# The IACLE Contact Lens Course

# MODULE 5

## Care and Maintenance

First Edition

*Published in Australia by*
*The International Association of Contact Lens Educators*

*First Edition 2000*
*This Version Printed 2002*

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# Acknowledgements

The IACLE Curriculum Project is the result of a desire to raise the standard of eyecare education, to make contact lens wear safer and more successful, and to develop the contact lens business by creating the educational infrastructure that will produce the teachers, students and practitioners of the future.

The concept of the world's best educators making available their most creative educational contributions for the common good without any recompense, other than a sense of satisfaction, was born out of IACLE's idealism.

The Curriculum Project could not be successful without the assistance and generosity of a large number of talented and dedicated people. To all those contributors of lectures, laboratory notes, videos, slides, etc., we say thank you. Your generosity of spirit will benefit many educators, hundreds of thousands of students and millions of patients throughout the world.

The Vice President of IACLE, Professor Desmond Fonn, has made a tremendous contribution since the inception of IACLE, and has provided his considerable expertise in the final editing stage of the Curriculum. This project was commenced under Professor Brien Holden's leadership. The original plan and layout for the Curriculum was prepared by Sylvie Sulaiman, IACLE's Director of Education. Sylvie's dedication and excellent understanding of practitioner and community requirements have given the Project focus and depth.

More recently, the IACLE Curriculum Project has benefited from the work of Dr Lewis Williams as Manager, Educational Development. Dr Williams has done an amazing amount of work to achieve an impressive collation of diverse material, and has created what I believe to be an invaluable collection of contact lens knowledge. Dr Williams has also been assisted by Rob Terry's considerable experience and understanding of the contact lens field.

Kylie Knox has done an excellent job as Project Editor. To complement the efforts of the editors, layout coordinators Barry Brown and Shane Parker have done an admirable job, as have the rest of the graphics team. The Cornea and Contact Lens Research Unit (CCLRU) at the University of New South Wales has contributed substantially to this project through the donation of time, resources and editorial support.

The IACLE global staff including Director of Administration Yvette Waddell, Global Coordinator Pamela O'Brien and Executive Secretary Gail van Heerden, have expertly managed the considerable tasks of production and distribution.

No acknowledgments page in an IACLE document would be complete without a reference to its sponsors. Bausch & Lomb have been a major corporate sponsor since 1990, providing the original stimulus for IACLE's growth by contributing financial support and the involvement of individuals from their International Division. It was Dr Juan Carlos Aragon (when he was at Bausch & Lomb) who first suggested that if IACLE was to be taken seriously by industry, it needed a global plan to address the educational requirements for the safe, effective growth of the contact lens business. Johnson & Johnson Vision Products is our other major corporate sponsor. They have provided excellent assistance through their provision of industry coordinators for Europe, Africa, and the Middle East. CIBA Vision has been a corporate contributor and also provided excellent industry coordination in Latin America. Allergan and Wesley Jessen/PBH have contributed generously as corporate donors, with Alcon Laboratories, contributing as IACLE donor.

IACLE is a cooperative effort, and none of its activities are more collective than the Curriculum Project. The IACLE Contact Lens Course which resulted from this project is provided to assist educators in accredited institutions to impart eyecare and contact lens knowledge. All the contributors deserve recognition for their selflessness and talent.

Debbie Sweeney

President of IACLE

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- **Contact Lens Care Products**
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- **Overview of Care and Maintenance**
- **Contact Lens Deposits**

# Educators Guide to the IACLE Contact Lens Course

## Overview

The IACLE Contact Lens Course is a comprehensive package of educational materials and other resources for teaching the subject of contact lenses. This package was designed to encompass *The IACLE Contact Lens Course Syllabus* and covers 360 hours of lectures, practicals and tutorials in ten modules, containing material at basic, intermediate and advanced levels.

The teaching resources have been designed for flexibility, allowing the educator to select the materials appropriate to the students' knowledge and the educational requirements of the class, school, institution or country. The separate document, *The IACLE Contact Lens Course Syllabus,* summarizes the course and includes outlines of Modules 1 to 10.

The English language reference used for the IACLE Contact Lens Course is: Brown L (Ed.). *The New Shorter Oxford English Dictionary.* 1993 ed. Clarendon Press, Oxford (UK). The only spelling exception is *mold* and *mould.* The Oxford dictionary suggests *mould* in all contexts. We chose to use *mold* for manufacturing-related matters and *mould* for fungi since both meanings and spellings appear regularly in contact lens literature. This differentiation is based on common usage. Where words are 'borrowed' from a language other than English they are reproduced in their native form where possible.

Where standards have been ratified by the International Organization for Standardization (ISO), or where draft ISO standards are at an advanced stage, their relevant terminology and symbology are used. Système International (SI) units of measure are used wherever possible.

Many major contact lens textbooks from around the world, and some important journal articles, are referenced in the Course, and copyright illustrations are reproduced with permission of the original publishers and/or copyright owners. The reference section at the end of each unit details the information sources used throughout.

## Teaching Resources - Module 5

Module 5 of the IACLE Contact Lens Course has the following materials:

1. **Contact lens manual**

   The contact lens manual consists of:

   - Course overviews
   - Lecture outlines and notes
   - Practical outlines, exercises and notes*
   - Tutorial exercises and notes*

     * Not all units have these sections.

   The suggested lecture, practical and tutorial hours of the module are outlined in the Summary of Module 5 on page *x*. The manual provides recommended activities, references, textbooks and evaluation techniques in the interests of their standardization. Ultimately however, the design and

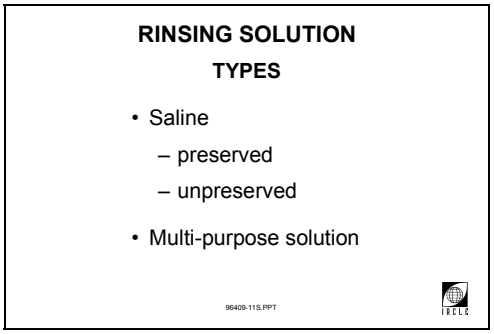
methodology of the course is left to the discretion of the contact lens educator.

**2. Slides for lectures, practicals and tutorials**

The slides have been numbered according to the sequence in which they appear in each lecture, practical and tutorial. Single or dual slide projection can be accommodated. Each slide has an identification code which is based on a cataloguing system in use at the IACLE Secretariat and which should be used in any communication with IACLE regarding the slides.

For example:

To re-order this slide please quote this identification code

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# Symbols, Abbreviations and Acronyms Used in the IACLE Contact Lens Course

| SYMBOLS | | | |
|---|---|---|---|
| ↑ | increase, high | { | collectively produced by |
| ↓ | decrease, low | } | collectively produces |
| → | produces, towards | Σ | sum of |
| ← | produced by, from | ± | plus or minus the value of |
| ↔ | no change, not obvious | + | plus, add, include, and |
| ↑↑ | significant/great increase | – | minus, reduce |
| ↓↓ | significant/great decrease | ≈ | approximately |
| % | percentage | = | equal to, the same as |
| < | less than | & | and, as well as |
| > | greater than | *x*° | degrees: e.g. 45° |
| ≥ | equal to or greater than | @ | in the meridian of |
| ≤ | equal to or less than | D | dioptres |
| ? | unknown, questionable | X | axis: e.g. –1.00 X 175. –1.00D cylinder, axis in 175° meridian |
| $n$, $n_{sub}$, $n_{sub}$´ | refractive indices | Δ | prism dioptres or difference |
| ∝ | proportional | | |

| ABBREVIATIONS | | | |
|---|---|---|---|
| μg | micrograms (.001 mg) | min | minute, minutes |
| μL | microlitres (.001 mL) | mL | millilitres (.001L) |
| μm | microns (.001 mm) | mm | millimetres |
| μmol | micromoles, micromolar | mmol | millimole, millimolar |

| | | | |
|---|---|---|---|
| cm | centimetres (.01m) | mOsm | milliosmole |
| d | day, days | nm | nanometres ($10^{-9}$ m) |
| Endo. | endothelium | Px | patient |
| Epi. | epithelium | Rx | prescription |
| h | hour, hours | s | second, seconds |
| Inf. | inferior | Sup. | superior |
| kg | kilograms | *t* | thickness |
| L | litre | | |

| ACRONYMS | | | |
|---|---|---|---|
| ADP | adenosine diphosphate | LPS | levator palpebrae superioris |
| ATP | adenosine triphosphate | NADPH | nicotinamide adenine dinucleotide phosphate |
| ATR | against-the-rule | NIBUT | non-invasive break-up time |
| BS | best sphere | OD | right eye (Latin: *oculus dexter*) |
| BUT | break-up time | OO | orbicularis oculi muscle |
| CCC | central corneal clouding | OS | left eye (Latin: *oculus sinister)* |
| CCD | charge-coupled device | OU | both eyes (Latin: *oculus uterque* - each eye, or *oculi uterque* - both eyes) |
| cf. | compared to/with | PD | interpupillary distance |
| CL | contact lens | PMMA | poly(methyl methacrylate) |
| Dk | oxygen permeability | R | right |
| DW | daily wear | R&L | right and left |
| e.g. | for example (Latin: *exempli gratia*) | RE | right eye |
| EW | extended wear | RGP | rigid gas permeable |
| GAG | glycosaminoglycan | SCL | soft contact lens |
| GPC | giant papillary conjunctivitis | SL | spectacle lens |
| HCL | hard contact lens | TBUT | tear break-up time |
| HVID | horizontal visible iris diameter | TCA | tricarboxylic acid |
| i.e. | that is (Latin: *id est*) | UV | ultraviolet |
| K | keratometry result | VVID | vertical visible iris diameter |
| L | left | WTR | with-the-rule |
| LE | left eye | | |

# Summary of Module 5: Care and Maintenance

## Course Program

| Lecture | | | Practical Session | | | Tutorial (Small Group Teaching) | | |
|---|---|---|---|---|---|---|---|---|
| ***Title*** | ***Hrs*** | ***Level**** | ***Title*** | ***Hrs*** | ***Level**** | ***Title*** | ***Hrs*** | ***Level**** |
| L 5.1 Overview of Care & Maintenance | 2 | 1 | P 5.1 Patient Education: Use and Care of Contact Lenses | 2 | 1 | T 5.1 Care and Maintenance Procedures | 1 | 1 |
| L 5.2 Contact Lens Care Products | 2 | 2 | P 5.2 Pre- and Post-Cleaning Appearance of Contact Lenses | 2 | 2 | T 5.2 Review of Contact Lens Care Products: General | 1 | 2 |
| L 5.3 Care and Maintenance of SCLS | 2 | 1 | | | | T 5.3 Review of Soft Contact Lens Care Systems | 2 | 2 |
| L 5.4 Care and Maintenance of RGP Lenses | 1 | 1 | | | | T 5.4 Review of RGP Contact Lens Care Systems | 2 | 2 |
| L 5.5 Contact Lens Deposits | 1 | 1 | | | | T 5.5 Identification of Deposits on Contact Lenses | 1 | 1 |

* Level 1 = Basic: essential knowledge
Level 2 = Intermediate: desirable knowledge
Level 3 = Advanced: useful knowledge

## Course Time Allocation

| Level | Lecture | Practical (Laboratory) | Tutorial (Small Group Teaching) | Total Hours |
|---|---|---|---|---|
| Basic | 6 | 2 | 2 | **10** |
| Intermediate | 2 | 2 | 5 | **9** |
| Advanced | 0 | 0 | 0 | **0** |
| **TOTAL** | **8** | **4** | **7** | **19** |

# Request for Feedback

As this is the first edition it is our intention to revise and update it periodically. To ensure each revision is an improvement on its predecessor we request your help. We invite you to provide feedback in the form of comments, corrections or suggestions for improvement which you feel will enhance the accuracy or quality of the Course. Such feedback may then be incorporated in subsequent revisions of the Course. We are particularly interested in receiving corrections to, and suggestions for improvements in, the text and slides of the lectures.

To facilitate this feedback process a *pro forma* is included on the next page. This can be photocopied. Please complete your contact details as the team may wish to discuss your suggestions in greater detail or even ask you to participate in any revision resulting from your input.

# The IACLE Contact Lens Course
# Feedback / Corrections / Suggestions Form

Name: _____ Date: _____
(dd-mm-yy)

Institution: _____

Address: _____

_____

_____

_____

_____

Module: _____ Unit: _____ Page Number: _____

Slide Code: _____ Section: _____

Comments:

Thank you

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Forward to: _____
Action:

# Unit 5.1

(4 Hours)

**Lecture 5.1:** Overview of Care and Maintenance

**Practical 5.1:** Patient Education: Use and Care of Contact Lenses

**Tutorial 5.1:** Care and Maintenance Procedures

# Course Overview

**Lecture 5.1: Overview of Care and Maintenance**

I. Purpose of Care and Maintenance
II. Functions and General Procedures
III. Summary

**Practical 5.1: Patient Education: Use and Care of Contact Lenses**

**Tutorial 5.1: Care and Maintenance Procedures**

# Lecture 5.1

(2 Hours)

# Overview of Care and Maintenance

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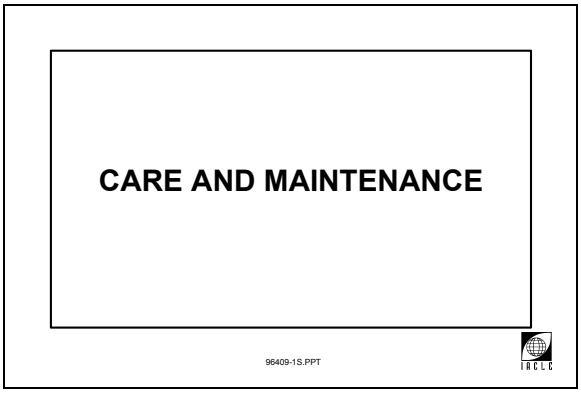
## I Purpose of Care and Maintenance

1

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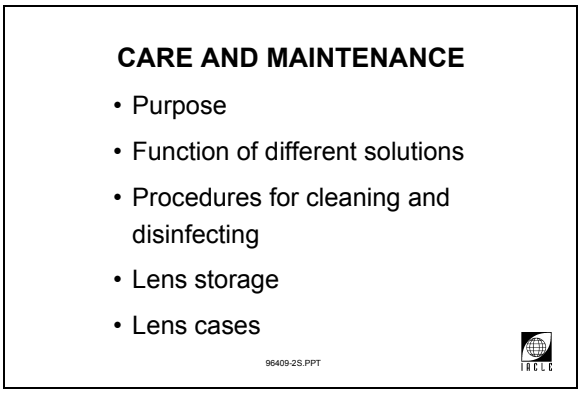
### Overview of Care and Maintenance

Care and maintenance is one of the most crucial aspects of contact lens wear. It can influence the success of contact lens wear and patients' satisfaction with their lenses.

Patient compliance and contact lens wear success depend on prescribing the appropriate lens care regimen. Choice of regimen depends upon factors such as lens type, lens material, lifestyle and specific patient needs. Close questioning is necessary to ensure the relevant information is obtained before choosing a lens care system.

In this lecture, the issues summarized in slide 2 will be discussed.

2

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3

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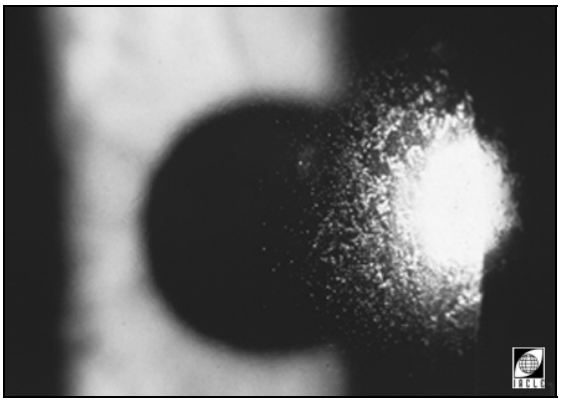
### Purpose of Care and Maintenance

Because contact lenses are in intimate contact with the eyes and are bathed in tears, over time they become soiled. While it is important for the practitioner to monitor the 'condition' of the lenses, steps need to be taken to ensure the wearer maintains the lenses properly. Failure of the wearer to do this may result in reduction in comfort and vision as well as an increased risk of contamination, complications and possibly infection.

It is imperative that the purposes and importance of proper care and maintenance be impressed upon the prospective contact lens wearer as soon as contact lens wear is considered seriously. Such messages should be reinforced at every subsequent opportunity.

4



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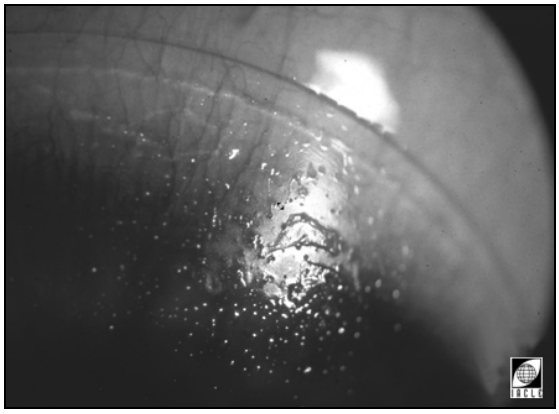
## Examples of Deposits and Associated Complications

This picture illustrates heavy denatured protein deposits on a contact lens. These can cause discolouration, clouding and reduced surface wettability.

5



5L11908-94

Lipid and protein deposits reduce the surface wetting of contact lenses, thereby also reducing vision and comfort.

6

5L10469-91

In the longer term, heavy protein deposition causes lid changes such as CLPC or, in extreme cases, Giant Papillary Conjunctivitis (GPC). These lid changes are associated with increased redness, roughness and the formation of papillae.

## II Care and Maintenance Components: Their Functions and Procedures

7

**CARE AND MAINTENANCE**

**COMPONENTS**

- Daily cleaner
- Rinsing solution
- Disinfecting solution/unit
- Weekly/protein cleaner
- Lubricating/rewetting solution
- Lens storage case

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### Care and Maintenance - Components

Regardless of the type of contact lens (except daily disposables), an appropriate care system must be used. A typical care system consists of the components listed opposite.

8

5L10954-92

Many manufacturers have formulated their own solutions and systems. This gives practitioners a wide selection of care regimens from which to choose. Usually, one can be found which accommodates the patient's lifestyle, needs and tolerances, lens type and material.

Patients must avoid mixing products from different manufacturers even when they have the same apparent function or chemical basis.

9

5L12063-93

### Multi-Purpose Solution

Many modern lens care systems use one solution to perform the functions of a number of components, thereby reducing the actual number of solutions required.

For ease of use and patient convenience, multi-purpose solutions (one-bottle systems) are formulated to allow the cleaning, rinsing and disinfecting functions to be combined.

10

**CONVENIENCE OF SYSTEM**

Determines:

- Patient compliance
- Frequency of lens wear
- Patient satisfaction
- Continued use of recommended care system components

96409-35S.PPT

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### Convenience of System

In determining the convenience aspect of the care regimen to be prescribed, the practitioner should consider such factors as:

- Patient needs.
- If travelling, travel conditions and special requirements.
- Home and working environments, etc.

A patient engaged in occasional athletic pursuits may require a different lens care

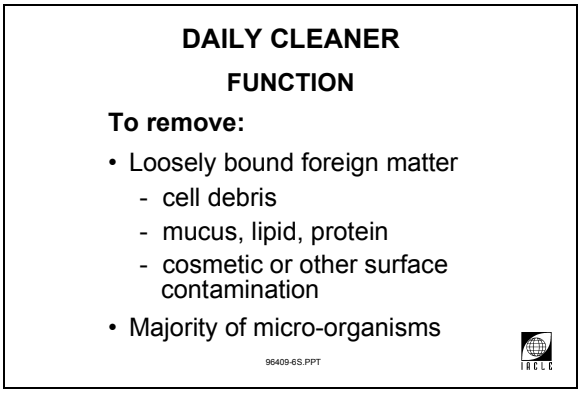
system from someone who regularly spends many hours at a desk.

It is prudent to accept that patients are likely to take the simplest or quickest path to a goal. Consequently, patients may modify the recommended care regimen according to what 'suits them'.

It is the practitioner's responsibility to ensure that compliance with the care regimen is maintained. The key to compliance is good initial patient education and re-education/reinforcement at subsequent opportunities. The choice of a regimen that takes into account aspects of a patient's lifestyle may make compliance easier to attain and maintain.

## II.A Daily Cleaner

11

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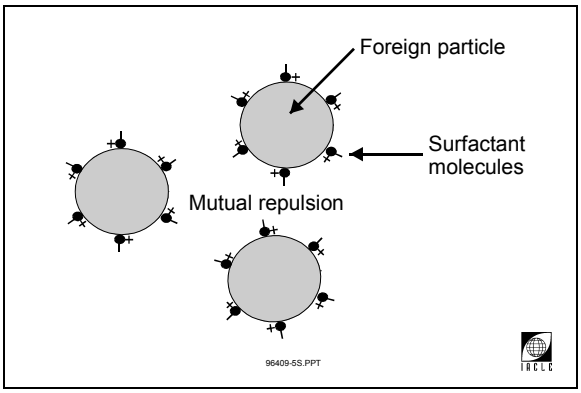
### Daily Cleaner - Function

Daily cleaners usually contain surfactants and are used to remove most loosely bound foreign matter on the lens surface. Such matter includes:

- Cell debris.
- Mucus.
- Lipid.
- Protein.
- Cosmetics.
- Micro-organisms.

12

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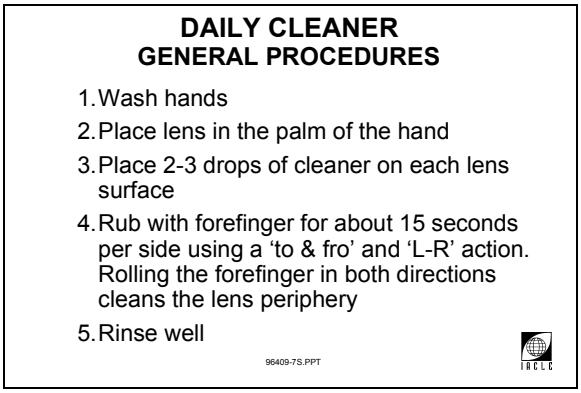
Surfactant molecules emulsify, dissolve and/or disperse lipid globules, debris and other lens contaminants. This is accomplished by the surfactant forming a mono-molecular layer over the contaminant using the polar ends of its molecules to bind the layer to the contaminant's surface. The 'coated' contaminants repel one another mutually or exhibit a lowered surface tension.

Viscosity-enhancing agents such as polyvinyl alcohol or methylcellulose also facilitate cleaning.

Hypertonicity and abrasiveness are properties that have been added to enhance the efficacy of some lens cleaners. Hypertonicity results in extraction of water from soft lenses which may help remove some soluble contaminants. Polymeric beads in some cleaners have a mildly abrasive effect on protein and other surface deposits.

13

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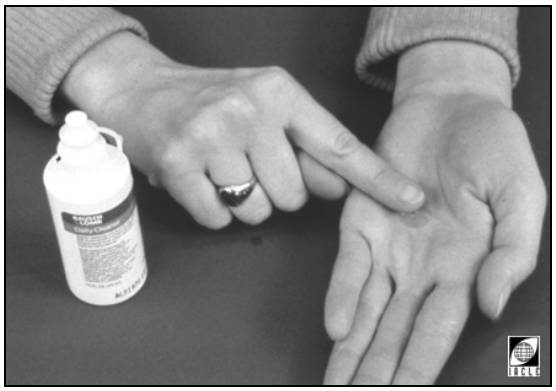
### Daily Cleaner: General Procedures

Lenses should be cleaned each and every time the lenses are removed from the eye regardless of the duration of the wearing period This is usually daily.

