

APPROXIMATELY 90 per cent of care solutions prescribed for contact lens wear are multipurpose.¹ Multipurpose solutions were introduced to improve patient compliance and despite initial fears that they would compromise disinfection of contact lenses, it is now clear that this is not the case. Studies have confirmed that compliance is generally better with multipurpose solutions than a multi-step care regimen.² Multipurpose solutions offer excellent cleaning and disinfection properties, together with being easy to use. With 60-70 per cent of soft lenses prescribed in the UK requiring care products,¹ prescribing appropriate care solutions is still an important area of contact lens practice.

Bausch & Lomb claims to have enhanced the performance of multipurpose solutions using a new disinfectant/preservative, alexidine, and a proprietary combination of non-ionic surfactants and moisture-retaining polysaccharides. Alexidine has an altered chemical structure compared to other compounds of the biguanide group, resulting in highly effective disinfection, but low toxicity. ReNu with MoistureLoc consists of two main polymers that work synergistically with the lens:

- ◆ **Polyquatium 10** is a naturally occurring cellulosic backbone, which has been combined with hydroxyethyl groups to create a long-lasting cushion of moisture bound to the lens surface for sustained comfort day after day. The cellulosic backbone features cationic (positively charged) sites that help it bind to the anionic (negatively charged) surfaces of ionic lenses, such as those in FDA Group IV. The polymer can also bind to uncharged (non-ionic) lens surfaces via hydrogen bonding interactions.

- ◆ **Poloxamer 407** works to improve moisture retention, forming a protective shield, stabilising proteins and removing dirt and debris from the lens surface. It is a relatively small non-ionic surfactant polymer. Its hydrophilic ends attract moisture, while the hydrophobic centre binds to Polyquatium 10 or debris on the lens surface.

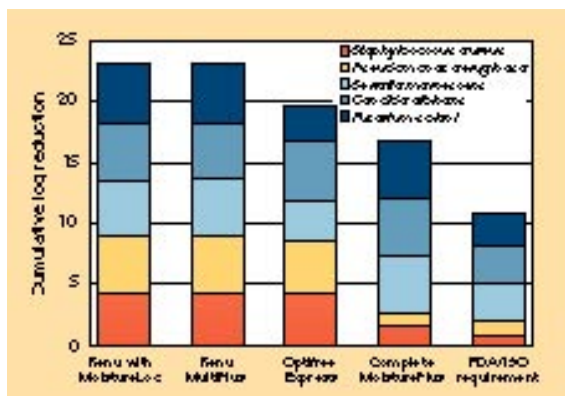


FIGURE 1. Log reduction of microorganisms at minimal soak time compared to FDA/ISO challenge organisms

ReNu with MoistureLoc

A literature review

Dr James Wolffsohn, in co-operation with Roya Borazjani, Sue Groeminger and Dharmendra Jani, reviews the literature regarding the performance of a multipurpose solution

In addition to these components, ReNu also contains poloxamine 1107, a high molecular weight surfactant that assists with the wettability and cleaning properties of the solution.

What would make you prescribe a different soft lens cleaning solution?

To examine this question, one first needs to consider what you expect a multipurpose contact lens cleaning solution (MPS) to deliver:

- ◆ Strong bactericidal and fungicidal properties
- ◆ No effect on corneal physiology/integrity
- ◆ No induced change in lens parameters
- ◆ Prevent adhesion/remove of surface deposits
- ◆ Comfort (good wetting) following contact lens cleaning.

Bacteriocidal/fungicidal properties

Alexidine is a new disinfectant, belonging to the biguanide family. Alexidine is a molecule containing two active sites compared to the biguanide PHMB used in ReNu Multiplus (with six to eight active sites). It works by disrupting the acidic phospholipid groups in a microorganism's cytoplasmic membrane causing disintegration and contents release.

