CHAPTER 4

CONTACT LENS CARE PRODUCTS ON THE SOUTH AFRICAN MARKET

The basics of contact lens solutions are some of the most important aspects of lens care to understand: how do they clean, disinfect and wet the lens surface to provide a comfortable and safe lens to wear. Bacterial growth on a lens and in a lens storage case is believed to be mostly biofilm; a static adherent group of microorganisms encased in polymeric material [103]. The biofilm is composed of polysaccharides, proteins, nucleic acids and lipids produced simultaneously by the microorganisms in the biofilm and host cells or fluid. Biofilms are characterised by their resistance to stressful conditions, such as; pH variation, osmotic shock, desiccation, and biocidal substances such as disinfectants and preservatives. Characteristics of contact lenses, such as hydrophobicity and the type of surface may also be factors in adhesion and biofilm formation respectively. Hydrophobicity is a factor in the adhesion and the type of microbes on contact lenses because it affects the lipid layer of the tear film. Microbes that adhere hydrophobic surfaces tend to use polymers that are non-polar while microbes that adhere hydrophilic surfaces tend to use EPS and lipopolysacchardies (LPS) [103]. Biofilm formation tends to be on the posterior surface of the contact lenses rather than the anterior surface. There is less defense against adherence and colonisation on the posterior surface, where the contact lenses would meet the cornea. The interaction between the two surfaces could cause the natural defense mechanisms present on the ocular surface to not function properly, enhancing biofilm growth. Microbes that grow in a biofilm environment often aggregate and are 10–1000X more resistant to biocides/disinfectants compared to single microbial cells exposed to a liquid disinfectant environment [103]. The most common microorganisms found in lens storage cases are coagulase-negative staphylococci and gram-positive bacilli. Of concern is that gram-negative bacteria like *Pseudomonas aeruginosa* and *Serratia marcescens*, which are much more likely to be potentially virulent ocular pathogens, can also be isolated, sometimes at very high levels [104] [105].

Many different contact lens solutions are available in the market. Depending on the specific purpose of the contact lens solution, it may contain many of the following chemicals [106].

BUFFERS AND SALTS

Buffers are introduced to keep the pH at narrow limits (pH 6–7) for comfortable contact lens wear. The buffers are normally sodium phosphate, borate, tromethamine or bicarbonate. Of these buffers, borate and bicarbonate are the most commonly used. Phosphate is only used in a minority of products. The purpose of a salt is to make the solution isotonic with the tears – sodium chloride is commonly used [106].

PRESERVATIVES

Preservatives restrict the growth of microorganisms and biofilms on the lens and case surfaces. The key to preservative/disinfection use is to have sufficient concentrations for antimicrobial efficacy. Yet, low enough to prevent toxicity. Toxicities are dose related events. All preservatives/disinfectants are toxic if used in excess concentrations. The preservatives used in contact lens solutions include [106]:

Benzalkonium Chloride (BAK)

BAK was primarily used in soaking and cleaning solutions in concentrations between 0.004–0.01%. BAK destabilises the tear film in concentrations over 0.004% and although effective with PMMA lenses, its use with gas permeable RGP lenses have been questioned due to surface absorption [106].

Chlorhexidine Digluconate (CHX)

Usually used in concentrations of 0.006% with other preservative systems for RGP lenses. Can also be used with soft lenses in concentrations of 0.002–0.005%. When used alone kill time is slow – up to 10 hours.

Thimerosal

This is a mercurial derivative used in concentrations of 0.001–0.002% with both RGP and soft lenses. It is also effective against fungi. But, toxic reactions are common. It is slow acting and therefore used in combination with other preservatives such as CHX or EDTA [106].

Polyquats

Polyquats is the collective name for the two main antimicrobials found in the current generation of multipurpose solutions. It was originally used as anti-malarial water treatment in the early 1960s. Subsequently it was used as a swimming-pool disinfectant, cosmetics preservative, antifungal in water-based inks (for pens), as an industrial disinfectant, as well as in antibacterial wipes. These chemicals are from the same family as chlorhexidine. But, due to their greater molecular size and weight, they are unable to penetrate the matrix of soft contact lenses. The polymeric nature of the polyquat molecules also causes proportionally more damage to microorganisms and can therefore be used in lower concentrations. Polyquats are cationic disinfectants and they are effective against gram-positive as well as gram-negative bacteria. Although they are moderately effective against *Acanthamoeba* and fungi, this can be enhanced by employing combinations of polyquats and other preservatives in the solutions. All cationic polyquats bind to negatively charged anionic phospholipids in the bacterial plasma membrane. Their action results in cellular lysis rather than disrupting cell walls as with the other antimicrobials. Polyquats include biguanides and polyquatrinim-1 (PQ-1) [106].