The first step in a good lens care regimen is a thorough hand washing prior to handling the lenses. Soaps without fragrances, oils or lotions are recommended, as these ingredients can contaminate the lens surface and/or irritate the eye when the lens is next

14



5L11306-91

worn.

Usually, the procedure outlined in the slide opposite is recommended and demonstrated to the patient. Generally, an orbital rubbing action provides less control over the lens than a 'to and fro' action.

15

**DAILY CLEANING**

- Daily cleaning is more important than brand of cleaner
- Must be done with:
  - all lens types
  - all care systems

96409-9S.PPT

5L196409-9

## Daily Cleaning

Shih *et al.* (1985) showed that daily cleaning and rinsing is an important step in the lens care regimen.

It is important to understand that performing the cleaning is, in most cases, more important than the brand or type of cleaner used. Cleaning should be done with:

- All lens types including disposables.
- All care systems, especially multi-purpose solution-based care.

The mechanical action of rubbing and rinsing reduces significantly the amount of loose debris and the number of micro-organisms on a lens. Rubbing also enhances the efficacy of the cleaning solution's surfactant properties.

## II.B Rinsing Solution

16

**RINSING SOLUTION FUNCTION**

- To remove:
  - Daily cleaner
  - Loosened deposits
  - Micro-organisms
- Rinse lenses after overnight storage

96409-10S.PPT

5L196409-10

17

**RINSING SOLUTION**

**TYPES**

- Saline
  - preserved
  - unpreserved
- Multi-purpose solution

96409-11S.PPT

5L196409-11

18

**RINSING SOLUTION**

Carney *et al.*, 1990

Property changes in saline solution

with inappropriate storage conditions

96409-12S.PPT

5L196409-12

### Rinsing Solution

After cleaning, lenses should be rinsed. Rinsing performs a variety of functions.

Buffering agents are included in rinsing solution formulations so that their pHs approximate that of tears. The pH of normal tears is, on average 7.2, but is subject to individual variation. To enhance the compatibility of solution and tear pHs at lens insertion, the solution is normally buffered lightly (see Unit 5.2).

Many different types of solutions can be used for rinsing.

A once-common form of rinsing solution was bulk unpreserved saline. However, if this type of saline (sometimes called hospital saline and not to be confused with intravenous saline) is to be used, it should be supplied in small bottles with narrow necks and small dispensing jets. To reduce the likelihood of contamination, such bottles should be discarded two weeks or sooner after opening. Sweeney *et al.* (1992) even suggested such products be removed from the market because of safety concerns raised by their real-world study of 500 mL bottles of bulk unpreserved saline.

Unpreserved saline is also supplied in aerosol cans and unit-dose vials or sachets. In an investigation by Donzis *et al*. (1987), all aerosol cans of saline solution studied remained uncontaminated. However, Donzis (1997) reported a case of corneal ulceration associated with *Pseudomonas aeruginosa*-contamination of the spray tip of a can of aerosol saline. The saline in the can remained sterile, it was the dispensing nozzle and the 'dead space' after the can's valve that was contaminated. Once contaminated it is probable that the usual precaution of discarding the initial saline discharged, will not protect the user from further risk of infection. The instruction to not allow

the dispensing nozzle to make contact with anything, applies equally to aerosol packages and conventional bottles. Unit-dose packaging avoids all these shortcomings. However, it is more expensive.

Homemade saline has no role in contact lens care. In the Donzis *et al.* (1987) study, homemade saline was contaminated with bacteria and some preparations were contaminated with *Acanthamoeba sp.* Meanwhile, preserved saline solution remained uncontaminated for a period of up to 21 days after opening. However, the possibility of a sensitivity problem when using preserved saline warrants consideration.

The efficacy of saline solution relies on the stability of its properties including pH, buffering capacity, osmolality and refractive index. Carney *et al*. (1990, 1991) reported changes in these properties (except refractive index which showed little variability) after opening, for both preserved and unpreserved solutions. Their study has implications for practitioners in ensuring patients comply with instructions for solution usage, storage and disposal (expiry dates and discard-after periods).

## II.C Disinfecting Systems

19

**PURPOSE OF DISINFECTION**

**Contact lenses may compromise the eye's natural defence by:**

- Inhibiting tear film washing action
- Introducing more micro-organisms
- Compromising epithelial barrier function

96409-13S.PPT

5L196409-13

### Purpose of Disinfection

Contact lenses interfere with the smooth flow of tears over the anterior eye. This interference may reduce the ability of the tears to wash away foreign bodies and other anterior eye contaminants.

Micro-organism adherence to contact lenses increases the ocular environment's exposure time to potential ocular pathogens. Generally, the eye defends itself. However, if the number of micro-organisms is too large, the eye's defence systems may be unable to cope and infection can ensue.

20

**DISINFECTING SOLUTION FUNCTIONS**

- Kill or deactivate potentially pathogenic organisms including:
  - bacteria
  - fungi
  - viruses
  - amoebas
- Maintain lens hydration

96409-14S.PPT

5L196409-14

Proper disinfection becomes imperative should the number of micro-organisms increase and/or the efficacy of the eye's natural defence mechanism be compromised. The eye normally contains a number of ocular flora including bacteria, fungi and viruses which can behave opportunistically should defence mechanisms be reduced. Disinfection reduces the number of these micro-organisms to safer levels.

As disinfecting solutions are also used for storage, their function as a hydrating medium is obvious. Hydration helps maintain the stability of contact lens parameters and physical properties.

21

**DISINFECTION SYSTEM TYPES**

- Heat (thermal unit, microwave)
- Chemical
  - oxidative
    - hydrogen peroxide
    - chlorine
  - cold chemicals
    - various disinfectants

96409-15S.PPT

5L196409-15

### Disinfection Systems

The two main types of disinfection systems available for soft contact lenses are heat and chemical.

Heat-based disinfection systems use heat in the range from 70°C to 125°C to kill or deactivate living lens contaminants. However, heat can cause problems for the patient due to alterations that occur within the lens following long-term use. Recently, a system for thermal disinfection of contact lenses in a domestic microwave oven has been released (Micro Clens™ from Oculi of the UK).

22

**ANTIMICROBIAL ACTIVITY**
**LEVELS OF EFFICACY**

- ***Sterilization:*** Killing of all microbial life forms - sterilizers
- ***Disinfection:*** Killing and/or removal of vegetative microbial and viral contamination from inanimate objects - disinfectants
- ***Preservation:*** Killing and/or inhibition of growth of selected micro-organisms - preservatives.

96409-34S.PPT

5L196409-34

23

**DISINFECTION SYSTEM**

**AVOID**

- High temperatures
- Strong disinfectants/preservatives:
  - thimerosal
  - chlorhexidine

96409-16S.PPT

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Chemical disinfection systems vary greatly and a wide variety of types exist. Included in the chemical systems category are the current hydrogen peroxide and multi-purpose solutions. Chemical disinfection can be subdivided into oxidative (hydrogen peroxide and chlorine) and conventional cold chemical. Sometimes, the distinctions can seem confusing and complicated to patient and practitioner alike.

The use of strong disinfectants (many of which are also used in lower concentrations as preservatives) in chemical-based disinfection systems can cause problems for the patient.

The most common problem is the development of a sensitivity to the chemical(s) used as disinfectants or preservatives.

Antimicrobial activity can be divided into three levels of efficacy (Anger and Currie, 1995). Although all levels involved killing, removing or reducing the microbial loads in solutions or on lenses, they differ in their speed of action and spectrum of activity. The levels are:

- *Sterilization* is the killing of *all* microbial life forms, a situation impossible to achieve with normal lens care products and procedures.
- *Disinfection* is a dynamic process, usually preceded by a cleaning and rinsing step, intended to kill and/or remove microbial and viral contaminants from contact lenses.
- *Preservation* is the killing or inhibition of growth of a select range of micro-organisms to prevent product spoilage during consumer use. The choice of preservative is governed to a large extent by the resistance of the microbial targets and the sensitivities of the eye exposed to the preservative via contact lenses or eye drops.

24

**HEAT DISINFECTION**

**Asepticize using:**

- 'Low' heat 70 - 80ºC
- 'High' heat 70 - 80ºC
- Can cause denaturation of protein

96409-17S.PPT

5L196409-17

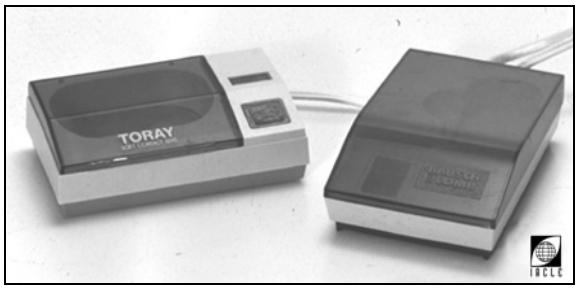
## Heat Disinfection

Eradication of microbiological contamination is best achieved through sterilization. However, such an absolute state is not possible with some contact lens materials because the high temperatures required can result in their molecular breakdown.

Such breakdown is most significant with high water content SCLs.

Since most bacterial, fungal and viral micro-organisms are killed at 70 - 80°C, and lens materials remain stable at temperatures up to 85°C, heat disinfection rather than sterilization is the preferred technique.

25

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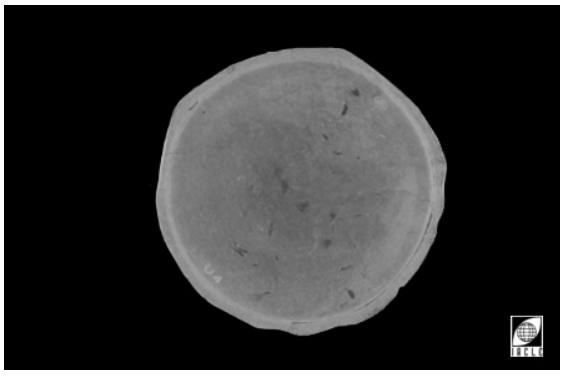
Slide 25 shows two heat disinfection units. Soft contact lenses are placed in the lens case with saline solution and heated to 70 - 80°C for 10 - 20 minutes. The controlled heating and automatic shut-off prevents over-heating and possible shortening of lens life.

Heat disinfection systems generally decrease lens life span and eventually cause lens discolouration. Slide 26 shows a protein-deposited SCL whose optical and physical properties have been altered by excessive heating and the resultant denaturation of the protein in and on the lens.

26



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27

**CHEMICAL DISINFECTION**

Strong disinfectants in chemical systems can cause sensitivity problems

96409-18S.PPT

5L196409-18

## Chemical Disinfection

### Disinfectant-Based Solutions

Disinfectants such as thimerosal, chlorhexidine, benzalkonium chloride and sorbic acid should be used with caution because of their potential for disinfectant-induced sensitivity reactions.

**Thimerosal** (American) or thiomersal (British), a mercurial antibacterial, is effective as an antifungal agent. However, it is reported to have reduced

28

**CHEMICAL DISINFECTION**

**DISINFECTANT-BASED SOLUTION**

**Thimerosal:**

- Effective as antifungal agent
- Reduced effect when combined with EDTA (?)
- Cytotoxic to corneal epithelium

96409-19S.PPT

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29

**CHEMICAL DISINFECTION**

**DISINFECTANT-BASED SOLUTION**

**Chlorhexidine gluconate (CHG):**

- Antibacterial agent
- Adsorbed until saturation
- Leaches from Group I and IV lenses

96409-20S.PPT

5L196409-20

30

**CHEMICAL DISINFECTION**

**DISINFECTANT-BASED SOLUTION**

**Benzalkonium chloride (BAK):**

- Antibacterial agent
- Cytotoxic
- Adsorption can reach toxic concentrations

96409-21S.PPT

5L196409-21

31

**CHEMICAL DISINFECTION**

**DISINFECTANT-BASED SOLUTION**

**Sorbic acid:**

- Antibacterial with limited antifungal activity
- Not cytotoxic
- Causes discolouration of old lenses

96409-22S.PPT

5L196409-22

activity in combination with ethylenediamine tetracetic acid (EDTA or sodium edetate).

Cytotoxic reactions of the corneal epithelium reported by Tripathi *et al*. (1992) demonstrated cell retraction, cessation of mitotic activity and total cell destruction in *in vitro* human corneal epithelium. Clinical evidence of a delayed hypersensitivity reaction in the form of subepithelial opacities was reported by Eggink *et al*. (1991) when solutions containing thimerosal were used.

**Chlorhexidine gluconate** (CHG - a biguanide antimicrobial) uptake and release has also been studied because of its historic use by manufacturers in combination with thimerosal or other agents to enhance its effectiveness.

Reports of hypersensitivity reaction with chlorhexidine were supported by the *in vitro* study of Schlitzer (1992) who showed that CHG leaches out from Groups I and IV (FDA classifications) soft contact lenses significantly more than other non-oxidative chemical entities. CHG is adsorbed onto RGP lenses (siloxane acrylates) as a monolayer until they become saturated and no further uptake occurs (Rosenthal *et al*., 1986).

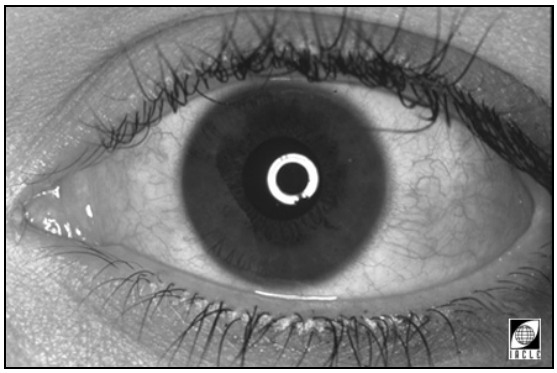
**Benzalkonium chloride** (BAK) is another commonly used antibacterial agent. However, it has been shown during *in vitro* studies (Tripathi *et al*., 1993) to create cytotoxic reactions in the corneal epithelium in a shorter period of time than thimerosal or chlorhexidine. BAK's uptake by rigid gas permeable (silicone acrylate) lenses has been shown to be one of self-aggregation whereby the positively charged molecules continue to bind to the negatively charged surface of the lens until they reach toxic concentrations. The build-up of BAK layers is explained by Rosenthal *et al*. (1986) as being caused by the longer hydrophobic chains of BAK which form a template allowing adjacent hydrocarbon tails of the BAK molecules to adhere in

layers over the lens surface.
BAK release onto the cornea from soft and rigid contact lenses has been shown to be beyond the critical limits of safety (Chapman *et al*., 1990).

**Sorbic acid** has antibacterial and limited antifungal activity. Its concentration in SCLs has not been shown to cause death of the corneal epithelial cells (Tripathi *et al*., 1993).

Adherence to contact lenses is facilitated by its organic reaction with the amino acid (lysine) in tear proteins (Sibley and Chu, 1984), causing a yellow or brown discolouration. This implies that worn lenses are more prone to sorbic acid interactions than new lenses, and that thorough cleaning is required prior to storage in solutions containing sorbic acid.

32



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**Disinfectant/Preservative Sensitivity**

The most common observable sign of this condition is mild conjunctival redness in both eyes which affects the exposed nasal and temporal quadrants as well as the upper and lower bulbar conjunctiva.

Typical symptoms and signs presented by the patient with preservative sensitivity problems are listed in slide 33.

33

**DISINFECTANT/PRESERVATIVE SENSITIVITY**

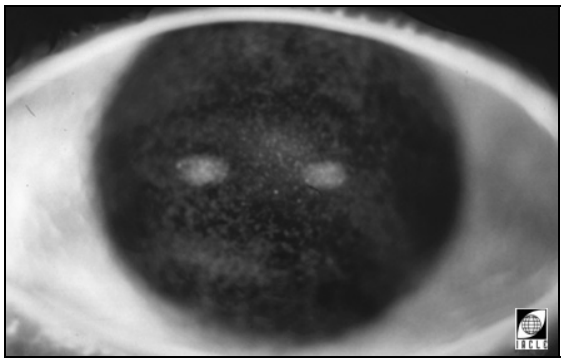
| SYMPTOMS | SIGNS |
|---|---|
| • Sudden increase in dissatisfaction | • Conjunctival redness (general/local) |
| • Decreased wearing time (3-4 hours) | • Epithelial damage (diffuse corneal staining) |
| • Burning, grittiness, dryness | • Corneal inflammation (if severe) |

96409-23S.PPT

5L196409-23

If fluorescein and a Burton lamp or slit lamp with cobalt blue light is used in combination with a yellow Kodak Wratten #12 filter, the diffuse corneal staining can be observed in the affected eye(s). Slide 34 shows a generalized and diffused punctate corneal staining covering a significant area. This indicates a chemical toxicity reaction.

34



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35

**PEROXIDE ($H_2O_2$) DISINFECTION NEUTRALIZATION**

**One-step:**

- Catalytic disc
- Delayed-release neutralizing tablet

**Two-step:**

- Dilution
- Chemical (stoichiometric)
- Catalytic disc
- Catalase

96409-24S.PPT

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36

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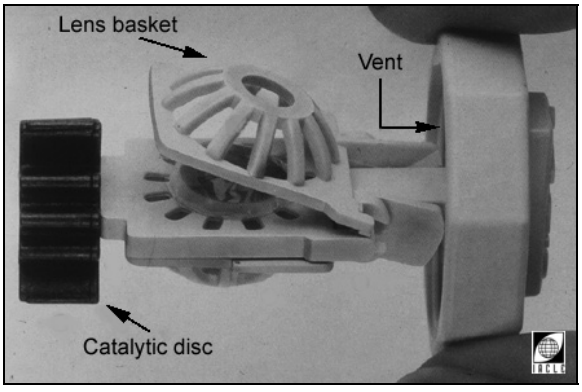
37

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## Chemical Disinfection

### Hydrogen Peroxide-Based Solutions

Hydrogen peroxide based solutions are another type of chemical disinfectant.

Hydrogen peroxide-based disinfection systems may be either preservative-free or preserved and can be divided into two main types:

- One-step systems (slide 36).
- Two-step systems.

Hydrogen peroxide disinfection systems are normally formulated with a 3% peroxide concentration (lowest concentration marketed was 0.6%) whose pH is often acidic at 3.0 - 4.0. For a lens to be wearable following disinfection, neutralization is required. Various neutralization techniques have been designed by manufacturers to simplify the disinfection and neutralization steps and thereby lessen the likelihood of non-compliance or discomfort on insertion. Most systems decompose hydrogen peroxide into saline and oxygen catalytically.

Disinfection in hydrogen peroxide is reasonably effective in 10 - 15 minutes.

**One-step systems** are formulated so that the peroxide disinfection and neutralization are performed during the recommended time. With tablet-using systems a delay is applied to the neutralization phase. With disc-based

systems, no delay is applied to the neutralization phase. Regardless of which of these systems is used special vented lens cases are required to allow the oxygen generated to escape. One-step systems use either a catalytic (platinum) disc (see slide 37) or a time-delayed catalase tablet.

When neutralization is performed as a separate step, the system is called a **two-step system**. Very early systems 'neutralized' peroxide using pre-measured quantities of sodium bicarbonate for a minimum of 10 minutes. In fact, the process was not true neutralization and usually took longer than 10 minutes. Rather, the bicarbonate altered the solution pH (upwards) to levels at which peroxide was inherently less stable. The peroxide solution then began to decompose slowly into water and oxygen.

With two-step systems it is recommended that lenses are stored overnight in the peroxide and neutralized immediately before lens usage.

## II.D Protein Remover

38

**PROTEIN REMOVER**

**FUNCTION**

Help to remove/loosen tightly bound protein deposits

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5L196409-25

39

5L1TABLETS

40

**PROTEIN REMOVER**
**GENERAL PROCEDURES**

- Used weekly, after the daily cleaner and rinsing step
- Heavy protein depositors, especially high water content lens wearers, may require treatment more often
- Lenses should be cleaned and rinsed again after enzyme cleaning

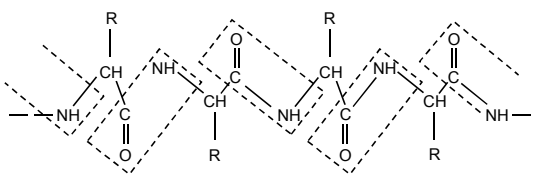
96409-26S.PPT

5L196409-26

41

**CLEAVING OF PEPTIDE BONDS**

After Stewart-Jones *et al*., 1989




R = residue of amino acids

= peptide bonds

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5L196409-27

### Protein Remover

Protein removers, also known erroneously as enzymatic cleaners, are included in the care systems for soft contact lenses, and some RGP lenses, that are not replaced regularly (>1 month). Not all protein removers are enzyme-based. Those that are, are usually supplied in tablet form. Chemical-based systems are usually supplied as ready-to-use liquids. These cleaners are effective in loosening tightly bound protein deposits. However, they cannot be expected to remove all proteins.

Prior to protein removal, the lenses should be cleaned and rinsed before being placed in the recommended container with the tablet or solution for the recommended time. Protein treatment is usually done *weekly* or at a frequency dependent on the rate of patient protein deposition. Heavy protein depositors, especially ionic high water material lens wearers, may require an increased frequency.
Lenses should be soaked in the remover for 15 minutes to two hours, depending on the type of protein remover used and rate of protein build-up. Enzymes used include papain, subtilisin, pronase and pancreatin.

Slide 39 shows examples of protein remover tablets.

### Cleaving

Enzyme tablets act as protein removers by cleaving the peptide bonds in tear proteins deposited on contact lens surfaces. Since the action of the enzyme tablet only loosens the protein, it is important to instruct the patient to clean the lenses by rubbing and rinsing upon completion of the deproteinizing process.

## II.E Re-Wetting Eye Drops and Lubricants

42

**REWETTING DROPS & LUBRICANTS FUNCTION**

- To alleviate discomfort resulting from insufficient lubrication by the tear film
- To rehydrate the contact lens while being worn
- To flush debris from lens and eye

96409-28S.PPT

5L196409-28

43

5L11692-91

44

**LUBRICANTS: Do They Work?**

Efron *et al.*, 1990

"Neither lubricant tested was found to be significantly superior to saline".

96409-29S.PPT

5L196409-29

### Re-Wetting Eye Drops and Lubricants

Tear fluid supplements are often used by contact lens wearers to:

- Promote comfort.
- Overcome the sensation of dryness that can occur with soft lenses due to insufficient lubrication by the tear film.
- Rehydrate the lens and flush debris from the surface of the eye and lens.
- Reduce the deposit-induced friction between the eyelids and the corneal surface.
- Cushion the lens on the eye.

They should only be prescribed when needed, and caution should be exercised to ensure that they are not used to mask underlying problems.

Generally, the effect of conventional re-lubricating eye drops is relatively short lived and the patient may find their frequent use to be an inconvenience. New technology with improved residence time is imminent.
Lubricants may be beneficial in the first few days of lens wear as the patient is adapting to their new contact lenses.

Lubricating and re-wetting eye drops are formulated with viscosity-enhancing agents (commonly polyvinyl alcohol, methylcellulose, etc.).

Efron *et al.* (1991) examined the effect of two lens lubricants on SCL patients who experienced symptoms of dryness.

They found that the lubricants tested were not significantly superior to saline. Any type of lubricant provided relief in approximately equal amounts.

It is also noteworthy that generally, the use of lubricants did not affect lens water content or lens hydration.

