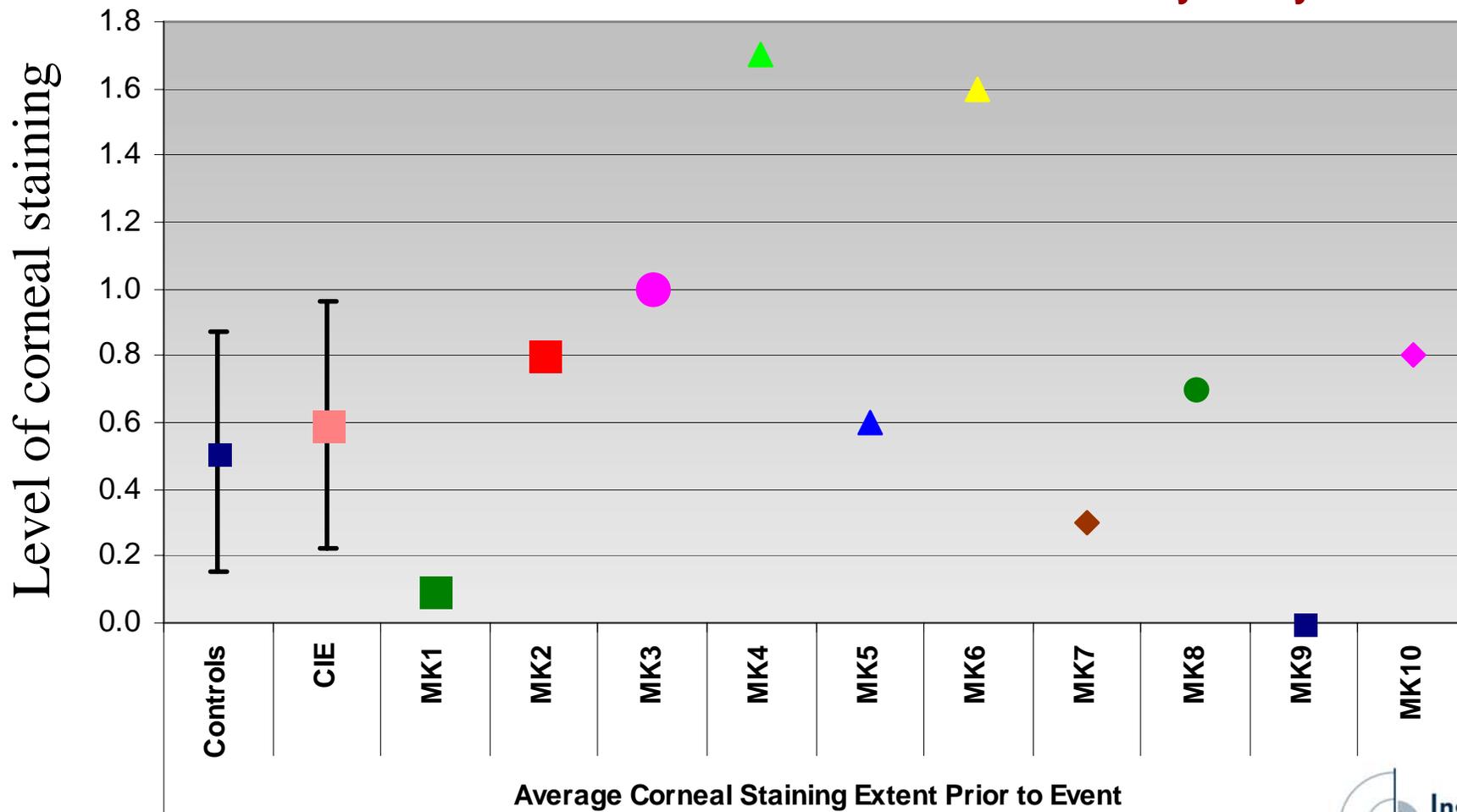
<i>Factor</i>	<i>Referent (1.0)</i>	<i>Odds Ratio</i>	<i>p value</i>	<i>95% CI</i>	
				<i>Lower</i>	<i>Upper</i>
Use of multipurpose solution (MPS)	Hydrogen Peroxide	10.2	0.028	1.3	81.5

