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An objective and subjective comparison of Clear Care versus various multipurpose solutions

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An objective and subjective comparison of Clear Care versus various multipurpose solutions

Abstract
In this study funded by Ciba Vision, Ciba's Clear Care one-step hydrogen peroxide solution was objectively and subjectively compared to various multipurpose solutions. Twenty-three soft contact lens wearers with various habitual multipurpose solutions (Optifree=5, Complete=6, Renu=11, Solocare=1) were assigned to either their own solution or the Clear Care solution for disinfection and storage of their lenses for two-week phases. A seven day “wash-out” period without lens wear was completed before each phase to eliminate any corneal staining. At the initial, one-week, and two-week visits, subjects were asked to complete a subjective questionnaire, visual acuity with contact lenses was recorded, and a detailed slit lamp examination of external ocular health was performed. The depth, area and type of any corneal staining was determined by fluorescein staining and documented using a five region template. Clear Care was statistically found (p<0.001) to provide better overall comfort and vision, and reduced symptoms of dryness to a greater extent than various multipurpose solutions. The depth of corneal staining was consistently found to be superficial and Clear Care was found to have a smaller average area and lesser average type of corneal staining after a two-week period as compared to multipurpose solutions. This study showed that Clear Care is an excellent alternative to multipurpose solutions.

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AN OBJECTIVE AND SUBJECTIVE COMPARISON OF CLEAR CARE VERSUS VARIOUS MULTIPURPOSE SOLUTIONS

BY
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A thesis submitted to the faculty of the
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Ericka was born and raised in Medford, WI. She attended both Northwestern College and Bethel College for three years. She finished her B.S. in Visual Science at Pacific University. Upon graduation in May of 2002, she plans to complete a residency in ocular disease.

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Kathy was born and raised in South Carolina. She attended Michigan State University where she graduated with a B.S. degree in Biology. At Pacific University, she held various leadership positions in student government, served as the NOSA liaison, and was a member of Amigos. Upon graduating in May of 2002, she plans on practicing in a private office in Seattle, WA.

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Ben was born and raised in Grundy Center, Iowa. He graduated from Wartburg College in 1998 with a BA in Biology. Ben is currently involved in Beta Sigma Kappa Optometric Honors Society and Amigos Eye Care. He was awarded a two year Air Force Scholarship in 2001. Future plans are to work for the Air Force after graduation for three years and sharpen his skills then work in a partnership practicing primary care and specializing in vision therapy and contact lenses.

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Pam was born in Edmonton, Alberta and raised in Richmond, B.C., Canada. She completed three years of undergraduate work in the Faculty of Science at the University of British Columbia and received her B.Sc. in Vision Science from Pacific University in June 2000. Pam is excited to be involved in bringing vision care to the underserved with the student-run Amigos Eye Care at Pacific University. Upon graduating with a Doctor of Optometry in May 2003, she plans to practice primary care optometry specializing in paediatrics and contact lenses in the beautiful Pacific Northwest.
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Abstract

In this study funded by Ciba Vision, Ciba’s Clear Care one-step hydrogen peroxide solution was objectively and subjectively compared to various multipurpose solutions. Twenty-three soft contact lens wearers with various habitual multipurpose solutions (Optifree=5, Complete=6, Renu=11, Solocare=1) were assigned to either their own solution or the Clear Care solution for disinfection and storage of their lenses for two-week phases. A seven day "wash-out" period without lens wear was completed before each phase to eliminate any corneal staining. At the initial, one-week, and two-week visits, subjects were asked to complete a subjective questionnaire, visual acuity with contact lenses was recorded, and a detailed slit lamp examination of external ocular health was performed. The depth, area and type of any corneal staining was determined by fluorescein staining and documented using a five region template. Clear Care was statistically found (p<0.001) to provide better overall comfort and vision, and reduced symptoms of dryness to a greater extent than various multipurpose solutions. The depth of corneal staining was consistently found to be superficial and Clear Care was found to have a smaller average area and lesser average type of corneal staining after a two-week period as compared to multipurpose solutions. This study showed that Clear Care is an excellent alternative to multipurpose solutions.
Introduction

With the many advances in contact lens materials and designs, the number of options available for our patients has never been greater. These options (toric, bifocals, cosmetic, etc.) have dramatically increased the number of patients that can be successfully fit with soft contact lenses. However, recent studies have shown that in the US, approximately 2,000,000 patients a year abandon their soft contact lenses for alternative modalities such as glasses or refractive surgery. Today, the most common reason cited for lens discontinuation is ocular dryness. Contact lens related dry eye is often not remedied by change in lens design, materials or supplemental artificial tears. In these situations it is important to investigate the lens care products as a possible cause of the symptoms.

