



Clinical Evaluation of a Non Preserved Saline Solution

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Abstract

With the advent of more and more contact lens pharmaceutical care products, and the manufacture of hydrophilic lenses which, by their nature, absorb and retain fluids, the question of the sterility of contact lenses is more important than ever. This evaluation assesses the clinical efficacy of Lens Plus, a non preserved saline solution, with a variety of heat and chemical disinfection systems.

Résumé

Avec la prolifération des produits pharmaceutiques d'entretien des lentilles et la mise en marché de lentilles hydrophiles qui, de par leur nature même, absorbent et retiennent les fluides, la question de la stérilité des lentilles de contact est plus importante que jamais. Cette évaluation détermine l'efficacité clinique de Lens Plus, une solution de trempage non préservée, avec une variété de systèmes d'aseptisation thermiques et chimiques.

Introduction

All contact lenses which are currently approved for human eyes in Canada can only be worn if certain procedures are followed to maintain their sterility. This has led to the manufacture of a large number of solutions specifically designed to clean, disinfect and dissolve protein from worn lenses. Since lenses must come into contact with these solutions and then be re-inserted into the eye, it is essential that the care products be free from contamination by pathogens which may be harmful. The question of sterility became more important with the advent of hydrophilic materials, which by their nature could absorb fluids and easily become contaminated. Many systems are now available to prevent contamination of lenses.

Disinfection of lenses is carried out by one of two methods, heat or chemical. Surfactant cleaning has always been done using chemicals. In order to keep these chemicals pathogen free, preservatives have been developed and used for many years in the majority of these systems. Although these solutions remained pathogen free, patients began to develop hypersensitivity reactions to the various preservatives, in varying degrees and with varying severity.^{1, 2} The frequency of such reactions, although relatively low, led to the development of effective systems which were preservative free, or with alternative preservatives in which the frequency of reactions was reduced.

One of the mainstay solutions in all hydrophilic lens systems is saline. In order for all hydrophilic lenses to remain in a wearable state, they need to remain in a fluid environment at all times.

The best fluid for this has proven to be 0.9% saline solution, preferably at a pH similar to the tears (7.4). Most of the currently available systems use preserved saline solutions which fail to meet the above pH requirement.³ The object of this evaluation is to determine the clinical efficacy of a non preserved saline (Lens Plus), with different systems and lenses.

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Method

90 patients from 10 offices in different geographical areas throughout Canada were randomly enrolled in a clinical evaluation of Lens Plus saline. Lens Plus was used in conjunction with several different systems encompassing both heat and chemical disinfection. The preservatives and disinfectants with which it was used are listed in Table 1. Table 2 shows the types of lenses which patients were wearing during the evaluation. Patients were instructed to carry on with their currently used system, but to substitute Lens Plus for rinsing in the case of chemical disinfection, storage and rinsing for thermal disinfection and for use with enzyme tablets in all systems for protein removal. All patients rinsed with Lens Plus prior to insertion. Patients were problem free on entry, with no positive biomicroscopic findings. Patients were examined monthly for any adverse biomicroscopic findings which could be related to the use of

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Lens Plus. Patients were asked to comment on their experiences with the solution, with regard to comfort, any differences from previous solutions used and any problems relating to its use. Responses and findings were recorded and graded on a standard form for ease of recording and analysis.

Table 1

LENS PLUS	
CHEMICAL	THERMAL
Sorbic Acid	Thimerosal
Thimerosal	Sorbic Acid
Polyquat	
H202	

Table 2

LENS TYPES	
HEMA	GMA
38% H2O	38% H2O
70% H2O	
55% H2O	

Results

Over the 90 day period of the evaluation, no adverse ocular response was noted by any of the practitioners which could be attributed to the use of Lens Plus. Patient response to the use of Lens Plus as compared to saline previously used, indicated a preference by 70% for the Lens Plus. Thirty percent found no difference.

The 70% preference was mostly related to a reduction of stinging during insertion. One patient of the ninety reported that Lens Plus was less comfortable than the previous saline and reported that it felt 'drier'.

Ease and convenience of use was preferred by 90% of the patients. The 10% who did not find the system easy and convenient, reported difficulty with use of the aerosol nozzle, especially when the saline level was low or the can had to be tipped. Cost of the aerosol can as opposed to other systems was found to be a problem by 5% of the patients. No adverse reactions were reported, which could be correlated with the combined use of Lens Plus with different preservatives or lenses.

Discussion

A 90 day clinical evaluation of a non preserved aerosol saline system, used by 90 patients, indicated that the majority preferred Lens Plus over previous systems for a variety of reasons. All patients used Lens Plus for rinsing prior to insertion of their lenses and for dissolving protein removal tablets. A significant finding was the subjective report of increased comfort by 70% of the patients on insertion. This may be related to the neutral

pH of Lens Plus as compared to other saline solutions which had been used by the group entered into the study. Convenience, ease of use and maintenance of sterility by virtue of the aerosol system, appear to be positive factors in the use of Lens Plus. No positive biomicroscopic findings were found relating to the use of Lens Plus. There were no differences found when correlated with different preservatives, disinfectants or lens materials and water contents. Notwithstanding the difficulty in carrying out a clinical study of this nature, and the pitfalls relating to the analysis of the data, it does appear that Lens Plus is safe and effective and well received by patients as an adjunct to other systems.

References

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