Biguanides – Polyhexylmethyl and polyaminopropyl biguanide (Dymed). Dymed or PHMB is used in concentrations of 0.00005–0.0001%.

Polyquatrinim-1 – Polyquad (PQ-1). Polyquad is a cationic surfactant that is larger (molecule 14x larger than CHX and 4x larger than Dymed) in size than PHMB. It also affects the bacterial phospholipid membrane by reducing surface tension at interfaces, denaturing proteins of the cell walls, leading to cell death. Because of its molecule size, uptake is reduced on in contact lenses and cases eliminating potential release into the tear film and cornea. It is bactericidal but its action against fungi is questionable. Concentrations of 0.001% are commonly used [106].

Amidoamine

Myristamidopropyl dimethylamine – Aldox. This cationic surfactant is effective against fungi and *Acanthamoeba* by interacting with the cell wall components to allow penetration. Concentrations of 0.0005% are normally used in conjunction with polyquad [106].

Even at low concentration, these preservatives will cause some degree of ocular tissue damage. Decreasing order of preservative/disinfectant toxicity:

- Thimerosal
- BAK

- Polyquats/Aldox
- Sodium perborate
- EDTA

CLEANING AGENTS OR SURFACTANTS (SURFACE ACTING AGENTS)

Surfactants can be stand-alone or added to multipurpose solutions. Their function is to remove biofilms from the contact lenses. Surfactants disrupt surface forces thereby lowering surface tension. Surfactants are amphiphilic, which means they possess hydrophilic heads and hydrophobic tails. These compounds chemically attach to the biofilms by the hydrophobic tails and the free hydrophilic ends are then able to interact with water and the biofilm can then be rubbed of the surface of the lens. This is a similar process to what happens when we wash our hands with soap and water. Newer generation contact lens solution surfactant cleaners are specifically designed to interact with the hydrophobic silicone surface to give a comfortable and long lasting wearing experience [106]. Common surfactants include: Poloxamines (Tetronics) examples: Tetronic 1107 (ReNu MultiPlus), Tetronic 1304 (Alcon's OPTI-FREE products); Poloxamers (Pluronic and Poloxamer) examples: Pluronic F87 (Poloxamer237), Pluronic F127 (Poloxamer 407); Isopropyl alcohol (CIBA Vision's Miraflow); Tyloxapol (AMO's Complete MoisturePlus).

CHELATING AGENTS

Ethylenediamine tetra acetic acid or EDTA is a cationic chelating agent that binds free metals such as calcium (Ca++) and magnesium (Mg++), competing with positively charged or anionic preservative molecules for active sites on microbial cell walls. Consequently, microorganisms become more susceptible to preservative penetration [106]. This then enhances the disinfection action of preservatives such as BAK with which it has a synergistic action. EDTA

DEMULCENTS

Propylene glycol is used to enhance comfort.

WETTING AGENTS/LUBRICANTS

These chemicals decrease the wetting angle of a contact lens material by changing the surface energy. Examples include: povidone (polyvinyl purrolidone), tetronics, polyvinyl alcohol, polysorbate 80). Lubricants attract moisture [106]. Examples include hydroxypropyl methylcellulose, hyaluronic acid, carboxymethylcellulose, hydroxypropylguar, tetronic, depanthenol, sorbitol, and poloxamine.

HYDROGEN PEROXIDE

The active ingredient in peroxide-based systems is micro-filtered, stabilised and buffered 3% hydrogen peroxide. It eliminates a wide variety of organisms including: bacteria, fungi, yeasts, spores and viruses. Hydrogen peroxide is self-preserved and unlike other disinfectants it is unaffected by organic matter or salts. Peroxides can penetrate biofilms which preservative based multipurpose systems cannot. Approximately 10 minutes full strength exposure will kill most bacteria. But, fungi and protozoa require longer exposure times [107]. Hydrogen peroxide works by producing hydroxyl free-radicals that attack the microorganisms' lipid membrane, its DNA, as well as the mitochondria and other cell components. These free-radicals only exist for a short time. But, they are highly reactive and because hydrogen peroxide is lipid soluble, they can penetrate the cell destroying it.

The human body is accustomed to peroxide and has a mechanism (antioxidant enzyme catalase which catalyses the decomposition of hydrogen peroxide) for handling it. Therefore, as long as the hydrogen peroxide is sufficiently

neutralised to less than 20 ppm and the tear film is stable, thick and robust, the body will deal effectively with the residual peroxide which may remain in the lens matrix ensuring comfort [106, 108].

