
Contact Lens Disinfection Systems: Recommendations for Pre-clinical Testing and Development

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Representations

- American Academy of Ophthalmology
- American Society of Cataract and Refractive Surgery
- Contact Lens Association of Ophthalmologists
- The Cornea Society



CLAO



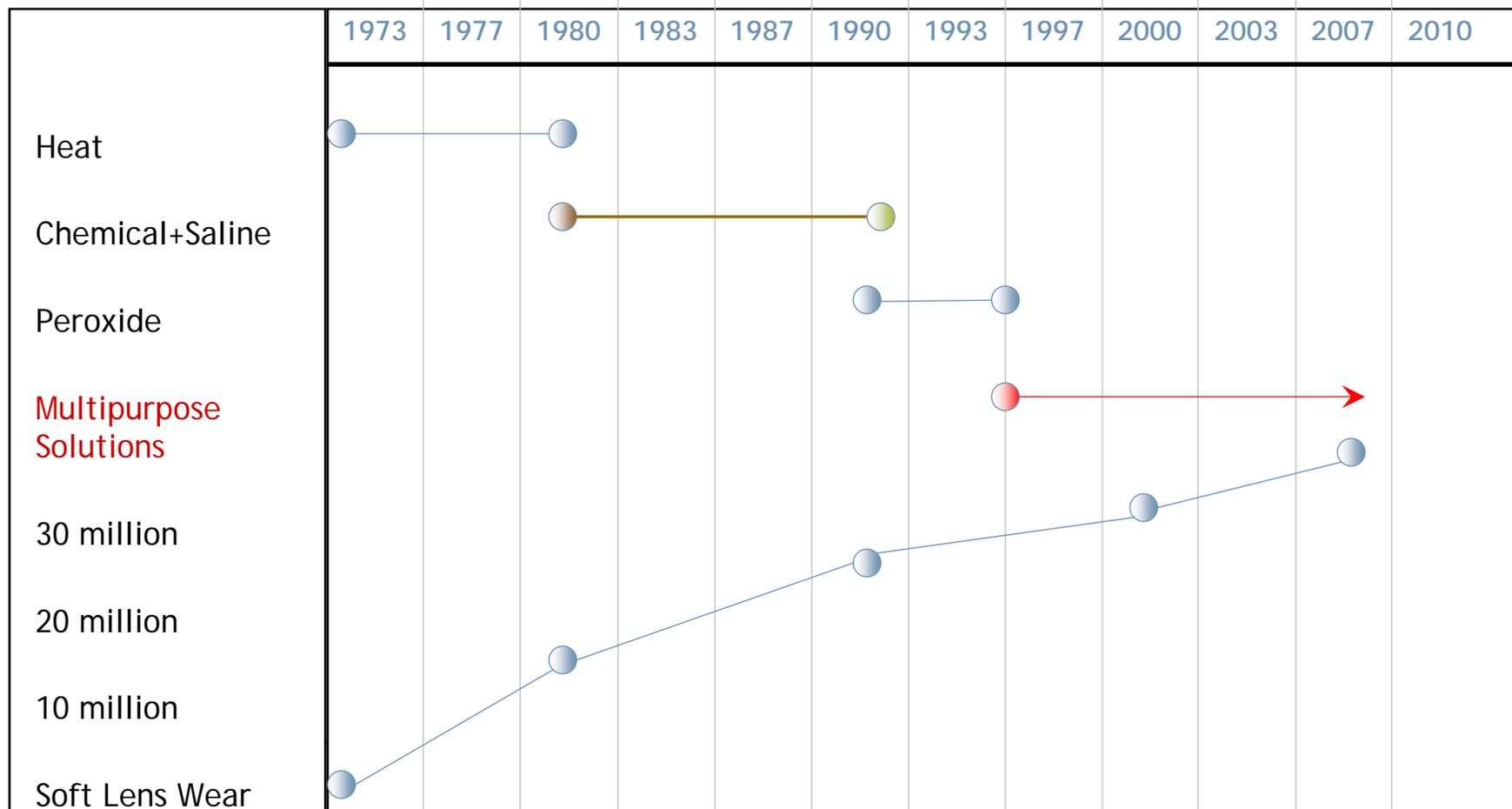
Disclosures

- I have received honoraria and travel expenses from Allergan and Alcon for educational activities unrelated to my testimony today.
 - My related research has been funded by private non-profit groups as well as federal grants.
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Introduction

