

This is the first of two CET articles on contact lens care and will look at the current thinking and likely improvements that could be made to the regulation and testing of contact lens solutions. Part 2 will look at the latest product developments, solution ingredients and formulations.

A delicate balance exists between the contact lens, its care system, the health of the ocular surface and the comfort of our patients in contact lens wear. As the current decade closes, it is interesting to reflect on developments in lens care over the past 10 years. During this period we have seen much change including:

- The introduction of new disinfectants
- Two global product withdrawals in as many years
- The observation and description of, as well as controversial and conflicting research into, solution-induced corneal staining (SICS)
- The introduction and subsequent abandonment of 'no rub' labelling by manufacturers
- New recommendations for solution testing and regulation.

Around the turn of the millennium many 'experts' predicted the rapid demise of the lens care industry as contact lens companies tracked a parallel path towards single-use lenses for either daily or extended/continuous wear. So it is interesting to reflect that, as the decade closes, lens care is still very much on the contact lens industry's agenda. Currently 55 per cent of new soft lens fits (67 per cent of refits) are still with reusable lenses¹ and at the time of writing there are also two new solution introductions from global companies.

When it comes to the importance of lens care, the author agrees with this statement made in a presentation by the American Optometric Association (AOA) in its 2008 presentation to the US Food and Drug Administration (FDA): 'It has become apparent that contact lens care products are as important as the lenses we prescribe.'²

However, with generally happy patients using such a variety of apparently similar products, and the recalls coming as a result of problems elsewhere in the world and not affecting the UK, it is perhaps understandable that many practitioners still seem blasé about lens care and pay little attention to formulation differences. Consequently these articles are designed to help

Contact lens care

Part 1 - Current thinking

Nick Atkins offers an update on contact lens care and the latest developments. C15419, one specialist point for CLOs, one general point for optometrists and dispensing opticians



Figure 1
ReNu with
MoistureLoc

practitioners to reconsider the priority they place on their lens care selection, as well as to provide information to help understand the challenges the profession and regulator face and the limitations of the current and any future standards.

Efficacy versus toxicity

All the contact lens care products ever developed and commercialised have been formulated to achieve a balance between efficacy and toxicity; in that the solution must kill harmful ocular pathogens and yet not irritate or damage the delicate tissues of the ocular surface. The ideal solution can be said to require the following key features:

- Kills all ocular pathogens
- Is non-toxic to the ocular surface
- Simple to use
- Effectively removes deposits
- Affordable.

While other benefits such as additives to improve lens comfort, may be desirable, these are the core attributes required.

Global product withdrawals

In May 2006, less than two years after its launch, ReNu with MoistureLoc

(Figure 1) was voluntarily withdrawn globally by Bausch+Lomb due to its disproportionately high use among those affected by outbreaks of fungal keratitis, particularly in the Asia-Pacific region. *Fusarium solani*, the organism causing the infections, is currently a test panel organism which all the current disinfectants, including ReNu with MoistureLoc, are effective against (including ReNu retained samples after the outbreak) on a stand-alone basis (no rub and rinse) when tested under laboratory conditions compliant with the standard. Subsequent testing under laboratory conditions simulating some level of non-compliance, confirmed suspicions that a combination of formulation challenges in certain conditions, combined with non-compliance to basic lens care procedures, such as rubbing and rinsing and replacing the solution in the case daily, led to reduced biocidal efficacy.³

Within a year the subsequent reports of an increase in *Acanthamoeba* keratitis, this time in the US, resulted in the voluntary withdrawal of Complete MoisturePlus by AMO. The US Centers for Disease Control and Prevention found that of 46 patients interviewed who had developed *Acanthamoeba* infections since January 2005, 39 were soft contact lens wearers, 21 of whom reported using Complete MoisturePlus as their lens care product.

As a result of these two incidences, as well as the ongoing battle to reduce the incidence of microbial keratitis (MK) around the world, interested parties began reviewing the standards and making recommendations on how testing can be enhanced to improve the standards and reduce the incidence of solution-related complications.