In recent years, in an attempt to increase consumer compliance with lens cleaning and disinfection, MPS have been developed that do not require the

'rubbing' step. With the advent of 'no rub' lens care products, it is important to understand the inherent biocidal activity of various multi-purpose solutions.

From the *Guidance Document for Contact Lens Care Products*, the FDA has outlined a 'stand alone' test procedure to evaluate this biocidal activity without the rub procedure and is comparable to the current ISO standards for disinfection of contact lenses (revised in 1995).

As such, the 'stand-alone' method provides a quantitative measure to assess the relative antimicrobial efficacy of different 'no rub' lens care solutions.

Per the FDA/ISO test procedure, microbial challenge inoculums of *Pseudomonas aeruginosa* (ATCC 9027), *Staphylococcus aureus* (ATCC 6538), *Serratia marcescens* (ATCC 13880), *Candida albicans* (ATCC 10231) and *Fusarium solani* (ATCC 36031) were prepared. ReNu with MoistureLoc showed a reduction in the number of bacteria of 4.3-4.8 log units, much greater than the 3.0 log units required by the standard ISO test (Figure 1).

Acanthamoeba spp are the cause of a rare but painful and vision-threatening keratitis, often related to soft contact lens wear. *Acanthamoeba* possess a feeding trophozoite stage that under conditions of environmental stress (such as a lack of moisture) assume a non-motile globular shape. This is thought to be the intermediate stage before a dormant, thick-walled cyst is formed.³⁻⁵ To compare the susceptibilities of representative strains of *Acanthamoeba* to MPS, test parameters were adapted from those approved under FDA (510(k)) guidelines for bacteria and fungi. In trials using cysts and tropho-

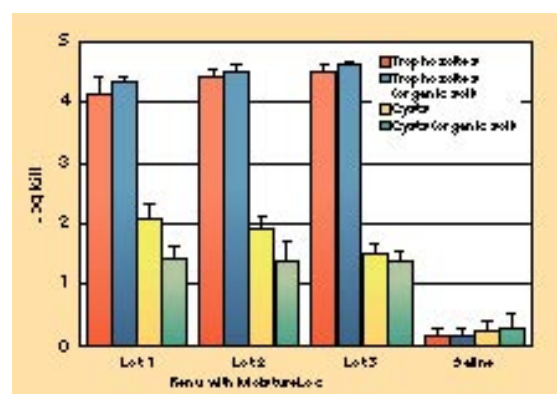


FIGURE 2. Log reduction of trophozoites and cysts of *A. castellanii* (ATCC 30868) after four hours of exposure to ReNu with MoistureLoc (three lots) and saline solution

zoites of *A. polyphaga* and *A. castellanii* in a 'soak only' (no lenses) regimen, with and without organic soil, Borazjani *et al*⁶ revealed that Bausch & Lomb's new MPS exhibited more than 99.99 per cent reduction in the number of recoverable trophozoites and a 99 per cent reduction in recoverable cysts, both with and without organic soil within four hours (Figure 2). Increasing the concentration of organic soil up to 40 per cent had no significant effect on trophozoite and cyst recoverability. Exposure to ReNu caused trophozoites to assume a globular shape within 30 minutes, followed by a high incidence of lysis in this *in-vitro* study.

No effect on corneal physiology/integrity

Toxicity data indicated that the test solutions are compatible with the eye. In 152 patients using ReNu with MoistureLoc, corneal staining, limbal injection, bulbar injection and tarsal conjunctival abnormalities occurred at a similar level to other commonly prescribed MPS (Figure 3).

No induced changes in contact lens parameters

With the introduction of silicone hydrogels and recently the launch of new materials in this category, the compatibility of these materials with the lens care product prescribed is important. The most frequently prescribed modality for silicone hydrogels is daily and flexiwear, both requiring a care regime.

Changes in Acuvue Advance, Purevision, Focus Night and Day and O₂Optix contact lenses cleaned with 30 repeat cycles of ReNu with MoistureLoc were less than those permissible by ISO standards (8321-2).

