CONTACT LENS

Safety and Efficacy of a New Hydrogen Peroxide Disinfection System for Soft Lenses — In-a-Wink™

D. Lutzi*
M. Callender**

Abstract

A six-month study was conducted to establish the safety and efficacy of Ciba Vision 'In a Wink™' hydrogen peroxide disinfection system. Patient acceptance, ocular response and lens cleanliness were good for all twenty nine subjects evaluated. However, a small number of subjects found greater lens comfort when they used a longer neutralization time than is currently recommended by the manufacturer.

Abrégé

Une enquête d'une durée de six mois a été menée pour déterminer la sureté et l'efficacité d'un système de désinfection à base de péroxide d'hydrogène (In-a-Wink) de la maison Cibavision et 29 sujets de l'enquête ont rapporté favorablement la commodité du système, la propreté de la lentille et le confort oculaire. Toutefois, quelques sujets ont rapporté un plus grand confort en prolongeant le temps de la neutralisation recommandé par le fabricant.

The search for the ideal contact lens care system has been ongoing since the introduction of soft contact lenses. Heat disinfection was the first system to be approved by the US Food and Drug Administration. Although heat is effective in killing vegetative microorganisms, there are a number of shortcomings with this system, notably its inconvenience for some patients where the electrical supply may be different (or non-existent) during travel, malfunctioning of the system, reduced longevity of the lens due to denaturation of tear proteins on the lens surfaces and polymer degradation of high water content soft lenses.[1-5]

Chemical disinfection was later developed as an alternative to heat. Unfortunately, many of the systems currently available appear to precipitate adverse ocular responses in a number of patients.[5] These adverse responses may be related to patient non-compliance, inadequate cleaning, cytotoxicity and/or allergic response to one or more of the disinfectants (Thimerosal and Chlorhexidine) in the system.[6-8]

The use of hydrogen peroxide as an alternative to other chemical disinfection systems has been well-received by Canadian practitioners since the introduction of the Septicon® system by Warner-Lambert.[9] In addition to having a shorter disinfecting time, this system appears to aid in the cleaning of the soft contact lens.[10] However, there is a potential risk to the eye if the residual hydrogen peroxide is not neutralized. With the Septicon system, a six-hour period of neutralization by a platinum catalytic disc in a preserved saline is required before the lens can be placed on the eye. Also, the platinum disc becomes spent after three months of daily use and must be replaced to ensure neutralization of the residual peroxide.

Because of this shortcoming of the Septicon® system, other methods of neutralizing the residual peroxide have been developed recently by the major pharmaceutical companies. Cooper Vision Inc. has accomplished this by using sodium pyruvate as the neutralizer in their Mira-Sept® system, while Ciba Vision Care and Allergan Pharmaceuticals both utilize an enzyme, catalase, as the neutralizing agent in their "In-a-Wink™" and Oxysept® systems respectively. With these new hydrogen peroxide systems, the neutralization procedure is completed in 20 minutes.

The purpose of this clinical study was to evaluate the safety and efficacy of one of these new hydrogen peroxide systems, Ciba Vision Care, "In-a-Wink®", for a period of six months.

Materials and Methods

Care System

The care system consisted of Ciba's 'In a Wink™' daily cleaner, 'In a Wink™' disinfectand and 'In a Wink™' neutralizing rinse. The daily cleaner is a sterile isotonic solution containing sodium chloride

* O.D. Clinical Supervisor
** O.D., M.Sc., F.A.A.O., Member of Faculty School of Optometry University of Waterloo

and cleaning agents, preserved with 0.25% sorbic acid and 0.50% edetate disodium. The disinfectant is 3% hydrogen peroxide. The neutralizing rinse is a sterile isotonic solution containing sodium chloride, catalase, a neutralizing agent and is preserved with 0.1% sorbic acid and 0.20% edetate disodium.

Selection of Subjects

A total of 29 subjects (15 male and 14 female) were chosen from our clinic population. All subjects were previously successful Ciba soft lens wearers. The previous care systems used by the participants are tabulated in Table 1. Two of the patients had previously confirmed adverse reactions to a chemical care system. One of the two had a reaction to the Flexcare® system while the other reacted to the Hydrocare® system. Both were subsequently successful with the Septicon® system.

Table 1

Previous Care Systems Used

Hydrocare (Allergan)	11
Unicare (ICN)	6
Septicon (AOCO)	5
Bausch & Lomb Chemical	4
Flexcare (Alcon)	3

Lens Evaluation

All subjects were supplied with a new pair of lenses upon commencement of the study. Each lens received from the manufacturer was analysed for deposits using the Rudko technique for inspection and classification.[11] As well, a spectrophotometric analysis was done in the lens optic zone on a Zeiss DMR21 spectrophotometer at wavelengths 500nm and 280nm respectively. Wavelength 500nm was selected to obtain baseline data for visible light transmittance which, for a new lens, should be at least 97% T. Wavelength 280nm was chosen for protein detection since most proteins strongly absorb ultraviolet radiation at this wavelength.

Initial and Follow-up Procedure

At the initial visit each subject received the new pair of Cibasoft® lenses, the In-a-Wink® system and a Barnes-Hind Hydra-MatII® case.

All subjects were instructed to clean the lenses nightly with the daily cleaner followed by a rinse with the neutralizing solution before storing in the hydrogen peroxide disinfectant for a minimum of 20 minutes.

The participants were given the option of either leaving the lenses for 20 minutes in the disinfectant followed by overnight in the neutralizing rinse or overnight in the disinfectant followed by 20 minutes in the neutralizing rinse.