Disinfection

Disinfection is one of the primary objectives of a contact lens soaking solution and since 1995, following a switch from Medicine Control Agency to Medicines and Healthcare products Regulatory Agency (MHRA) control, has been covered by ISO standards, with



a CE mark being placed on products meeting the standard in the European Union. With all commercialised solutions having achieved a CE mark it is perhaps understandable how practitioners might assume them to be equal, but while an important safety control, the only standards to which solutions must adhere are those for disinfection. All other aspects of performance must simply be supported by clinical data in the product technical file.

Antimicrobial activity

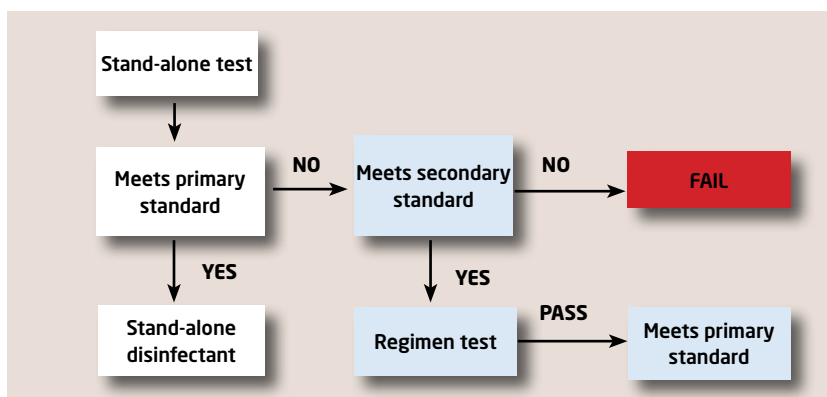
ISO/DIS 14729 is the standard for the antimicrobial efficacy of lens care products and Figure 2 shows how a solution can meet the standard either as a stand-alone disinfectant or as part of a regimen where a rub and rinse is required. The standard requires the solutions to demonstrate the required log reduction against three bacteria and two fungi. The primary standard for stand alone disinfection requires a 1 million organisms/ml challenge (6 log units) and the for the organisms to be killed to the levels shown below:

TABLE 1

The effect of the log reduction on the percentage of organisms killed

Logarithmic scale	Log reduction	% of microorganisms killed
$10^6 = 1,000,000$		
$10^5 = 100,000$	1	90% (ISO standard for fungi)
$10^4 = 10,000$	2	99%
$10^3 = 1,000$	3	99.9% (ISO standard for bacteria)
$10^2 = 100$	4	99.99%
$10^1 = 10$	5	99.999%

Figure 2 ISO standards ISO/DIS 14729



Bacteria

- 99.9 per cent (3 log) reduction in stated soaking time
 - *Staphylococcus aureus*
 - *Pseudomonas aeruginosa*
 - *Serratia marcescens*.

Fungi

- 90 per cent (1 log) reduction in stated soaking time
 - *Candida albicans*
 - *Fusarium solani*.

Table 1 shows the effect of the log reduction on the percentage of organisms killed.

Current thinking on how standards can be improved

Calls have been made from all sides of the industry, and on an international basis, for the testing of solutions using more resistant standardised challenge organisms under more realistic conditions. Currently the use of standardised isolates such as the European Pharmacopeia test panel, used for CE marking, and the American Type Culture Collection, required for FDA approval, is limited and needs to be updated as the strains have become overused and as new ones begin to prevail.

Based on climate and resistance, the common may become less common. In fact, *Serratia* is becoming a more prevalent pathogen for contact lens-induced microbial keratitis in



Figure 3 Prevalent pathogens in MK are changing

Australia (Figure 3). *Acanthamoeba* is difficult to kill in the cyst form and there are many variations in how these organisms are cultured.

Organic soil and/or biofilm

The creation of a biofilm on the lens case and bottles contributes to contamination, increased virulence, and reduced bioavailability of the biocidal agent. The soil and/or biofilm can be organic but also, as has been seen with some recalled solutions, additional ingredients added to enhance lens comfort might have contributed to proliferation of microorganisms as they acted as a source of nutrition. In the future the biocidal activity could be tested utilising *in-vitro* organic soil to better simulate those conditions in which microorganisms have a potential food source.

Interaction with the contact lens and lens case materials

Recent studies by industry and practitioner experience have shown that undesired effects from poor lens/solution combinations can occur just as medications can have poor drug interactions.

