Evaluation of the PuriLens® Contact Lens Care System: An Automatic Care System Incorporating UV Disinfection and Hydrodynamic Shear Cleaning

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Purpose: This study evaluates lens care using the PuriLens® System, an advanced way to clean and disinfect soft hydrophilic lenses using subsonic agitation and UV radiation, respectively.

Methods: A two-period crossover lens cleaning and safety investigation was conducted using 80 patients. Disinfecting efficacy was tested in accordance with standard FDA protocols. Lens compatibility was studied with Group I and Group IV lenses during the equivalent of a 6-month care regimen by measuring: lens power, base curve, wet diameter, refractive index, clarity, and tint. Safety was evaluated through slit-lamp findings, wearing time, comfort, and visual acuity.

Results: The mean wearing time of patients in the study was 13.79 hours. No slit lamp findings greater than grade 2 were noted. Visual acuity was 20/25 or better in 92.5% of examinations. None of the patients lost more than two lines of acuity. Lens surface evaluation showed no deposits (grade 0) to very slight deposits (grade 1) in 94.4% of examinations. Lenses cleaned with the PuriLens System were cleaner by a statistically significant margin (P=0.02) compared to lenses digitally cleaned with a leading multi-purpose solution (ReNu®, Bausch & Lomb). Overall, neither the Group I nor Group IV lenses were affected after 180 cleaning cycles.

Conclusions: The PuriLens System provides automatic lens care compliance, superior antimicrobial efficacy, and eliminates the need for daily digital cleaning.

Introduction

Contact lens wearer satisfaction is often less than optimum despite disposable lenses and significant advances in today’s contact lens materials, designs, and fitting techniques. Industry sources estimate that as many as 10% of all contact lens wearers stop wearing their lenses in any given year, and the dropout rate for new wearers may be as high as 20%.

A significant contributing factor to these rates relates to contact lens care, both from a compliance and effectiveness perspective. Indeed, contact lens care systems are often an overlooked cause of contact lens wearer problems and complaints. Lens care-related problems occur as a result of a variety of factors. These include patient compliance, the effectiveness of care systems, or difficult-to-diagnose sensitivities to lens care system ingredients.

To put the issues of compliance into proper perspective, Collins and Carney reported that 43.3% of patients follow instructions, 27.1% do not follow instructions but think they do, 13.3% are confused or unreliable, and 16.3% know they are not following instructions.1 In many cases, patients never received proper instructions, or they’ve forgotten them.2 Failure to comply with a lens care regimen can damage a patient’s contact lenses, cause significant ocular irritation, and lead to sight-threatening infections.
Mechanical cleaning (rubbing) loosens deposits and debris but may adversely affect lens surfaces. Contact lens solutions containing disinfecting agents, enzymes, surfactants, or preservatives can cause transient stinging, burning, frank allergic reactions, or lead to delayed hypersensitivity. Solutions containing disinfecting agents, enzymes, surfactants, or preservatives can even cause changes in lens thickness and power.

Multipurpose solutions have been shown to lead to multipurpose solution-induced lens dryness sensations in some patients. Patients with multipurpose solution lens dryness complaints may have a delayed sensitivity reaction to multipurpose lens care regimens. They present with completely normal external findings and complain of only one symptom, ocular dryness. This condition may represent one of the leading causes of patient dissatisfaction with soft contact lenses including disposable lenses.

Rinsing is an integral step in all contact lens care systems. The rinsing step is required to carry away debris. This critical step contributes to the disinfecting efficacy and biocompatibility of a lens care system. Many contact lens wearers do not realize that hydrogel lenses must be rinsed in an isotonic saline or balanced salt based solution. Rinsing with tap water can cause significant changes in lens parameters, and contaminants in tap water can invade the lens matrix. Disinfectants reduce the microbial contamination of lenses and the lens storage system. However, studies have shown that heat, hydrogen peroxide, and chemical disinfection regimens are not always effective in eradicating bacteria from solutions in patients’ contact lens cases, even when the disinfection technique is performed properly. Finally, one of the greatest sources of contamination is the lens case itself. There are places in the case that never come into contact with the disinfectant and may harbor bacteria within accumulated biofilm layers.