Time saving and user-friendly improvements have been the focus of new contact lens solutions. With the advent of the one-step multipurpose solutions, this idea of quick, easy contact lens care has revolutionized the current generation of solutions. Until now, hydrogen peroxide based care regimens have not made this transition. The newest lens solution designed by Ciba Vision is a no-rub, one-step preservative free hydrogen peroxide solution. The cornea and its protective tear layer can be sensitive to preservatives and this may result in a contact lens related dry eye. According to an article written by Campbell et al, "sensitivities to contact lens care products have many manifestations, such as diffuse punctate keratitis, conjunctival injection, subepithelial infiltrates, pseudodendritis and superior limbic keratoconjunctivitis." The greatest challenge with contact lens related dry eye is the ambiguity of its signs. When comparing the subjective complaints of this condition with the objective findings there is often a non-linear comparison. Another difficult factor is its delayed onset. The symptomology often presents after weeks to months of use and may gradually increase over time.

Contact lens related dry eye often goes overlooked and misdiagnosed. There are not many studies conducted or published supporting or refuting this issue. A study funded by Ciba Vision was conducted comparing both subjective symptomology and objective findings comparing the general category of multipurpose solutions to the new one-step hydrogen peroxide solution.

Materials and Methods:

This study was designed to compare subjective and objective dry eye signs and symptoms with Ciba’s one-step hydrogen peroxide lens care system versus various multipurpose lens care systems in alleviating subjective and objective dry eye findings.

23 optometry students (45 eyes) who wore contact lenses were recruited for this study. Each subject habitually wore either two week or one month planned replacement soft contact lenses a minimum of 8 hours a day. All subjects habitually used a multipurpose lens care system for disinfection and storage at night. The subjects were screened to make sure they were free of any systemic disease, had known ocular or systemic hypersensitivity to any contact lens products, and had no known ocular, immunosuppressive, or infectious diseases.

Prior to the initial visit all subjects discontinued their contact lens wear for 7 days. Each subject deemed eligible for the study was given a randomized lens care system and instructed to begin wearing a new pair of their habitual soft contact lenses. This study was done in two phases over a period of 18 weeks. In Phase I, 15 subjects were placed on the CIBA Clear Care system and 15 subjects began their habitual multipurpose solution. The subjects were given oral and written instructions on the proper use of each lens care system as outlined in the manufacturer’s package inserts. The subjects were given a subjective questionnaire to complete and were evaluated for objective findings (corneal staining) at three different intervals: initial/dispensing visit, one week and two weeks.
At the initial enrollment visit the investigators performed a modified ocular examination, which included the following:

- Detailed patient history
- Habitual contact lenses and solutions
- Distance visual acuity with best corrected spectacle Rx
- Slit lamp examination with white light
- Corneal staining evaluation with sodium fluorescein, a #12 Kodak Wratten filter, and cobalt blue light
- Completion of the subjective questionnaire which rated various aspects of the comfort, dryness, grittiness, and visual acuity of their contact lenses
- Read and sign the Statement of Informed Consent

A standard fluorescein staining procedure was performed for both eyes of each subject. A five region corneal staining template was utilized for recording staining (central, nasal, temporal, inferior, and superior) (Figure 2). If a region had more than one type or depth of staining, the greatest amount of staining was graded and recorded.

The subjects were instructed to soak their lenses for a minimum of 8 hours per night in the given disinfecting lens care solution, wear their lenses for a minimum of 8 hours a day, wear the same pair of lenses throughout the course of the two-week phase, and return for scheduled follow up visits. They were instructed to report any ocular complications, lost or damaged contacts lenses, or abnormalities to the investigators.

At the one week follow-up visit the subjects were asked to complete a subjective questionnaire, visual acuity with contacts lenses was recorded, and a detailed slit lamp examination was performed to both verify the surface quality and fitting of the lenses. Edema, neovascularization, bulbar and tarsal hyperemia, and any other abnormal findings were graded on a scale of 0 to 4. The lenses were then removed, fluorescein dye was placed in the eyes, and any corneal staining was recorded and graded.

At the two-week follow-up visit the same protocol was followed as the one-week visit. At the completion of the two-week visit, the subjects were asked to discontinue wearing their contact lenses for 7 days. After baseline measurements were obtained, Phase II ("solution crossover") was initiated with the subject using a new pair of lenses and the second lens care system. The same protocol was followed as in the initial phase.
The various habitual chemical disinfection multipurpose systems (MPS) consisted of a surfactant cleaner and a rinsing/disinfection solution. One step multipurpose solutions are simple and convenient however, the potential exists for hypersensitivity reactions and increased epithelial staining.²

CIBA Vision's Clear Care hydrogen peroxide disinfection system included a sterile solution containing 3% micro-filtered hydrogen peroxide, 0.79% sodium chloride, phosphonic acid for product stability, a phosphate buffered system, and Pluronic17R4 (cleaning agent). The goals of hydrogen peroxide neutralization are to bring the concentration of the solution to less than .005 to .006% (an effective percent as a preservative), neutralize the pH of the solution (7.0–7.4) with a platinum disc, and bring it to an isotonic solution (equal to 0.9% NaCl).