At the initial and all subsequent visits, data were collected on visual acuity, refractive status, biomicroscopy, pachometry, keratometry and lens performance. Follow-up visits were scheduled for 1 week, 1 month, 2 months, 3 months and 6 months after lens delivery. Additional visits were scheduled when problems occurred. On each visit any abnormalities were noted and quantified. In addition, each lens was examined for deposits according to the Rudko procedure. The six month visit also included a spectrophotometric analysis of all lenses worn for the entire six month period. Lenses that had been replaced for loss or rippage during the span of the study were not included in the spectrophotometric analysis.

Results

Patient Response

The overall response to the In-a-Wink™ system was good. A total of 28 subjects completed the six month study. One subject was deleted because she missed the three and six month visits.

Table 2 summarizes the subjects' responses when asked to compare the investigational care system with their former care system — with respect to comfort, cleanliness and convenience. In general, 90% of the subjects found the new system was as comfortable or more comfortable than their former system. 97% reported that their lenses felt as clean or cleaner than with the former system. Those subjects who used a weekly enzyme cleaner with their former system found the new system more convenient while those using an all-in-one solution found the system less convenient.

Table 2

Subjects' Comparative Assessment of the Investigational System With Former Care System

	Enhanced	Unchanged	Reduced
Comfort	8 (28%)	18 (62%)	3 (10%)
Convenience	11 (38%)	14 (48%)	4 (14%)
Cleanliness	12 (42%)	16 (55%)	1 (3%)

It was noted that the lens case "exploded" during the neutralization cycle. This was due to a lack of venting for the oxygen produced when hydrogen peroxide is decomposed by the catalase. The currently marketed case is not prone to this problem.

Since the subjects were allowed to choose between 20 minutes and overnight disinfection followed by neutralization depending on their life style, it is interesting to note that 15 subjects (52%) chose to disinfect overnight. Seven subjects (24%) chose to disinfect for 20 minutes and the remaining seven subjects (24%) varied between overnight and 20 minutes disinfection.

Five of the subjects who chose overnight disinfection experienced burning and stinging with lens insertion. In one of these cases, biomicroscopy revealed a mild conjunctival injection, grade 2 corneal staining and corneal edema. Biomicroscopy was negative for the other four subjects. In all five cases, these signs and/or symptoms were alleviated by switching to a 20 minute disinfection followed by overnight neutralization.

Biocompatibility of the In-a-Wink™ system with the ocular tissues was good in all but the one case described above. None of the findings listed in Table 3 are particularly significant. The frequently observed grade I staining is a clinically acceptable finding among the various types of care systems including heat.

Table 3
Frequency of the Biomicroscopy Signs

	Initial	1 wk.	1 mo.	2 mo.	3 mo.	6 mo.
Injection						
— mild	2	1	0	0	0	2
— moderate	0	0	0	0	0	0
— severe	0	0	0	0	0	0
Staining						
— Gr. 1	1	5	8	5	10	9
— Gr. 2	0	4	2	1	1	2
— Gr. 3	0	0	0	0	0	0
Striae	0	0	0	0	0	0
Edema	0	1	0	0	0	0
Infiltrates	0	0	0	0	0	0
Vascularization	0	0	0	0	0	0
Conjunctival Changes						
— mild	0	0	0	4	6	6
— moderate	0	0	0	0	0	0
— severe	0	0	0	0	0	0
Total eyes	57	57	57	57	55	55

Lens Deposits

Following six months of wear, only six of the 55 lenses showed deposits according to Rudko's classification. Table 4 summarizes these findings.

Table 4

Classification of Deposits Observed on Lenses During the Six months Study Period

I	49	(89.0%)
II	3	(5.5%)
III	3	(5.5%)
IV	0	(0 %)

27 of the original 57 lenses underwent spectrophotometric analysis at the end of the six month period. At wavelength 500nm, no apparent change in visible light transmission occurred over the six month period. Average transmission at this wavelength was 97.96% at baseline and 97.28% at 6 months. As well, there was no apparent change in UV transmission at wavelength 280nm. Average transmission at this wavelength was 90.63% at baseline and 89.72% at 6 months. One would expect that the presence of protein deposits on the lens would reduce UV transmission. However, incidence of lens deposits was apparently low in this study and, if located outside of the 0.1mm slit area measured by the spectrophotometer, would not be analysed.

Conclusions

The new Ciba 'In-a-Wink™', system appears to be a safe and effective soft lens care regimen. Adverse effects during the course of the study were minimal. The edema and red eye response of one patient was easily resolved by allowing the lenses to soak in the neutralizer rather than the disinfectant overnight. The initial burning and stinging experienced by those subjects who stored their lenses overnight in the disinfectant followed by a 20 minute neutralization may be due to a temporary acid shift in the pH of the neutralizer rather than residual hydrogen peroxide. Laboratory analysis shows that all residual peroxide is neutralized within the first 5 minutes of exposure to the neutralizing rinse.[12] Copious rinsing with fresh neutralizing rinse prior to lens insertion effectively alleviates these symptoms.

The In-a-Wink™ system appears to be an effective cleaner as the presence of lens deposits was minimal. For those patients who tend to show heavy deposits, one of the currently marketed enzymatic cleaners may be used in conjunction with this care system.

This hydrogen peroxide system has many advantages over other chemical and heat disinfection systems. It can be used with all types of hydrogel lenses including high water content extended wear lenses. This system does not contain thimerosal or other known ocular sensitizers. It has the flexibility of overnight or a 20 minute disinfecting cycle geared to the varying life styles of patients. However, patient compliance must be stressed for the inadvertent omission of the neutralization step would result in an adverse ocular response from the residual peroxide absorption.

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