A Fresh Look at One-Step Hydrogen Peroxide Lens Disinfection

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Hydrogen peroxide-based contact lens disinfection systems are known for their exceptional disinfecting efficacy and ocular biocompatibility. These traits have enabled hydrogen peroxide disinfection to remain an important option for contact lens wearers over almost three decades. In that time, peroxide disinfection grew to become the market leader and then, with the advent of “no-rub” multi-purpose disinfecting solutions, declined substantially for some years. Yet one-step peroxide disinfection has endured, and today it again holds a sizeable and steadily growing share of the market. Over the years, the advantages of peroxide disinfection have been proven in many types of studies.1-3 Human clinical studies have characterized the eye’s tolerance for low levels of residual peroxide to which contact lens wearers may be exposed. And laboratory research has enabled developers to design effective neutralization systems and formulate the peroxide solution and system for maximum comfort as well as efficacy in cleaning and disinfection. A review of these studies shows how hydrogen peroxide-based contact lens care products in general, and CLEAR CARE® Cleaning & Disinfecting Solution in particular, can combine exceptional disinfection and cleaning with reliable neutralization of residual peroxide for safe and comfortable contact lens wear when used as directed.

When I entered contact lens research in the 1980s, one of my first research assignments was to explore the ocular effects of residual hydrogen peroxide (H$_2$O$_2$) from the then relatively new peroxide-based contact lens disinfection systems.4,5 In the ensuing decades, the popularity of peroxide-based contact lens disinfection grew substantially and then waned, almost to the point of being an afterthought among contact lens wearers. In recent years, however, H$_2$O$_2$ has reemerged as an important option for contact lens care. And for good reason: The large body of peer-reviewed research on H$_2$O$_2$ contact lens disinfection shows that peroxide’s recent gains in respect and market share rest on a solid base of scientific evidence, not to mention years of continued use by many loyal contact lens wearers.

The Eye and H$_2$O$_2$

In 1989 and 1995 I published two review papers explaining that, more than just a man-made disinfectant, H$_2$O$_2$ is generated in many normal physiological processes. Since it is a common physiological by-product, the human body is well equipped to metabolize H$_2$O$_2$ in low concentrations (up to 800 ppm in topically applied ophthalmic drops).5,6 In 1993, Michael Riley and Graeme Wilson, esteemed corneal physiologists, wrote a review of the safety of topical exposure to H$_2$O$_2$ and the degree to which H$_2$O$_2$ is able to penetrate an intact rabbit cornea.5,7

With colleagues, I determined the human detection threshold for buffered isotonic H$_2$O$_2$ and the speed with which residual H$_2$O$_2$ is neutralized by the ocular surface.5,6 Wilson and Riley then used a rabbit model to conduct in-vivo and in-vitro studies determining the safety of topical exposure to H$_2$O$_2$ and the degree to which H$_2$O$_2$ is able to penetrate an intact rabbit cornea.5,7

Taken as a whole, this body of work clearly demonstrates that exposure to low levels of H$_2$O$_2$
from peroxide disinfection systems is fully compatible with ocular surface health in human and animal models. This is so because 1) in a properly functioning peroxide disinfection system, the cornea is exposed only to low residual concentrations of H2O2 (target range < 60 ppm); and 2) the eye’s natural enzyme mechanisms can break this small amount of peroxide down to completely benign byproducts (water and gaseous O2) in a very short time.6 This straightforward chemistry provides excellent comfort and low rates of inflammation in contact lens wearers who use H2O2 systems.9-11 Here we will summarize the peer-reviewed works on hydrogen peroxide-based contact lens cleaning and disinfection, to introduce the research to younger contact lens practitioners and to refresh the memories of their more experienced colleagues. In addition, this review will highlight the extensive body of research on the clinical performance of CLEAR CARE® Cleaning & Disinfecting Solution, with emphasis on its ability to deliver comfort and a positive contact lens wearing experience.

