Importance of lens disinfection and lens care compliance

Cheryl Donnelly takes a closer look at an issue critical to successful contact lens wear

Contact lenses are available for a wide variety of prescriptions and the flexibility that they offer both in vision correction and in lifestyle is reflected in their wide use – approximately 125 million wearers worldwide.[1] Lens disinfection is a vital component of successful contact lens wear, and there are two key aspects to effective disinfection of lenses:

- Patient compliance with prescribed lens care regimens
- The disinfection abilities of the contact lens care solutions used.

Patient compliance with lens care regimens

Compliance with prescribed lens care regimens plays a vital role in minimising the occurrence of ocular infections and inflammation.[2] Despite the importance of adhering to prescribed lens care regimens, complete patient compliance has historically been low, ranging from approximately 20 per cent to 90 per cent depending on the definition of compliance, ie correct solution use, handwashing, changing the lens case.[2] There are many possible reasons for why patients are not compliant, including lack of time to properly care for their lenses and lack of education. Perhaps the fact that contact lenses are available via many channels, may also impact compliance as patients may not recognise their lenses as medical devices.

With so many aspects to compliance, there is a multitude of ways that patients can be non-compliant with contact lens wear and care regimens. The first method of non-compliance that will be discussed involves the contact lenses themselves, specifically duration of wear and frequency of replacement. In a review of two large consumer studies (N = 3771) conducted in Europe (UK, Germany, France, Italy, Spain [both studies]; Russia, Poland, Netherlands, and Sweden [one study each]), 77 per cent of those surveyed said they had worn their lenses beyond the manufacturer-recommended replacement frequency period.[3]

Patients will wear their lenses for longer than that prescribed for a variety of reasons, including not feeling a need to replace a lens that is still comfortable and providing adequate vision correction.[4] Economic factors can also play a significant role in patient non-compliance with their contact lenses. In a survey of over 2,100 adults conducted in 2009, 40 per cent of respondents said they would switch contact lens brands on their own to save money, and 20 per cent said they would wear their lenses longer than prescribed for the same reason.[5] Age may also be a factor, as younger contact lens wearers are less likely to be compliant with replacement schedules than older patients.[3] Another reason for non-compliance is the patient being unaware of the correct day on which to replace their lenses, and this was the most common reason given by non-compliant contact lens wearers in a recent study.[6] In general, the level of compliance with prescribed lens replacement schedule is best with daily disposable lenses, although patients who wear monthly lenses have greater compliance than those who wear two-week lenses.[6] Patients may not always be entirely at fault for wearing their lenses beyond the manufacturer recommended durations. In a recent study by Dumbleton *et al*, 34 per cent of Canadian and 18 per cent of US eye care practitioners recommended a replacement frequency for two-week lenses that was longer than that recommended by the manufacturer.[6]

Figure 1 Poor compliance with cleaning has always been a concern

Not following a prescribed lens care regimen is another way for patients to be non-compliant. Some examples of this type of non-compliance include not properly washing hands (Figure 1), not replacing solution in lens cases as prescribed, not covering the contact lens with solution while it is in the lens case, and not checking expiration dates on lens solutions.[2] Patient non-compliance may be the result of poorly delivered patient instructions, economic issues, and patient confusion due to the overwhelming number of lens care solutions that are available to those who choose to self select.[7]

Another source of non-compliance, which is often overlooked by the user, involves the contact lens case (Figure 2). Monthly replacement of the lens case and cleaning of the lens case are two areas of high noncompliance in both daily and flexi-wear lens users.[3] Of those contact lens wearers who do clean their cases, two-thirds of them do so incorrectly by using water, water and soap, antiseptic liquids or by other means.[3] Other forms of non-compliance include sharing a lens case with others and not using a case to store the lenses.[2] The importance of the lens case to contact lens cleanliness is highlighted by a recent study that found that up to 92 per cent of lens cases used for one month were contaminated with various levels of bacteria or fungi, depending on the contact lens solution used.[8] This study demonstrates the importance, not only of disposing of lens cases when indicated, but of the effect the choice of lens care solution can ▶

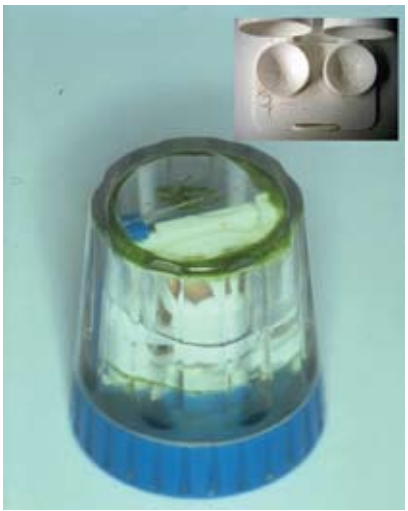

Figure 2 Dirty contact lens cases

have on lens case disinfection.