Prevent adhesion/remove surface deposits

It is well recognised that microbial

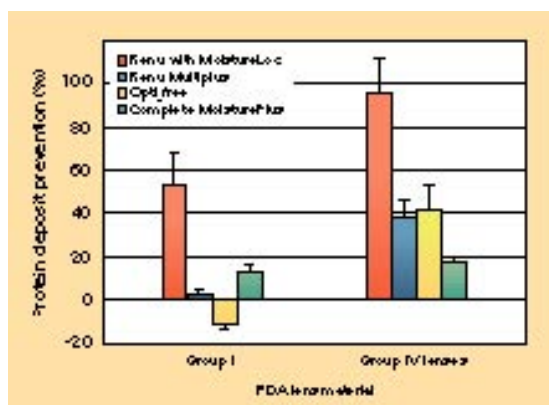


FIGURE 4. Prevention of protein deposition comparison with FDA Group I and Group IV contact lenses against a phosphate buffer control

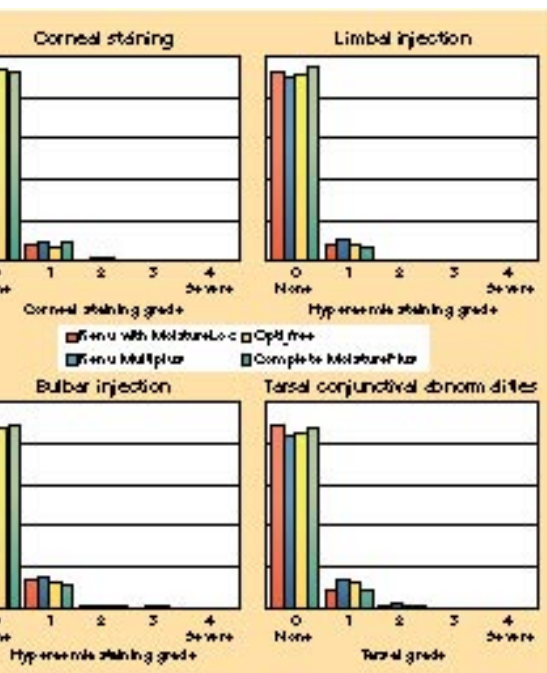


FIGURE 3. Toxicity of MPS as assessed by corneal staining, limbal injection, bulbar injection and tarsal conjunctival abnormalities over three months' use

keratitis associated with soft contact lens wear can lead to serious corneal complications. The most common causative organism of contact lens associated microbial keratitis is *P. aeruginosa*. This ubiquitous bacterium is found typically in moist soils and water. It is one of the most virulent microorganisms causing keratitis, and if left untreated is capable of causing blindness within several days. The adhesion of *P. aeruginosa* to epithelial cells is known to be important in the infection process, and the factors that enhance adherence of bacteria to host tissues increase the risk of infection.

The contact lens is presumed not only to be a vector that transports microorganisms from the contaminated solutions or the environment to the eye, but also a possible substratum for proliferation of the bacterium.⁷⁻¹⁰

Any treatment that could reduce 'primary adhesion' (that is, the number of irreversibly bound cells on the lens) has the potential for reducing the risk of adverse bacterial reactions.

The results of *in vitro* bacterial attachment studies carried out by Borazjani *et al* showed that soaking contact lenses in ReNu with MoistureLoc for four hours reduced the degree of primary attachment of *P. aeruginosa* to unworn one-day and silicone-hydrogel contact lenses by up to 90 per cent, even in the presence of organic soil.¹¹

This decrease in the degree of bacterial adhesion to contact lenses is thought to be related to changes in hydrophobic and ionic interactions between the bacteria and the contact lens surface, possibly involving blocking of a binding site or competitive displacement of bacteria from the substratum. Deposit formation and build-up on soft contact lenses has been associated with discomfort and decreased visual acuity.¹² Deposits have also been implicated as a source of giant papillary conjunctivitis (GPC).¹³

Studies show that ReNu with MoistureLoc is more effective in preventing denatured lysozyme, the major tear protein, from depositing on FDA Group I (1.4 to 100X) and Group IV (2.1 to 5.6X) soft contact lenses than other MPS (Figure 4).