**Results**

Objective and subjective data were collected and recorded for the two-phase study. At each of the follow-up visits, the subjects completed a questionnaire surveying overall comfort, the degree of dryness and the overall vision during the previous week of lens wear (Figure 3,4,5).

![Overall Comfort At Two Weeks](image)

Figure 3. Overall comfort of lenses at two weeks.

Patients gave Clear Care an average comfort rating of 4.4 (SD=0.6) on a scale of 1 to 5, with 5 considered excellent. The average comfort rating for the multipurpose solutions was 3.7 (SD=0.8). The ratings for the AOSept Clear Care were statistically significant (p<0.001) when compared to the patient's current multipurpose solution.

Figure 4. Overall subjective dryness of lenses at two weeks.

A 1 to 5 scale was used to evaluate the patient's perception of the degree of dryness with each lens care system, where 1=constantly felt dry and 5=never felt dry. The dryness rating for AOSept Clear Care was 3.7 (SD=0.7) compared to 2.9 (SD=0.3) for the multipurpose preserved solutions. Clear Care provided significantly ($p<0.001$) less symptoms of dryness than the multipurpose solutions.

Figure 5. Overall subjective vision at two weeks.
The patients were also asked to rate the overall comfort of lens wear while using each solution on a 5 point scale where 1=poor and 5=excellent. **AOSept** Clear Care received an average rating of 4.5 (SD=0.7) and the multipurpose solutions received an average rating of 3.6 (SD=0.9). This higher rating for Clear Care was statistically significant (p<0.001).

The depth of staining was consistently found to be superficial so the focus was then placed on the area of staining and type of staining. The average of both categories at the baseline, 1 week, and 2 week evaluation was determined for each solution. The average area of staining for the multipurpose solution was 4.6% at baseline, 2.9% at 1 week, and 5.8% at 2 weeks while Clear Care solution was 5.6% at baseline, 2.4% at 1 week, and 3.4% at 2 weeks (Figure 6).

![Ave. Area of Staining](image)

Figure 6. Average area of staining at weeks 1, 2 and 3.

The type of staining was rated on a scale of 0=none, 1=micropunctate, 2=macropunctate, 3=coalesced macropunctate and 4=patch (>1mm). The average type of staining for the multipurpose solution was 0.31 at baseline, 0.23 at 1 week, and 0.37 at 2 weeks while Clear Care was 0.44 at baseline, 0.23 at 1 week, and was 0.31 at 2 weeks (Figure 7).

![Ave. Type of Staining](image)

Figure 7. Average type of staining at weeks 1, 2, and 3.
Discussion

The purpose of this study was to compare corneal staining and symptoms of dryness with a one-step hydrogen peroxide system versus a preserved multipurpose solution care regimen. It has been shown in various studies that the numerous preservatives added to multipurpose solutions cause dry eye symptoms. These symptoms often lead to discontinuation of lens wear or a reduction in lens wearing time.

What is contact lens related dry eye? According to an article in Contact Lens Spectrum February 2001, Nichols et al reported that some feel that contact wear alters composition of tear film creating an unstable lipid layer. Dry eye is defined as a "disorder of the tear film resulting from a tear deficiency and increased evaporation leading to interpalpebral ocular surface damage accompanied by dry eye symptoms." Contact lens wear is a known cause of an increase in dry eye symptoms. According to the Dry Eye Investigation (DREI), contact lens wearers reported more frequent ocular discomfort, dryness, visual disturbances, soreness, irritation, and foreign body sensation than non-wearers. In fact, 50% of contact lens wearers reported intense eye dryness in the evening versus 22% in non-wearers. Survey results show that the top two reasons why students stopped wearing their lenses were due to eye dryness and discomfort later in the day.

In this study, subjective results clearly supported the participants' preference for Clear Care over their current multi-purpose solutions. Results indicated a statistically significant reduction in dryness, an increase in comfort and better overall vision. For the purposes of this study, corneal staining was used as the objective measure of dry eye although SPK findings do not always reflect the severity of dry eye symptoms and cannot solely be used as an indication of dry eye relief with the changing of care regimens. The objective results were mixed; there was a trend for long term improvement but the study length of 2 weeks was insufficient to differentiate a decrease in corneal staining with the use of Clear Care from normal variations in corneal staining.

In conclusion, it has been shown statistically that Clear Care is an excellent alternative to multipurpose solutions.

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