ENZYME CLEANERS

Enzyme cleaners are used to remove or hydrolyse protein from lens surfaces. Weekly cleaning is suggested, but patients using peroxide systems can use them less frequently. Some of the second-generation multipurpose solutions incorporate a sequestering agent making the use of enzyme tablets unnecessary. Enzyme cleaners include papain (not for use in high water content lenses without hydrogen peroxide) derived from the papaya plant, pancreatin (made from porcine pancreas and therefore should not be used with Jewish, Muslim or vegan patients) and subtilisin A&B derived from *Bacillus sp*. bacteria which may be more effective than papain [106].

"TO RUB AND RINSE OR NOT TO RUB AND RINSE"

The primary culprits of contact lens-associated microbial keratitis that can be found in contact lens case biofilms are *Staphylococcus aureus, Pseudomonas aeruginosa, Serratia marcescens, Fusarium solani* and *Acanthamoeba*. To adequately prevent or reduce biofilm formation, it is necessary to first understand how biofilms occur. The five stages of biofilm formation and transferability are listed below [103, 109]:

Stages 1 & 2. The biofilm begins as a reversible collection of floating cells in the solution near the case or lens surface (stage 1). It then forms an attachment of the cells to the case or lens surface (stage 2).

Stages 3 & 4. More cell layers are constructed (stage 3), followed by the creation of a protective outer covering (stage 4).

Stage 5. The microbes detach and disperse into the solution within the case or onto the posterior surface of the contact lens itself.

A poorly fitting or potentially contaminated contact lens may alter the integrity of the corneal epithelium, allowing easy access from possible freeloading microbes from a biofilm to penetrate the compromised cornea causing an infection [45, 46]. Furthermore, the presence of a contact lens on the eye can also negatively influence the antimicrobial action of the tear layer causing an increase in the bacterial load and subsequent corneal invasion from transported biofilm microbes [109].

Both multipurpose and hydrogen peroxide-based contact lens solutions are designed to clean and disinfect contact lenses. For the most part, debris, makeup residue, proteins and mucus all need to be removed from the lens during the cleaning process. This must occur prior to the disinfection process in which the bacteria are destroyed [110]. If the lenses are not thoroughly cleaned prior to disinfection, the antimicrobial action of the solution is reduced. This highlights the importance of mechanically cleaning or rubbing the contact lenses prior to soaking them in contact lens solutions for disinfection. Simply rubbing and rinsing lenses yields a 1-log reduction of microbes from the lens surface [110].

To summarise, "rubbing and rinsing":

- Removes lipids, inorganic deposits, some proteins and insoluble contaminants by manual action
- Overcomes the hydrophobicity of oily deposits with surface-active agents, especially important with silicone hydrogel lenses
- Assist in chemical disinfection by removing deposits that could interfere with antibacterial activity
- Remove contaminants that supply nutrients to bacteria
- Disperse mucus films to minimise the potential for binding of any large molecular size antimicrobial agent
- Remove microbes as well as *Acanthamoeba* cysts and trophocytes from the surfaces of hard and soft lenses

SOLUTION AND LENS MATERIAL COMPATIBILITY (WWW.STAININGGRID.COM)

Silicone hydrogel materials are less likely to deposit protein compared to their predecessors, however, in some instances they are more likely to deposit lipids. We are still learning the nuances of their on-eye performance, particularly their interactions with lens care systems. As a result, it is most prudent to recommend care solutions that were specifically developed for these materials.

The Andrasko Corneal Staining Grid modified for the South African market highlights the fact that not all lens care multipurpose products are compatible with all lens materials. Care should be taken to ensure the solution you recommend is compatible and with the specific lens prescribed to maintain health and comfort.

The Staining Grid is an easy-to-use reference tool informing the eye care practitioner as to the level of biocompatibility of various contact lens/multipurpose solutions. It appears as a "grid" with the solutions listed across the top and the lens materials in the first column. The percentages which appear in each cell represent the average percentage of the cornea which was stained 2 hours after lens/solution insertion.