Three enzymes abundant in tears and on the ocular surface can neutralize either endogenously produced or topically applied oxidative threats: superoxide dismutase, catalase, and glutathione peroxidase

The Rise of Multi-Purpose Disinfecting Solutions

H2O2 systems were the most widely used contact lens care systems in the 1980s.12 But by the late 1990s, H2O2 systems had lost ground to multi-purpose disinfection systems (MPDSs) with “no rub” labeling. Only later did it become apparent that the perceived simplicity of these MPDSs may have come at a price: low regard by patients for the importance of using the solutions as instructed. Indeed, misuse of lens care systems was one of the factors implicated in two serious outbreaks of microbial keratitis—one due to Fusarium and the other to Acanthamoeba—that resulted in the recall of two MPDSs containing polyhexamethylene biguanide (PHMB) soon after their introduction into the marketplace.13-15 In these outbreaks, microbial keratitis was significantly associated with “topping off,” the practice of adding a bit more solution to what is leftover in the lens case, rather than emptying, rinsing with solution, and refilling the case with fresh solution every day.13,14 Noncompliance was not the only factor that was hypothesized as a contributor in one of these outbreaks; Tu suggested that the addition of a moisturizer to the formula of one MPDS may have compromised the efficacy of the solution’s disinfection components against Acanthamoeba.15 Although the popularity of MPDSs grew rapidly at the expense of H2O2 disinfection, the peroxide lens care systems never disappeared entirely. Now, as the pendulum swings back, established practitioners are beginning to rethink peroxide disinfection, and young doctors may for the first time come to consider this recommendation for their contact lens patients. Ironically, an H2O2 system like CLEAR CARE® Solution, with its 14-year history, may be the most innovative recommendation a practitioner can make for today’s soft contact lens wearers. In particular, for daily soft contact lens wearing patients who experience symptoms of dryness and discomfort, turning to H2O2 disinfection with highly biocompatible CLEAR CARE® may be an effective option.

The Peroxide Comeback

In the last decade, the proportion of patients using H2O2 systems in general, and CLEAR CARE® Solution in particular, has nearly doubled. Before 2005 there had been a long, gradual decline in H2O2 market share: from dominance in the early 1990s, to 20% in 1997, to about 5% in 2005.17 The decline of peroxide disinfection was not limited to the United States; in Canada, from 2000 to 2006, fewer than 10% of contact lens wearers were using H2O2.18 At that point, the popularity of H2O2 began to rebound; in North America, a large multi-center chart review covering 2006 to 2009 found that approximately 10% of soft contact lens wearers were using one-step H2O2 systems, and that the proportion of H2O2 users rose with increasing age from 8 to 33 years old.19 In 2008 in the UK, Efron reported an increase in the proportion of one-step H2O2 users from 7% to 16% in one year—after many years of declining use.20 By 2011, in the United States, CLEAR CARE® was the second most popular branded lens care system overall.21 It currently has an 18% market share (in dollars) in the US.22 This pattern is reflected internationally: Efron and the International Contact Lens Prescribing Survey Consortium recently reported that approximately 20% of daily soft contact lens wearers use H2O2 systems.23

How H2O2 Works

The popularity of CLEAR CARE® rests on several pillars. The first of these is peroxide’s efficacy against even the toughest microbial contaminants. Like many antimicrobial agents, CLEAR CARE® is highly effective against planktonic (free-swimming)
organisms. But organisms in biofilms are much harder to eradicate, and biofilm formation on lenses or in the lens case is thought to play a major role in contact lens-associated microbial keratitis.24,25 One study investigating the efficacy of CLEAR CARE® and five MPDSs against bacterial biofilms found that only CLEAR CARE® was effective against the biofilms produced by all three bacterial species tested.3

Another important pillar on which the popularity of CLEAR CARE® rests is the absence of preservatives such as those in MPDS formulations that can be found at the end of the disinfection cycle. Multi-purpose disinfection solutions do not undergo such transformation during the disinfection cycle, leaving chemicals that may accumulate in the lens material or in the lens case or biofilm. With neutralization, 3% H₂O₂ is converted to oxygen gas and water, and the highly active disinfectant is transformed to what is essentially a buffered saline solution, with only low amounts of easily metabolized residual H₂O₂.