The PuriLens® System is a contact lens care system for cleaning and disinfecting all soft, hydrophilic contact lenses. The System uses PuriLens Solution, a non-preserved sterile isotonic solution of sodium chloride buffered with boric acid and sodium borate. The cleaning step is accomplished by a magnetic pedal suspended on the end of a flexible arm. The pedal is located at the bottom of the cleaning chamber. When activated by the electronic connection, the pedal oscillates in a subsonic range of 60 cycles per second. This creates hydrodynamic shear that strips deposits and microorganisms from the lens surfaces and suspends them in the preservative-free solution. The disinfection step is accomplished by ultraviolet irradiation of the loosened, suspended microorganisms. The PuriLens System radiates microorganisms with UV-C at 253.7 nm = 1000 µW/cm² at 1 inch for 15 minutes. The UV radiation is absorbed by the microorganisms’ DNA, causing cross-linking and breaking of the nucleic acid bonds, resulting in rapid cell death.

Ultraviolet (UV) lamps are widely used in industry for their germicidal effectiveness. UV radiation appears to be 10 times more effective than two-step H₂O₂ disinfection and 100 to 200 times more effective than other currently available disinfecting solutions. The cleaning and disinfection activity of the PuriLens System is completed in a 15-minute cycle without the use of preservatives, chemical disinfectants, or digital cleaning of the lens by the patient. The present study was designed to evaluate the safety, cleaning and disinfection efficacy, and lens compatibility of the PuriLens System.

Methods and materials

A safety and cleaning investigation was conducted as a two-period crossover design using 80 patients. Sample size was determined by StatXact software with the upper 95% confidence limit set at 5%. The study design is shown Table I.

Participants were normal patients from 18 to 60 years of age of either gender, with no previous corneal disease or abnormality. Of the 80 patients, 60 were female. In the first period, 40 patients were randomly assigned to the PuriLens System for three months and 40 to the Baush & Lomb ReNu Multipurpose Solution, a sterile isotonic solution containing boric acid, edetate disodium, poloxamine, sodium borate, and sodium chloride preserved with 0.00005% polyaminopropyl byguanide. After a 1-week washout period, each group of 40 crossed over to the other regimen for three months. Patients were instructed to use their customary disinfection regimens and a new set of lenses during the washout period. Therefore, the total elapsed time for the investigations was approximately 7 months. Parameters were measured at days 0, 7, 30, 60, 90, during crossover, and days 97, 104, 127, 157, and 187.

System safety was determined by monitoring patient visual acuity and slit lamp findings. Visual acuity loss of two or more lines in any patient would indicate that visual performance was compromised. Slit lamp findings were monitored on each visit. Any findings of grade 3 or worse on a scale of 0 to 4 would indicate safety concerns. The slit lamp evaluation included epithelial edema, epithelial microcysts, stromal edema, corneal neovascularization, corneal staining, bulbar hyperemia, and palpebral conjunctival observations. The average daily wearing time for study participation was approximately 7 months. Parameters were measured at days 0, 7, 30, 60, 90, during crossover, and days 97, 104, 127, 157, and 187.

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Lens cleanliness using the PuriLens System was evaluated qualitatively, using slit lamp evaluation and a 5 point grading scale, and quantitatively using image analysis of
deposits according to the method of Lowther and coworkers. Lowther’s test consisted of a cell modified to accept and drain a flow of normal saline while maintaining a maximal fluid level for the contact lens. This cell was arranged with circular fluorescent lamp and black background to produce a dark-field stage for video microscopy. The video camera (Pulnix TM-70) output was routed to an EPX digitalization frame-capture board functioning in a Pentium 200 microcomputer running the Windows NT operating system. Contact lenses were worn by subjects at five remote clinical sites for a specified period. At period end, lenses were removed, rinsed in saline, and heated in a microwave to “fix” deposits. Lenses were then express-mailed, next day delivery, to the test laboratory for analysis. Once at the test laboratory, lenses were rinsed again with saline and placed into the test cell with soft-tipped tweezers under saline flow to remove incidental dust specks and other debris. The video image capture was then initiated. Video data acquisition consisted of capture of 10 consecutive video frames. These frames were mathematically averaged to eliminate variance in signal. A standard 10 mm sample circle was then centered within the test lens image. The 10 mm sample circle contained 16,420 pixels, which record the white light brightness on a scale between zero (dark) and 255 (white) brightness units. For each lens, the mathematical mean of the 16,420 measurement points was calculated and became the data point for that lens.