It has become apparent that the materials to which the solution will be exposed – the actual lens and case – are another area of concern (Figure 4). One area that is currently being investigated is the amount of solution that is being absorbed by the contact lens or case, thereby reducing the availability of the biocide.

Anti-Acanthamoeba activity

Acanthamoeba keratitis (AK) may be uncommon, but given that more than 90 per cent of AK infections are in contact lens wearers, to our patient population it is significant. It is interesting to observe that the apparent obsession with performance against *Acanthamoeba* seen in the 1990s has become more balanced in line with the low number of reported cases presenting with this debilitating infection.⁴

Equally interesting is that this also coincides with the increased usage of multipurpose solutions (MPS) with 89 per cent¹ of patients now prescribed a lens care modality that some quarters of the profession chastised for its lack



of *Acanthamoeba* activity.

In fact MPS do have an effect on *Acanthamoeba* counts, whether by simple physical removal or some level of disinfection. Additionally, it seems highly likely their multifunctional approach, in that they do not necessitate nor inadvertently encourage the use of tap water in the regimen, plays an important part in this reduction in infections.

There are currently no agreed test organisms or standards to which solutions must conform in their efficacy against *Acanthamoeba*. However, a workshop of leaders in this field have made early recommendations including the species/strains that should be tested, methods for culturing trophozoites and producing cysts, size of inoculum and an acceptable rate of kill.⁵

Until there is an approved standard being implemented, clinicians should take care in comparing claimed performance against amoeba and the continued use of a cleaning step would seem to be the best protection against contamination by this organism.



Figure 4 Lens cases are a significant source of infection

'No rub'

It is important to understand that the development of 'no rub' claims was a reflection of a solutions disinfection efficacy, not its cleaning ability. By demonstrating data supporting at least a 3-log unit and 1-log unit reduction in bacteria and fungi respectively, in the presence of organic soil (thus meeting

ISO/DIS 14729), a product can claim that adequate disinfection is achieved without the need to rub and rinse the lens. Products are tested under no-rub and no-rinse conditions to assure greater anti-microbial ability as it is known that some patients do not rub and rinse even when advised to do so.

However, there are additional benefits from rubbing including the removal of biofilms and deposits, especially with the increased usage of silicone hydrogel lenses.

FDA activity

While the FDA has no jurisdiction in the UK, it is interesting to observe recent activity in this product area in the highly regulated environment that is the world's largest contact lens market.

Along with other stakeholders, The American Optometric Association made a presentation to the FDA concerning improvements it would like to see in the testing and regulation of contact lens solutions. Its primary recommendations were supportive of testing products under more realistic conditions, testing under known situations of non-compliance and enhancing the labelling of care products.²

With respect to testing under known situations of intractable non-compliance, the lack of hand washing, dirty cases, the topping up/off of solutions, evaporation and the absence of a proper rub and rinse were noted as the key challenges. With regard to improved labelling, the AOA representatives felt that major non-compliance issues should be more prominently displayed on the bottle label. In particular:

- 'Wash hands before handling products and lenses'
- 'Do not top off solutions'
- 'Rub and rinse necessary' (Figure 5)
- Mandatory discard date (not currently a requirement in the US).

Discussion

Work has begun discussing the key changes that will ultimately be incorporated into a new ISO standard. However, as we have seen, this process will take some time and is retrospective. This will always mean that the current standards will never be able to legislate for the latest unforeseen threat.

Another challenge is what strain of a particular organism do we pick? A study published in *Journal of the American Medical Association*⁶ isolated 10 species of *Fusarium* in the US outbreak: this is still the dilemma for *Acanthamoeba* in becoming a test panel organism.