There are some trends that can be seen regarding patient compliance. In a study of those who wore daily lenses and those who wore extended-wear lenses, good compliance (>80 per cent of patients) was found in both groups when the steps to be followed were self-evident and simple, such as using the correct solution, storing lenses in a case, and closing the case lid tightly. Moderate compliance (40 per cent to 80 per cent of patients) occurred with lens care steps that were more complex and whose consequences were less clear, such as wearing lenses for the manufacturer recommended amount of time, washing hands correctly, and replacement of all lens care solution in the lens case each time lenses were stored. The poorest compliance (<40 per cent of patients) was seen in steps that were probably never covered in any eye care practitioner-patient communication and which were viewed by the patient as unlikely to cause any clinical problems, such as monthly replacement of the lens case and always cleaning the lens case.[3]

Contact lens solutions: different formulations, different results

The high rate of non-compliance among lens wearers means it is important the contact lens solutions used be as efficacious as possible at killing micro-organisms. However, not all solutions have the same level of efficacy.

Contact lens solutions have different combinations of ingredients, which can result in varying levels of disinfection efficacy against bacteria and fungi. Table 1 lists the different antimicrobial agents used in a number of contact lens care products. Although several of the lens care products use the same antimicrobial agents, it is the complete combination of ingredients that contribute to the disinfecting efficacy of the product

For contact lens solutions to be approved, they must be able to achieve certain levels of disinfection. In the past, European countries each had their own standards for antimicrobial activity. For example, the Dutch FDA and British MCA guidelines included *Aspergillus niger* as a test organism, and there were different time points at which levels of efficacy needed to be reached.[15] However, in 2001 an ISO standard (ISO 14729) was adopted to:

- Provide controlled and reproducible conditions so that an accurate estimation of antimicrobial activity could be achieved
- Make it easier and less costly for new products to gain approval
- Establish disinfection requirements that were not so strong that they could potentially damage the eye. The American Type Culture Collection (ATCC) (Table 2) is used as the basis for establishing disinfection efficacy by both the US Food and Drug Administration and in the ISO 14729 tests. For a solution to be approved, it must be able to show in a stand-alone test a standard 3-log reduction for bacteria, and a standard 1-log reduction for fungi. For a solution to pass a regimen test, it must achieve at least a 5.0-log reduction that is the sum of the average log reductions for all three bacteria and a minimum average of 1-log reduction for any single bacterial type within the recommended soak time, which is typically between four and six hours.[16-18]

Changes have recently been proposed to these antimicrobial standards. In a meeting of the US FDA Ophthalmic Devices Panel in June 2008, recommendations were made to include testing of new bacterial strains that have increased in prevalence and to include 'real-world' scenarios that reflect the conditions and environments that contact lens wearers experience, such as assessing antimicrobial efficacy against clinical isolates taken from used contact lenses and contact lens cases.[19,20] While the current FDA/ISO standards are high enough that lens care solutions provide an effective level of disinfection, the addition of these proposed changes can help to expand the scope of disinfection that contact lens solutions provide to patients. As yet, no changes to the FDA or the ISO 14729 standards have been incorporated. The following section highlights the importance of providing disinfection against micro-organisms not contained in the ATCC Collection, such as methicillin-resistant *Staphylococcus aureus* (MRSA), which is carried by one out of every 100 patients that visit a practice,[21] and *Acanthamoeba*.

New challenges

One reason for the re-examination of the antimicrobial standards is the emergence of bacteria that are not included in the ATCC and which can have a serious impact on ocular health. The most well-known of these new challenges is MRSA. There are two different types of this 'super bug': health-care associated MRSA (HA-MRSA) and community-associated MRSA (CA-MRSA).[22] The greater degree of pathogenicity of CA-MRSA organisms allows them to spread more easily (CDC) but they are also more susceptible to antibiotics, such as doxycycline, clindamycin, and rifampicin (although not as

TABLE 1

Disinfectants used in contact lens solutions

Product information for Biotrue, Renu MultiPlus, Renu Sensitive, Focus Aqua, Complete Easy Rub, Opti-Free Express, Opti-Free RepleniSH, and Clear Care.[9-14]

Disinfectant	Contact lens solution
Polyhexamethylene biguanide (PHMB)	Renu MultiPlus
	Renu Sensitive
	Focus Aqua
	Complete Easy Rub
Polyhexamethylene biguanide (PHMB) & Polyquaternium – 1) (Polyquat)	Biotrue
Polyquaternium -1/polidronium chloride (Polyquad) & Myristamidopropyl dimethylamine (Aldox)	Opti-Free Express Opti-Free RepleniSH
Hydrogen peroxide	Clear Care