Lysozyme serves as one of the eye's

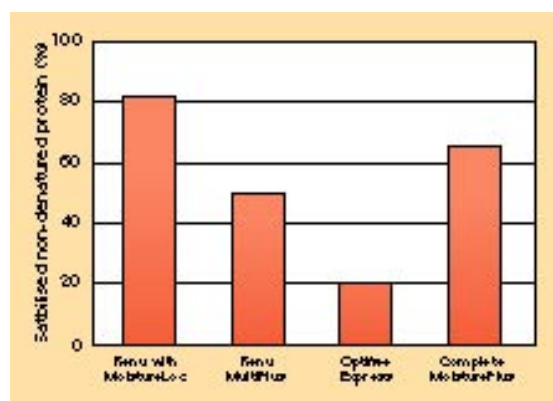


FIGURE 5. Stabilised non-denatured lysozyme protein following MPS usage

first lines of defence against microbial attack, by possessing antimicrobial properties when it is in its native form. Native lysozyme had also been linked to a contribution in lens wettability.¹⁴ In the past, manufacturers focused on how much protein was removed from the surface of contact lenses by cleaning solutions. However, these total protein assays of worn lenses do not distinguish between native and denatured proteins. Studies have generally found that total protein is not related to patient comfort ratings.^{15,16} It is now thought that visible denatured protein deposits, and not transparent native lysozyme on the surface of the contact lens, lead to reductions in comfort¹⁷ and may cause immunological reactions such as giant papillary conjunctivitis.¹⁸ The state of the protein and not simply its presence on the surface of the lens is important and therefore the ability of lens care solutions to influence the state of protein is also important. ReNu with MoistureLoc stabilises much of the lysozyme rather than denaturing it (Figure 5). MoistureLoc also acts to inhibit the proteins from reaching the lens surface.

Comfort/lens wetting following cleaning

Discomfort related to contact lens dryness has been reported to be the primary complaint among soft contact lens wearers.¹⁹ The wettability of a contact lens surface is believed to impact on comfort, end-of-day dryness, and overall performance. The ability of ReNu to

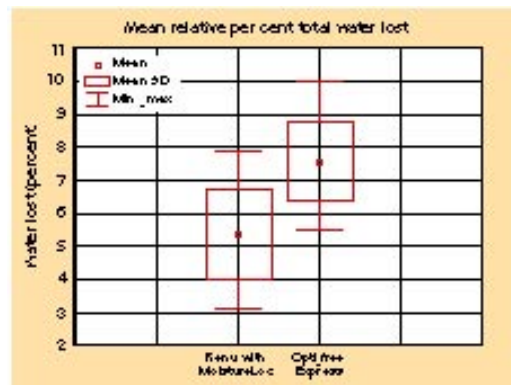


FIGURE 6. Fluid retention of Acuvue 2 lenses soaked in MPS

resist binding of denatured proteins, which can cause discomfort and shorten lens wearing times, has already been discussed. Furthermore, lenses cleaned with ReNu have been found to be less susceptible to changes in water content in dry-eye subjects following the wearing of Acuvue 2 lenses compared to Alcon Opti-Free Express MPS cleaned lenses (Figure 6) and this effect is consistent at all time points measured; 30,60,90 and 120 minutes. Also, ReNu with MoistureLoc soaked lenses have longer lasting wetting (smaller dynamic contact angle; Figure 7) and a consistently greater reduction in surface tension than other MPS for FDA Group IV lenses (Figure 8). Therefore, ReNu with MoistureLoc may improve the comfort of dry eye lens wearers, compared to their previous lens care system. This has been confirmed clinically using *in-vivo* studies, showing approximately 5.5 per cent improvement in comfort over the patient's habitual lens

CONCLUSION

This data clearly shows that not all MPS are the same and that the new generation ReNu with MoistureLoc not only offers lens disinfection and removal of surface deposits without affecting the lens parameters, but also provides enhanced lens comfort, minimises denaturing of protein, prevents denatured protein adhesion to the lens surface and does not affect corneal physiology or integrity. Even with silicone hydrogel lenses, ReNu with MoistureLoc performs well.