The CLEAR CARE® System

The CLEAR CARE® system consists of a patented 3% H₂O₂ disinfecting solution and a 10-mL clear lens cup with a vertically oriented lens basket, to which a platinum disc is attached at the lower end for neutralization of the peroxide (Figure 1). The buffered disinfecting solution is near neutral in pH, and an added proprietary surfactant, Pluronic 17R4, aids in the removal of deposits and improves lens wetting.26 Positioning the neutralizing disc at the end of the lens basket ensures that lenses are introduced into full strength 3% H₂O₂ in the cup, and that the oxygen bubbles formed during neutralization pass vertically across the lens surfaces (Figure 2).

The rate of neutralization is critical: the H₂O₂ concentration must be kept high enough for a long enough period to provide effective disinfection, but should approach the < 60 ppm range when the lens is ready to be placed back on the eye. The platinum coating on the neutralizing disc used in the CLEAR CARE® system is precisely controlled to allow for powerful disinfection and to provide the right rate of neutralization, to a range of 5 to 60 ppm for 100 cycles.27 Provision of a new cup and disc, which is designed to last far beyond the normal use of one bottle, with each purchase of CLEAR CARE® offers the lens wearer a big margin of safety from over-exposure to residual H₂O₂, and allows for irritant-free wearing comfort when used as directed. However, it is recommended that users replace the case with each new bottle of CLEAR CARE®.

In use, CLEAR CARE® differs markedly from MPDSs. Hydrogen peroxide actively bubbles during the disinfection cycle, and with the CLEAR CARE® system's transparent lens cup, the patient can see this process in action. The presence of bubbling lets the patient see that the solution is working; absence of bubbling at the start of disinfection sends a visual cue that something is amiss, which may help patients adhere to their regimen and discourage topping off.

Neutralization of Residual Peroxide

Even before H₂O₂ was used as a contact lens disinfecting agent, there was a significant body of research on how physiologically-generated H₂O₂ was metabolized inside the eye. The challenge of living with reactive oxygen species has been fully described by Fridovich, who explained the elaborate physiologic defense mechanisms that hold oxygen free-radicals in check.28 Subsequent reviews of enzyme systems on the ocular surface and in anterior segment tissues have described these mechanisms in detail.5,6

In brief, three enzymes that are abundant in tears and on the ocular surface can neutralize either endogenously produced or topically applied oxidative threats; these enzymes are superoxide dismutase, catalase, and glutathione peroxidase. Superoxide dismutase converts superoxide to gaseous oxygen and H₂O₂. Catalase and glutathione peroxidase convert H₂O₂ to water and gaseous oxygen. Catalase is abundant in the bulbar and tarsal conjunctival epithelium; while the corneal epithelium has high levels of all three neutralizing enzymes. Early in the development of peroxide-based contact lens disinfection systems, human clinical testing with a two-step H₂O₂ system showed that the pH of the peroxide solution had a large
bearing on the H₂O₂ detection threshold, the lowest concentration the eye can detect.²⁹ As the pH of the test solution was raised from 6.0 to 7.1, the proportion of clinical subjects who could detect a peroxide concentration of 60 ppm dropped from 95% to 10%. In one study, 20 subjects were exposed to various concentrations of hydrogen peroxide at pH 7.1; at 60 ppm, 10% could detect it; at 100 ppm, 40% could detect it; and at 200 ppm, 85% could detect it.²⁹ This shows that the lower the residual peroxide, the more likely patients are to avoid irritation in general clinical use.

Later studies evaluated one-step H₂O₂ disinfection systems employing buffered and stabilized solutions (closer to the final AOSept and CLEAR CARE® formulations) to determine detection thresholds. With a team of clinical researchers, we either instilled drops of H₂O₂ solution or inserted H₂O₂-soaked contact lenses (from FDA groups I and IV) on subjects’ eyes. Both drops and soaking formulas were buffered, stabilized, isotonic (0.9% NaCl) H₂O₂ solutions, with concentrations ranging from 30 to 1470 ppm.¹ With both the clinical investigator and the subject masked, a test lens or solution drop was applied to the subject’s eye in stepwise fashion at increasing concentrations until the subject reported mild stinging twice in a row (the detection threshold).