TABLE 2

FDA/ISO standard ATCC organisms

Gram negative bacteria	Gram positive bacteria	Fungi
Pseudomonas s aeruginosa (ATCC 13880)	*Staphylococcus aureus* (ATCC 6538)	*Fusarium solani* (ATCC 36031)
Serratia marcescens (ATCC 13880)		*Candida albicans* (ATCC 10231)

Mowrey-McKee MF. Contact Lens Disinfection Efficacy Test Methods. Slide kit available at: www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM130748.ppt.

monotherapy).[23] HA-MRSA, which may not spread as easily as CA-MRSA, is the more dangerous of the two because it is typically resistant to multiple antimicrobial agents.[23] In addition to being difficult to treat, another alarming aspect of MRSA is the increase in its incidence. The European Antimicrobial Surveillance System (EARSS), which is funded in part by The European Centre for Disease Prevention and Control (ECDC) of the European Commission, has found a significant number of methicillin-resistant infections in blood isolates collected from European hospitals. In its 2008 report, which was based on 700,000 isolates collected from almost 1,500 hospitals located in 33 different countries, 11 countries were found to have an incidence of MRSA bloodstream infections of at least 25 per cent, with Portugal and Malta having prevalence rates >50 per cent.[24]

An additional challenge to ocular health comes from *Acanthamoeba*, which is an omnipresent organism that has been isolated from soil, air, and dust. These organisms have also been isolated from virtually all water sources, including swimming pools, hot tubs, and tap water.[25] In a study of tap water in the UK, 89 per cent of tap water outlets were found to contain amoeba, and one-third of these contained *Acanthamoeba*.[26] This micro-organism can cause granulomatous amebic encephalitis (GAE) and disseminated granulomatous amebic disease, both of which carry poor prognoses and occur in patients who are immunocompromised. It can also cause *A keratitis*, a local infection that can potentially cause blindness. Its prognosis is favorable if treated early, but treatment can be complicated by the presence of cataracts, hypopyon, and increased intraocular pressure.[27] The incidence of *A keratitis* is significantly higher in the UK compared with the rest of the EU and the US.[26]

Disinfection ability of contact lens solutions

Biotrue is a new multipurpose solution from Bausch + Lomb that provides unsurpassed disinfection, even when compared with a hydrogen peroxide product. Figure 3 shows that Biotrue provides unsurpassed disinfection compared with Opti-free RepleniSH, Opti-free Express, Complete Easy Rub, and Clear Care for the standard ATCC organisms used in FDA/ISO stand-alone testing. It should also be noted that Biotrue requires a recommended soak time of four hours compared with the six hours stated on instructions for these other solutions.

The standard ATCC organisms used in FDA/ISO testing are not the only challenges to ocular health that contact lens-wearing patients face. Therefore, the microbiocidal efficacy of Biotrue was also tested against *Acanthamoeba*[29] and clinical isolates (microbial strains collected from clinically worn lenses, lens cases, and infected eyes) of *F solani*, *S aureus*, and MRSA.[30] Biotrue multipurpose solution proved to be efficacious against all of these threats (Figure 4). Biotrue was also effective against *A castellanii* trophozoites and cysts.[30]