## II.F Lens Storage and Cases

45

**LENS STORAGE AND CASES**

**Contact lenses should be stored in:**

- A clean contact lens storage case
- Fresh disinfecting solution

96409-30S.PPT

5L196409-30

46

5L10341-91

### Lens Storage and Cases

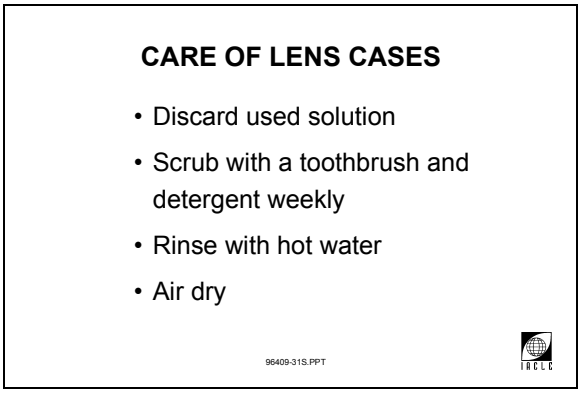
To avoid contamination, the lens case should be rinsed after every use and the lenses stored in fresh solution.
A soiled lens case can be the cause of ocular irritation when contaminants are transferred to a contact lens and from the lens into the eye. It can also be the cause of lens discolouration. If a case is heavily contaminated with micro-organisms, it may reduce the efficacy of the disinfection system by exceeding the disinfectants capacity to kill the target micro-organisms.

Bacterial contamination of storage cases for both soft and rigid contact lenses has been reported by a number of investigators (Larkin *et al*., 1990; Wilson *et al*., 1990; Dart, 1990). *Acanthamoeba* and other free living protozoans are especially prevalent among those using tap water for rinsing their storage cases, using home-made saline as a rinsing solution for contact lenses, or swimming with contact lenses. Patients may be symptom-free.

Biofilm or glycocalyx formation on the surface of contact lens storage cases can harbour *Pseudomonas aeruginosa* and *Serratia marcesens.* The biofilm is produced by the bacteria themselves. It protects the host bacterial cells from chemical or preservative attack and traps nutrient particles and organisms. *Pseudomonas aeruginosa* and *Serratia marcesens* are also able to produce their own biofilm in storage cases (Feldman *et al*., 1992).

Slide 46 requires no further comment.

47

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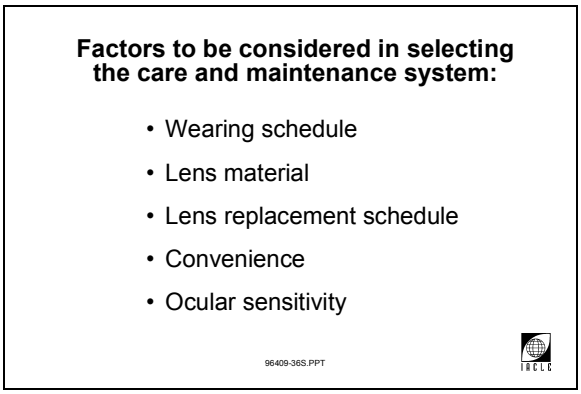
## Care of Lens Cases

- Discard all the used solution from the case. This prevents loss of disinfecting efficacy when fresh solution is mixed with used solutions.
- Scrub with a toothbrush and detergent weekly. Oil free soaps or detergents are recommended for this step.
- Rinse with hot water and rub thoroughly with a clean, dry tissue. *Acanthamoeba* can be killed at temperatures of ≥70°C. Rubbing will help disrupt the biofilm that may be forming on the case surfaces.
- Air dry. Keeping the lens case dry will prevent colonization by micro-organisms such as protozoa that thrive in moist or wet environments.

It is also recommended that the lens case be replaced at frequent intervals (monthly when a new case is supplied with each bottle of disinfecting solution) to reduce the risk of contamination/biofilm build-up.

## III Wear Modalities and Lens Types

48

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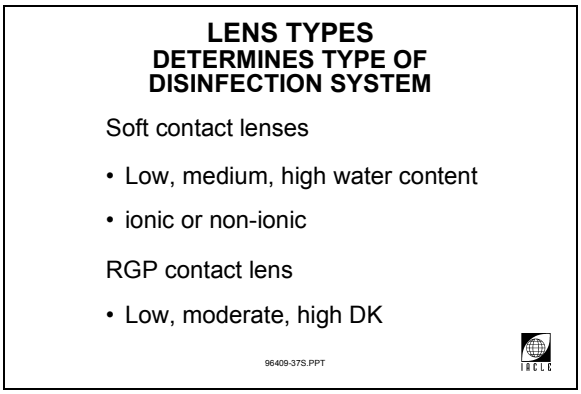
### Selecting the Care and Maintenance System: Important Considerations

When selecting a system, a number of factors need to be considered (slide 48).

Aspects of the care and maintenance system may have to be modified to cater to the specific needs of the patient. These are:

- Procedures for cleaning and disinfecting lenses.
- Combination of solutions to be prescribed.
- Schedule for lens replacement.

49

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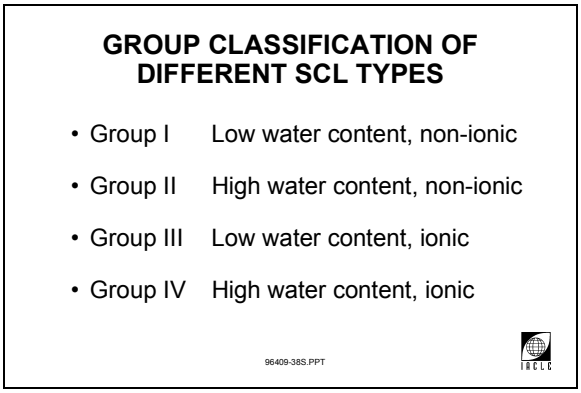
### Lens Types

Different lens types may require alteration of the solutions to be used, because of:

- Chemical absorption or adsorption.
- Attraction of surface deposits.
- Behaviour of the deposits *in situ.*

(Further discussed in Unit 5.5, *Contact Lens Deposits*). The different lens types are summarized in slide 49.

50

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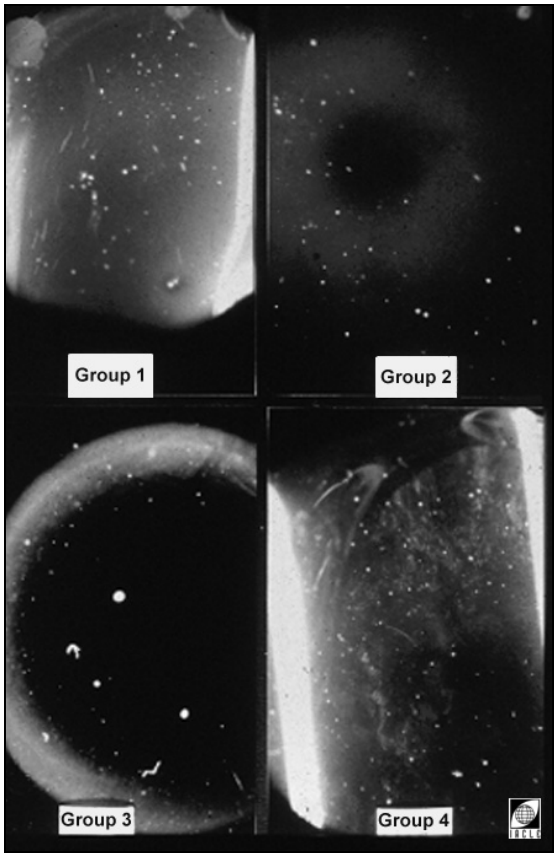
### FDA Classification of Different SCL Types

The FDA classification defines four groups of SCLs (slide 50).

Because of their water content, SCLs can absorb preservatives from the care system used. If the preservatives concentrate in the lens materials and reach saturation point, they can leach out on to the ocular surface. A soft lens material's ionicity and water content increase its propensity to accumulate protein deposits on its surfaces (see below).

51

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## Different Types of SCLs and Deposit Accumulation for Each Type

Generally:

- Ionic lenses tend to attract more protein deposits than non-ionic lenses.
- Higher water content lenses tend to accumulate more deposits than lower water content lenses (see slide 51, Group 4).

Slide 52 presents a summary of recommended disinfecting systems based on these two factors.

*NOTE: The choice of lens care system is discussed in more detail in Unit 5.2.*

52

| | HEAT | $H_2O_2$ | PEROXIDE | MULTI-PURPOSE |
|---|---|---|---|---|
| **SCL** | | | | |
| Low, Non-ionic | ✓ | ✓ | ✓ | ✓ |
| Low, Ionic | X | ✓ | X | ✓ |
| High, Non-ionic | some | ✓ | ✓ | ✓ |
| High ionic | X | ✓ | X | ✓ |
| PMMA | X | ✓ uncommon | ✓ | ✓ |
| **RGP** | X | ✓ uncommon | special formulations | ✓ |

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## IV Lens Replacement Schedule and Care Regimen

53

5L40076-95

54

**CARE AND MAINTENANCE**

**REGULAR DISPOSABLE**
**(lenses replaced weekly, or bi-weekly)**

- Multi-purpose solution (for cleaning, rinsing and disinfecting)
- Re-wetting solution or sterile saline
- No weekly/enzyme cleaner

96409-40S.PPT

5L496409-40

55

**CARE AND MAINTENANCE**
**DISPOSABLE**

Other options

- Surfactant cleaner
- One-step hydrogen peroxide

96409-41S.PPT

5L496409-41

### Care and Maintenance - Disposables

Daily disposables:

- Because of its single use concept, this lens does not require use of surfactant cleaner, disinfecting solution or weekly enzyme.
- If needed, the patient can use in-eye re-wetting drops or sterile saline for rinsing prior to insertion.

Regular disposables:

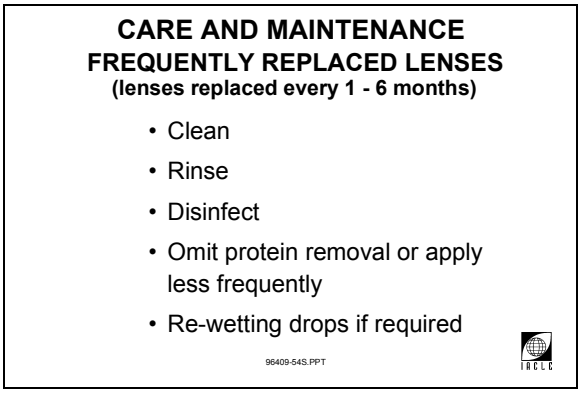
These lenses are replaced weekly or bi-weekly. Suitable care includes multi-purpose solutions given as a complete care system. If preferred, lenses can be rinsed with aerosol saline prior to insertion or a lubricating solution used to re-wet the lenses. No weekly protein removal is needed.

Other options:

- Single-purpose surfactant cleaner.
- One-step hydrogen peroxide disinfection.
- Lubricating/re-wetting solution or sterile saline.

If a multi-purpose solution causes irritation and/or discomfort, or is not available locally, one-step hydrogen peroxide can be used as an alternative. However, a surfactant cleaner will also be required.

56

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## Care Regimen Guidelines for Frequently Replaced Lenses

- **Clean**. This step may be done with a multi-purpose solution or a surfactant cleaner.
- **Rinse**. This step may be done with a multi-purpose solution or a saline solution (unit-dose, aerosol or preserved).
- **Disinfect**. This step may be done with heat, cold chemical, oxidative or multi-purpose systems. The final choice depends on the lens material as some cannot be disinfected thermally. The choice may also depend on patient compliance.
- **Remove protein.** This may be required (especially >1 month replacement), but possibly at a lower frequency compared with conventional lens systems. In many cases, especially with monthly replacement, it may be possible to omit this step altogether. However, eye health should not be compromised by a desire to 'cut corners'.

If required:

- **Lubricating/re-wetting**. Some wearers may benefit from occasional use of comfort/re-wetting/lubricating drops, particularly if they spend much time in an air-conditioned environment. The apparent need for frequent use of such solutions should arouse suspicion of deeper underlying problems with the wearer, lenses or environment.
  Efron's comment (slide 44) may be worth further consideration. However, his comment must be reconciled with the need for a *sterile* solution in a convenient, easily-carried form. Only unit-dose saline matches most of the advantages of special-purpose re-wetting drops.

Depending on the individual patient:

- Single-purpose surfactant cleaners may be recommended to symptomatic

wearers.

- Weekly protein remover use is strongly recommended for lenses replaced every three to six months, especially for heavy depositors.

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**CARE AND MAINTENANCE**
**CONVENTIONAL**
**(lenses replaced >6 months - yearly)**

- Clean
- Rinse
- Disinfect
- Remove protein
- Re-wetting drops if required

96409-42S.PPT

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**Care Regimen Guidelines for Conventional Lens Wearers**

- **Clean**. This step may be done with a multi-purpose solution or a surfactant cleaner.
- **Rinse**. This step may be done with a multi-purpose solution or a saline solution (unit-dose, aerosol or preserved).
- **Disinfect**. This step may be done with heat, cold chemical, oxidative or multi-purpose systems. Final choice depends on lens material. The choice may also depend on patient compliance.
- **Remove protein**. This step is done periodically, usually weekly. It is performed using a tablet or liquid form of protein remover which may be chemical or enzymatic in nature.

If required:

- **Lubricating/re-wetting**. Some wearers may benefit from occasional use of comfort/re-wetting/lubricating drops, particularly if they work in an air-conditioned environment

For regular wearers of conventional lenses, DO NOT recommend heat or thimerosal/chlorhexidine-based disinfection.

Choices of care system based on lens replacement schedule are summarized in slide 58.

58

**SUMMARY**

| | Conv > 6mth | F Repl 1m,≤ 3m | Disp ≤1m |
|---|---|---|---|
| • Surfactant cleaner | ✓ | maybe | X |
| • All purpose | X | ✓ | ✓ |
| • Peroxide | | | |
| One-Step | ✓ | ✓ | ✓ |
| Two-Step | ✓ | X | X |
| • Enzyme | ✓ | maybe | X |
| • Clean lens cases weekly | ✓ | ✓ | ✓ |

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## V In-Office Diagnostic (Trial Set) Lenses

59

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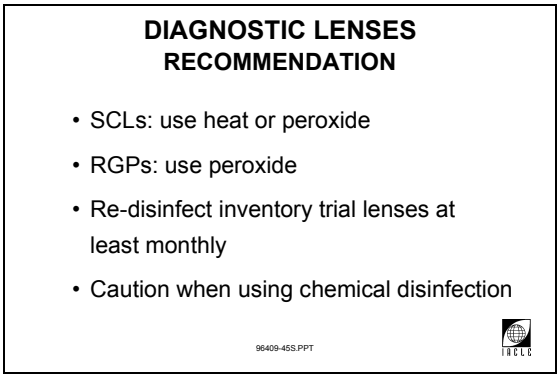
### In-Office Diagnostic (Trial Set) Lenses

In-office disinfection of diagnostic or trial contact lenses is extremely important. Failure to maintain the safety of trial lenses could easily result in a contact lens practitioner becoming a vector of ocular infective agents.

60

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### Diagnostic Lenses

- SCL: Use heat if possible, otherwise peroxide.
- RGP: Use peroxide or store lenses dry.
- Re-disinfect non-disposable inventory trial lenses at least once a month. (Chalmers *et al.,* 1992)

Caution is required when using chemical disinfection.

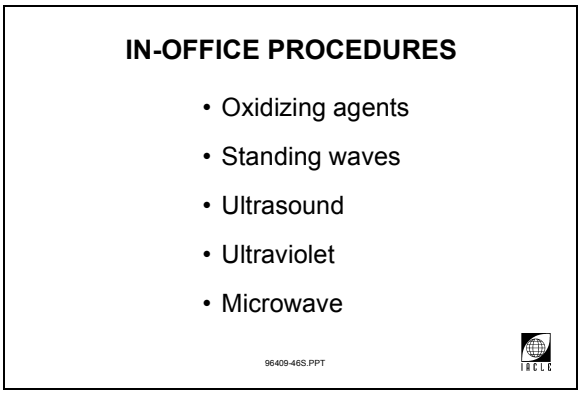
Convenience systems, e.g. one-bottle or multi-purpose solutions should only be applied to trial lenses used very frequently. Such solutions are not suitable for long-term lens storage (trial or patient lenses). Regardless of the storage method, all trial lenses should be cleaned and rinsed thoroughly before storage.

It is important to use thermal disinfection with preserved saline and, only as a last resort, multi-purpose solution for in-office disinfection of diagnostic lenses. A multi-centre study by Callender *et al*. (1992) showed lens contamination rates of 14% (with polyaminopropyl biguanide) and 41% (with polyquaternarium-1) when chemical disinfection was used. This is unacceptably high, and a more conservative approach is desirable.

Vials must be securely sealed at all times.

## VI In-Office Procedures

61

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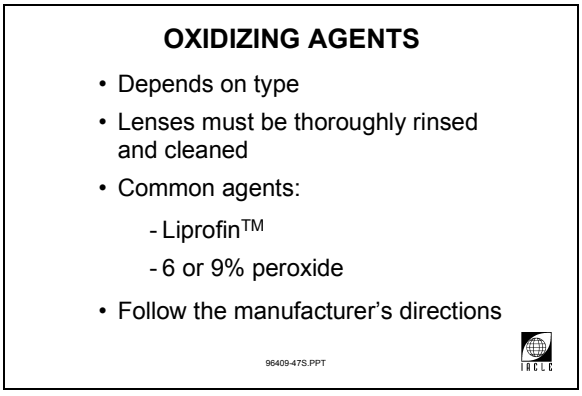
### In-Office Procedures

- Heater/stirrer units with/without:
  - special-purpose care products
  - oxidizing agents ($H_2O_2$, sodium perborate, sodium percarbonate, sodium hypochlorite, etc.)
  - special saline (e.g. saline with a calcium chelating agent).
- Oxidizing agents (e.g. 6 or 9% $H_2O_2$ with or without heat).
- Standing waves. A lens cleaning system involving low-frequency agitation of a lens vial containing contact lenses and a cleaning solution.
- Ultrasound. Ultrasonic agitation and removal of particulate matter from contact lens surfaces.
- Ultraviolet. A lens disinfection system using either direct UV irradiation of microbes or the production of ozone by a UV-emitting discharge tube. The ozone is the actual disinfectant.
- Microwaves. This is an alternative form of heat disinfection, albeit high heat. While undoubtedly effective against micro-organisms, the temperatures involved may also have deleterious effects on the lenses and decrease their life expectancy. See Harris *et al.,* 1990.

62

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### Oxidizing Agents

Method(s) of application:

- Depends on oxidizing agent.
- The lens must be thoroughly rinsed and cleaned first.

A common intensive cleaner, before the advent of regularly replaced lenses, was Liprofin™ (based on sodium perborate).

Another method involves the use of 6 or 9% hydrogen peroxide with or without heating and agitation. Caution with this method is required because:

- Hydrogen peroxide, especially when hot, almost instantly denatures proteins in the skin leading to white skin 'burns'
- Stabilizers used in some commercial peroxides may rapidly discolour SCLs (often a brown hue).

Follow the instructions provided by the manufacturer.

Cleaning depends on the presence of an oxidizing agent or the generation of oxygen with or without heat. Before further wear, lenses must be thoroughly rinsed and cleaned to remove all traces of the active ingredients.

Because of the differences between products, the actual procedures vary. It is prudent to follow the manufacturer's directions exactly, unless you have a good working knowledge of the chemical basis of the product. If using a new or untried method, apply it to an unwanted lens first.

Some intensive treatments shorten lens life and can only be applied once or twice before the lens has to be discarded. If restoration requires a 'miracle', consider a programmed replacement scheme instead.

63

5L71540-92

**Standing Waves**

- Vertically oriented high energy standing waves are generated by a vibrating plate. This results in turbulence which is claimed to dislodge surface contaminants.
- The technique is for cleaning, and *not* disinfection.

Example: Softmate Professional Cleaning Unit which is used in conjunction with the Hydra-Mat II lens case.

Efron *et al.* (1991) showed that the Soft Mate device was as effective as manual cleaning (with surfactant), for removing mascara but probably not for soilants which adhere more tenaciously to lens surfaces.

Periodically, new techniques for cleaning

contact lenses are advertised, often with ambitious performance claims. Results are usually similar or even inferior to those for manual cleaning. Claims for the efficacy of systems which are hands-free, i.e. no manual lens rubbing, should be viewed with skepticism.

64

**ULTRASOUND**

- High frequency audible waves between 15 and 20kHz. Cleaning is achieved by cavitation (intense agitation of small bubbles at the lens surface).
- Effective on LWC SCLs
- Limited antimicrobial effect
- Example: Sonasept™ Ultrasonic cleaner

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## Ultrasound

Originally, ultrasound was used for contact lens cleaning. More recently, a device intended for both cleaning and disinfection was introduced (Sonasept, slide 65). It is intended to clean lenses, and destroy the cell walls of microbial lens contaminants ultrasonically. The device has several temperature settings but offers no control of its ultrasonic function.

Efron *et al.* (1991) showed that ultrasound reduced soilants on LWC lenses (findings were similar to manual cleaning). It was less effective on HWC lenses and almost ineffective on RGPs.

65

5L71539-92

The HWC result can be explained by the reduced effectiveness of the acoustic interface between saline and HWC lens materials. No explanation was provided for the ineffectiveness of the device on RGP lenses.

Although the study showed some reduction in the populations of selected bacteria after use of the ultrasonic device, the reduction was considered inadequate. The device was not recommended for contact lens disinfection.

66

**ULTRAVIOLET**

- UV radiation, $\lambda = 253.7$nm
- Kills micro-organism's by breaking bonds and cross links between nucleic acids
- Source: specialized fluorescent tubes
- Storage: lens vials with saline solution
- Effective: disinfection for SCLs and RGPs

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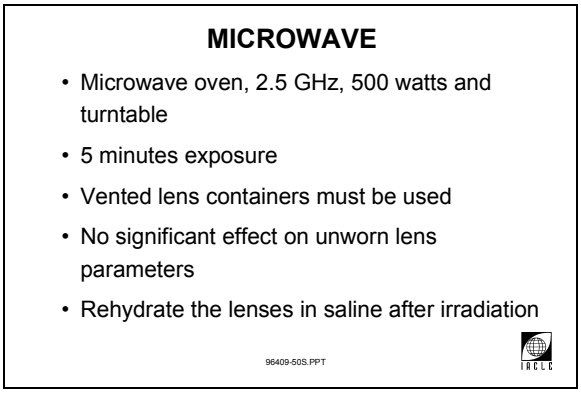
## Ultraviolet

Harris *et al.* (1993) used Sylvania Germicidal G15 T8 15 W fluorescent tubes to produce 253.7 nm UV radiation.

They concluded that UV radiation is an effective method of disinfecting SCL and RGP contact lenses.

Caution was advised in the choice of storage solutions to be used, as some solutions can absorb UV and shield micro-organisms from the UV radiation.

67

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## Microwave

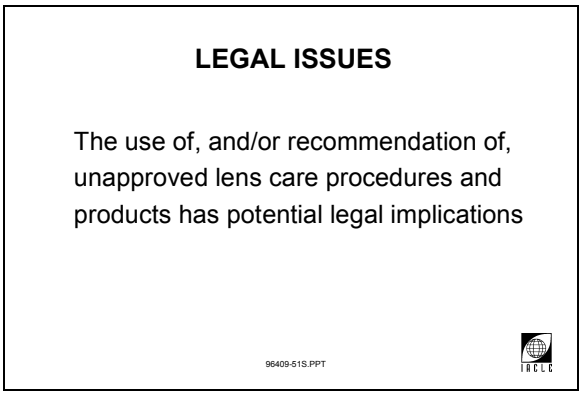
This system allows disinfection of a large number of contact lenses at once (up to 40).

