



Much Ado About Staining

What do we really know about the relationship between corneal staining and contact lens multipurpose solutions? **By Paul M. Karpecki, O.D.**

Recently there has been much discussion about corneal staining and contact lens solutions. Although much of the research is sound, some conclusions have little clinical basis. This month's column will serve to sort out what we know.

The Science

Beyond the stated hypothesis, we must also look closely at the science behind any given study and its execution to determine its validity. Critical study components include the number of patients enrolled (the N number) as well as inclusion of data outliers within the results, which by definition will always skew findings toward a particular outcome.

For example, a study suggested that ReNu MultiPlus (Bausch & Lomb) was associated with significant reduction in relative corneal sensitivity vs. Opti-Free Express Lasting Comfort No Rub formula (Alcon) and that this may play a role in contact lens-related dry eye and discomfort.¹ But, only four patients were enrolled within each arm of the study—an extremely small sample.

Another confounding variable: the decision to include outliers within the final data set. One aesthesiometry (corneal sensitivity) reading in this study was significantly lower (20.00) vs. all other data in either group. If there is a reading of 20.00 in one case when all the other measurements averaged 82.86, with 100% representing highest degree of comfort, the patient who registered a 20.00 probably would have trouble

wearing contact lenses to begin with. We should probably classify this data point as an outlier to be footnoted but excluded from final study results. The new result would likely show no statistical difference between the solutions.

Still, a literature review did not uncover any link between decreased corneal sensitivity and increased symptoms of discomfort. Studies suggest the exact opposite—that patients who have corneal staining and reduced corneal sensation tended to have fewer symptoms of discomfort.²

Further, we must differentiate the terms “statistical trends” and “clinically significant.” Statistical trends favor a potential direction, as in this particular study, and represent a conclusion drawn by the author. Statistically significant findings indicate that the results are not likely to occur by chance.

Multiple Studies

Realize that for every study that shows one outcome, there are studies that show another. For example, in a study conducted at Wills Eye Hospital in Philadelphia, a sodium fluorescein permeability assay and scanning electron microscopy demonstrated that the two Opti-Free Express solutions were significantly more damaging to the epithelium than ReNu MultiPlus, SOLO-care (CIBA Vision)

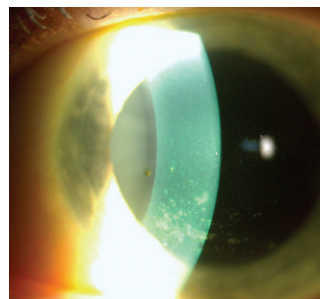
and Complete Comfort Plus (AMO) solutions. Cultures also showed a greater loss of tight junctions and cell membrane damage with Opti-Free.³

Another study comparing cytotoxicity potential *in vitro* of soft lens care regimens stated that Opti-Free Express (with ALDOX) may have a higher potential than any other solution tested for ocular irritation correlating to severe cytotoxicity.⁴

Keratitis Link?

Making that leap certainly applies

to an association between staining and bacterial corneal ulcers. One error is to overstep the bounds of the clinical data. For example, the incidence of bacterial keratitis must appear to be rising given that corneal staining is noted



Fluorescein revealed this corneal staining pattern.

with multipurpose solutions, yet a review of more than 50 papers showed that this is not the case. In one study, researchers concluded that “the study results commend use of multipurpose solutions by contact lens wearers in Hong Kong to achieve the lowest expected rates of infection.”⁵

The incidence of keratitis in daily contact lens wear remains at about four per 10,000 and in extended wear at 18 per 10,000 wearers, which is very similar to the previous incidence of keratitis.⁶⁻⁸ Other studies

Research Review

show the incidence of keratitis is lower with high-DK silicone hydrogel lenses than with low-Dk lenses during extended wear.⁹ Wills Eye Hospital reported a decrease in the number of contact lens-related corneal ulcers in each of the four subsequent years data were available.^{10,11}

Meanwhile, researchers at The Ohio State University examined 500 full-time, successful soft contact lens wearers and found that corneal fluorescein staining occurs to some extent in many soft lens wearers and is influenced by noncompliance with the lens care system, replacement schedule and lens power.¹² Type of wear (extended, flexible or daily), average wearing time and type of care system were not significantly associated with corneal staining.

So, patients must be educated about proper contact lens compliance. However, they should feel confident in contact lens wear, and so should well-educated clinicians. ■

Dr. Karpecki is a paid consultant to B&L but has no financial interest in any products mentioned.

1. Epstein AB. Contact lens care products effect on corneal sensitivity and patient comfort. *Eye Contact Lens* 2006 May;32(3): 128-32.
2. Adata FA, Michaeli-Cohen A, Naor J, et al. Correlation between corneal sensitivity, subjective dry eye symptoms and corneal staining in Sjogren's syndrome. *Can J Ophthalmol* 2004 Dec;39(7):767-71.
3. Tchao R, McCanna DJ, Miller MJ. Comparison of contact lens multipurpose solutions by in vitro sodium fluorescein permeability assay. *CLAO J* 2002 Jul;28(3):151-6.
4. Mowrey-McKee M, Sills A, Wright A; CIBA Vision Corporation. Comparative cytotoxicity potential of soft contact lens care regimens. *CLAO J* 2002 Jul;28(3):160-4.
5. Houang E, Lam D, Fan D, Seal D. Microbial keratitis in Hong Kong: relationship to climate, environment and contact-lens disinfection. *Trans R Soc Trop Med Hyg* 2001 Jul-Aug;95(4):361-7.
6. Lam DS, Houang E, Fan DS, et al. Incidence and risk factors for microbial keratitis in Hong Kong: comparison with Europe and North America. *Eye* 2002 Sep;16(5):608-18.
7. Schein OD, McNally JJ, Katz J, et al. The incidence of microbial keratitis among wearers of a 30-day silicone hydrogel extended-wear contact lens. *Ophthalmology* 2005 Dec;112(12): 2172-9.
8. Cheng KH, Leung SL, Hoekman HW, et al. Incidence of contact-lens-associated microbial keratitis and its related morbidity. *Lancet* 1999 Jul 17;354(9174):181-5.
9. Holden BA, Sweeney DF, Sankaridurg PR, et al. Microbial keratitis and vision loss with contact lenses. *Eye Contact Lens* 2003 Jan;29(1 Suppl):S131-4; discussion S143-4, S192-4.
10. Rattanatham T, Heng WJ, Rapuano CJ, et al. Trends in contact lens-related corneal ulcers. *Cornea* 2001 Apr;20(3):290-4.
11. Cohen EJ, Fulton JC, Hoffman CJ, et al. Trends in contact lens-associated corneal ulcers. *Cornea* 1996 Nov;15(6):566-70.
12. Nichols KK, Mitchell GL, Simon KM, et al. Corneal staining in hydrogel lens wearers. *Optom Vis Sci* 2002 Jan;79(1):20-30.