Carnt *et al.*, ARVO, 2007



# Corneal staining is not associated with MK

Sydney and India



Sweeney *et al.*, BCLA, 2008



# Rub/Rinse vs “No Rub”

- 2 different MPS
  - OPTI-FREE RepleniSH®
  - ReNu MultiPlus ®
- “Panel” microorganisms
- 5 second rinse
- 5 second rub



# MultiPlus

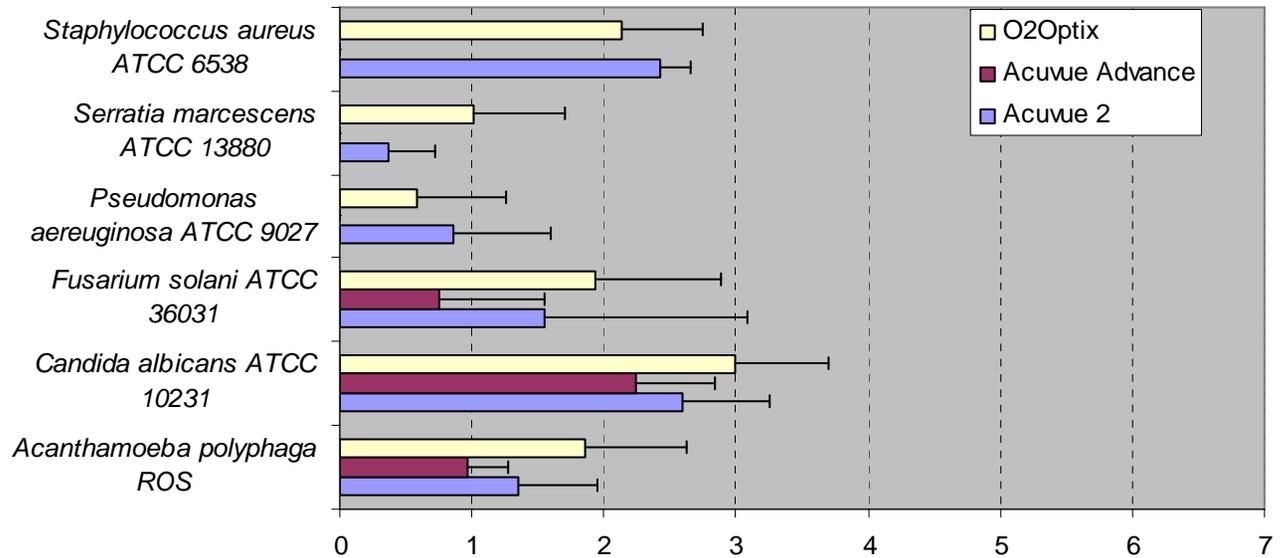
Rinse only

VS

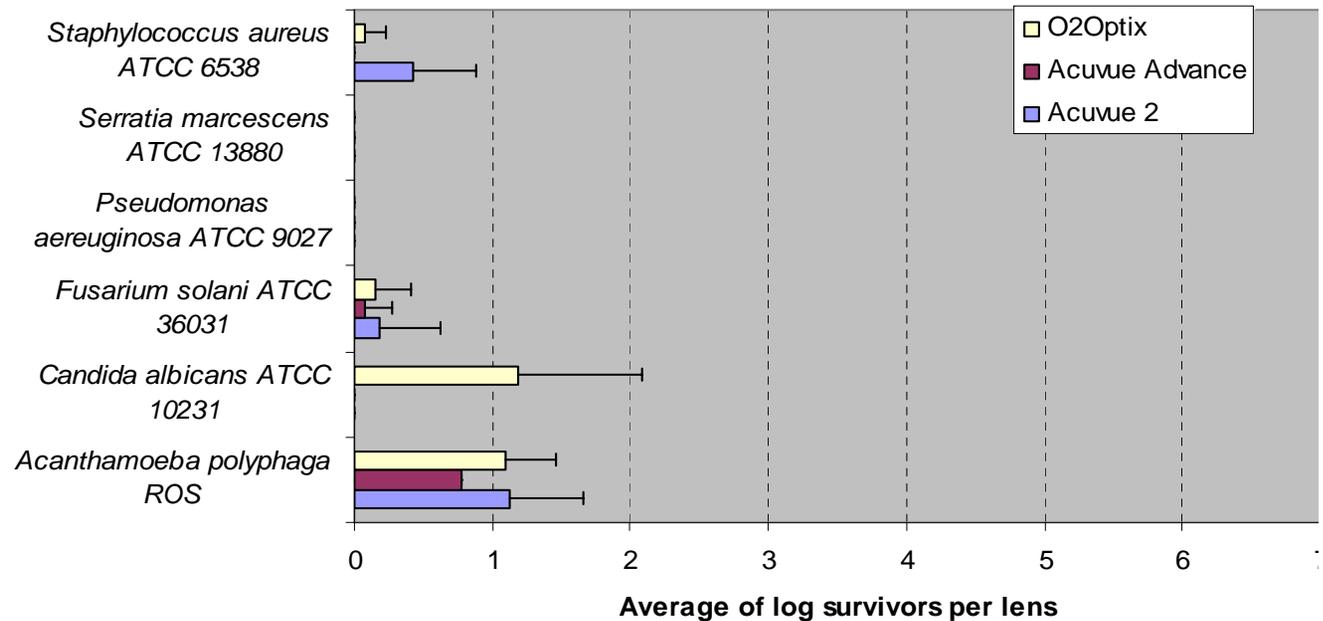
Rub and

Rinse

ReNu MultiPlus (Rinse Only)



ReNu MultiPlus (Rub/Rinse)