With microwave heating, it is essential that a vented lens case be used to allow the escape of steam generated by the boiling saline. The use of a sealed case will result in a rupturing, or even an explosion, of the lens case.

Harris *et al*. (1990) studied the efficacy of microwave disinfection. In this study, unworn contact lenses of various water contents and ionicity were placed in vented lens containers (AOSept™ cases). Results showed that there were some changes in parameters but they were small and clinically insignificant. Caution was advised when using the method on HWC lenses because, like other forms of thermal dinsinfection, excessive heating can have deleterious effects on the lens.

## VII Legal Issues

68

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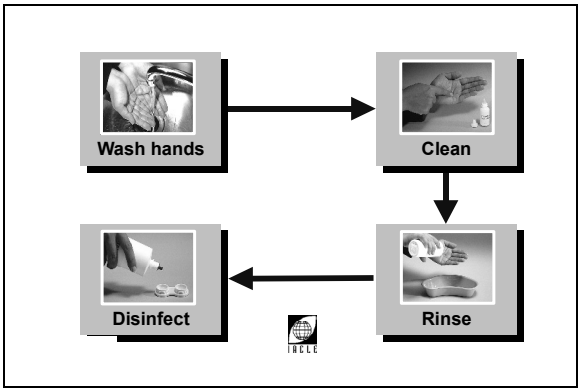
### Guidelines

To avoid liability:

- Explain procedures carefully and fully.
  - test patient's understanding during instructional session
  - provide illustrations to supplement manufacturer's directions
  - consider developing your own instructions (with illustrations).
- Document instructions properly.
- Use a signed informed consent pro forma.

## VIII Summary

69

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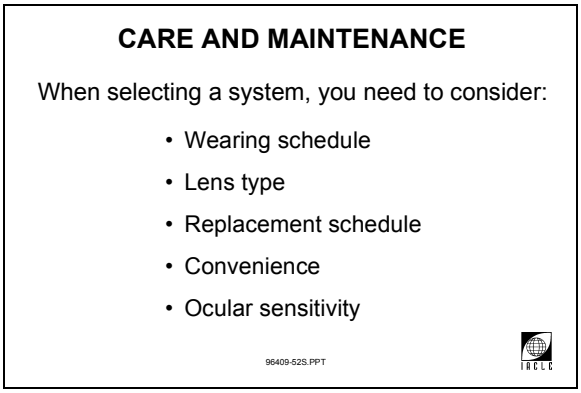
### Care and Maintenance: Important Steps for Patients

- Wash hands prior to handling lenses.
- Rub each side of each lens for 10-15 seconds using a surfactant cleaner. Pay particular attention to the front surfaces.
- Rinse each lens thoroughly in normal saline.
- Disinfect contact lenses in fresh disinfecting solution in a clean storage case.

Emphasize that lens care and maintenance can be straightforward and that compliance with issued instructions will lead to successful lens wear.

70

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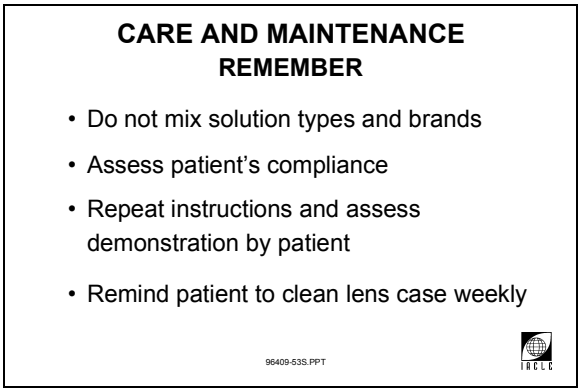


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### Care and Maintenance: Important Points for the Practitioner

A number of questions should be considered by the practitioner when investigating the care system and regimen. Is the patient:

- Wearing lenses every day or only a few days a week or less?
- Which contact lens type is used? SCL/RGP? If SCL, which type?
- How often does the patient replace the lenses?
- How convenient is the care system and does the patient find the solutions effective in maintaining comfortable lens wear?

Patients should be instructed not to mix solution types and brands. Practitioners should encourage their patients to consult them before substituting solutions.

Practitioners should review the patient's compliance at each after-care visit.

Practitioners should ask patients to repeat their lens care instructions and demonstrate the techniques and procedures they have been taught.

| | |
|---|---|
| | Practitioners should remind patients to clean their storage case weekly. |

# Practical 5.1

(2 Hours)

## Patient Education:
## Use and Care of Contact Lenses

# Schedule of Practical Session

**Practical Session (1 hour)**

**Instructions:**

I. Students are to be divided into groups of four.

II. Each group is randomly assigned with the following tasks:

   A. Two students take the role of practitioner.

   B. Two students take the role of patient.

III. The practitioners are given a set of solution packages*.

IV. The practitioners are required to provide instructions to the patients on how to use and care for the contact lenses.

V. The patients are asked to record what instructions were given to them.

VI. Supervisors are to review the results and if the understanding of the instructions appears inadequate, request either the practitioner/patient group to demonstrate the procedures based on the written instructions.

* The package should include: cleaner, disinfecting solution, enzyme. Disinfection solution can be heat, peroxide or chemical.

**Discussion and Review (45 minutes)**

# Practical Session

## Practitioner Record Form

**Group:**_____ **Date:**_____

**Solution package assigned:** _____

**Instructions**: In the space below, write down the care and maintenance instructions you gave the patient.

**Care and maintenance instructions given to patient:**

# Practical Session

## Patient Record Form

**Group:**_____ **Date:**_____

**Solution package assigned:** _____

**Instructions**: Based on the instruction you received from your practitioner, please tick the appropriate box.

1. Which solutions were you given?

| | Yes | No |
|---|---|---|
| a) daily cleaner | ❑ | ❑ |
| b) disinfecting solution | ❑ | ❑ |
| c) rinsing solution | ❑ | ❑ |
| d) enzyme | ❑ | ❑ |
| e) in-eye drops | ❑ | ❑ |

2. Did the practitioner cover the following areas?

| | Yes | No |
|---|---|---|
| a) purpose of care and maintenance? | ❑ | ❑ |
| b) function of different solutions? | ❑ | ❑ |
| c) cleaning and disinfecting procedures? | ❑ | ❑ |
| d) lens storage? | ❑ | ❑ |
| e) care of lens cases? | ❑ | ❑ |
| f) how frequently the procedures should be performed? | ❑ | ❑ |
| g) consequences of not complying with the instructions? | ❑ | ❑ |
| h) demonstration of the procedures? | ❑ | ❑ |

3. How would you describe the instructions you received? (please tick)

- ❑ confusing
- ❑ inadequate
- ❑ adequate
- ❑ clear
- ❑ very easy to follow and understand

4. Do you think you could repeat the instructions given to you and demonstrate them to others?

❑ Yes ❑ No ❑ Maybe ❑ Not sure

# Tutorial 5.1

(1 Hour)

## Care and Maintenance Procedures

# Exercises

**Group No:_____** **Date:_____**

**Instructions:** Students will be assigned to groups to design a care regimen and maintenance procedure for each of the following conditions:

**Group 1**

The patient is a nurse working a night shift and studying a vocational course in the afternoons. High water content SCLs are prescribed. Lens BVP is -3.00 D sphere for both eyes. She has sensitivity to preservatives.

Which care regimen would you recommend for her?

What would be your instructions to her for care and maintenance procedures?

**Group 2**

The patient is a 50 year old male fitted with monovision SCL(s). He has just undergone treatment for epithelial erosion because he accidentally instilled the lens cleaner he thought was lens lubricant. His cornea has completely recovered and he can resume contact lens wear.

How would you counsel the patient? Explain your approach.

**Group 3**

The patient is a female RGP lens wearer who has a history of heavy protein deposition. She is a stage actress and wears heavy make-up. Her contact lens prescription is
-8.00 D sphere. She wears her lenses every day for extended periods.

Which care regimen would you recommend for her?

What would be your instructions to her for care and maintenance procedures?

**Group 4**

The patient is a 23 year old male wearing a cosmetic coloured soft contact lens which was prescribed to disguise a corneal scar. He wears his lens every day. The patient is not able to afford a spare lens.

Which care regimen would you recommend for him?

What would be your instructions to him for care and maintenance procedures?

## 🕮 References

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# Unit 5.2

(5 Hours)

**Lecture 5.2:** Contact Lens Care Products

**Practical 5.2:** Pre- and Post-Cleaning Appearance of Contact Lenses

**Tutorial 5.2:** Review of Contact Lens Care Products: General

# Course Overview

**Lecture 5.2: Contact Lens Care Products**

I. Components of Care Products
II. Formulation of Solutions (Cleaners, Disinfectants, etc.)
III. Antimicrobial Agents and Their Efficacy
IV. Solution and Case Contamination

**Practical 5.2: Pre- and Post-Cleaning Appearance of Contact Lenses**

- Instrumentation
- Procedures

**Tutorial 5.2: Review of Contact Lens Care Products: General**

# Lecture 5.2

(2 Hours)

# Contact Lens Care Products

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**II Care and Maintenance Components** ..... **50**
**III Solution Characteristics** ..... **61**
**IV Micro-Organisms** ..... **68**
**V Antimicrobial Agents** ..... **72**
**VI Antimicrobial Efficacy** ..... **86**
**VII Unpreserved Solutions** ..... **92**
**VIII Hypersensitivity** ..... **94**

## I Introduction

1

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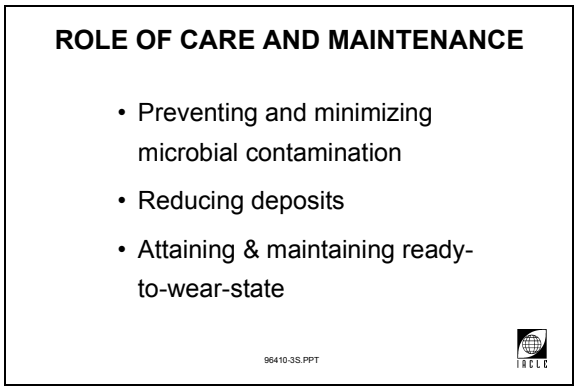
### Contact Lens Care Products

A knowledge of the chemistries and formulations of contact Lens Care Products (LCPs) provides an insight into their modes of action, likely performance characteristics, possible side-effects and potential interactions with other LCPs.

2

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### Role of Care and Maintenance

The overall aims of care and maintenance are summarized in the slide opposite.

The contribution made to the achievement of the these aims by the choice of lens care system and the products themselves, should not be underestimated.

## II Care and Maintenance Components

3

**CARE AND MAINTENANCE**
**FUNCTIONS**

- Cleaning
- Disinfection
- Protein removal
- Wetting
- Re-wetting

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4

**CONTACT LENS CLEANERS**
**MAIN FUNCTIONAL COMPONENTS**

- Surface-active agent(s)
- Non-ionic or ionic compound(s)
  - anionic
  - cationic
  - amphoteric
- Antimicrobial agent(s)

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5

**CONTACT LENS CLEANERS**
**ADDITIONAL COMPONENTS**

- Osmolality-adjusting agent(s)
- Buffer-system
- Chelating agent
- Viscosity-enhancing agent
- Other constituents

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### Contact Lens Cleaners

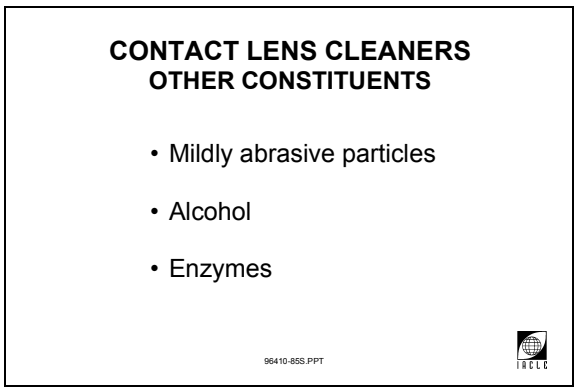
Contact lens cleaners usually contain the following functional components:

- Surface-active agent(s), also known as surfactant(s).
- Non-ionic or ionic chemical compound(s). Their role is to reduce the interaction between the solution and the lens. Amphoteric compounds, i.e. chemical entities which may act as either an acid or a base, can have either a positive (cationic) or a negative (anionic) net charge, depending on the pH of the surrounding medium.
- Antimicrobial agent(s). Antimicrobials are used primarily as preservatives to prevent contamination of the cleaning solution after it is opened.

Additional ingredients may include:

- Osmolality-adjusting agent(s). These agents control the osmolality of a solution. Solution osmolality may be influenced by the osmotic effects, if any, which other solution components have. An osmolality adjusting agent or agents may be required to raise the final solution tonicity to the level required.
  Solution tonicity can influence contact lens parameters (especially of soft lenses). An osmotic pressure gradient between a soft lens and its environment can drive water into, or out of, a hydrogel lens. The resulting

6

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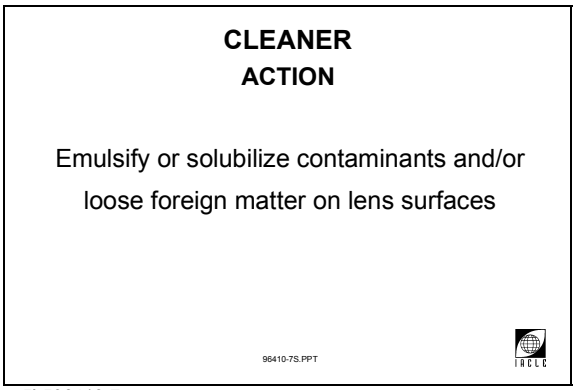
alteration in lens parameters may assist in the loosening , dislodgement and removal of surface deposits.

- A buffer system. A buffer system is often included to adjust and maintain the pH of the cleaner. pH, like tonicity, may influence the effects a cleaner has on lens parameters.
- A chelating agent. Chelating agents are compounds (usually organic) which have two or more sites within their structure to which metal atoms can be appended thereby forming a ring-type structure. They are used to assist in the removal of lens contaminants, especially calcium compounds. Some common chelating agents (e.g. EDTA) also enhance the antimicrobial activity of the preservatives contained in the solution.
- Viscosity-enhancing agent. The viscosity of a solution is often increased in the interests of solution lubricity, its 'stay time' (residence time) on the lens during cleaning and the solution delivery rate via the container nozzle. In some cases, the viscosity is enhanced purely for marketing reasons because market research has shown that users associate high viscosity with 'effectiveness'.

Other ingredients which may be included are:

- Mildly abrasive particles such as polymeric beads (e.g. poly(amide)) to enhance the physical aspects of cleaning.
- Alcohol (isopropyl alcohol or ethanol) to remove lipids, etc.
- Enzymes to digest tear proteins on a daily, rather than a periodic, basis.

7

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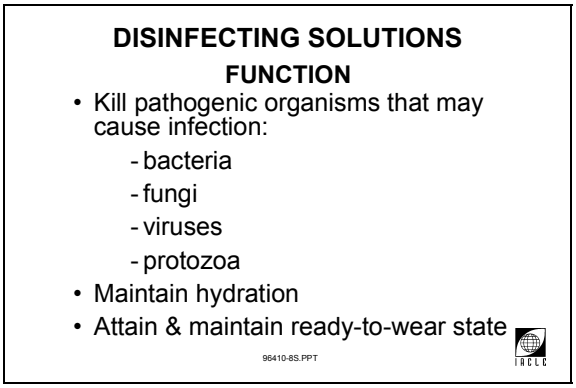
## Cleaner: Action

Used in conjunction with mechanical rubbing (using fingers and/or palm), the cleaner emulsifies and/or solubilizes finger and tear-borne contaminants and/or loose foreign matter on the lens surface.

The use of a cleaner should always be accompanied by mechanical cleaning.

It is important to impress on contact lens wearers that household cleaners or other cleaning products must never be substituted for the prescribed contact lens cleaner. They normally consist of anionic detergents and usually contain perfumes and solvents that can affect the contact lens and/or irritate the eyes.

8

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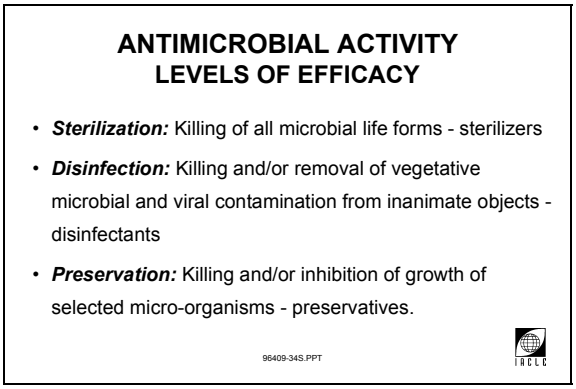
## Disinfecting Solutions: Functions:

- Kill ocular pathogenic organisms that may cause infection. Such organisms may include bacteria, fungi, viruses and protozoa. Disinfection should reduce the level of viable *ocular* pathogens to zero or almost zero and therefore minimize contact lens-related infections. Disinfection should also reduce the number of all types of micro-organisms and viruses to a safe level, although reduction to zero is obviously more desirable.
- Restore and maintain lens hydration. While obviously more important for soft lenses, the maintenance of low levels of hydration is also required for RGP lenses.
- Attain and maintain the lenses in a ready-to-wear state. This requires satisfactory performance of the first two functions. Contact lenses must be maintained in a pathogen-free state for the storage period, and their parameters must be as intended, in the interests of rapid settling and equilibration after insertion.

9

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10

**MODES OF DISINFECTION**

- Cell membrane disruption
- Enzyme inhibition
- Protein coagulation or complex formation
- A combination of one or more of the above

96410-9S.PPT

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11

**DISINFECTANTS**

**ADDITIONAL COMPONENTS**

- Sodium Chloride
- Buffering agents

Their purpose:

- To adjust osmolality & ph

96410-10S.PPT

5L296410-10

## Types of Disinfectants

Disinfectants are rapidly acting chemicals whereas preservatives are slower to achieve their goals of eliminating viable organisms from a solution and maintaining this state. There are three main modes of action exhibited by disinfectants:

- Cell membrane disruption.
  Surface-active agents such as benzalkonium chloride (BAK or BAC), a cationic surfactant, disrupt cell-membrane integrity resulting in a loss of cell contents and eventually, cell death.
- Enzyme inhibition.
  Compounds such as the mercurials react with specific chemical groups on enzymes and poison their normal activities. Once so inhibited, cell metabolism is adversely affected. Disinfectants using enzyme inhibition tend to be slower acting.
- Protein coagulation or complex formation.
  Chelating agents can form a complex with metal ions within cells or in cell walls, making the metal ion unavailable for use in cell metabolism. Further, in the case of cell wall complexing, the cell's structural integrity may also be disrupted thereby enhancing the efficacy of the disinfecting agent. This formation of complexes is also used to prevent and/or remove calcium deposits, e.g. EtheleneDiamine Tetraacetic Acid or EDTAcetate (both EDTA).

  Quaternary ammonium compounds, e.g. Alkyl Triethanol Ammonium Chloride (ATAC) can precipitate proteins thereby removing them from metabolic cycles and functions essential to cell viability.
- A combination of one or more of the above is also possible.

(After Anger and Curie, 1995.)

As well as the agents responsible for these modes of action, solutions may

contain:

- Sodium chloride (NaCl).
  - added in small amounts to alter the solution osmolality directly
  - used in much larger amounts to enhance antimicrobial action (by osmotic imbalance-induced dehydration?).
- Buffering agents, such as acetates, borates, bicarbonates, citrates or phosphates.
  Buffers stabilize and maintain solution pH under varying conditions. The stabilizing influence of buffers is limited but seldom exceeded in the normal contact lens context.

These components adjust the tonicity and pH of solutions that come in direct contact with the eyes, so that they are similar to those of tears. This prevents stinging or discomfort on lens insertion, and assists in the rapid settling of the lens on the eye.

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**DISINFECTING SOLUTION**
**CONCENTRATION OF PRESERVATIVES**
**Used alone or in combination**

| | |
|---|---|
| Benzalkonium Chloride | 0.002 - 0.01% |
| Chlorhexidine | 0.001 - 0.006% |
| Thimerosal | 0.001 - 0.004% |
| Dymed | 0.00005 - 0.0015% |
| Polyquad | 0.001 - 0.005% |

96410-70S.PPT

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**Disinfecting Solution: Disinfectants**

Some of the more common disinfectants and their range of concentrations are listed in the slide opposite.

It should be stressed to the patient that a sufficient disinfection period, at least complying with the manufacturer's instruction but preferably overnight, should be allowed. Fresh solution must be used every time a lens care procedure is performed.

Solutions should be replaced as soon as the 'discard-after' time expires. The date depends on a number of factors including the concentration of preservatives in the solution, the type of preservative, the container and its dispensing aperture, etc.

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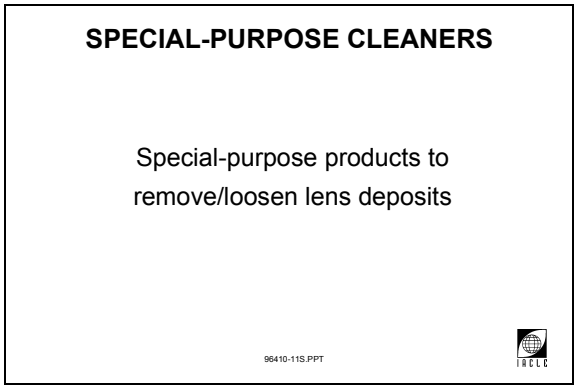


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## Special-Purpose Cleaners

Special purpose cleaners are usually single-function products intended to offer superior performance to more broadly aimed products. The most common category of special products is *protein removers,* although many products so described have wider applications.

The advent of disposable or frequently-replaced contact lenses has virtually eliminated the *intensive cleaners* category from the market-place. These were intended for either wearer or practitioner use. They were often two-part products and frequently shortened the life expectancy of the lenses, albeit with some immediate improvement in lens acceptability. Such products were supplied in liquid, powder or tablet form. Few are still available and they will not be discussed in this unit.

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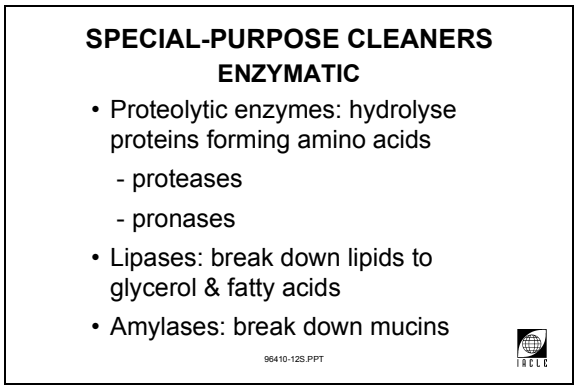


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## Special-Purpose Cleaners: Protein Removers, Enzymatic Cleaners

Protein removers especially if enzymatic, are special-purpose products formulated to 'digest' tear proteins bound to the surfaces of contact lenses. The main proteins they attack are lysozyme, the albumins and the immunoglobulins. Conventional enzymatic cleaners are intended for periodic rather than daily use. However, daily cleaners containing an enzyme and an enzymatic additive for daily cleaners have been recently released.

The frequency of use of these products is ultimately an issue for the prescribing practitioner. Most manufacturers suggest a weekly regimen. Frequency may depend on the life expectancy of the lens, the type of lens and the tear characteristics of the wearer.