- Experts agree that estimated rates of microbial keratitis have not substantially declined despite the evolution of contact lens disinfection systems.
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US Contact Lens Wear and Dominant Solution Systems



Microbial Keratitis in CL Wearers 1989-1999

- Incidence varies by contact lens type
 - GPHCL 1 in 10,000
 - Daily Wear SCL 3-4 in 10,000
 - Extended Wear 10-20 in 10,000
- Morbidity
 - 0.3-3.6 in 10,000 > 2 line loss of BCVA

Poggio EC, Glynn RJ, Schein OD, et al. The incidence of ulcerative keratitis among users of daily-wear and extended-wear soft contact lenses. *N Engl J Med* 1989;321(12):779-83.

Cheng KH, Leung SL, Hoekman HW, et al. Incidence of contact-lens-associated microbial keratitis and its related morbidity. *Lancet* 1999;354(9174):181-5.

Introduction

- Research shows that the disinfection regimen is but one element of the risk of infection.
 - Extended wear of lenses
 - Reduced tear exchange under the lens with current designs
 - Environmental factors
 - Poor consumer hygiene
 - Additional research is required into all of the factors involved.
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Currently Approved Contact Lens Disinfection Systems

- **Discard date on lens care products (in addition to expiration dates)**
 - Disinfection efficacy
 - Secondary Contamination
 - **Extended storage**
 - **The FDA should encourage industry to conduct additional research to verify the duration for safe extended storage of lenses.**
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Currently Approved Contact Lens Disinfection Systems

- Labeling contact lens solutions for use with specific lens types
 - Although corneal staining with certain combinations of disinfection products and specific types of contact lens types has been reported, available evidence is very preliminary. Furthermore, it has not yet been demonstrated what the long term consequences are, if any, for ocular surface health or the risk of microbial keratitis.
 - **Additional information should be gathered regarding biocompatibility of solutions and lenses. This is particularly important as new materials and lenses are developed and introduced.**
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Contact Lens-Related Outbreaks of 2006 and 2007

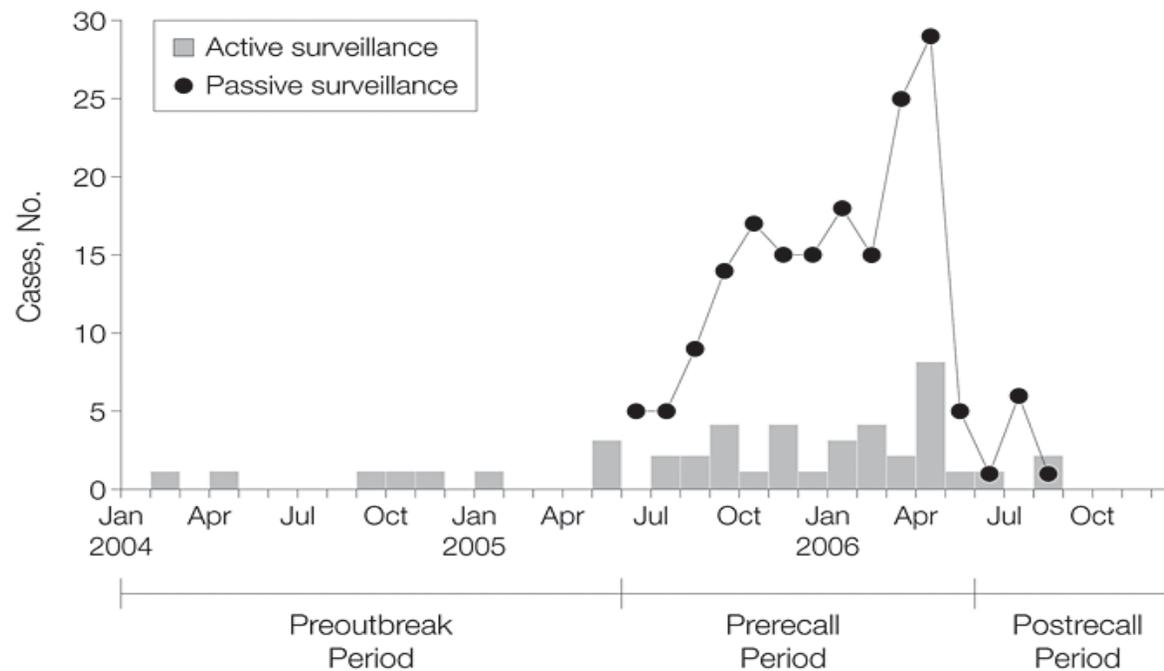
- **Fusarium Keratitis**
- **Acanthamoeba Keratitis**