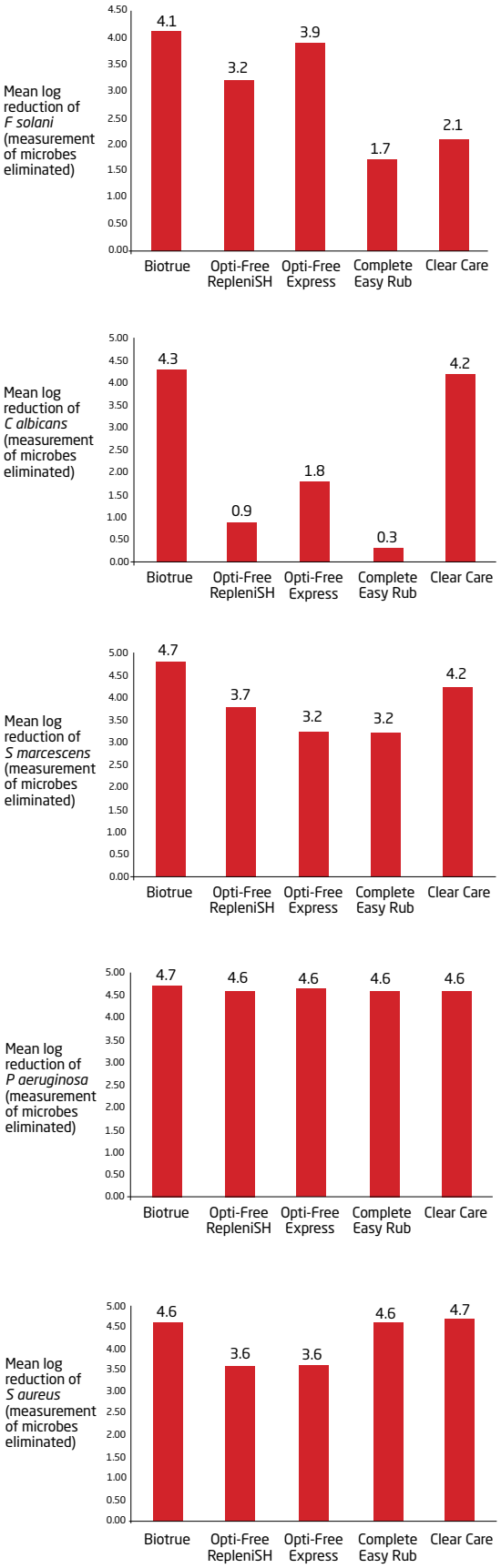

Figure 3 Contact lens solution disinfection against standard ATCC organisms used in FDA/ISO testing.[28] Biotrue and Clear Care results from separate *in vitro* studies performed following identical test procedures

Conclusions

Patient compliance with lens care regimens generally fluctuates between inconsistent and poor, and there are opportunities for non-compliance with the contact lenses, the contact lens solution, and the contact lens case.

Eye care practitioners need to take the lead in educating their patients on the benefits of compliance and the consequences of non-compliance. This initial education should be reinforced at every interaction, whether it is a practice visit or an email communication. Practitioners should continue to highlight the importance of disinfection, and to work with patients to improve their compliance with prescribed lens care solution regimens.

Disinfection of contact lenses can have a significant impact on the risk of developing inflammation and infection in the eye, and on the contact lens-wearing experience.[31-32]

Lens care solutions are efficacious in disinfecting lenses, but lens care solutions do not all have the same level of antimicrobial ability. Biotrue provides unsurpassed disinfection against all standard ATCC organisms that are used in FDA/ISO testing. However, while these standards are a good baseline for disinfection, we must not lose sight of the emergence of more-resistant micro-organisms, such as *Acanthamoeba* and MRSA. Biotrue has also been proven to provide consistently high log reductions against MRSA and is effective against *A polyphaga* (both cyst and trophozoite forms).

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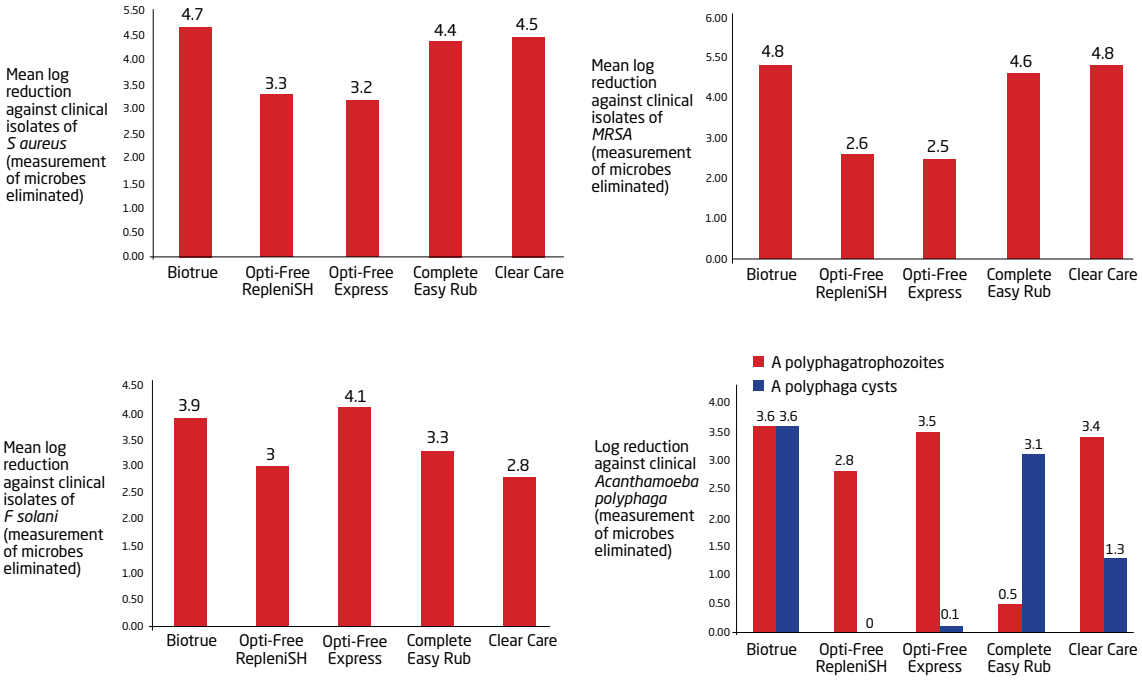

Figure 4 Disinfection efficacy against clinical isolates of MRSA, *S aureus,* and *F solani,* and against *A polyphaga*[29-30]

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