A combined total of 311 PuriLens and control multipurpose solution lenses were shipped and evaluated. Each lens arrived in a separate sealed contact lens vial, labeled with the site, patient, and eye. The investigators and technicians remained blind as to whether a lens was test or control group during data collection. Lenses that were not worn for the full study period were identified and excluded from analysis. A total of 30 lenses were found to not be full-term lenses, leaving 281 lenses for valid analysis. To accommodate for variance in tube illumination, daily ground-glass standard test-control cases were identified.

Disinfection efficacy was tested with strict adherence to the Good Laboratory Practice Act and in accordance to standard operating procedures and applicable standard FDA protocols. Using Bacillus pumilus at 3.4 x 10⁹ colony forming units (cfu) per milliliter, the following time points were selected for definitive study: 3 minutes, 4 minutes, 7 minutes, 10 minutes, and 15 minutes. Percent reduction in cfu/mL using this organism was 99.958% after one minute and 99.998% after only two minutes. Organisms used in this study included: Pseudomonas aeruginosa, Staphylococcus aureus, Serratia marcescens, Candida albicans, Bacillus pumilus, and Fusarium solani.

PuriLens System Lens compatibility was studied using FDA protocol guidelines, with a test designed to assess the effect of the PuriLens device and the PuriLens buffered solution on Group I hydrophilic lenses (Bausch & Lomb Optima FW polymacon visitinted lenses) and Group IV hydrophilic lenses (Sunsoft Revolutions methafilcon A visitinted lenses) during the equivalent of a 6-month (180 cycles) recommended care regimen. Optical, physical, and chemical parameters were evaluated. All lens types were labeled with the following parameters: –2.0 Rx, 14.0 diameter, 8.7 BC.

Fourteen Group I lenses and 14 Group IV lenses were used in this study. Lenses were removed from their storage vials and placed in PuriLens Solution for 24 hours to equilibrate. After equilibration, the following were measured: 1) lens power, 2) lens base curve, 3) lens wet diameter, 4) refractive index, 5) UV/visible light transmittance (for lens clarity), and 6) UV/visible light absorbance (for discoloration and tint). After initial parameters were measured, lenses were rinsed with PuriLens Solution and placed into PuriLens disinfection units (2 lens/unit) along with fresh PuriLens Solution.

After a disinfection cycle (13–16 minutes), each lens was removed from its holding basket and flexed, to simulate actual patient handling, before it was returned to its PuriLens unit containing fresh PuriLens Solution. This procedure was repeated for each of 30 cycles. Following each 30th cycle, parameters were re-measured after removal of the lens from the PuriLens unit and rinsing with PuriLens Solution. The process was repeated until each lens had undergone 180 cycles. After the 180th cycle, parameters for each cycled lens were measured, each lens was equilibrated with PuriLens Solution for 24 hours at room temperature, and parameters were re-measured. The following parameters measured after each group of 30 disinfection cycles are listed below.

**Diameter:** the average of two measurements along both the x and y axes for each lens was determined using a calibrated Nikon Projector.

**Base Curve:** base curve was determined using a calibrated Mitutoyo Profile PH-350 Projector and calculated using the following formula:

\[
BC = \frac{(d/2)^2 + s^2}{2s}
\]

where BC = base curve; s = sagittal height; and d = diameter.

**Power Measurements:** power was determined using a Marco LM-770 Lensometer.

**Refractive Index:** the refractive index was determined for Group I and Group IV lenses using an Abbe Refractometer (Mark II).

**UV/Visible Light Absorption Spectra (Color):** spectra were monitored between 325 and 800 nm using a UV/Vis Spectrophotometer. The ultraviolet and visible light absorption spectrum of a contact lens material can be used to
monitor changes in the lens material and in associated dye molecules in the case of tinted lenses.

**UV/Visible Light Transmittance (Clarity):** UV/visible light transmittance was measured from 325 to 800 nm for all lenses studied using a UV/Vis Spectrophotometer. The objective of this measurement was to determine whether cycling affected lens clarity.

**Results**

**Clinical Studies:** Over the course of the study, visual acuity was 20/25 or better in 92.5% of examinations. Visual acuity data showed no statistical difference between the PuriLens group and the multipurpose solution control group.