These products may be used:

- As supplied (solution form).
- Dissolved in normal saline (tablet or powder form).
- In a lens care solution (tablet or

powder form).

- In hydrogen peroxide (tablet form formulated for use in most solutions or exclusively for use in peroxide).

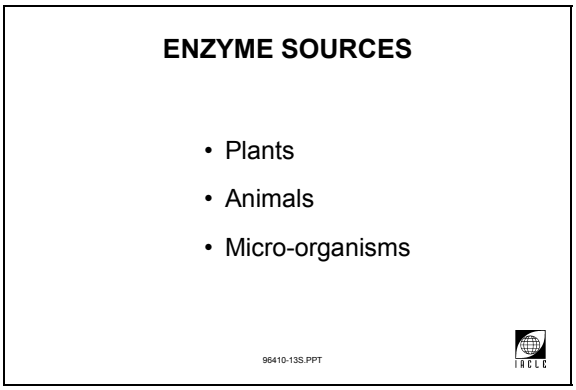
Protein removers may contain:

- A protease (a proteolytic enzyme).
- A combination of enzymes whose actions are specific to tear components, particularly the tear protein lysozyme.
- Inorganic chemicals or organic entities which are not enzymes

Other enzymes which may be included are:

- Lipases which are lipid-specific. Lipases break down triglycerides (fats and oils) to glycerol and fatty acids.
- Pronases which, while proteolytic, are aimed at mucin.
- Amylases which are polysaccharide-specific, and therefore also aimed at mucins.

15

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Some products contain several of these enzymes and have a broad purpose. The action of these enzymes is to break target proteins into smaller molecular units (by breaking proteins into their component amino acids, usually by hydrolysis of their peptide bonds). Once broken, the hydrolyzed amino acids are more easily removed physically or are more soluble.

Many such products also contain surfactants. If supplied in liquid form, they may also contain a preservative and possibly a chelating agent (e.g. EDTA which also acts as a preservative enhancer).

It is important for the practitioner to emphasize that lenses be thoroughly cleaned and rinsed *after* using enzymes because some are known to induce sensitization and/or irritation in susceptible users.

The sources of suitable enzymes are:

- Plant (e.g. papain, a protease).
- Animal (e.g. pancreatin, a complex of

proteases, amylases and lipases).

- Micro-organisms (e.g. the subtilisins, proteases).

16

**ENZYMATIC CLEANERS**

Formulated as a solid tablet and containing a small amount of enzyme

Other ingredients

- Bulking agent
- Effervescent system
- lubricant
- Liquid vehicle

96410-14S.PPT

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## Enzymatic Cleaners

Because the amount of active ingredient (enzyme(s)) required is relatively small, a 'delivery system' needs to be provided. Such a delivery system may be in the form of a liquid or tablet, the latter being much more common.

Apart from the enzyme(s), other ingredients in enzymatic protein removers may include:

- **Bulking agent:** Used to form a conveniently sized tablet. This agent does not affect the cleaning efficacy and is inert.

17

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- **Effervescent system**: Vigorous effervescence is frequently used to assist the dissolution of the tablet and the dispersal of the active ingredients. Commonly, this system is a combination of the anhydrous forms of sodium bicarbonate and citric acid. When exposed to water these ingredients react, liberating carbon dioxide vigorously. This results in the disintegration of the tablet and helps the active ingredients to dissolve and/or disperse.

  For obvious reasons, the tablet must be protected from atmospheric moisture until it is required. Commonly the tablets are packaged in sealed foil 'blister packs'.

- **Buffer system:** This ensures the pH is in the range within which the enzyme is optimally active.

- **Lubricant or mold-releasing agent:** A coating is usually applied to the tablet during the manufacturing process. This is done so that the tablets do not stick to the molds when separation of product and mold is attempted.

- **Liquid vehicle:** If the protein remover is to be supplied in liquid form, some vehicle or liquid medium is required to 'carry' the enzymes or active

ingredients and other product components to the lenses. As with bulking agents, the vehicle must be inert and not impede the cleaning efficacy.

18

**WETTING SOLUTION**

- Mainly for RGP lenses
- Makes lens wettable
- Increases initial comfort
- Provides initial cushion between lens and corneal surface

96410-15S.PPT

5L296410-15

19

**WETTING SOLUTIONS**
**CONTENTS**

- Poly(vinyl alcohol)
  - wetting agent
- Methylcellulose (and its derivatives)
  - to increase viscosity

96410-16S.PPT

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### Wetting Solution: Contents

Wetting solutions often use poly(vinyl alcohol) (PVA) as a wetting agent. Surface solute molecules orient their hydrophobic tails towards the lens and their hydrophilic tails towards the surrounding environment. In this way, a hydrophilic surface is presented to the eye and tears.

PVA is a synthetic, long-chain polymer of low viscosity. It requires an acidic pH (approximately pH 5-6) and is compatible with most preservatives. PVA is also a good viscosity-enhancer.

Viscosity-increasing compounds, such as methylcellulose and its derivatives (hydroxyethyl cellulose and hydroxypropyl methylcellulose (or hypromellose)) make solutions more viscous. This enhances their adherence to lens surfaces.

Other ingredients such as tonicity-adjusting agents, a buffer system, and preservatives are added. The preservative's main role is to inhibit microbial growth in the solution once the container is opened.

Unpreserved solutions are normally supplied in unit dose containers.

20

**WETTING SOLUTION**
**OTHER CHARACTERISTICS**

- Saline is usually the major component
- Sterile
- Preserved

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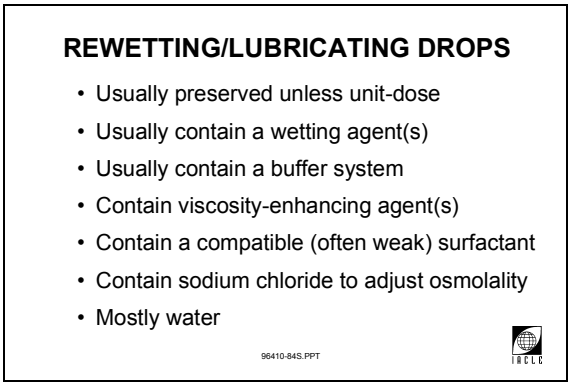


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## Rewetting/Lubricating/Rehydrating Drops

The solution characteristics of these drops appear opposite.

22

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## Stability of Solutions After Opening

Once opened, do solutions change their properties over time?

Generally, within the normal time of use (and certainly within their discard-after period) solutions remain stable. For example, Harris *et al., 1990* found that hydrogen peroxide changes its pH and concentration little over its six month life (after opening). This is due largely to stabilizers included specifically to reduce the natural tendency of hydrogen peroxide to decompose into oxygen and water.

Therefore, discomfort experienced by users on lens insertion where their solutions have been opened for some time is more likely to be due to other factors such as incomplete neutralization leaving residual peroxide. If discomfort is experienced from the outset, the solution pH should be suspected as a likely cause and a rinse with sterile buffered saline may be required.

Other ingredients used in LCPs are chosen for their specific task(s) only after due consideration is given to their stability under normal circumstances.

The recommendation for the 'discard-after' time period is based on real time and accelerated aging tests of both the ingredients and the complete product. Separate and combined testing is required as interactions may accelerate or slow decomposition of individual components.

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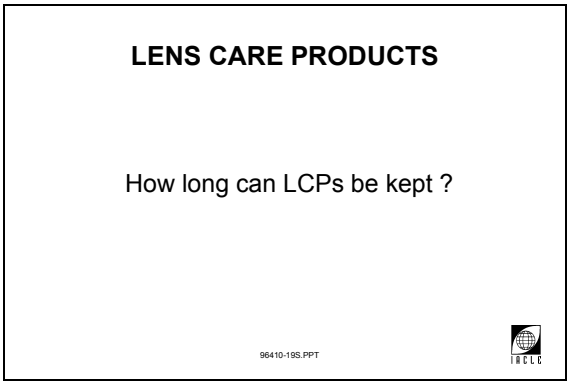


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## How Long Can Solutions Be Kept?

To use or sell solutions after their expiry date is imprudent legally and potentially unsafe. It is probable that unopened solutions are still safe (i.e. not harmful). However, their efficacy can no longer be assumed as decomposition of the active ingredients may have reduced or even eliminated their effectiveness.

Generally, solutions can be kept or used for as long as:

- The solution remains within the expiry date/use-by-date (unopened and opened).
- The discard-after time has not expired (after initial opening).

Patients must discard expired lens care products.

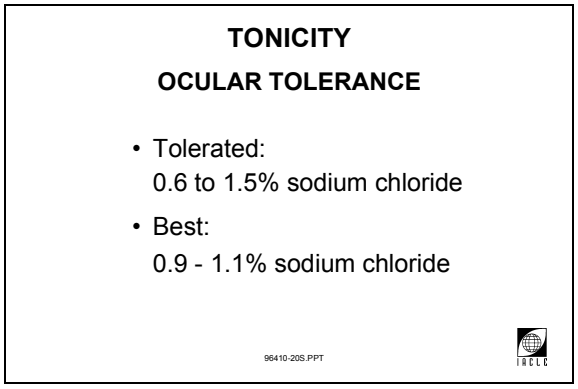
For expiring stock, practitioners should ensure it is not exposed to sun or elevated temperatures and that it remains within the storage temperature range advised by the manufacturer. If some products are kept at too low a temperature, the active ingredients come out of solution, rendering the product ineffective or even useless.

As a general rule-of-thumb, for every 10° C increase in temperature, chemical reactions double their rate. As a consequence, if a solution is stored 10° C above recommended temperature, the expiry date should be brought forward by at least the time of such exposure (measured in days or parts thereof).

Because of the difficulty of calculating alternative expiry dates and the untested legality of storage at incorrect temperatures, it should be avoided at all costs.

## III Solution Characteristics

24

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### Tonicity

Tonicity is important when a solution comes in direct contact with the eye. To avoid discomfort due to osmotic gradient-driven fluid movements into/out of the cornea, a solution must be adjusted to be *isotonic.*

For the human cornea:

- 0.6 to 1.5% sodium chloride can be tolerated.
- 0.9 to 1.1% sodium chloride is best.

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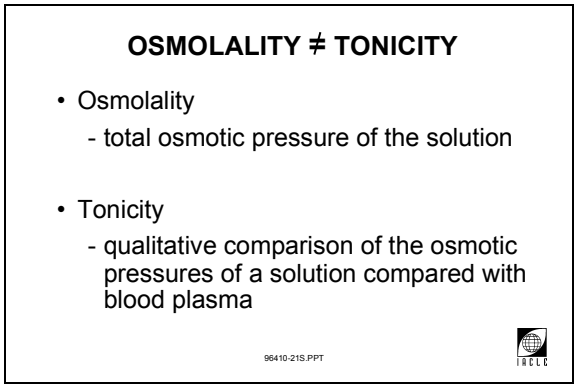


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### Osmolality or Tonicity?

- Osmolality is a physico-chemical parameter of a solution. It is the total osmotic pressure of the solution, expressed in mOsm/kg. This figure may be the result of sodium chloride only, or may be the sum of the osmotic equivalence of all solution components, only one of which may be sodium chloride.
  Each component has a characteristic osmotic effect when in solution. Few demonstrate ideal behaviour in such circumstances.
  When formulating a lens care product (or ocular pharmaceutical), the osmotic pressure contributions of all the ingredients must be taken into account before the solution can be adjusted to isotonicity.
- Tonicity is a qualitative description of the osmotic pressure of a solution compared with the tonicity of blood plasma (equivalent to 0.9% NaCl). A solution is said to be isotonic when the osmotic pressures of solution and blood plasma are equal. Similarly, a solution is said to be hypertonic or hypotonic when its osmotic pressure is greater or less than that of blood plasma respectively. Unfortunately, the figure can be misleading, since normal tear tonicity is not the same as that of blood plasma (i.e. strictly, therefore the tears are not isotonic).

Most ophthalmic solutions need to have the same tonicity as tears, *not* blood plasma. Normal tear tonicity has been described as being between 0.89% (prolonged closed eye, Terry and Hill, 1978) and 0.99% (waking hours, Benjamin and Hill, 1983). Most figures in the literature on open eye are in the narrow range 0.94 -0.97%, i.e. tears are normally hypertonic relative to blood plasma.

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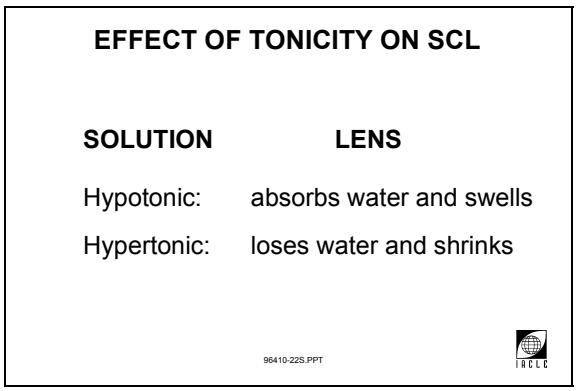


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## The Effect of Tonicity on SCL

Solution tonicity can have a significant effect on soft contact lens parameters. The degree of lens shrinkage or swelling resulting from contact with solutions is greatest for high water content SCL materials.

In general, most changes are temporary and reversible.

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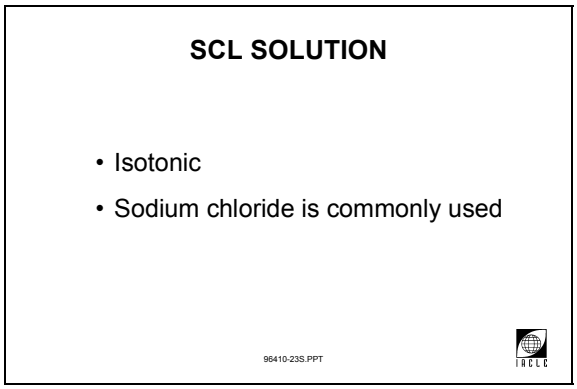


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## Soft Contact Lens Solution

Many SCL solutions are isotonic, at about 0.9% sodium chloride equivalence. However, not all isotonic solutions actually contain 0.9% sodium chloride. Most of the solutions which do contain 0.9% NaCl (as opposed to having an osmotic pressure equivalent to 0.9% NaCl) are simple unpreserved normal salines.

Other common salts used in solutions include: phosphates, borate, chlorides and sometimes citrates (although citrates are less suitable for products that come in contact with the eye).

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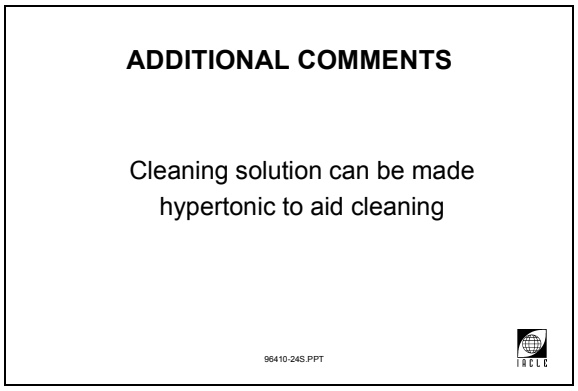


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## Hypertonic Solutions

Hypertonic solutions draw water *out* of the lens. This may assist in the removal of absorbed chemical entities. Greater water movements can be achieved by exposing the lens to a hypotonic solution initially (driving water into the lens) and then replacing it with a hypertonic solution.

Some intensive cleaners have used tonicity or widely disparate solution pHs to move water in and out of a lens and to alter its parameters by modulating its water content.

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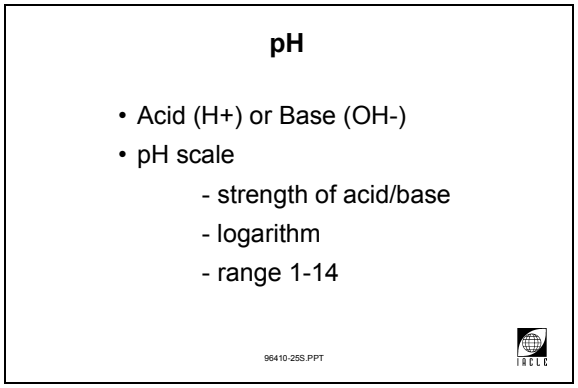


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## pH

Solution pH is the negative log (base 10) of its hydrogen ion concentration, i.e. pH = –log $[H^+]$.

(In reality the situation is more complex and the $H^+$ ion *per se,* does not exist. Rather, it exists as the hydrated hydronium ion (or hydroxonium ion), $H_3O^+$ which is sometimes written as $H_3O^+(aq)$, or even $H_9O_4^+$ because it surrounds itself with, and tightly binds, three water molecules).

When pH is measured with a pH meter it is actually the negative log of the hydrogen ion *activity* which is being measured, *not* the negative log of the hydrogen ion concentration.

Most pHs fall into the range 1 – 14. However values outside this range are often realized. A low pH represents an acidic solution while high numbers represent a basic solution. pH = 7 is defined as neutral. Pure water at 25°C has a pH of 7.00.

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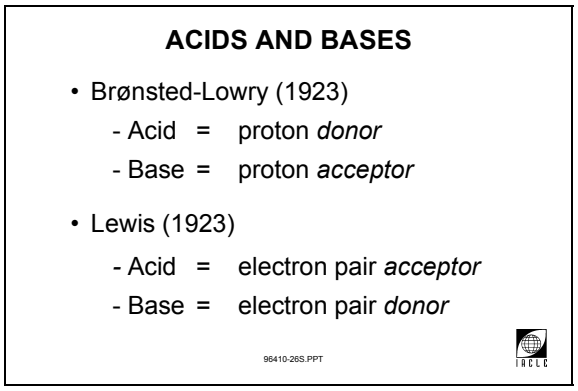


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## Acids and Bases

There are several accepted concepts of what defines an acid or a base. The two most common are:

- Brønsted-Lowry definition (1923):
  - An acid is a proton donor.
  - A base is a proton acceptor.
- Lewis definition (1923):
  - An acid is an electron pair acceptor.
  - A base is an electron pair donor.

The Lewis definition is more generally applicable.

- For aqueous chemistry, it is useful to define an acid as a substance which increases the concentration of $H_3O^+$(aq) when added to water.
- Similarly, a base is a substance which decreases the concentration of $H_3O^+$(aq) when added to water. Alternatively, a base is a substance which increases the concentration of $OH^-$ (aq) (the hydroxyl ion) in aqueous solution.

  The two concentrations are inter-related, i.e. as the concentration of $H_3O^+$ increases, the concentration of $OH^-$ decreases. This is because they are both derived from the same pool of water molecules.
- A solution is acidic or basic depending on which ions ($H_3O^+$ or $OH^-$) are in the higher concentration, i.e. in which direction the equilibrium between 'acid' and 'base', has shifted.

*For a more detailed treatment of pH, acids and bases see Harris, 1987 and Mahan, 1975.*

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**pH**
**EFFECT ON CONTACT LENS**

If lens is stored in solution outside normal pH range, reversible changes will occur in lens parameters and water content

96410-27S.PPT

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## pH Effect on Contact Lenses

If a lens is stored in a solution outside the normal pH range, changes in water content, and therefore lens parameters, may result. More significant changes occur with ionic materials, especially high water, ionic materials.

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**pH**
**EFFECT ON CONTACT LENS**

Clinical significance of the lens changes include:

- As pH decreases → $H_2O$ content decreases and lens fit tightens
- Reduced comfort and visual acuity until tear film adjusts to normal pH and lens returns to original shape

96410-28S.PPT

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The clinical significance of the lens changes include:

- Altered lens fit due to parameter changes.
- Reduced comfort and visual acuity until the lens and the external eye environment reach an equilibrium and the lens returns to the shape and fitting originally intended.

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**pH**
**EFFECT ON CONTACT LENS**

Extremely acid/basic solutions:

- Brittleness
- Discolouration
- Loss of physical properties
- Permanent breakdown of material polymer

96410-29S.PPT

5L296410-29

## pH: Effects

Lens care solutions whose pHs are extreme can have adverse effects on contact lens materials. Some effects are presented in the slide opposite.

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**DISINFECTING SOLUTION**
**pH**

Important for:

- Cleaning agents to ensure their efficiacy
- Stability of the preservatives
- Ocular comfort

96410-30S.PPT

5L296410-30

## pH of Disinfecting Solution

- Cleaning agents are normally most effective when their pH is about 7.4. Alkaline pHs tends to aid the removal of protein. Acidic pHs can be used to induce stresses at the lens surface which aid the removal of surface deposits.
- The performance of preservatives is normally pH dependent, i.e. chlorhexidine and thimerosal are stable at neutral pHs, while

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**BUFFERS**

- Maintain solution at preferred pH
- Generally, a combination of weak acids or bases and their salts
- Preservative type will determine buffer(s) used

96410-31S.PPT

5L296410-31

chlorobutanol is more effective and stable in acidic conditions (low pHs).

- The use of pH values similar to, or within the tolerance range of tears will usually prevent any initial discomfort on lens insertion. pH values outside this range may lead to burning, tearing and conjuctival hyperaemia.

To maintain the desired pH of a solution, buffers are normally included in the formulation. Examples of buffers are: acetates, borates, bicarbonates, citrates and phosphates. Buffers themselves are normally a combination of weak acids or bases *and* their salts.

If a One-Bottle System (OBS) is used, one of its roles is disinfection. The OBS solution will be carried to the eye on the lens and compatibility with the eye is therefore an issue. Ocular comfort requires a pH within the range 6.6 to 7.8. While pH tolerance is subject to some individual variation, a pH outside this general range can be expected to cause some discomfort.

Generally the type of preservative will determine which buffers should be used because incompatibility between buffers and preservatives can lead to the formation of precipitates. For example: borates are incompatible with benzalkonium chloride, and borates mixed with poly(vinyl alcohol) can form a gel-like deposit.

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**VISCOSITY**

- 'Thickness' of solution
- Viscosity-enhancing agents are used in daily cleaners, lubricating drops and RGP wetting solutions
- Units - Pascal seconds (Pas)

96410-32S.PPT

5L296410-32

**Viscosity**

In general, viscosity-enhancing agents increase the time a solution remains in contact with the lens during use. More viscous ('thicker') solutions resist the eye's flushing action, thereby slowing the drainage of the solution from the eye. Generally, more viscous solutions are also easier to dispense and use.

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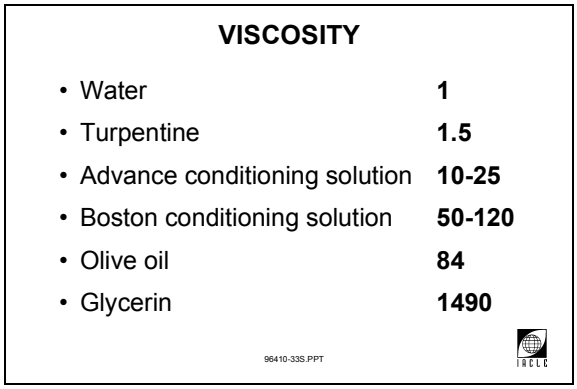


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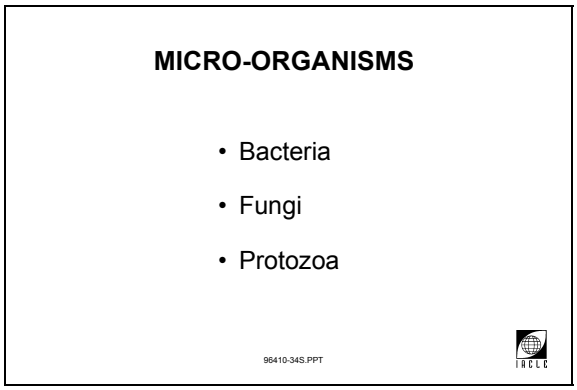
## Viscosity: Units of Measure

Viscosity (dynamic viscosity) is measured in either centipoise (cps) (an older cgm unit) or Pascal second (Pas) (current SI unit) (1 cps = 1 mPas). Sometimes the milliPascal second (mPas) is used for biological and ophthalmic solutions because of their generally low viscosity.

