A Clinical Evaluation of a Multipurpose Soft Contact Lens Solution: Unicare®

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Abstract

A three-month study was conducted to establish the safety and efficacy of Unicare® — a multipurpose soft contact lens solution. Patient acceptance of the solution was good in spite of one case of an adverse ocular response among the twenty-one subjects evaluated.

Abrégé

Nous avons institué une étude, d'une durée de trois mois, pour établir la sûreté et l'efficacité de Unicare® — une solution à fins multiples pour les lentilles souples. L'accueil de ce produit a été satisfaisant malgré un cas d'effets secondaires sur les 21 personnes participant à l'étude.

Introduction

Since the introduction of hydrophilic soft contact lenses several chemical disinfection regimes have been developed as an alternative to heat disinfection.[1,2,3]

While these chemical systems have increased the longevity of the soft lens and reduced the formation of tenacious surface deposits, they have increased the incidence of eye irritation.[4,5,6] The complexity of some of these chemical systems predisposes the patient to developing red eyes due to an incompatibility of the ocular tissues with the solution and/or patient noncompliance with the prescribed procedures.[5]

The purpose of this study was to evaluate the safety and efficacy of Unicare®, a multipurpose soft contact lens solution, for a period of three months.

Materials and Methods

1. Care System

The care system consisted of a multipurpose solution, Unicare®, which is designed to clean, disinfect and rinse the soft contact lens. The main components of this solution are buffered saline with Poloxamer 407, a surfactant, and thimerosal as the preservative. Each bottle is supplied with a disposable case.

2. Selection of Subjects

Subjects were screened to exclude those with any obvious ocular pathology, known allergies, subnormal tear production, low tear break-up time (BUT) and other health problems contraindicating contact lens wear.

A total of 21 subjects (13 female and 8 male) between the ages of 16 and 62 were selected (Table I). One subject was a presbyope and the rest were young myopes. Six of these myopes had previously worn soft contact lenses.

3. Lens Selection and Evaluation

Table II lists the number of subjects fitted with each of the four types of soft lenses used in the study. All lenses were of the ultrathin design to allow for optimum corneal physiology. The presbyope was fitted with Ciba bifocal soft lenses.

Each lens received from the manufacturers was analyzed for deposits using the Rudko technique for inspection and classification (Table II)[7]. In addition, 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 protein absorption occurs with UV radiation.

4. Initial and Follow-up Procedures

At the initial visit baseline data were collected on visual acuity, refractive status, biomicroscopy, pachometry, keratometry and lens performance. Each subject was supplied with the new pair of lenses and the Unicare® system. Instructions were given on the recommended procedure for using this system. It was stressed that the case should be cleaned and filled daily with fresh Unicare®. Additional bottles of the solution were dispensed on request or at the follow-up visits. There were four follow-up visits — 1 week, and 1, 2, and 3 months after lens delivery. Additional visits were scheduled when problems occurred.

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At each follow-up visit the procedures used at the initial visit were repeated to assess the biocompatibility of the solution and lens with the eye. Any abnormalities were noted and quantified. In addition, each lens was examined for deposits according to the Rudko procedure. The three month visit also included a spectrophotometric analysis of each of the lenses worn for this period.

Results

1. Patient Response

The results show that the overall response to the Unicare® system was good. Twenty of the 21 subjects completed the study with minimal adverse effects. The one subject who was discontinued developed an intolerance to the Unicare® solution after two weeks of use. This adverse reaction was characterised by a progressive increase in corneal staining and injection together with complaints of persistent burning and stinging. The lenses were purged and the subject was put on the same heat disinfection procedure she had used prior to this study.

A more complete listing of the signs and symptoms associated with the use of Unicare® is given in Table III. Among the objective ocular manifestations the appearance of debris in the tear film was most prominent during the first month. The composition of this debris appeared to be mucus, dead cells and the viscosity-building additives of the solution.