Slit lamp microscopic evaluation indicated no findings above grade 2 throughout the study for the PuriLens System. The slit lamp findings at the end of each period (day 90 and day 187) are of primary interest because they capture the longest exposure of the subjects’ lenses and eyes to the lens care system. An analysis to determine any difference between the PuriLens and the control system showed a lack of statistical significance ($P<0.05$). Most of the slit lamp findings were related to low-grade (grade 1) bulbar hyperemia. A total of 584 slit lamp examinations of patients using the PuriLens System were conducted during the clinical study. Grade 1 and 2 positive findings are shown in Table II.

The mean average wearing time of patients using the PuriLens System during the study was 13.79 hours. PuriLens System patients reported lens comfort as comfortable, very comfortable, or excellent in 94.4% of examinations. Patient lens comfort rating by grade, based on a total of 296 examinations over the course of the study are shown in Table III.

Lens cleanliness was evaluated qualitatively via slit lamp examinations of lens front surfaces using a grading scale of 0 to 4. The lens surface characteristics of PuriLens cleaned lenses, based on a total of 295 slit lamp examinations over the course of the study are shown in Table IV.

A quantitative analysis of the clinically worn lenses was conducted on a double blind basis. This quantitative analysis used microcomputer enhanced image analysis designed to measure light transmission through lenses according to the method of Lowther and coworkers.¹³ The results showed that the PuriLens-cleaned lenses measured 2.61 image brightness units (10.4%) lower (cleaner) than the multipurpose solution digitally cleaned lenses when matched for patient and eye. The cleanliness improvement of the PuriLens-cleaned lenses compared to the multipurpose solution cleaned lenses was statistically significant at $P=0.02$.

**D-value Studies:** Disinfection efficacy was evaluated according to current FDA guidelines. PuriLens System D-value results are provided in the Table V. The test results demonstrated that a 99.99% reduction was achieved for all organisms by the 10 minute mark with the exception of *Candida albicans* (99.98% reduction at 10 minutes) and *Fusarium solani* (99.98% reduction at 10 minutes). All organisms achieved a D-value of greater than 99% reduction in all three runs at the 3 minute time point of the cycle. The results demonstrate that the PuriLens System reduces the population of microorganisms by a minimum of 4 logs at the end of the 15 minute cycle at the lowest energy setting of the device (280 mamps). Significant reductions were achieved at much shorter times for gram negative, gram positive, yeast, mold, and spores.

**Lens Compatibility Studies:** Results of studies conducted to determine lens compatibility of the PuriLens System are presented below.
TABLE V D-value results

<table>
<thead>
<tr>
<th>Organism</th>
<th>Trial</th>
<th>Inoculum</th>
<th>3 min.</th>
<th>4 min.</th>
<th>7 min.</th>
<th>10 min.</th>
<th>15 min.</th>
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</tr>
<tr>
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<td>$1.0 \times 10^0$</td>
<td>$4.0 \times 10^0$</td>
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<tr>
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<td>$9.0 \times 10^0$</td>
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<td>$9.0 \times 10^0$</td>
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<tr>
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<td>$1.3 \times 10^0$</td>
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<tr>
<td><em>F. solani</em></td>
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<td>$1.6 \times 10^0$</td>
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</table>

**DIAMETER**: Pre-cycle Group I lens average diameters (14±0.02 mm) were not significantly different from Group I average diameters (14±0.03 mm) after 180 cycles ($P<0.05$). Pre-cycle Group IV lens average diameters (14.3±0.3 mm) were found to be slightly elevated (14.4±0.05 mm) after 180 disinfection cycles (within lens manufacturers specifications).

**BASE CURVE**: The Group I lens base curve average value (8.7 mm) after cycling did not change from the initial base curve average value measurement (8.7 mm). Group IV lens base curve averages showed an increase after cycling, as the pre-cycle value (9.6±0.05) was increased by cycling to 9.7±0.06 mm (within manufacturers specifications).

**POWER MEASUREMENT**: Lens power measurements between pre-cycle and post-cycle were less than 0.25 diopters. The systematic error for lens power measurement was determined to be 0.25 D and all lens power variation was within this range.

**REFRACTIVE INDEX**: Determining the refractive index of a contact lens is sometimes useful for detecting chemical changes, such as extent of cross-linking, in the lens material and for monitoring changes in the lens water content. Refractive index values of 1.44 for Group I lenses and 1.40 for Group IV lenses were not affected by cycling.