A solution's viscosity is increased by the inclusion of viscosity-enhancing agents such as carboxymethyl cellulose, hydroxypropyl methyl cellulose and hydroxyethyl cellulose.

## IV Micro-Organisms

38

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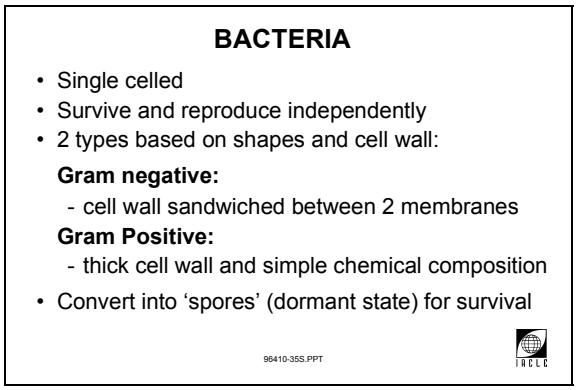
### General Microbiology

Micro-organisms can be simply defined as 'microscopically small, individual, autonomous forms of life'. This definition covers bacteria, fungi and protozoa.

A virus, unlike micro-organisms, needs a host to survive and cannot therefore be considered autonomous and categorized as a micro-organism. Micro-organisms and viruses are all potentially serious ocular pathogens.

39

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### Bacteria

Bacteria are single-celled micro-organisms which can survive and reproduce independently.

There are two main types of bacteria, categorized on the basis of their cell wall structure:

- Gram negative

  The cell wall proper is sandwiched between two membranes.

- Gram positive

  The cell wall is thick and of simple chemical composition.

- Examples:

  gram + *Staphylococcus sp., Bacillus sp.*

  gram – *Pseudomonas sp., Serratia sp.*

  Gram negative bacteria are more resistant to anti-microbial agents because their outer membrane lipid layer provides an extra level of protection.

  Bacteria can revert to a 'spore' form (dormant state) as a survival strategy.

40

**BACTERIAL CELL COMPONENTS**

- Cell wall
- Cytoplasm
- DNA
- Plasma membrane

96410-36S.PPT

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41

**MOST COMMON BACTERIA**
**NORMAL EYES**

| | |
|---|---|
| • *Staphylococcus* | |
| - *epidermidis* | ***76%*** |
| - *aureus* | ***25%*** |
| • *Diptheroids* | |
| - *corynebacterium* | ***35%*** |
| • *Streptococcus sp.* | ***4%*** |
| • *Miscellaneous* | ***<21%*** |
| • *Pseudomonas* | ***<1%*** |

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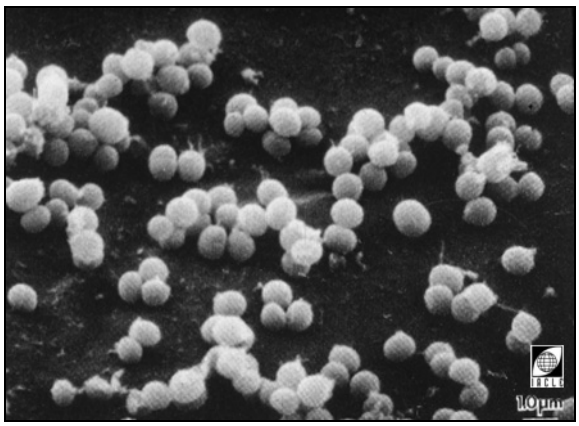
42



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## Bacterial Cell Components

- Cell wall.
- Cytoplasm forms the bulk of the cell contents.
- DNA which holds genetic information to be passed on at reproduction.
- Plasma membrane. A semi-permeable membrane just inside the cell wall which regulates the passage (in and out) of substances such as water, nutrients and waste products. It is important to cell survival.
- The external eye is not usually 'sterile' and has a population of micro-organisms resident on its surfaces.

In normal eyes, the most common bacteria found are *Staphylococcus epidermis* and *Corynebacterium diphtheriae.*

The incidence of various bacteria in normal eyes is presented in the slide opposite. More than one type is usually present. While some bacteria are poorly represented, their potential for serious adverse effects increases their significance beyond what their low incidence would suggest, e.g. *Pseudomonas sp.*

Slide 42 shows *Staphylococcus aureus* (golden staph) on a lens surface.

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**FUNGI**

- Many types (>100,000)
- 2 forms: yeasts (single-celled) or moulds (multi-celled)
- Slower rates of reproduction compared to bacteria
- Reproduction via budding or spores
- Grow best in warm, moist conditions

96410-38S.PPT

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## Fungi

There are many types (>100,000) of fungi, occurring in two forms - yeasts or moulds.

- Yeasts are rounded and single celled while moulds are multi-celled.
- Yeasts reproduce by budding while moulds form spores.

  Fungi have a slower reproduction rate than bacteria. Fungal spores are different from bacterial spores. Fungi produce spores to reproduce whereas

bacteria produce spores to survive in adverse circumstances.

Generally, fungi are more difficult to kill than bacteria.

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**FUNGI CELL STRUCTURE**

Similar to a plant cell consisting of:

- Cell wall
- Plasma membrane
- Nucleus containing DNA
- Organelles

96410-39S.PPT

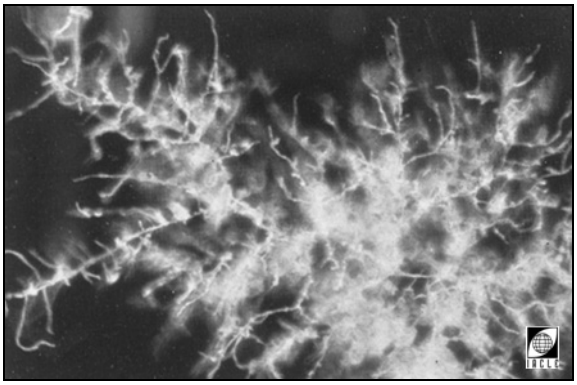
5L296410-39

## Fungi Cell Structure

Fungal cells are similar to plant cells and consist of:

- Cell wall: some are thicker and tougher than bacterium cell walls.
- Plasma membrane: of a different composition to a bacterium.
- Nucleus: contains DNA.
- Organelles: small specialized organs for respiration, energy production and nutrient storage.

45



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Slide 45 shows a fungus-contaminated soft contact lens. The hyphae (filamentous branches) are clearly visible.

46

**PROTOZOA**

- Microscopic, single-celled animals
- Mobile forms
- Found in fresh and salt water
- Form 'cysts' for survival
- Grow best in warm, moist conditions (hot tubs, ponds)

96410-40S.PPT

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## Protozoa

- Microscopic, single-celled animals of Phylum: Protozoa.
- Many are mobile.
- Found in fresh and salt water.
- Form 'cysts' as a survival strategy. The encysted form can revert to the active form, referred to as a 'trophozoite', when conditions become more favourable.
- Grow best in warm, moist conditions (hot tubs, ponds).

An example of a protozoan is *Acanthamoeba sp*. Some protozoa can also exist as parasites.

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**PROTOZOAN STRUCTURE**

- No cell wall
- Plasma membrane acts as outer boundary, stronger compared to bacteria/fungi
- Organelles
- True nucleus
- Most have locomotory feature, e.g. pseudopodia, flagella, cillia

96410-41S.PPT

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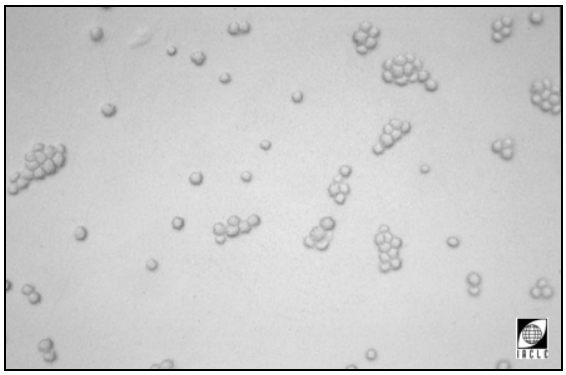
## Protozoan Structure

- No cell wall.
- Plasma membrane acts as an outer barrier and is stronger than the membranes of either bacteria or fungi.
- Organelles.
- True nucleus.
- Locomotory feature (most protozoa are mobile) e.g. pseudopodia (literally 'false foot'), whip-like flagella or hair-like cilia.

48



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Slide 48 shows *Acanthamoeba sp.* on a contact lens.

49

**VIRUSES**

- Not free-living
- Requires a living host cell
- Rapid reproduction in host cell
- Generally destroys the host cell or is released once host cell resources are depleted

96410-42S.PPT

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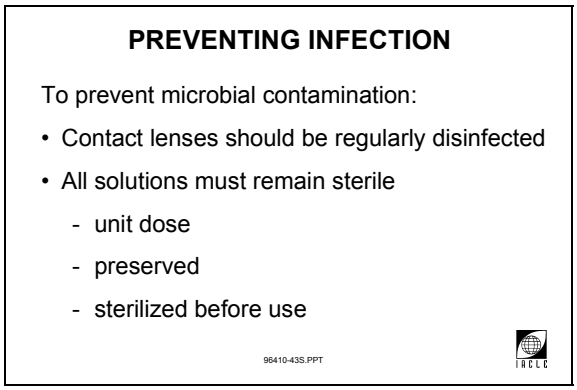
## Viruses

Viruses are sub-microscopic and can only be observed with a superior scanning electron microscope or a transmission electron microscope. While virus colonization of a contact lens *per se* is not visible, the virus' hosts may be.

## V Antimicrobial Agents

50

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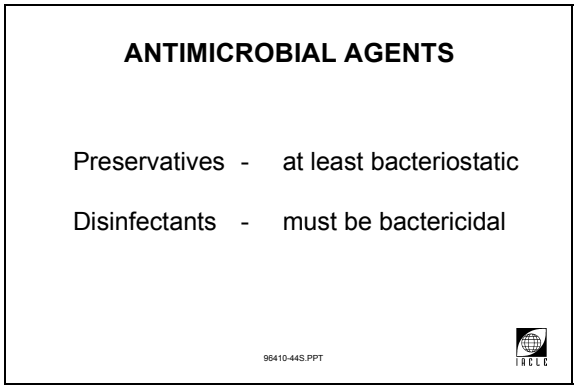
### Preventing Infection

To prevent microbial contamination of contact lenses and the possibility of ocular infection, contact lenses must be regularly disinfected.
Further, lens care products must be sterile when used. This usually means they must either be:

- Preserved. To remain sterile after initial opening, an agent is required to kill any micro-organisms that find their way into the product. Some solutions do not require the addition of a preservative because the action of one or more of the active ingredients preserves the solution effectively (e.g. 3% hydrogen peroxide solutions).
- Unit-dose (single-dose). Single-use products are delivered sterile in a sealed sachet, blister pack, glass or plastic vial. Any remaining product must be discarded after initial use because the product is not usually protected in any way from subsequent microbial contamination.
- Sterilized immediately before use. While uncommon, it is possible to sterilize, especially thermally, many LCPs immediately prior to use. The inconvenience of such an approach has the potential to encourage non-compliance and it is therefore not widely used.

51

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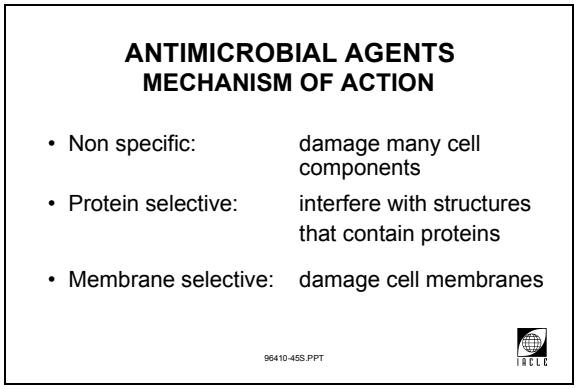
### Antimicrobial Agents

- Preservatives - bacteriostatic.
  Some preservatives only inhibit microbial growth but do not necessarily reduce the number of micro-organisms present in a solution.
- Disinfectants – bactericidal, viricidal, fungicidal.
  Disinfectants actually reduce the number of micro-organisms present in a solution. This is different from sterilization which is a process that destroys or eliminates *all forms* of

viable micro-organisms, including the spore and cyst forms. It is noteworthy that even if all forms of 'life' are destroyed, some micro-organisms produce exotoxins which are heat stable and/or chemical/radiation-resistant. These exotoxins remain capable of having potentially deleterious effects after sterilization.

52

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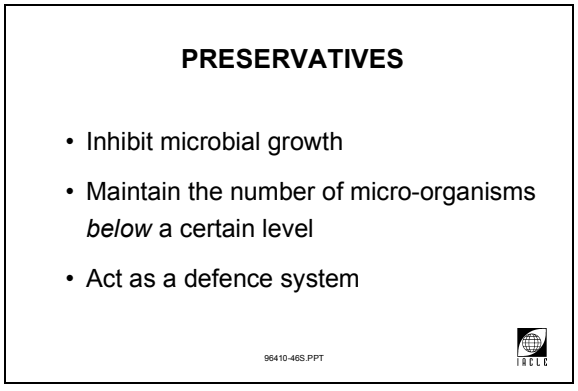
**Antimicrobial Agents: Modes of Action**

Antimicrobial agents can work in one of three ways or by a combination of these ways:

- Non-specific: Non-specific antimicrobial agents damage many cell components, e.g. hydrogen peroxide and active chlorine.
- Protein-selective: These agents interfere with structures that contain protein(s), in some cases by protein coagulation. Alternatively they may inhibit enzymes (which are proteins). Examples of such agents include the mercurials thimerosal and phenylmercuric nitrate. Some quaternary ammonium compounds can precipitate proteins (Anger and Curie, 1995).
- Membrane-selective: Agents which damage (dissolve, disrupt or alter) cell membranes include: BAK, chlorhexidine, poly(aminopropyl biguanide) and poly(quaternium-1).

53

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**Preservatives**

Normally, unopened bottles of solution are in a sterile state. Once opened, micro-organisms from the air can contaminate the solution. It is important to realize that temperature variations of the air inside a container tend to expand or contract the volume of air contained. Contraction of the air space can result in the 'ingestion' of contaminants with the air 'inhaled' when the lid is loosened. Grasping a flexible container may squeeze it as well as warm it.

Preservatives prevent micro-organisms from multiplying to unsafe levels in

solutions.

The roles of preservatives in solutions are to:

- Inhibit microbial growth.
- Maintain the number of micro-organisms below a certain level (i.e. one considered safe according to current knowledge).
- Act as a solution defence system.

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**CHARACTERISTICS OF PRESERVATIVES**

- Compatible with other ingredients
- Non-toxic and non-irritating
- Stable over time
- Effective against a wide range of organisms

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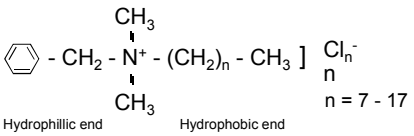
54

**BENZALKONIUM CHLORIDE - BAK**

- Quaternary ammonium compound
- 

- Cationic

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**Benzalkonium Chloride, Alkylbenzyldimethyl Ammonium Chloride, BAK, BAC**

BAK (molecular weight, 350 (Morgan, 1987), range, 283.89 to 424.16, mean approximately 354) is used mainly for hard contact lenses (i.e. PMMA). BAK is a mixture of alkylbenzyldimethylammonium chlorides where the number of alkyl groups (see slide opposite) ranges from 7 to 17.

Long-term use of this preservative may cause the lens surface to become hydrophobic. This is because the cationic (positively charged) hydrophilic group (the benzene ring end of the molecule) binds with the lens material thereby presenting its hydrophobic group (the hydrocarbon end of the molecule) to the outside world.

BAK is normally used in conjunction with a good wetting agent and a chelating agent (EDTA) to increase its effectiveness. It is not used in soaking solutions for obvious reasons.

55

**BENZALKONIUM CHLORIDE - BAK**

Action: absorb onto cell membrane, increases its permeability → cell rupture

Concentration: 0.001 - 0.01%

Effective at alkaline pH 8

96410-49S.PPT

5L296410-49

## Benzalkonium Chloride: Mode of Action

BAK, a cationic (positive charge) quaternary ammonium compound, works by adsorbing to a cell's membrane, thereby increasing its permeability. This ultimately leads to rupture of the affected cell.

Normally, the BAK concentration of solutions is 0.001-0.01%. Corneal damage occurs when a concentration of 0.005% is used and major corneal epithelial damage occurs when the concentration is 0.0075-0.01%. It is obvious therefore that corneal exposure should be avoided if possible or at least minimized.

BAK is most effective in an alkaline environment and optimally effective at pH 8. BAK decomposes in light.

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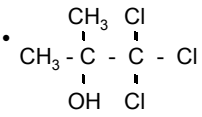
**CHLOROBUTANOL**

- Alcohol preservative
- 
- Unstable and poor bacteriostat
- Effective at acidic pH
- Used with other preservatives e.g BAK

96410-50S.PPT

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## Chlorbutanol, Chlorbutol (trichloroisobutyl alcohol)

Chlorbutanol (molecular weight, 177.46) is a chlorinated alcohol preservative with a broad spectrum of action. It is, however, slow acting against fungi and bacteria. It is relatively unstable, volatile, relatively poor bacteriostatically, with a distinctive odor.

Originally used on PMMA lenses, it is now not a common LCP ingredient. It is more effective in an acidic (low pH) environment and is normally used in conjunction with other preservatives, i.e. BAK.

It is normally used at a concentration of around 0.5% which is close to the limits of its solubility in water and makes its manufacture difficult.

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**BENZYL ALCOHOL**

- - $CH_2$ - OH
- Bactericide and Viricide
  - ineffective against *P. aeruginosa* in low concentrations
- Low ionicity, low affinity for RGP materials
- Unsuitable for use with SCLs

96410-51S.PPT

5L296410-51

## Benzyl Alcohol

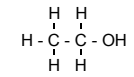
Benzyl alcohol (molecular weight 108.1) is a disinfectant and preservative of LCPs for RGP and PMMA contact lenses. It is unsuitable for use with soft contact lenses. It is claimed to be non-cytogenic and relatively non-sensitizing (especially relative to BAK, CHX and THI).

While it is bactericidal and viricidal it is known to be ineffective against *Pseudomonas aeruginosa* in low concentrations.

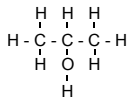
The molecule is bipolar and of relatively low ionicity. It therefore has little affinity for RGP lens materials. Like other alcohols, it behaves as a lipid solvent.

58

**OTHER ALCOHOLS**



**Ethanol**



**Isopropyl alcohol**

- Used at 1 - 20% concentration
- Isopropyl alchol more effective

96410-52S.PPT

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## Isopropyl Alcohol, Isopropanol, propan-2-ol, Ethanol

Another family of ingredients used in various roles in CL solutions are the alcohols (chlorbutanol, while an alcohol, is treated separately under its own name in this series).

The two most common are ethanol and isopropyl alcohol. Until recently both have only been used in contact lens cleaners in which their main role is that of lipid solvent. One, Miraflow™, contains 20% isopropyl alcohol (molecular weight, 60.1) and is marketed for use with hard, rigid and soft lenses. Ethanol (molecular weight, 46.07) is used in some cleaners usually in concentrations below 5% (e.g. Barnes Hind Cleaner No 4).

Alcohols, especially at high concentrations, are very effective antimicrobial agents (isopropyl alcohol is the more effective). However alcohols generally are ineffective against bacterial spores.

Spore-forming bacteria include *Clostridium botulinum and tetani, Bacillus subtilis* most of which are also very heat resistant (requiring moist heat >100° C for long periods, up to several hours, Borick, 1973).

Recently, a disinfecting system

(InstaCare™ or Quick Care™ in some markets) based on a very hypertonic (13% NaCl) isopropyl alcohol-containing (16%) solution has been released. The combination of alcohol and salt makes a very effective and rapid disinfectant arguably only second to heat in killing power.

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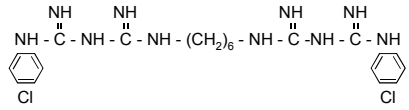
**CHLORHEXIDINE**




- Action: interferes with cell membrane functions
- Not effective against certain bacteria and fungi

96410-53S.PPT

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60

**CHLORHEXIDINE**

- Binds to protein deposits
- Stable at neutral or slightly acidic pH
- Used with other preservatives

96410-54S.PPT

5L296410-54

**Chlorhexidine, CHX (a biguanide)**

Chlorhexidine (molecular weight of root molecule, 505.46) is a weakly cationic (+ve) preservative which has been used in both hard and soft contact lens solutions (concentrations from 0.0025 to 0.006%). It may be present in the gluconate (molecular weight, 897.77), hydrochloride (MW, 578.38) or acetate (MW, 625.56) form. Clinically, there are few differences between these forms.

Chlorhexidine inhibits cation (+ve) transport and membrane-bound ATP in cell membranes.

While not absorbed by lens materials, it does bind to protein deposits on lenses. Once bound it can irritate the eyes, although not as severely as BAK. It is less stable at alkaline pHs and has been used in combination with thimerosal.

Its use in early LCPs was associated with a significant adverse response rate. However, subsequent understanding strongly suggests that the problems lay in its use combined in combination with thimerosal. The resulting reactions were of a toxic rather than a hypersensitivity nature (Garwood, 1994).

Studies have shown that some bacteria such as certain strains of *Serratia marsecens* develop resistance to this type of preservative. However, chlorhexidine has been found to be effective against both the trophozoite and cyst forms of *Acanthamoeba sp.* (Seal *et al.*, 1993).

A tablet form of chlorhexidine (0.004%) is marketed under the name OptimEyes™ in several areas of the world. It retains most of the properties of chlorhexidine and shares its potential side-effects.

The product contains water treatment

agents and is intended for dissolution in water of drinkable quality (potable). Tap water treatment includes chlorine removal, a 'de-ionizer' to remove metallic ions, a tonicity-adjusting agent which is also claimed to reduce chlorhexidine-lens material interaction and a buffer system.

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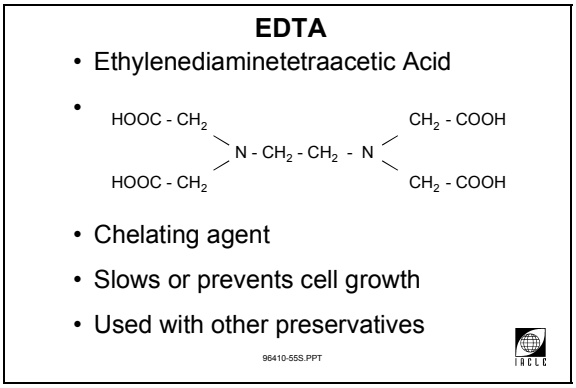


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**EDTA, Edetate, Disodium Edetate, Edetic Acid**

EthyleneDiamineTetracetic Acid (molecular weight, 292.25) or EthyleneDiamineTetraAcetate (both abbreviated to EDTA) are not strictly preservatives. They are variously described as preservative enhancers, preservative potentiators and chelating agents. EDTA is contained in most CL solutions.

