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Clinical Comparison of Disinfecting Systems for Hydrophilic Contact Lenses

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Abstract

The disinfection of hydrogel lenses is presently administered in one of three ways; thermal, chlorhexadine based chemical and the new Quaternium-16 based chemical disinfecting system. Although siginificant differences exist among practitioners regarding the disinfection method of choice, there is reasonable agreement to switch from chlorhexadine disinfection solution to thermal with lens discomfort and/or other problems. The new Quaternium-16 based chemical disinfection may be a better alternative then thermal when switching from chlorhexadine solutions. A clinical comparison of patients who have changed disinfection systems was surveyed at Portland and Forest Grove Clinics of Pacific University College of Optometry.

INTRODUCTION

Up until 1977, thermal disinfection of hydrogel lenses system was the only system approved by the U.S. Food and Drug Administration. At that time, the Burton-Parsons chemical system was approved. This utilized chlorhexadine, thimerosal, and EDTA. In 1980, the chlorhexadine-free Allergan systems gained approval in this country. All three currently approved systems have problems associated with them. The methods of choice should be based upon the demands and characteristics of each individual patient. This study is undertaken to clinically compare these available systems with patients seen at the Portland and Forest Grove Clinics of Facific University College of Optometry.

The efficacy of heating methods has been accepted since soft lenses were first marketed. Studies have shown that boiling lenses for 15 minutes kills all vegetative forms of microorganisms.[1,2] Solutions used along with the thermal method include freshly prepared saline, preserved saline or a non-preserved single unit of saline.

The marketed preserved saline solutions normally contain edetate disodium (EDTA) and thimerosal as preservatives in varying percentages and osmolarities. Some products contain buffers, chelating agents and viscosity additives. While the presence of thimerosal meets the need for safety with heat disinfection, some patients are sensitive to mercury-containing compounds. EDTA and the other additives may also cause allergic reactions. To patients sensitive to the preserved saline, an unpreserved saline solution is commercially available.

Some of the problems associated with thermal methods include the rapid aging of the lens. This is listed by Roth as 1.2 years versus 4.9 years with chemical disinfection.[3] Also multiple re-use in mercurial systems causes deposits on the lens surface.[4] Thimerosal decomposes as the contaminant load becomes greater with each use. Eventually gray-black spots discolor the lenses. Convenience may also be an important factor. The special equipment used for thermal disinfection imposes limitations on the mobility of the system due to the need for an electrical outlet. Other problems include bacterial contamination of the storage case due to poor construction or thermal unit breakdown.[5]

The conventional chemical disinfection regimen developed by

Burton-Parsons incorporated EDTA (0.1%), thimerosal (0.001%), and chlorhexadine (0.005%). These chemicals have been known to lead to sensitivity reactions in some soft lens wearers either as a direct allergic response, by binding directly to the lens (as with chlorhexadine), or by binding to protein deposits on the lens (as with thimerosal).[6] When binding of the preservative occurs, the solution may lose its anti-microbial effectiveness.

Chlorhexadine in a concentration of 0.005% has a powerful bacteriacidal effect. Its safety has been demonstrated even when used in significantly higher concentrations than required for antibacterial action.[7]

Chlorhexadine binds to the lens surface but only to a small extent. The preservative is bound by the first few protein deposits which are allowed to remain on the lens material due to carelessness. The deposits then accumulate, one on another. As more chlorhexadine is bound to the lens during the storage period, the effectiveness of the disinfectant is lessened. Contaminants drawn from lipids and the tears build up on the lens surface, and the lenses may become carriers of pathogenic microorganisms. The saturation of chlorhexadine can render lenses hydrophobic[3,8] thus absorbing lipids on the surface which leads to poor wettability and drying between blinks.

Since chlorhexadine is a poor antifungal, thimerosal is generally incorporated as a fungicide. Usually, EDTA is added to heighten the antibacterial effect, particularly against Pseudomonas.[9] EDTA is a chelating agent which may play a role in removing inorganic deposits.