Fusarium keratitis 2005-2006

- Multiple reports of contact lens related infection worldwide
- Singapore
 - 93.9% reported Renu solution use
 - 42/66 reported Renu with MoistureLoc
- Hong Kong
- CDC Case Control Study
 - Renu with MoistureLoc
 - OR 13.3 (CI:95% 3.1-119.5)
 - No other solution associations

Confirmed and Presumed Fusarium Keratitis Cases From January 2004 Through December 2006



Grant, G. B. et al. JAMA 2007;298:2867-2868.

Fusarium Keratitis Outbreak 2005-2006

- Renu with Moistureloc
 - Performed well in required pre-clinical testing
 - Fusarium test organism
 - Highly effective with optimal use
 - Additives + “Real world” use
 - May have encouraged growth
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Consensus Recommendations

- Pre-clinical testing should include more rigorous and standardized “real-world” scenarios that more accurately replicate the conditions and environment that contact lens products will be exposed to when used by consumers.
 - Effectiveness while in a contact lens case
 - Effectiveness when exposure time (amount of time the lenses are in the case) is less than recommended
 - Effectiveness when the solution evaporates
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Consensus Recommendations

- Given the complexity of the interaction of contact lens disinfectants, additives and the environment within which they are expected to work, each change in product formulation however minor should be subject to similarly rigorous regimens.
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Acanthamoeba Keratitis

- One of the most painful and debilitating corneal infections
 - 15-20% may require corneal transplantation during their course.
 - Patients may potentially lose their eye as a consequence of the infection
 - Strongly associated with contact lens wear
 - >90% if cases are found in contact lens wearers
 - Previous estimate of US incidence
 - OMIG and CDC
 - Schaumberg et al.
 - 1.49-2.01 cases per million contact lens wearers per year
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Current AK Outbreak

- University of Illinois Eye and Ear Infirmary
 - 55% reported EXCLUSIVE use of AMO products vs. 9% of controls
 - Odds Ratio 16.7 (95% CI 2.11-162.6)
 - Hygiene
 - Solution reuse
 - Infrequent rubbing of lenses
 - Showering with lenses

Joslin CE, Tu EY, et al. AJO 2007 144(2): 169-180.

- CDC Study
 - >54% reported primary use of AMO Complete MoisturePlus vs. ~10% market share
 - Significant association of AK with AMO use

Acanthamoeba Keratitis

- AMO Complete MoisturePlus
 - Use in only ~50% of patients in both studies
 - ~50% reported no use of AMO products
 - Chicago – 5 x greater number of cases than was estimated in the 1980's.
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Acanthamoeba

- Underlying factors are not yet fully known
 - Contact lenses
 - Materials
 - Hygiene/Care
 - Environmental factors
 - Acanthamoeba may represent an ongoing challenge for contact lens disinfection systems and pose a continuing risk for consumers
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Consensus Recommendations

- Testing requirements should be updated to ensure products are effective against a more diverse and representative set of infectious organisms, including *Acanthamoeba*. At the same time, tests currently required should be continued because of their historic use and for comparison purposes.
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Consensus Recommendations

- Pre-clinical testing of efficacy against organisms is complex and challenging. The testing protocol should be standardized and validated by the FDA to ensure all products are meeting current and, hopefully, future microbial challenges.
 - This should include a spectrum of clinical ocular isolates selected for their virulence and maintained in such a way as to maintain a wild type capacity for disease.
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Consensus Recommendations

- Expanded and strengthened testing of contact lens solutions does not guarantee that the next outbreak of eye infections will be able to be prevented or predicted. However, it will increase overall safety for contact lens wearers especially against those organisms most commonly responsible for contact lens-related infection.
 - Some mechanism for monitoring contact lens infections and the frequency and distribution of the organisms causing those infections could prove beneficial in both validating pre-clinical testing regimens as well as protecting the public from eye infections.
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Thank you for your attention.



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