EDTA potentiates the action of quaternary ammonium compounds against gram-negative organisms but not gram-positive ones. EDTA's action removes, by chelation, divalent cations such as calcium and magnesium ions from solutions and/or cell walls of gram-negative organisms.

Such cell wall disruptions slow or prevent cell growth. Cell death due to the action of EDTA alone is unlikely.

EDTA does not appear to bind to lens materials significantly.

The related form disodium edetate is also very common in LCPs. Both forms are also used in ocular pharmaceuticals.

EDTA is normally used in combination with other preservatives, especially BAK, with which it has a synergistic action. This synergy enhances the effectiveness of the blended solution.

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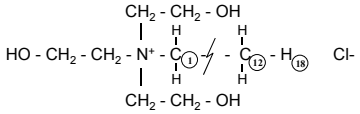
**ATAC**

- Alkyl Triethanol Ammonium Chloride
- 
- Quarternary ammonium compound
- Normally complexed with a surfactant to reduce lens penetration
- Often used with thimerosal

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## ATAC (ATEAC)

Alkyl Triethanol Ammonium Chloride (molecular weight, 353.98 to 438.14) is another quaternary ammonium preservative (cf. BAK) which, in its free form, is a powerful disinfectant. Like BAK, it is actually a mixture of chlorides with the number of alkyl groups varying between 12 and 18. In high concentrations it is often used in household liquid disinfectants and some swimming pool chemicals.

Its ability to readily penetrate lens materials results in a significant incidence of irritation. Therefore, it is usually supplied as part of a component complex to reduce its absorption. Unfortunately this also reduces its efficacy. Commonly, ATAC is complexed with a suitable surfactant, although ATAC itself also has some surfactant properties.

ATAC is a relatively slow acting disinfectant. The combination of thimerosal and ATAC has been reported to result in stinging on lens insertion in some patients.

63

**SORBIC ACID**

- $CH_3 - CH = CH - CH = CH - COOH$
- Weak preservative
- Concentration 0.1 - 0.2%
- Effective with pHs between 4.5 - 6.5

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## Sorbic Acid and Potassium Sorbate

Sorbic acid (molecular weight, 112.13) is used as a preservative in food (bread and dairy products), often in combination with EDTA.

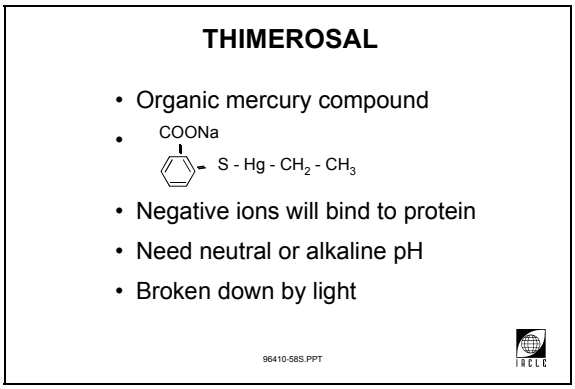
Although sorbic acid does not normally induce hypersensitivity reactions, its antimicrobial efficacy is lower that that of thimerosal and probably chlorhexidine. It is a poor anti-fungal.

Concentrations used range from 0.1-0.2% and it is more effective when pH is between 4.5 and 6.5.

One of its salts, potassium sorbate, has also been used in LCPs, and solutions containing either of these ingredients can cause lens discoloration (usually a yellowing) in some cases, especially if lenses are thermally disinfected in a saline containing them.

Dermatological allergies to sorbic acid have been reported.

64

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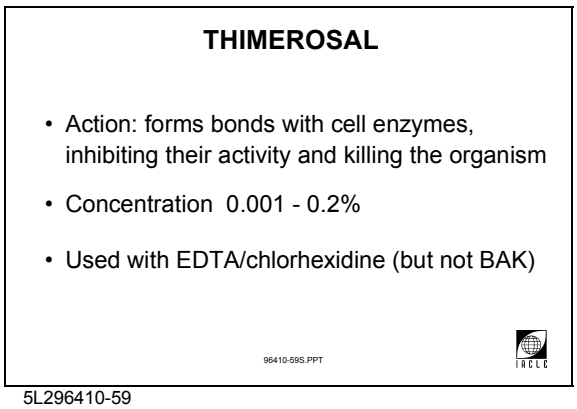


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**Thimerosal (thiomersal, thiomersalate, merthiolate, sodium ethylmercuric thiosalicylate) and Phenyl Mercuric Nitrate (PMN), Phenyl Mercuric Acetate, THI**

Thimerosal (molecular weight, 404.81) is an organic, mercury-containing compound used extensively in the past in solutions for both rigid and soft CLs.

It is most effective in neutral or slightly alkaline pHs. Its negatively charged ionic form can bind to protein deposits (lysozyme is +ve) resulting in prolonged eye exposure to thimerosal. It can readily penetrate lens matrices (pore size 3 to 5 nm) because of its small molecular size of 1.3 nm (Nilsson and Lindh, 1990).

It is effective against bacteria because its mercury ions form covalent bonds with the sulphydryl groups of cell enzymes and other proteins inhibiting their functions. Cell death results.

Thimerosal is used in concentrations ranging from 0.001 to 0.2% and is normally combined with chlorhexidine or EDTA. However, the latter has been found by one study to reduce the antimicrobial efficacy of thimerosal (Morton, 1985). Thimerosal is incompatible with BAK.

Chlorhexidine is a more effective antimicrobial than any of the mercurial compounds. However, the mercurials have a significant antifungal action unmatched by chlorhexidine. For this reason the combination of the two compounds makes a formidible disinfection system.

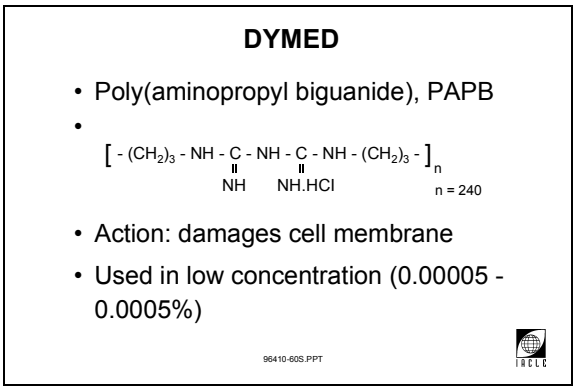
Since thimerosal can be decomposed by light, solutions containing it should be stored in light-proof (opaque) containers. A blackish or dark grey lens discolouration can result from repeated thermal disinfection in thimerosal-preserved saline, especially if the saline is changed infrequently.

Other mercurials, now uncommon in LCPs, include phenylmecuric nitrate

(PMN) and phenylmercuric acetate. Typically, these are used at concentrations of 0.004%.

Generally, the use of mercury-containing compounds for any purpose is frowned upon by regulators and environmental authorities world-wide. Few products now use them although their efficacy is seldom matched by the 'safer' products that have replaced them.

66




5L296410-60

**The New Generation: Poly(aminopropyl biguanide), PAPB, Poly(hexamethylene biguanide), PHMB, Poly(hexanide),**

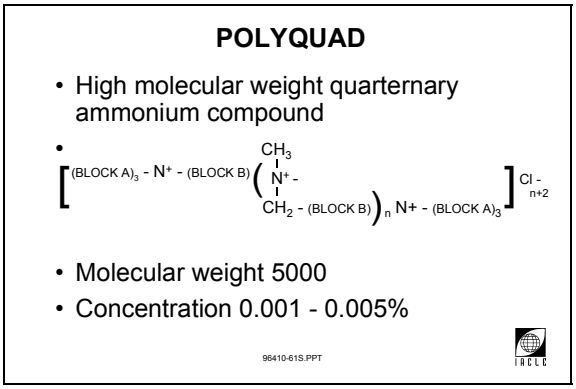
A new generation of CL solution preservatives was developed to address the problems previous (often stronger) preservatives created, i.e. ocular irritation, ocular hypersensitivity, etc.

One of the first products to take a novel approach was based on Dymed™, the marketing name for poly(aminopropyl biguanide) (PAPB) or polyhexanide. PAPB is a member of the biguanide family which includes chlorhexidine (it shares the hexamethylene-biguanide repeating unit with chlorhexidine but has approximately 4X the molecular weight of chlorhexidine (PAPB=1300)). Unlike chlorhexidine, PAPB binds to lens RGP materials 30-fold less often (McLaughlin *et al.,* 1991).

This 'new' chemical family started life in the early 1960s as an anti-malarial water treatment and was subsequently used as a swimming pool chemical, an industrial disinfectant and a preservative of water-based inks. Clinical quality variants became available following PAPB's 'discovery' by the cosmetics industry. From there, other applications emerged rapidly, including contact lens care. Other trade names for the PAPB/PHMB family include Bacquacil, Arlagard, Vantocil and Cosmocil. More recently, PAPB/PHMB has been used as an adjunct anti-protozoan ocular pharmaceutical for the treatment of *Acanthamoeba sp.* keratitis (Larkin *et al.*, 1992).

PAPB's positively charged molecule reacts with, and selectively binds with, negatively charged phospholipids of the cell walls causing membrane damage, cell content leakage and ultimately cell death. It is claimed that polymeric disinfectants are more effective because each molecule causes proportionally more damage than conventional disinfectants (Atkins and Allsopp, 1996). PAPB is used in solutions for both RGP and soft lenses. Examples include: B&L's ReNu (Multi-Purpose Solution or MPS in some markets), Boston's Simplicity Multi-Action Solution, Allergan's Complete and Complete Comfort Plus, CIBA's SOLO-care, Sauflon's ALL-IN-ONE, Abatron's Quattro and several clones made locally for regional markets.

67




5L296410-61

**The New Generation: Poly(quaternium-1), polidronium chloride, Onamer M**

Another 'new' generation preservative is Polyquad™, the marketing name for a high molecular weight (polymeric) quarternary ammonium compound.

Because of its large molecular size (22.5 nm cf. lens material 'pores' of 3 - 5 nm, Nilsson and Lindh, 1990, molecular weight 5,000, Morgan, 1987) it cannot find its way readily *into* lens materials. As a result the amount of lens-borne preservative is minimal and hence the incidence of ocular reactions is, at least theoretically, reduced.

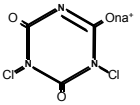
Polyquad, as polidronium chloride or Onamer M was also originally used in cosmetics as a preservative (Franklin *et al.,* 1995). In ophthalmic solutions, it was used initially in a borate-buffered product (Opti-Soft™) but this product was found to be incompatible with high water ionic lens materials. A change to a citrate buffer (Opti-Free™) solved the lens material compatibility problem.

This type of preservative is used on both rigid and soft lenses in Alcon's Opti-Free, Opti-Free Express, Opti-1, Opti-One and Opti-Soak, Polyclens II, Opti-Free Daily Cleaner, Opti-Clean II, Opti-Tears and

Opti-Free Comfort Drops. Solutions for RGP lenses have a higher concentration of Polyquad in their formulation. Interactions with other concurrent lens care products and/or medications have been reported (Roth, 1991).

68

**CHLORINE SYSTEMS**

- Supplied as choice-releasing effervescent tablets
- Sodium dichloroisocyanurate
- 
- 4 ppm available chlorine
- Requires sterile unpreserved saline
- 4 hrs exposure recommended

96410-62S.PPT

5L296410-62

## Chlorine Systems

The use of chlorine-releasing tablets in SCL disinfection systems dates back to the 1970s. Studies more recently have shown that the chlorine available is significantly reduced by the presence of biological soilage. Such a reduction in available chlorine combined with chlorine's relatively poor antifungal performance cast doubts on the overall utility and safety of such systems in the hands of the average (occasionally to regularly non-compliant) user.

The systems are supplied as convenient blister packed anhydrous effervescent tablets of either stabilized halane (sodium dichloroisocyanurate, molecular weight, 219.95, Rosenthal *et al.,*1992) (Softab™) or more recently stabilized halazone (poly(dichlorosulphamoyl) benzoic acid, molecular weight, 270.1, Rosenthal *et al.,*1992) (Aerotab™). The former is also used as a swimming pool chemical (supplied as 200 gram tablets), the latter as a drinking water disinfectant. Both products are conceptually similar and differ slightly in the amount of available chlorine (Softab, 62%, Aerotab 52%).

69

**CHLORINE SYSTEMS**

- Poly(dichlorosulphamoyl) benzoic acid
- Conceptually similar to sodium dichloroisocyanurate
-
- 8ppm available chlorine

96410-63S.PPT

5L296410-63

For contact lens disinfection, a tablet is dissolved in 10 mL sterile saline (unpreserved is strongly recommended since some preserved salines interfered with the chemistry of the tablet) to make a disinfecting solution with a pH between 5.5 and 7.5.

In solution, both tablet types are hydrolysed to produce hypochlorus acid which in turn dissociates into hydrogen and hypochlorite ions. However, the antimicrobial activity of these products depends largely on the concentration of undissociated hypochlorus acid which is directly related to the 'available chlorine' level. The dissociation dynamics depend

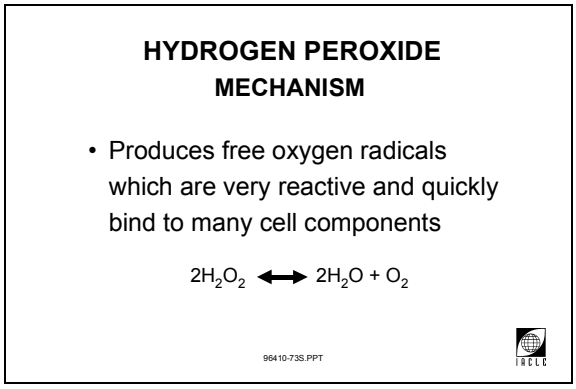
on solution pH and are not directly dependent on the theoretical 'available chlorine' levels. Acidic conditions leave hypochlorus acid largely undissociated. This suggests that antimicrobial efficacy decreases with increasing (alkaline) pH (Rosenthal *et al*., 1992).

Since hypochlorite and chlorine are also bleaching agents (many domestic bleaches are based on sodium hypochlorite) some lenses, particularly lenses tinted with reactive dyes, can have their colour altered or removed by such systems.

These systems produce chlorine concentrations of 4 to 8 ppm, requiring lens soaking times from 30 minutes to four hours.

If such systems are used, it is important that the lenses are cleaned and rinsed properly (with sterile saline) before disinfection and again before insertion to remove the residual chemicals from their surfaces.

70




5L296410-73

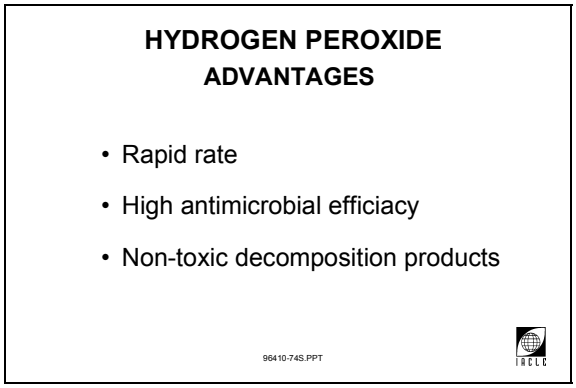
**Hydrogen Peroxide**

Historically, hydrogen peroxide is one of the earliest methods of soft contact lens disinfection. Hydrogen peroxide is a highly reactive oxidizing agent (molecular weight =34.015).

It produces free oxygen radicals which are very reactive and quickly bind to many cell components.

$2H_2O_2 \Leftrightarrow 2H_2O + O_2$

71



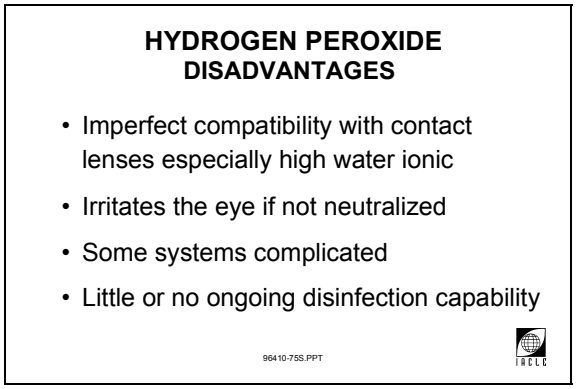

5L296410-74

**Advantages:**

- Rapid: kills large numbers of most organisms in a short time period, 10-20 minute soaking times (60 to 120 recommended).
- High antimicrobial efficacy: effective against a wide range of micro-organisms, especially when used unneutralized for long periods.
- Non-toxic decomposition products: water and oxygen. Normally, stabilizers are added and these can be a sodium stannate/sodium nitrate combination or proprietary peroxide stabilizers (e.g. the DeQuest series from Monsanto).

The effectiveness of hydrogen peroxide is controlled by its concentration and the duration of exposure.

72




5L296410-75

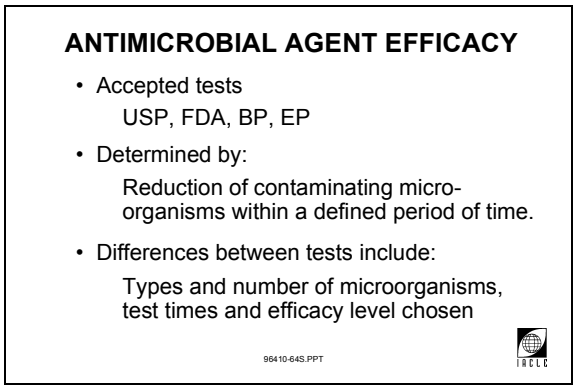
**Hydrogen Peroxide**

**Disadvantages:**

- Imperfect compatibility with contact lens: some peroxide solutions are neither isotonic nor of approximately 'normal' pH. As a result, they can *reversibly* alter lens parameters and water content.
- Direct contact with 3% $H_2O_2$ causes significant ocular discomfort. However, in the normal eye no serious long-term consequences have been reported. The experience is usually so unpleasant that users are unlikely to repeat their mistake (operant conditioning of compliance!).
- Multi-step peroxide systems can be overly complex and confuse the patient.
- Once it is neutralized, a peroxide system has no antimicrobial power because only water, sodium chloride and stabilizers remain.

## VI Antimicrobial Efficacy

73




5L296410-64

### Anti-Microbial Efficacy

There are a number of accepted tests used to establish anti-microbial efficacy. The regulatory authorities administering these tests include:

USP = United States Pharmacopoeia

FDA = Food & Drug Administration (USA)

BP = British Pharmacopoeia

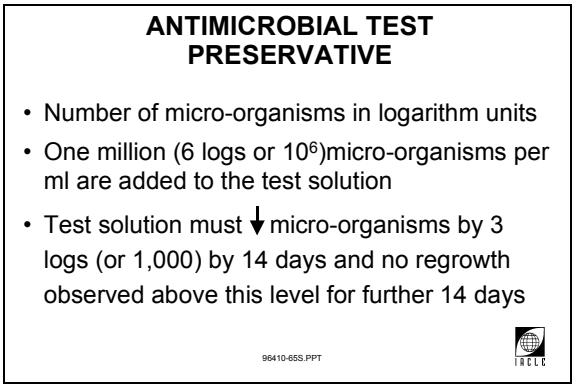
EP = European Pharmacopoeia

To measure the antimicrobial efficacy of a product, a large number (usually $10^6$ Colony Forming Units or CFUs) of each of the test micro-organisms selected to form a panel of test organisms, is exposed to the disinfectant. The time taken for the disinfectant to kill each log unit (i.e. each consecutive 90% reduction) for *three* consecutive log unit decreases, i.e. from $10^6$ to $10^3$ CFUs, is measured. Such a test produces an index of disinfection called a D-value which is covered in slide 77.

Another test monitors the number of surviving organisms after a defined period of time. The number killed is calculated by subtracting the number of survivors from the size of the original innoculum. A kill rate can be ascertained by dividing the result by the time period.

Differences between tests include the types and numbers of micro-organisms, test times including intermediate points and pass/fail criteria.

74




5L296410-65

## Antimicrobial Efficacy Test

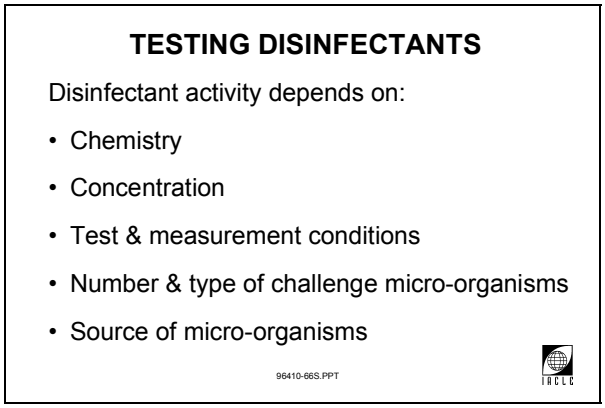
- Micro-organism numbers are measured in logarithmic units. Micro-organisms commonly used in FDA test include: *Staphylococcus epidermis* (bacteria)*, Pseudomonas aeruginosa* (bacteria)*, Serratia marcescens* (bacteria)*, Candida albicans* (yeast)*, Aspergillus fumigatus* (mold) *and Herpes simplex* (virus)*.*
- One million (6 log units or $10^6$) micro-organisms (CFUs) per millilitre are added to the test solution ($10^6$ CFU/mL).
- The USP *Preservative* Effectiveness Test requires a solution to decrease micro-organisms levels by 3 log units (or 1,000) after 14 days and allow no subsequent regrowth for a further 14 days.

  From this test, the basis of the disinfection test is derived. To pass as a *disinfectant* the FDA's Office of Medical Devices imposes two additional requirements on an agent:

  - at 14 days, the original solution is rechallenged by a $10^5$ CFU/mL innoculum and the solution must again cause a 3-log unit reduction in micro-organisms over the following 14 days
  - the solution must be fungistatic to yeasts and fungi during the 28 day test (after Houlsby *et al.* 1984).

The contribution any rinsing or cleaning step might make to the performance of a 'system' is not taken into account by these tests.

75



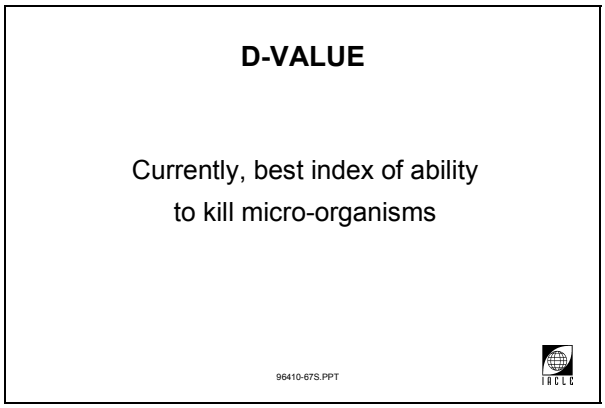

5L296410-66

## Testing Disinfectants

A direct comparison between specific disinfectants is difficult to make. The time required by each disinfectant to act depends on:

- Chemistry.
- Concentration.
- Test conditions.
- Method of measurement.
- Number and type of challenge micro-organisms. Micro-organisms are often given an identifying number ATCC (American Type Culture Collection). Organisms of the same ATCC number do not necessarily behave identically.
- Source of micro-organisms
  - 'off-the-shelf' (stock item from a specialist supplier).
  - 'from the field' (i.e. an organism which may have evolved and adapted to its environment. Organisms acquired from the field are usually more resistant than laboratory-based varieties of the same nominal genus and species or ATCC number).

76




5L296410-67

## D-Value (Death-Rate Kinetics)

The D-value of a solution or technique is currently the best index of its ability to kill micro-organisms.