MULTIPLE-CHOICE QUESTIONS - take part at opticianonline.net

1 Which of the following statements is false? Over the past 10 years, we have seen...

- A The introduction of new disinfectants
- B The introduction and subsequent abandonment of 'No rub' labelling by manufacturers
- C New regulations for solution testing
- D The observation and description of solution-induced corneal staining (SICS)

2 Which of the following is NOT a core attribute required for a contact lens solution?

- A Toxic to ocular pathogens
- B Simple to use
- C Removes deposits
- D Enhances lens comfort

3 Lens care products in the UK need to meet the standards of which of the following organisations?

- A EU standards for CE marking
- B FDA
- C ISO
- D MHRA

4 Contact lens solutions need to show efficacy against

- A A test panel of three fungi and two bacteria
- B *Acanthamoeba*
- C A test panel of three bacteria and two fungi
- D Clinical isolates of three bacteria and two fungi

5 Which of the following statements is true about 'No rub' solutions?

- A No rub claims were supported by manufacturers' cleaning data
- B No rub claims were supported by manufacturers' disinfecting data
- C No rub solutions protect patients non-compliant with lens cleaning
- D No rub decreases the development of biofilm

6 *Acanthamoeba* keratitis appears to be in decline in the UK...

- A Because MPS reduce the need for tap water use in the regimen
- B Despite MPS displaying varying efficacy against disinfection of *Acanthamoeba*
- C Because *Acanthamoeba* is removed by the rub and rinsing step
- D All of the above

Successful participation in this module counts as one credit towards the GOC CET scheme administered by Vantage and one towards the Association of Optometrists Ireland's scheme.

The deadline for responses is February 3 2011





Rub and rinse is necessary, says the AOA

Conclusion

The past few years should act as a reminder to the profession and patients that contact lenses and the solutions we use are medical devices with benefits and consequences. Both groups trust that those solutions and lenses are thoroughly tested before becoming available for use and that there are regulations controlling their safety for sale. It is important that practitioners understand the limitations of current testing and regulations, as well as the importance of correct lens care selection and use, in order to maximise the success of their patients. ●

References

- 1 Morgan PB, Efron N. Trends in UK contact lens prescribing 2010. *Optician* 2010;239:6255 34-35.
- 2 Scalfani L, Benjamin W. Presentation to the FDA Advisory Panel on contact lens solutions.
- 3 Seal DV. *Acanthamoeba* keratitis update - incidence, molecular epidemiology and new drugs for treatment. *Eye*, 2003;17:893-905.
- 4 Levy B, Heiler D and Norton S. Report on testing from an investigation of *Fusarium* keratitis in contact lens wearers. *Eye & Contact Lens*, 2006;32 256-261.
- 5 Steinemann TL. Editorial: Microbiological testing for contact lens care products - Public workshop. *Eye & Contact Lens*, 2009; 35:3 115-116
- 6 Chang C, Grant B, O'Donnell K *et al*. Multistate outbreak of *Fusarium* keratitis associated with use of a contact lens solution. *JAMA* 2006; 296:8 953-963.

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Q&A
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The latest lens care systems

Q Are there any new developments in contact lens care systems I should be aware of? I hear there are some new multipurpose solutions.

A **Nick Atkins replies:** During this decade we have seen much change in the lens care field, including the introduction of new disinfectants, product withdrawals and newly identified clinical entities, as well as solution labelling, testing and regulatory issues. These are covered in detail in the first of a two-part review published this week.

For me, these developments mean that, as practitioners, many of us need to rethink the priority we place on lens care selection, patient-by-patient and lens-by-lens.

While work has begun discussing the key changes that will ultimately

be incorporated into a new ISO standard, this will process will take some time. In the meantime, like the car industry with car safety, lens care manufacturers are endeavouring to stay one step ahead of the legislation and so we are starting to see improved efficacy against clinical isolates of organisms (rather than just test panel organisms), MRSA and *Acanthamoeba*.

Right now there are two new lens care products recently launched into the UK market – Complete RevitaLens from Abbott Laboratories (formerly AMO) and Biotrue from Bausch + Lomb. Interestingly, both companies decided to use a dual-disinfectant approach.

However, that is where the similarity ends, as each company has taken a different approach to the challenges of maintaining safe, clean and comfortable contact lens wear.

These approaches will be described in detail in Part 2 of this review, along with the latest lens care advice for practitioners and their patients.

Ultimately practitioners need to carefully review the data provided by these and the other lens care companies and evaluate the solutions with their own patients and preferred lens options.

Lens care selection is undoubtedly just as important as lens selection and should always be a carefully considered choice. ●



Image courtesy of Andrew Gasson

WHAT'S THIS?

Answer in next month's CLM