For instilled drops, the mean detection threshold was 812 ppm (range: 400 to 1470 ppm). For the group I and IV lenses, respectively, detection thresholds were lower: 267 ppm and 282 ppm (range 150 to 400 ppm). Note that all of these values greatly exceeded the historic threshold (60 ppm), perhaps because the solutions were now better designed, buffered, and had physiologically normal electrolyte levels. In addition, while subjects were able to detect peroxide, their symptoms went away quickly, and comfort scores between control (no H₂O₂) and H₂O₂-dosed lenses were equal after 30 minutes.

How Quickly is Residual Peroxide Metabolized?

The ocular surface can tolerate low concentrations of H₂O₂ because ocular surface enzyme systems neutralize it readily. The ideal upper goal of a roughly 50- to 60-ppm concentration of peroxide remaining in a neutralized one-step system is very quickly broken down by these naturally occurring peroxidases.⁴

In one study of peroxide neutralization, subjects inserted a contact lens soaked in buffered, isotonic 50 ppm H₂O₂ and then either closed the eye or blinked normally. Investigators found that after 30 seconds, all of the H₂O₂ on the contact lens in the closed eye was neutralized; it took slightly longer, about 1 minute, to neutralize all of the peroxide in the naturally blinking eye.⁴ Thus, contact with the palpebral conjunctiva appears to be the dominant method of neutralization, but both closed eyes and blinking eyes neutralized H₂O₂ very quickly. After just 15 seconds of wearing lenses soaked in 50 ppm of H₂O₂, the lens in the closed eye, with full contact between the lens and palpebral conjunctiva, had an average H₂O₂ concentration of 7.3 ± 7.3 ppm (85% reduction); and the lens in the open, blinking eye had 12.9 ± 5.6 ppm (74% reduction).

Thus, dilute H₂O₂ solutions, whether delivered as a drop or on a contact lens, have, at most, a fleeting effect on ocular comfort. The neutralizing disc in the CLEAR CARE® system is designed to leave between 5 and 60 ppm of residual H₂O₂ over a 100-use lifetime (Figure 3).³⁰

**Clinical Outcomes with CLEAR CARE®**

Time and again over the past 2 decades, lens care studies have found excellent outcomes among subjects using CLEAR CARE® (and its predecessor AOSept). In fact, CLEAR CARE® has been used as the gold-standard control against which MPDSs have been compared in studies of comfort, corneal inflammatory events (CIEs), and solution-induced corneal fluorescein staining (SICS).

**Comfort and Effects of Lens Wettability**

In 1994, in a crossover study of 85 adapted contact lens wearers, use of AOSept (CLEAR CARE®) resulted in significantly better overall and late-day comfort and significantly less corneal staining than use of a PHMB-containing MPDS.³¹ More than 10 years later, results were still positive. Better comfort on insertion, overall comfort, and end-of-day irritation with CLEAR CARE® compared with MPDS systems was noted in a larger crossover clinical trial reported in 2007, among 193 subjects using one of four silicone hydrogel lens brands for 1 month.³² CLEAR CARE® was accompanied by

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lower rates of corneal and conjunctival staining and palpebral redness ($P < 0.047$, all).

In an 8-week crossover study using silicone hydrogel lenses, Keir and coworkers found that while clinical signs were similar between lens care systems, subjects using CLEAR CARE® reported longer comfortable wearing times than those using the MPDS ($10.9 \pm 1.7$ vs $9.8 \pm 1.5$ hours; $P < 0.01$). Subjects reported, on average, over an hour more of comfortable wear while using the CLEAR CARE® system.