Thimerosal is anionic. It has been shown that thimerosal does not bind to soft lenses, but the negatively charges ions may react with

positively charged protein ions which may be on the lens. Thimerosal is a slow acting agent. Recent studies have shown that a 0.001% solution took 6-24 hours to kill Pseudomonas aeruginosa.[9]

Reactions to unclear lens surfaces and sensitivities to solutions can result in complaints of burning, itching, stinging, photophobia, reduced acuity, fluctuating vision, and decreased lens tolerance. Conjunctival injection, stippling, heavy mucoid deposits on the lenses, excess lens movement, and the presence of giant papillae on the upper tarsal conjunctiva may be observed by the examiner.[10,11] Variable acuity and blurry vision are more likely to occur with dirty lenses, while photophobia and increased lacrimation are more apt to be found with solution sensitivity. A mild solution reaction is generally characterized by foreign body sensation or lens awareness, increasing discomfort (burning, dry eye symptoms) throughout wearing time with punctate staining and minimal hyperemia.

Hypersensitivity may result in marked hyperemia, significant corneal staining, stinging, tearing, photophobia, and haloes around lights.[12,13] The allergic reaction may be evident immediately or take up to 48 hours to occur.[14] Gradual sensitization to solutions is generally a function of preservatives binding to protein deposits. These protein deposits may cause an immune reaction leading to giant papillary conjunctivitis.[15,16]

Clearly there are problems associated with both the thermal disinfection system and the conventional chemical disinfecting solutions containing chlorhexadine. The need for a comfortable non-thermal disinfection system was met in 1980 with the introduction by Allergan

Pharmaceuticals of the chlorhexadine-free "Allergan Cleaning and Disinfecting Solution". This product contains Quaternium-16 tris (2-hydroxyethyl) tallow ammonium chloride and thimerosal (0.002%) as the anti-microbial agent and preservative. This product is formulated in mixed micelle form with Quaternium-16 and the surfactant Polysorbate 80. In this micelle form, the anti-microbial agent is shielded from penetrating the lens material, but is still capable of disinfecting action. [17]

Eriksen reported that new soft lens wearers using the Allergan system were shown to be more successful in adapting to their lenses than users of commercial chlorhexadine systems. It was also found that successful chlorhexadine users experienced increased comfort with the Allergan Cleaning and Disinfecting Solution.[17]

METHODS:

A statistical survey was taken of contact lens patients at the Portland and Forest Grove Clinics in whom clinicians felt the need to change disinfecting systems. These were existing soft lens wearers who had been experiencing problems with the initially prescribed disinfection method. Listed in the survey were original system, reasons for rejection of that system, and type of regimen that the patient successfully adapted to.

Section A

Disinfection Regimens

Patient #	Rejected System	Successfully Adapted System
1	C*	A*
2	C	A
3	C	A
4	A	Th/salt*
5	C	A
6	C	A
7	Th/ps*	A
8	Th/ps	A
9	C	Th/ups*
10	C	A
11	C	A
12	A	Th/salt
13	A	Th/salt
14	C	A
15	A	Th/salt
16	A	Th/salt
17	C	A
18	Th/ps	A
19	C	A
20	C	A
21	C	A
22	C	A
23	C	A
24	C	Th/salt
25	C	A
26	A	Th/ups
27	C	Th/salt
28	C	Th/salt
29	C	A
30	C	A
31	C	A
32		

* C= chlorhexadine A= Allergan Th/salt= Thermal/salt tablets Th/ups= Thermal/unpreserved saline (Unisol) Th/ps= Thermal/preserved saline

Section B

Cause of Rejection of Initial Disinfection Regimen

tient #	burning	itching	stinging	reduced wearing time	injection	poor VA	tearing	other
1	x	x		x				
2	x	x		x		x		
3	x	x		x				
4		x			x			
5	x	x		x	x			
6	x	x		x				
7								convenience of not using heat
8								convenience of not using heat
9	x	x		x	x			
10	x	x		x				
11	x	x		x				
12			x	x	x		x	
13	x	x		x	x			
14	x	x		x				
15								punctate staining
16	x	x		x	x			
17	x	x		x				
18								poor hygiene/ deposits on lenses
19	x	x		x				
20	x	x		x				
21	x			x	x			
22	x	x		x				
23	x	x		x				
24	x	x		x	x			
25	x				x			
26	x	x		x	x			
27	x				x			
28	x	x			x			
29	x	x		x	x			
30	x	x		x	x			
31	x	x			x			
32	x	x			x			punctate staining/mucus

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