**TINT**: Results for Group I contact lenses before and after cycling (Figure 1 [left]) reveal the same two absorption maxima, approximately 590 and 650 nm. Thus, no change in the chemical composition of the lens material or in tint was detected. The data also indicate there was no discoloration of the lenses studied because no new absorption bands were apparent. There was, however, a decrease in the tint concentration, as evidenced by a decrease in the height of the 590 and 650 nm absorption bands.

Spectra using Group IV contact lenses before and after cycling are presented in Figure 1 (right). Absorption spectra for the lenses at the start of the cycling study are similar to the spectra for the same lenses at the end of the study. In both spectra, the maximum absorbance band is approximately 600 nm, and the absolute absorbances in both spectra are similar enough that they are nearly superimposable. In addition, no
new bands were detected, indicating unchanged tint with no apparent discoloration.

**CLARITY:** Results for Group I and Group IV lenses are presented in Figure 2 (left) and Figure 2 (right), respectively. The initial and the final spectra for both lens groups are comparable, indicating no change in lens clarity from the initial 98% light transmittance measurements.

**Discussion**

Although significant advances have been made in contact lens materials, designs, fitting techniques, and care systems, wearer problems persist. It is generally held that many problems that plague contact lens wearers relate as much or more to the lens care system they are using as to the specific lenses they are wearing. Allergic and toxic reactions related to chemical disinfection have not gone away. In fact, they may be more prevalent than we think because of the difficulty of diagnosing them. Lenses are still exposed to preservatives and disinfecting agents.

Patient compliance-related problems are well documented. It is the rare patient who, when confronted, will admit that they have not been following your instructions or the instructions on their care products package. Patient compliance is one of the most prevalent problems faced by all health care providers. Even with the advent of easier-to-use care systems, patient noncompliance is still extensive. Non-compliance has been reported in 40–70% of all contact lens wearers.1,15,16

Some problems with ultraviolet sterilization of extended wear contact lenses were previously reported and evaluated by Dolman and Dobrogowski.17 They reported that exposure of 3 minutes was germicidal for organisms used but that long-term exposure of lenses to UV caused softening and opacification of the lenses. Gritz and coworkers11 also documented the germicidal activity of UV but agreed that contact lens materials were altered and showed marked changes after only 2 hours of exposure. The lens care system evaluated in this study avoids these concerns with the incorporation of a unique patented method—a special lens holder that prevents direct exposure of the lenses to the ultraviolet light. Lens compatibility using the PuriLens System was studied using FDA protocol guidelines on Group I and Group IV hydrophilic lenses during the equivalent of a 6-month recommended care regimen. These studies and clinical studies of actual patient use have documented no lens changes even after prolonged use of the PuriLens System.

The PuriLens System uses subsonic agitation to create hydrodynamic shear in a preservative free solution that strips lipids, mucin, protein, and microorganisms from the lens surface. Disinfection is accomplished simultaneously using ultraviolet (UV) radiation. The disinfecting and cleaning cycle is automatically activated when the top is placed on the System unit, and the unit automatically shuts off at the end of the 15-minute cycle. Lenses can be worn immediately or can remain in the unit for storage up to 24 hours.

Patients participating in the PuriLens System clinical trials gave the System high ratings. On a scale of 1 to 5 with 5 as highest, patients rated wearing comfort 4.1, wearing time 4.2, and cleaning ability of the system 4.2. At the conclusion of the study, ratings by over 80% of patients showed the System provided “like new” lens comfort and clarity.

In summary, the PuriLens contact lens care system is fully automatic minimizing the role of patient compliance. It is simple and easy to use. It provides quick disinfection and superior cleaning (without digital rubbing) when compared to a leading multipurpose solution. It uses no chemicals, surfactants, or...
enzymes and, therefore, eliminates the risk of sensitivity reactions.

Increasing contact lens wearer satisfaction and wearing enjoyment is a primary goal of all contact lens specialists. Reducing problems related to preservatives, disinfecting agents, and patient non-compliance, while making it easier to care for contact lenses, should have a dramatic effect on reducing contact lens wearer dropout. This study indicates that the PuriLens System is highly user and lens compatible. It offers significant advantages compared to currently available contact lens cleaning and disinfection systems.

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References

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