More recently, Diec and co-workers reported on a large matrix study where sets of 40 subjects each used 28 combinations of lenses and lens care products. When subjects used CLEAR CARE®, they reported statistically significantly better comfort on insertion compared to users of the same lens types with MPDS systems ($8.5 \pm 1.4$ vs $8.2 \pm 1.5$, $P = 0.017$, on a 10-point scale where 10 = excellent and 1 = poor) and comfort equal to that reported by users of daily disposable lenses with no lens care products (average $8.5$ vs $8.4$ on the 10-point scale). A randomized crossover study testing the effect of CLEAR CARE® use compared with an MPDS in symptomatic soft contact lens wearers found that subjects had significantly longer non-invasive tear film break-up times after 3 months of use, and the effect was sustained after that point. The same study showed that tissue signs of poor wettability were significantly better with use of CLEAR CARE®: palpebral roughness and redness were both improved significantly after 3 months of use, but that lid margin staining was not affected by care system. This study suggests that there may be some period of “washout” of the effects of MPDS systems with reusable lenses that may take months to resolve fully. Unlike recovery from corneal staining, clinicians should expect improvements in palpebral conjunctival signs over a period of months, not days.

**Corneal Fluorescein Staining**

Other clinical studies have involved tightly controlled exposures to lenses and lens care combinations. In 2008 Andrasko and Ryen examined corneal fluorescein staining patterns after 2 hours of wear with a variety of lenses soaked in different lens care solutions. Thirty subjects were tested in each trial of 81 different lens/lens care combinations. The same lenses soaked in unpreserved saline served as the negative control. These investigators found that CLEAR CARE® performed similarly to the saline control, with corneal fluorescein staining over no more than 1% to 2% of the corneal area. In contrast, polyquaternium-1-preserved solutions produced corneal fluorescein staining areas ranging from 1% to 7%, while the “majority of the biguanide-based brands showed an excessive level of staining (reaching or exceeding 20%)” (Figure 4). They also reported an inverse relationship between the area of corneal staining and comfort scores, where comfort decreased as staining increased for the lens/solution combinations. Low staining with CLEAR CARE® and the saline control was accompanied by favorable comfort stores.

In a crossover study of 446 adapted contact lens wearers, who used CLEAR CARE® and one of two PHMB-containing MPDSs for 1 month each, Young and coworkers found significantly lower levels of corneal staining depth and area with CLEAR CARE®. In a large Australian study of multiple silicone hydrogel lens materials and current care systems, Carnt and coworkers concluded that CLEAR CARE® “consistently resulted in the lowest rates of toxic staining and corneal inflammation” compared with other disinfecting solutions.

**Corneal Inflammatory Events**

A large retrospective chart review of 3,549 soft contact lens wearers (4,663 years of wear) from age 8 to 33 found that users of $H_2O_2$ systems were at one-third the risk of having a CIE compared with users of MPDS systems (multivariate odds ratio 0.35 (95% CI, 0.16-0.76, MPDS referent). In this study, $H_2O_2$ was not identified as a significant risk factor for CIEs in the post-market clinical setting, compared with MPDS systems.

Researchers at the Brien Holden Vision Institute have reported that when CLEAR CARE® was used with six different silicone hydrogel lenses, CIEs occurred at rates from 0.8 to 2.7% per 100 participant-months (depending on lens type). Rates of CIEs were higher for the three MPDSs tested —1.1 to 10.6%, 1.0 to 5.2%, and 3.3 to 10.4%, respectively. Over 300 subjects were tested with CLEAR CARE® and a silicone hydrogel lens in that study.

Finally, The Brien Holden Vision Institute has just reported a study designed to determine the rate of CIEs and SICS using senofilcon A lenses on a daily
disposable basis (no reuse, no care system) compared with daily wear, using a variety of care systems.38 There were no CIEs at all when the lens was discarded each day. Among patients in traditional daily wear, use of CLEAR CARE® was associated with the lowest rate of CIEs (2.2% per 100 patient-months); this compares favorably with 3.6% rate for patients using a polyquaternium-1 system and 4.2% for the PHMB systems. With respect to SICS, the CLEAR CARE® group performed best, with a rate of 0.4% per 100 patient-months compared to 0.9% for daily disposables, 6.7% with polyquaternium-1 systems, and 10.7% for PHMB systems. As these studies show, patients using CLEAR CARE® have a great chance for successful outcomes with lens wear.