References

A complete list of references are available at www.opticianonline.net

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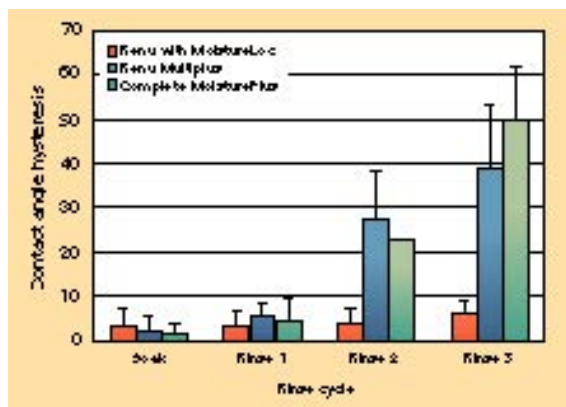


FIGURE 7. Contact angle hysteresis angle in contact lenses soaked in MPS. The lower the angle, the more wettable the surface

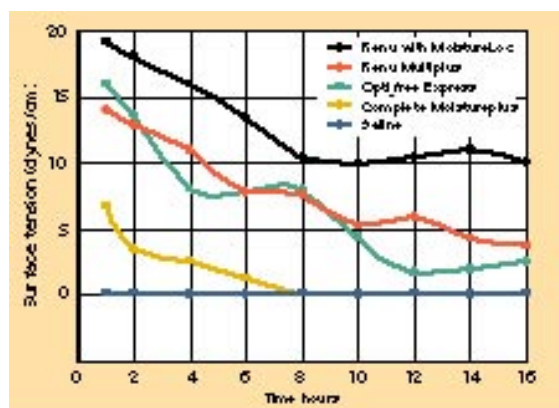


FIGURE 8. Surface tension over time with Group IV contact lenses soaked in MPS. The lower the surface tension, the more wettable the surface

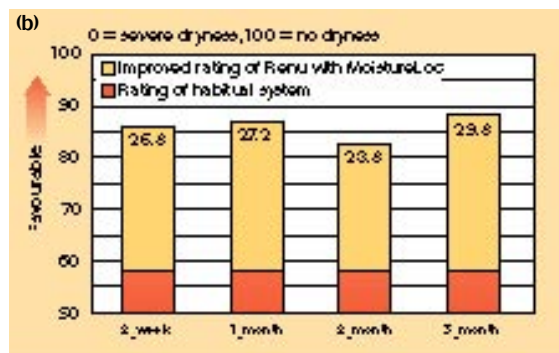
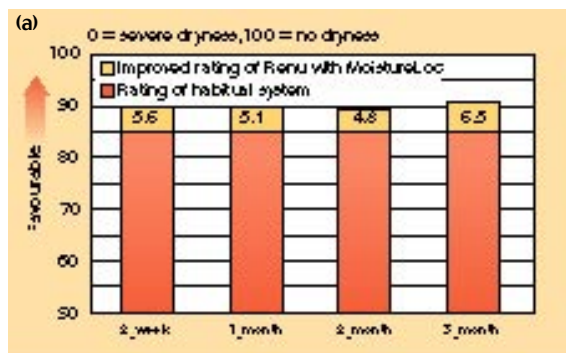


FIGURE 9. Comfort rating of lenses cleaned with ReNu with MoistureLoc compared to patient's habitual cleaning regimen in (a) general contact lens patients and (b) contact lens dry-eye patients