2. Lens Deposits

Visual inspection of the lenses under 7X magnification at each visit showed a tendency toward an increase in frequency of deposits with time. Sixteen of the forty-two lenses showed deposits. Table IV lists the classification of these deposits.

Spectrophotometric analysis at wavelength 500 nm showed no significant change in visible light transmission. However, at wavelength 280 nm UV transmittance was reduced in a few lenses. The absorption of UV radiation is indicative of the presence of a proteinaceous deposit. The number of lenses showing deposits by this method was less than that found with visual inspection (Table IV). The reason was that the observed deposits were randomly scattered on the lens surfaces and in many instances were located outside of the central 0.1 mm slit area measured by the spectrophotometer.

Conclusions

This study demonstrates the safety and efficacy of the Unicare® solution. Biomicroscopy data for the three-month study indicate that the solution does not have an adverse effect on most subjects. At the time of writing eighteen subjects have been using the solution for more than ten months without any signs of an adverse response. One subject developed an intolerance and two have voluntarily switched to another care system after completion of the study period. Symptoms of stinging on insertion and dryness may discourage some users. However the incidence of this occurrence is low and is not unlike that observed with other chemical disinfection systems now available.

The presence of deposits on some lenses suggests that the solution is not as effective as a cleaner. Therefore those patients who show a greater tendency to coating lenses because of the nature of their tear chemistry, should be given a weekly enzymatic cleaner.

Since this formulation contains thimerosal, judicial use of the system should be considered in light of the reports of thimerosal sensitivity among the population[9,10,11]. Preventive efforts should be aimed at screening prospective contact lens wearers and stressing proper cleaning techniques to avoid the complex created by thimerosal binding to the proteinaceous deposits. Such a complex can act as the irritant or allergen[12].

Patient acceptance of the solution was judged to be good. Those with previous contact lens wear experience felt it was a more convenient system for their lifestyle and that lens maintenance cost was less. While reduction in time and cost for lens maintenance are attractive features for the patient, the practitioner is assured of patient compliance because of the simplicity of this multipurpose solution.

Acknowledgement

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Table I Patient Profile

		No. of Patients
Age	less than 20	2
	20 to 30	15
	30 to 40	3
	40+	1
Sex	M	18
	F	3
Refractive error	Myope	20 (average -3.25D)
	Hyperope	1
Previous Contact Lens Experience	Y	6
	N	15

Table II Study Lenses

Manufacturer	Type	No. of Patients
Union Optics Corp.	Aquaflex St.	3
Bausch & Lomb	U3 & U4	7
Ciba Vision	Ciba Thin	10
Hydron	Hydron 06	1

Table III Frequency of the signs and symptoms during the three month investigation

Conditions	Initial	1 week	1 month	2 month	3 months
Signs					
Injection					
Mild	0	2	1	1	1
Severe	0	1	0	0	0
Straining					
Mild	0	2	1	0	0
Severe	0	1	0	0	0
Striae	0	0	0	0	0
Edema	0	0	0	0	0
Infiltrate	0	0	0	0	0
Poor tear quality (mucous debris)	0	4	2	1	1
Conjunctival changes					
Mild	0	1	2	2	2
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
Vascularization	0	0	0	0	0
Total #	21	21	20	20	20
Symptoms					
Burning/Stinging					
Transient	0	5	4	4	4
Persistent	0	1	0	0	0
Dryness	0	5	4	3	3
Discomfort	0	2	2	2	1
Total # patients					
positive	0	8	6	6	6
negative	21	13	14	14	14

Table IV Classification and Frequency of Deposits Observed on Lenses

Number of lenses with deposits					T_{280} < 85%
Rudko's classification	**1 wk.**	**1 mo.**	**2 mo.**	**3 mo.**	**3 mo.**
I	42	38	27	26	0
II	0	2	7	10	4
III	0	0	6	6	2
IV	0	0	0	0	0

N.B. T_{280} for new lenses ranges between 85% and 93% with the average = 91%.
T_{500} averaged about 97% all through the study.