

Review Article

Recent FDA-Sponsored Research: A Must Read

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2006 and 2007 rocked the world of optometry and ophthalmology with regards to some contact lens wearers. Suddenly, our peers were being interviewed live on Good Morning America and being read about in the Wall Street News. Stories about fungal and acanthamoeba keratitis were sweeping the globe and our patients were losing sight. We were frightened by the fact that contact lens patients were presenting without classic symptomatology and were ultimately being diagnosed with sight-threatening pathologies all due to the use of certain contact lens multi-purpose solutions (MPS). Reports of patients topping off solutions, leaving their cases uncapped, and other general behaviors indicative of poor compliance and hygiene gave us great concern [1-4]. The reaction was immediate; we inquired about what products contact lens patients were using when red eyes presented to our practices.

The November 2012 issue of Eye and Contact Lens focused squarely on the products and preservatives on hand today and gave us reason to pause, read, and alter behaviors in a manner to become habitual. The FDA conducted a 2-day Contact Lens Care Product Workshop in January 2009 after the keratitis outbreaks [5]. As a result, the FDA sponsored independent research and has recently published their findings. These papers are critical to patient health and contact lens wear success and will directly affect what we do as optometrists each and every day. The goal was to examine the PHMB and Polyquad disinfectant efficacy against *Staphylococcus aureus* and *Fusarium solani* independently, in the presence of a lens. The essence of the FDA's work was to specifically question what the soft contact lens (SCL) itself does to alter disinfection of commonly used disinfectants (i. e. preservatives). All current MPS formulations are brought to market via an antiquated approach to formulation approval (ISO 14729) [5-8]. This approach only examines efficacy in the test tube and does not require the physical introduction of a contact lens.

Polyhexamethylene biguanide (PHMB) is a commonly used disinfectant in MPS brand-name products and is nearly exclusively used in generic formulations. PHMB was challenged to disinfect Staph and *F. solani* when an assortment of 8 different SCLs (6 silicone hydrogels and 2 conventional hydrogels) were added to the solution and subsequently confronted with microbes during a 6, 12, 24, 72, or 168 hour soak [6]. The FDA found that a MPS containing PHMB can lose its bactericidal and fungicidal efficacy when the SCL is introduced [6,7]. When

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tested against Staph, the residual MPS used for 5 of the 8 lenses showed significantly reduced PHMB levels and a corresponding loss of antimicrobial activity [6]. In the *F. solani* study, 7 of the 8 solutions used for storage failed to obtain the recommended one log reduction of *F. solani* after only a 6 hour soak [7]. In fact, 3 of the lens materials induced more than a 50% reduction of PHMB concentrations after only 6 hours of soaking [7]. After a 24 hour soak, 3 had lost all or almost all fungicidal activity [7]. Several authors have indicated that MPS formulations have diminished antimicrobial activity after "real world" soaking with lenses [9,10]. The FDA papers have confirmed that PHMB containing antimicrobial activity after "real world" soaking with lenses, when used with lenses, can have less microbiocidal action against common eye pathogens [6,7]. With the aforementioned approach, the FDA sponsored a study challenging a MPS containing polyquaternium-1 0.001% and myristamidopropyl dimethylamine 0.0005% (POLYQUAD) in its activity against Staph, after being used to store 7 different SCL types [8]. Unlike the PHMB challenges, the POLYQUAD concentration in the cases was reduced only very slightly over time [8]. The presence of the lenses did not adversely affect the biocidal activity of POLYQUAD and, in some cases; the efficacy was significantly better [8].

Manufacturers introduced one-step MPS to afford our patients fewer steps to follow and thereby enhance compliance [6]. Today, we are working with very complex formulations that contain relatively low levels of biocides [8]. Though PHMB is frequently the antimicrobial of choice in many MPS formulations, its efficacy is brought into question when paired with various SCLs. The FDA and others have reminded practitioners that solution-lens interactions may contribute to adverse events related to contact lens wear [6,7,11,12].

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