To choose a biocompatible multipurpose solution for a specific lens brand:

- Find the lens material (if it has been tested) in the first column of the grid
- Follow across that row and select a solution which results in minimal corneal staining (i.e., green zone)

Lens and Solution Combinations
Percentage of Average Corneal Staining Area at 2 Hours
Modified from
www.staininggrid.com

	Unisol Saline	H_2O_2	Opti-free Express No Rub	Biotrue	Complete MPS Easy Rub	Renu Multipurpose Sensitive Eyes	Renu Multiplus
Acuvue 2 Hydrogel	1%	1%	2%	1%	1%	1%	1%
Proclear Hydrogel	1%	1%	1%	28%	6%	23%	61%
Soflens 66 Hydrogel	1%	1%	1%	52%	17%	32%	66%
Acuvue Oasys Silicone Hydrogel	2%	2%	3%	1%	4%	5%	12%
Biofinity Silicone hydrogel	2%	2%	3%	17%	2%	2%	4%
PureVision Silicone hydrogel	2%	2%	4%	46%	15%	43%	71%
AirOptix Silicone hydrogel	2%	2%	2%	21%	3%	7%	41%
Night & Day Silicone hydrogel	2%	2%	2%	17%	1%	11%	36%
	SALINE	H_2O_2	POLYQUAD / ALDOX	PHMB / POLYQUA TERNIUM	BIGUANIDE (PHMB)		

Staining Zone Color Codes

under 10% | 10% to 20% | over 20%

CONTACT LENS SOLUTIONS AVAILABLE ON THE SOUTH AFRICAN MARKET

Table 15: Contact lens care products available in South Africa

Trade name	Active ingredients	Indications
Optifree Daily cleaner	Polyquad - polyquaterium 0.001% EDTA – Edetate disodium 0.1%	Surfactant
AOSept	Hydrogen Peroxide 3%	Disinfectant
Polyrinse	Sterile isotonic saline, Chlorine dioxide, Oxychloro complex 0.005%	Rinsing
Optifree Express	Sodium nitrate, boric acid, sodium citrate, aminomethylpropanol tetratonic, EDTA, Polyquad, Aldox, and sorbitol	Multipurpose
Renu Multipurpose	Hydroxyaklyl-phosphonate, EDTA, sodium borate, boric acid, poloxamine, and sodium chloride	Multipurpose
Renu Multiplus	Dymed 0.0001%, EDTA, hydranate, boric acid, poloxamine, sodium borate, sodium chloride	Multipurpose
Biotrue	Polyquad 0.0001%, PHMB 0.000013%, boric acid, sodium borate, sodium chloride, poloxamine	Multipurpose
Sauflon	Polyhexanide 0.0001%, EDTA 0.1%, sodium chloride, sodium phosphate, and poloxamer	Multipurpose
Oxysept	Hydrogen Peroxide 3%	Disinfectant
Complete Revitalens	Alexidine 0.00016%, Polyquad 0.0003%, EDTA, boric acid, sodium borate, sodium chloride, tetronic 904, decahydrate	Multipurpose
Boston Advance Cleaner	Ether sulphate, triquaternary cocoa-based phospholipids, silica gel with titanium dioxide	Daily cleaner for RGP lenses
Boston Advance Conditioning Solution	CHX 0.003%, PHMB 0.0005%, poloxamine, boric acid, sodium borate, sodium chloride, HPMC	Conditioning solution for RGP lenses
Boston Simplus	CHX 0.003%, PHMB 0.0005%, EDTA 0.05%	Multipurpose solution for RGP lenses
Sauflon Delta Plus Daily Cleaner	BAK 0.005%, anionic and amphoteric surfactants	Daily Cleaner RGP lenses
Sauflon Delta Plus Disinfecting, Soaking, and Wetting Solution	Polyhexanide 0.0001%, polaxamer	Conditioning solution RGP lenses
Total Care Daily Cleaner	Amphoteric imidazoline derivative 5.1% Anionic Alkyl ether sulphate 0.64%	Daily cleaner for RGP lenses
Total Care Solution	Polyhexamethylene biguanide 0.0005% EDTA 0.01% Hydroxyethyl cellulose, phosphate buffer	Conditioning solution for RGP lenses
Total Care Protein Removal Tablets	Subtilisin A 0.4mg/tablet	Protein removal tablets
Optimum by Lobob	No polymeric solvents, cocoamphodiacetate and glycols	Daily cleaner for RGP lenses
Crystal Cleaner	Non-ionic cleaning agents	Daily cleaner for RGP lenses
Ultrazyme	Subtilisin A 0.4mg/tablet	Used with Oxysept hydrogen peroxide as a protein remover
Sensitive Eyes Plus Saline	Boric acid, sodium borate, potassium chloride, sodium chloride; preserved with polyaminopropyl biguanide 0.00003%, and EDTA 0.025%	Rinsing
Lens Plus Saline	Boric acid, sodium chloride, chlorine dioxide 0.005%	Rinsing