In one report on 80 daily wear patients, Dumbleton and coworkers found overall compliance with lens care was just 37% for MPDS users and, remarkably, 100% for CLEAR CARE® users.

Compliance and Loyalty

Of course, reaching the desired outcome of comfortable and incident-free contact lens wear depends not only on the lens care product but also on patient behavior. It has been estimated that if patients were simply to comply with instructions for care and replacement of their lens case, the incidence of contact lens related microbial keratitis could be reduced by over 60%.

The transparent lens case that is an essential part of the CLEAR CARE® system may help with some of these issues and encourage proper use of the system. Topping off with CLEAR CARE® will greatly reduce the bubbling activity, making it visually obvious to the user that the system is not working properly. With an MPDS and an opaque lens case, no such visual clue exists. In addition, the user is motivated to replace the CLEAR CARE® case and disc regularly, as the ability of the disc to neutralize the H2O2 diminishes over time and bubbling diminishes. The CLEAR CARE® disc has been shown effective for up to 100 uses, long after the solution bottle would be depleted. Regular replacement of the case and disc assembly avoids increasing levels of residual peroxide that may result in mild stinging upon lens insertion.

Contact lens researchers continually find that compliance with the multiple steps required for appropriate lens care is generally poor.40-42 Although there are clinicians who perceive the H2O2 system to be somewhat cumbersome, actual compliance with proper procedure is very high in comparison to MPDS users, who often skip either the rub step or the extended rinse step required by a no-rub regimen. In one report on 80 daily wear patients, Dumbleton and coworkers found overall compliance with lens care was just 37% for MPDS users and, remarkably, 100% for CLEAR CARE® users.43

Not surprisingly, CLEAR CARE® users have also demonstrated strong loyalty to the system in a number of surveys; a recent survey found more than 65% loyalty compared to MPDS users (40%), and nearly 9 out of 10 CLEAR CARE® purchasers report being “very satisfied.” This aligns with a 2007 survey, which found 65% to 70% retention rates with CLEAR CARE®, versus 40% to 50% for leading MPDS brands.32

Important Precautions

Although H2O2 systems in general offer significant advantages over other disinfection methods, there is a potential for users to inadvertently get the solution into their eyes without proper neutralization, eg, if the solution is used in a case designed for MPDSs. As discussed earlier in this paper, the eye is well equipped to neutralize low concentrations of H2O2; rapidly, but full strength 3% H2O2 applied directly to the eye can cause stinging and burning. Inadvertent dosing of full-strength 3% H2O2 is typically accompanied by corneal epithelial staining and edema as well as conjunctival injection—but all of this is temporary. Though accidental instillation of 3% H2O2 can be unpleasant and alarming to patients, a brief reprieve from lens wear is typically the worst outcome.

As a precaution, CLEAR CARE® carries several warnings on the packaging and on the bottle; and the bottle’s bright red tip and cap provide further indication that the product is not to be used directly in the eye. Fortunately, eye care practitioners are fully aware of this issue and typically make a point of providing new users with a solemn warning against misuse. As a result, such incidents tend to be rare among regular users. Those at greatest risk are patients who accidentally purchase an H2O2 system thinking it the same as their accustomed MPDS, and those who borrow or share lens care solution.

Conclusions

The simple, straightforward formulation of CLEAR CARE® has given contact lens wearers an excellent method to keep their lenses clean, disinfected, and comfortable to wear through the
end of the day. Its well-designed formulation leaves small amounts of residual H$_2$O$_2$ on lenses, which is metabolized by naturally-occurring enzymes in the ocular surface tissues. Study after study has shown that use of CLEAR CARE results in positive outcomes. This may be due, in part, to visual cues that help patients use the system properly; they can see the bubbles working when the cup is refilled with fresh solution. After many years of use by many soft contact lens wearers, CLEAR CARE remains a safe, successful option for a large and growing number of patients.

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