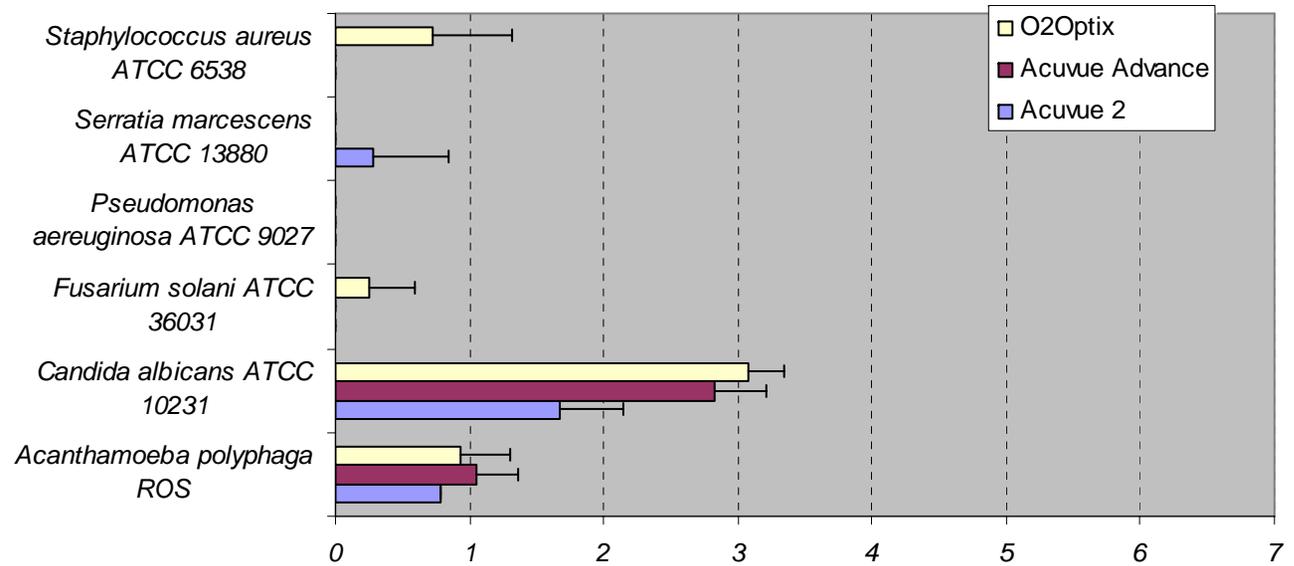
# RepleniSH

Rinse only

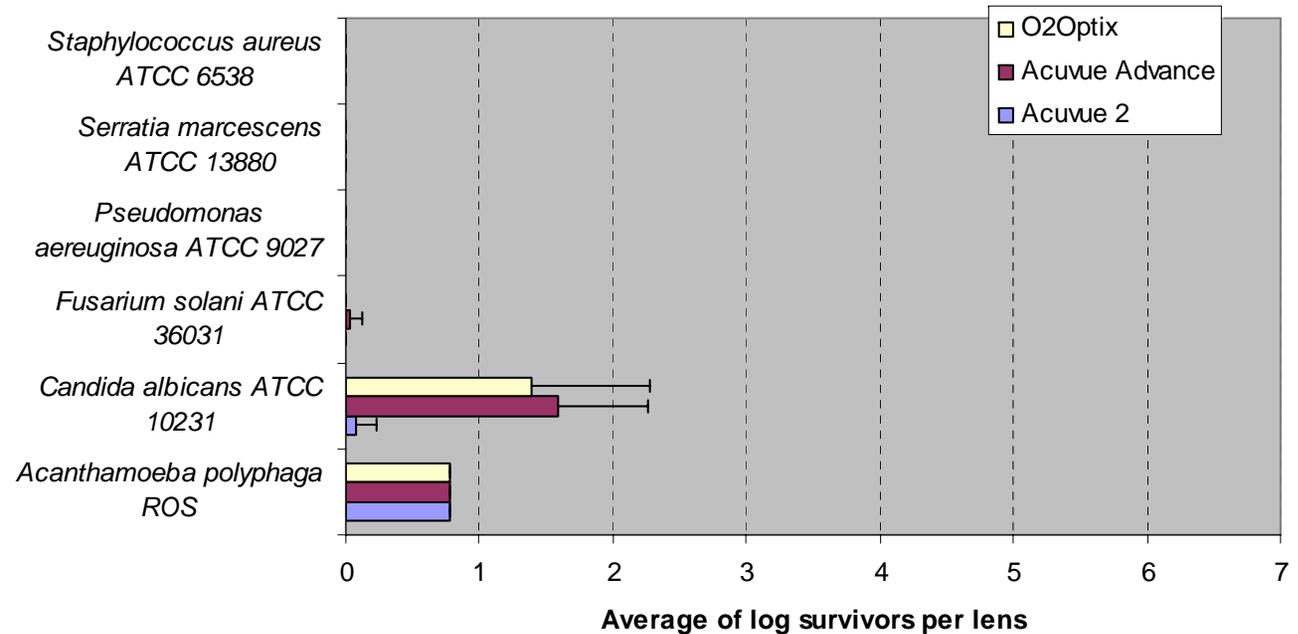
vs

Rub and Rinse

### Opti-Free Replenish (Rinse Only)



### Opti-Free Replenish (Rub/Rinse)



# Recommendations

- SICS is associated with Asymptomatic Infiltrates in Cornea but association is probably not causative
  - reliance on SICS as measure of inflammation is questionable and clinical consequences of SICS are not known
- Rub/Rinse combination much superior to No Rub and should be recommended to wearers