A D-value is the time required for the test substance (or method) to decrease the number of organisms by one log unit, i.e. the time to kill 90% of organisms originally present. The possible contributions from any prior rubbing and rinsing step is ignored when a D-value is stated, i.e. it is a measure of the performance of a solution (or method) used in isolation. The D-value is a guide to the time required to disinfect. Usually, the actual number of micro-organisms is unknown and a conservative assumption of $10^6$ is

77

**D-VALUE**

D-value is an index of disinfecting ability without a clean and rinse step.

This is a greater challenge to test solution, making it more difficult to pass.

96410-69S.PPT

5L296410-69

made.

A longer time indicates a slower killing rate but not necessarily less killing 'power' or a lower anti-microbial efficacy. Disinfectants that kill by damaging cell walls may be as effective as those that alter cell enzymes. However their time courses can be expected to be different.

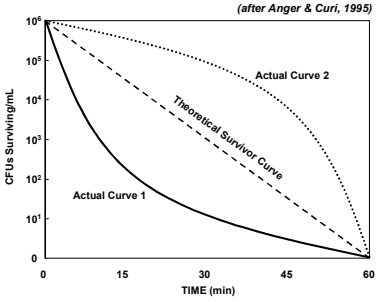
D-values decrease (suggesting more 'power') with lower micro-organism counts.

Even a 90% reduction in the number of a large innoculum can mean many viable organisms are still present (e.g. if original is $10^6$ and $10^5$ organisms survive, the level of organisms remaining is hardly 'safe'.)

78

**D-VALUE CURVES**

*(after Anger & Curi, 1995)*




96410-83S.PPT

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In practice, D-values are calculated over a 3-log reduction, i.e. $10^6$ reduced to $10^3$ CFUs/mL. A more rigorous treatment would present the different data usually found for *each* log-unit reduction, i.e. $D_1$, $D_2$ and $D_3$). In practice the reduction in CFUs by the physical action of cleaning and rinsing is significant at 3 to 4 log units (Houlsby *et al.,* 1984).

The actual kill curve is not usually linear and various paths may be taken by the 'kill *versus* time' curve (see slide 79). While the theoretical and two possible actual kill curves are depicted, almost any curve terminating at the same time point is possible.

79

**OTHER FACTORS AFFECTING EFFICACY**

- Exposure period
- Accessibility
- Formulation
- Number of micro-organisms

96410-71S.PPT

5L296410-71

**Other factors affecting efficacy**

- Exposure period. Kill rates (based on D-value data) determine soaking time. i.e. a slow kill rate (lower D-value) requires a longer soak.
- Accessibility. The antimicrobial agent needs to make contact with the micro-organism to kill it. When deposition is significant, the agent may bind to the surface of deposits rendering it less effective.
- Biofilm formation. Some bacteria

can produce a polysaccharide slime which facilitates adhesion to a host substrate and acts as a protective strategy. The coalescence of this slime results in a biofilm enveloping the 'colony'. Within it, the micro-organism can survive more readily. This strategy enables micro-organisms to better resist antimicrobials. The ability of the slime to trap passing debris and other micro-organisms assists the biofilm-formation process (M$^{c}$Laughlin *et al.,* 1991).
The superior resistance of *Serratia marcescens, Pseudomonas sp.* and *Staphylococcus epidermis* and *S. aureus* to antimicrobials has been attributed at least partially to their biofilm-forming capability (Driebe, 1995), especially *S. marcescens* (M$^{c}$Laughlin *et al.,* 1991).

- Formulation. Addition of other ingredients can increase or decrease the efficacy of the main disinfecting agent(s).
- Number of micro-organisms. A small number of micro-organisms is easier to deal with thereby increasing the *apparent* effectiveness.

Other influencing factors:

- Warm *versus* cold environments. Some preservatives are more effective at high temperature. This is probably due to the effect of heat on the kinetics of a chemical reaction
- Open *versus* closed container/lens case. A sealed lens case will protect lenses and solution from airborne contaminants.

The table in slide 81 (Lowe *et al*, 1992) shows the solution power (P) for bacterial and fungal challenges to disinfection solutions. Solution power is calculated by dividing the manufacturers' minimum recommended

80

**Solution power (P) for bacterial and fungal challenge of disinfection solution**

| | | BACTERIA | | FUNGI | |
|---|---|---|---|---|---|
| **Solution** | **MRDT** | **D** | **P** | **D** | **P** |
| Aerotab | 30 | 3.4 | 8.8 | 1190 | 0.0 |
| Hydrocare | 240 | 61 | 3.9 | 82 | 2.9 |
| MiraSept | 10 | 2.3 | 4.3 | 45 | 0.2 |
| Opti-Free | 240 | 20 | 12 | 510 | 0.5 |
| Oxysept | 20 | 1.8 | 11 | 48 | 0.4 |
| ReNu | 240 | 71 | 3.4 | 211 | 1.1 |
| Softab | 240 | 93 | 2.6 | 227 | 1.1 |

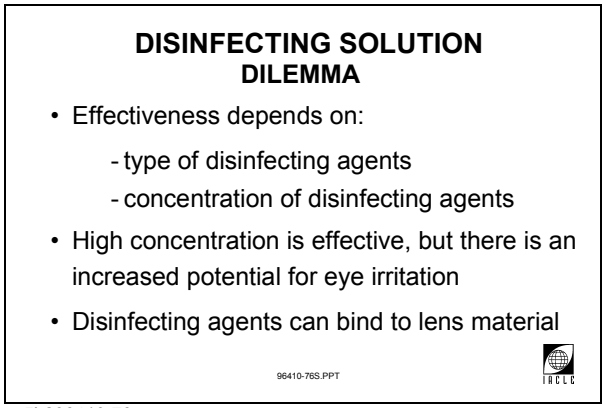
*Lowe, 1992*

96410-72S.PPT

5L296410-72

disinfection time (MRDT) by the D-value of the solution.

81




5L296410-76

**Disinfecting Solution**

Dilemma:

- If a strong preservative is used, it will kill micro-organisms effectively.
- However, a strong disinfectant, especially if used in high concentrations, may also kill cells of the anterior eye if introduced there inadvertently.
- Depending on the preservative used in the neutralizing solution (if any is used), all the usual side-effects of the preservative used can be expected, including the possibility of it binding to lens materials.

## VII Unpreserved Solutions

82

**UNPRESERVED SALINE**

Can be dangerous unless:

- Aerosol container
- Unit-dose
- Active ingredient also has preservation capacity

96410-77S.PPT

5L296410-77

83

5L20633-91

84

5L21661-92

### Unpreserved Solutions

Unpreserved saline is the main unpreserved solution. Other solutions are preservative-free because of the antimicrobial properties of their ingredients. Solutions containing such ingredients include cleaners and cleaner/disinfectants containing isopropyl alcohol or ethanol.

Homemade saline using salt tablets also produces a preservative-free solution. However, the resultant product should not be considered a lens care product. *Acanthamoeba* infection is just one of the potentially serious consequences of using such unsafe solutions. Their dangers are now well established and widely understood.

### Unpreserved Saline

Aerosol containers prevent micro-organisms from coming into contact with solution. A potential problem does exist however in the 'dead space' between the valve and the dispensing nozzle (jet).

The safest, albeit the most expensive, form of unpreserved saline is the unit-dose pack. This may be a sachet, plastic vial or glass vial.

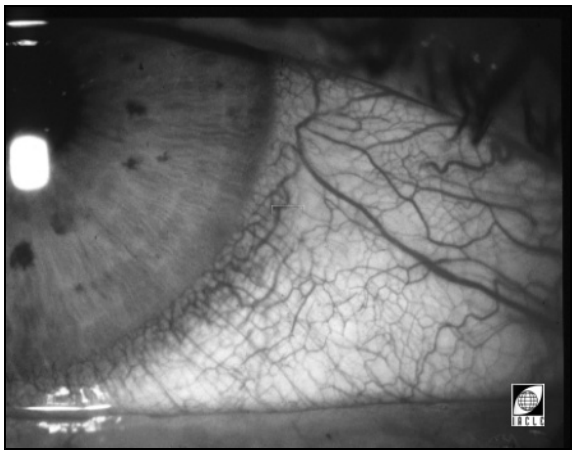
The least safe is bulk unpreserved saline for irrigation or similar purposes. Many such salines are packaged in 1 L plastic bottles with wide-aperture (>25mm) screw-top lids (slide 84). A comprehensive study of the safety of this type of product in the field was published by Sweeney *et al.* 1992. They showed that all bottles, regardless of package design, were contaminated after four weeks of use and that the wide-mouthed bottles were seriously contaminated (>$10^5$ CFU/mL) after just one week.

Saline supplied in a plastic bag and intended for intravenous use (slide 85) is not a reasonable alternative as few users replace the administration 'plumbing' regularly. Further, instances of contact

lens wearers being supplied inadvertently with ‘saline with dextrose’ have been reported. It is not until wearers experience their lids being ‘stuck’ together with such salines that the error becomes apparent.

## VIII Hypersensitivity

85



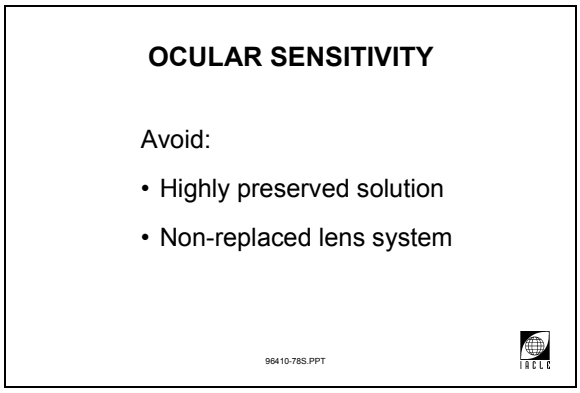
5L496409-26

### Ocular Sensitivity

It is possible that a potential candidate or current lens wearer has or will develop an ocular sensitivity. Patient history and signs or symptoms of ocular sensitivity need to be considered when choosing an appropriate lens care system.

Slide 86 demonstrates a red eye response due to a sensitivity to solution preservatives. Note the vascular injection of the bulbar conjunctiva and limbal area. Patients who suffer from allergies and hayfever may experience tearing, itchiness and swelling of the lids as well as the red eye response.

86




5L496717-78

### Ocular Sensitivity: Prevention

For patients with ocular sensitivity, avoid:

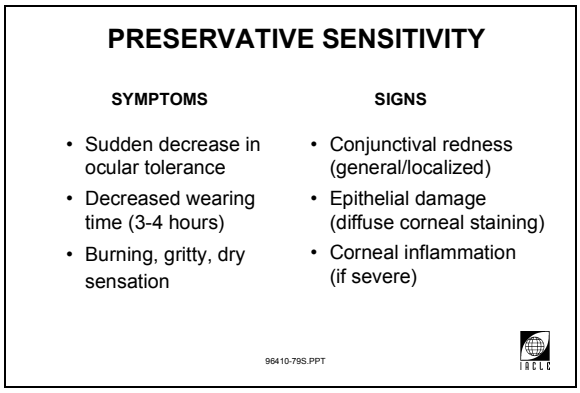
- Highly preserved solutions.

  Sensitivity to preservatives in disinfecting solutions has been well documented. Patients with ocular sensitivity are more susceptible to preservative sensitivity reactions. Since preservative absorption into contact lenses is also dependent on the rate of adsorption by the lens material, lens type should also be taken into consideration.

- Non-replaced lens systems.

  Regular lens replacement or disposable lenses should be used.

87



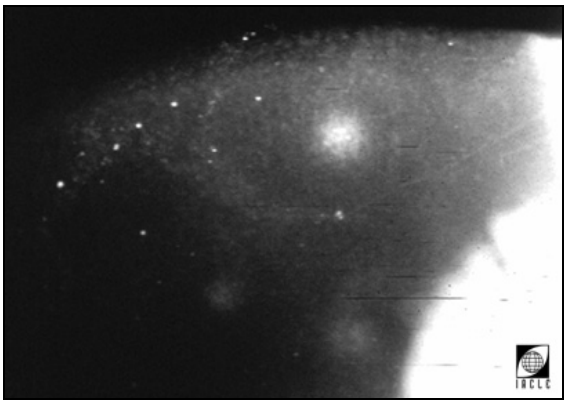

5L496717-79

### Preservative Sensitivity

A conservative approach to patient management is required with reactions to preservatives as they may lead to a delayed hypersensitivity reaction. Practitioners should familiarize themselves with signs and symptoms that are indicative of preservative sensitivity (slide 88).

The care regimen should be assessed fully to identify the specific solution component responsible for the reaction. This should then be replaced.

88



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Slide 89 demonstrates micro-punctate staining of the epithelium surrounding an infiltrate. Multiple infiltrates with surrounding staining are a likely manifestation of solution hypersensitivity.

Patients can experience stinging and/or irritation upon lens insertion. A common cause of discomfort is an incompatible (usually too low) solution pH, especially with unbuffered solutions. In the case of the latter, the pH shift is usually due to ingression of carbon dioxide.

Solution-induced sensitivity reactions can result in damage to the corneal and conjunctival epithelium, potentially allowing micro-organisms to penetrate the eye and cause eye infections.

# Practical 5.2

(2 Hours)

## Pre- and Post-Cleaning Appearance of Contact Lenses

# Schedule of Practical Sessions

**Practical Session**

**Instructions:**

1. Examine the lens surface appearance under the microscope.
2. Record it by using either a grading system or a photograph.
3. Clean the lens according to the assigned method.
4. Re-examine the lens surface appearance under the microscope and record it again.
5. Repeat for the other two stations.

Stations

Station 1: Surfactant cleaning and finger rubbing

Station 2: Enzyme cleaning

Station 3: Ultrasonic/mechanical cleaning

**Discussion and Review of Practical Sessions**

# Practical Session

## RECORD FORM

Name:_____ Date:_____

**Instructions:** Fill in the record form for each method used by a circling the appropriate observation rating and writing down your comments.

**A. SURFACTANT CLEANER AND FINGER RUBBING Lens No.___**

Surfactant cleaner used _____

1. Lens surface appearance, pre-cleaning:

| | very clean | | | | very dirty |
|---|---|---|---|---|---|
| Grade: | 0 | 1 | 2 | 3 | 4 |

2. Cleaning steps (specify in detail):

_____

_____

_____

3. Lens surface appearance, post-cleaning:

| | very clean | | | | very dirty |
|---|---|---|---|---|---|
| Grade: | 0 | 1 | 2 | 3 | 4 |

**B. ENZYME TABLET Lens No. _____**

1. Lens surface appearance, pre-cleaning:

| | very clean | | | | very dirty |
|---|---|---|---|---|---|
| Grade: | 0 | 1 | 2 | 3 | 4 |

2. Cleaning steps (specify in detail):

_____

_____

_____

3. Lens surface appearance, post-cleaning:

very clean very dirty

Grade: 0 1 2 3 4

**C. ULTRASONIC/MECHANICAL CLEANING Lens No._____**

Ultrasonic used _____

1. Lens surface appearance, pre-cleaning:

very clean very dirty

Grade: 0 1 2 3 4

2. Cleaning steps (specify in detail):

_____

_____

_____

3. Lens surface appearance, post-cleaning:

very clean very dirty

Grade: 0 1 2 3 4

# Tutorial 5.2

(1 Hour)

# Review of Contact Lens Care Products: General

# Quiz

Name:_____ Date: _____

### A. SLIDE SHOW

**Instructions:** The following slides will be shown. You are requested to provide information on what the slide demonstrates. Discussion will follow.

### B. SHORT QUESTIONS

Please answer the questions on the following page.

# A. Slide Show

A1

Bacteria

A2

Virus

A3

Protozoa

A4

Corneal staining due to sensitivity

A5

Protein deposits

## B. Short Questions

B.1 Please list three possible mechanisms of action for anti-microbial agents.

1. _____
2. _____
3. _____

B.2 List the two forms of fungi and their characteristics.

1. _____ characteristics _____
2. _____ characteristics _____

B.3 What are the three ways in which tests for preservative efficacy can vary?

1. _____
2. _____
3. _____

B.4 What is the D-value of an antimicrobial solution? _____

B.5 List two consequences of ocular toxicity.

1. _____
2. _____

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# Unit 5.3

(5 Hours)

**Lecture 5.3:** Care and Maintenance of Soft Contact Lenses

**Tutorial 5.3:** Review of Soft Contact Lens Care Systems

# Course Overview

**Lecture 5.3: Care and Maintenance of SCLs**

I. Product Categories
II. The Various Disinfection Methods
III. Protein Removers
IV. Trial Lens Disinfection
V. Re-Wetting/Lubricating Drops
VI. Lens Case Care

**Tutorial 5.3: Review of Soft Contact Lens Care Systems**

# Lecture 5.3

(2 Hours)

# Care and Maintenance of Soft Contact Lenses

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## I Introduction

1

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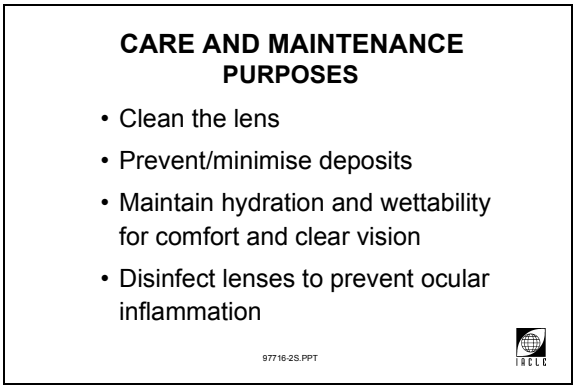


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### Care and Maintenance of Soft Contact Lenses

Soft contact lenses are susceptible to deposits. This is due, at least partially, to some or all of the following:

- The lenses are covered by the pre-lens tear film at all times.
- The tear film undergoes hydration-dehydration cycles as a result of blinking and evaporation between blinks.
- The lens is subject to atmospheric changes and pollutants.
- Decreased surface wettability is likely to accelerate deposition.

Because of these factors, and in the absence of a 'deposit-proof' contact lens or lens material, it is important to monitor the condition of all soft lenses.

While it is currently impossible to remove and/or prevent *all* soft lens deposits, every step must be taken to keep lens deposits to a minimum. It is only through the proper use of lens care products that optimum comfort, vision and safety can be maintained and the risk of lens or eye contamination minimized.

3

**DEPOSITS**
**COMPLICATIONS**

- Irritation and reduced comfort
- Reduced visual acuity
- Shortened lens life
- Increased potential for infection
- Increased incidence of GPC

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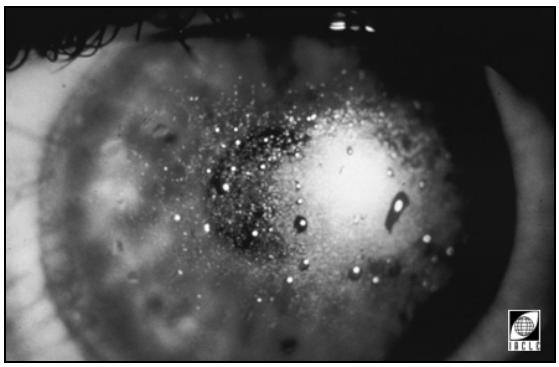
4



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Significant deposition on a SCL surface results in a non-wetting surface which may affect vision and comfort.

5

**COMPLIANCE vs NON-COMPLIANCE**

- Simple system and instructions → better compliance
- Complicated systems →
  - confusion
  - non-compliance
  - lens wear complications

97716-4S.PPT

5L397716-4

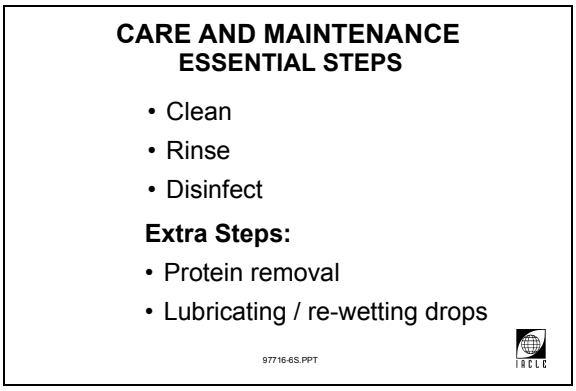
**Compliance *versus* Non-Compliance**

If the lens care system is simple and easy to use, the patient is more likely to comply with issued and printed instructions and is more likely to comprehend what is required of them. If the system is too complicated, patients may be discouraged from using it. Difficulty understanding or following instructions may lead to non-compliance.

Non-compliance has been shown to cause more dissatisfaction with lens wear, often as a direct result of an increased incidence of corneal staining, deposits and adverse symptoms.

## II Care and Maintenance: Product Categories

6

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### Care and Maintenance: Product Categories

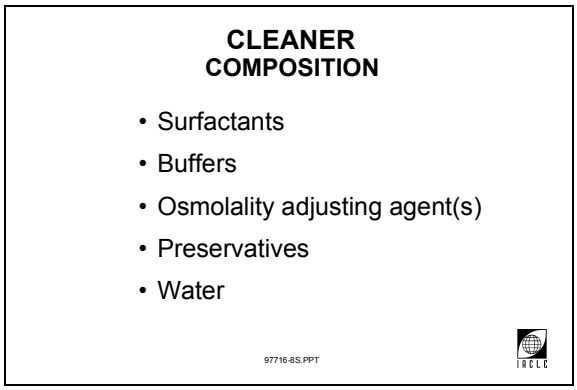
SCL care and maintenance involves the use of various products (most of which are solutions) for the purposes of cleaning, disinfecting and maintaining the lenses. The *essential* steps in lens care are summarized in the slide opposite. The *extra* steps relate to treatments which are optional. For example, it is uncommon for protein removal to be used on lenses which are replaced very frequently (every 2 - 4 weeks).

Some wearers may need special purpose *in situ* (in-eye) re-wetting/comfort drops for use on an as-and-when-required basis. The inclusion of some form of in-eye re-wetting/lubricating/rehydrating drops is very dependent on the wearer's response to lens wear and the assessment of the practitioner.

The care and maintenance of the lens storage case is an integral part of any care and maintenance programme.

## II.A Cleaners

7

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### Care and Maintenance: Cleaners

Most common components:

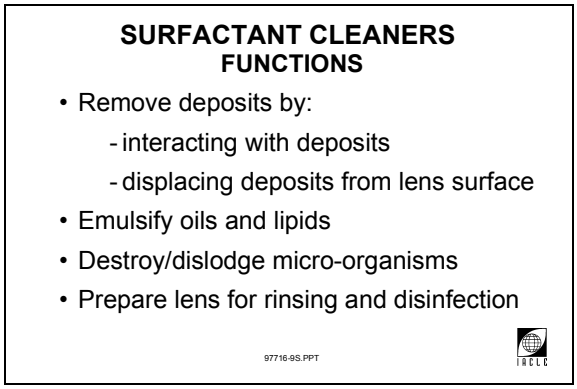
- Surfactants (surface-active agent(s)):
  - Non-ionic
  - Ionic:
    - anionic (–ve charge)
    - cationic (+ve charge)
    - amphoteric (charge is pH-dependent)
- Buffers.
- Osmolality adjusting agents -
  e.g. Sodium chloride.
- Preservative(s).
- Chelating agents (not in all solutions).
- Water (bulk of solution).

Cationic surfactants are not normally used on soft contact lenses because they may bind to the lens material (Stapleton and Stechler, 1994).

Contact lens cleaners are sometimes called surfactant cleaners because of their surface-active properties.

Preservatives (antibacterial compounds) are primarily used to protect the cleaning solutions from microbial contamination after opening.

8

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### Surfactant Cleaners

Surfactant cleaners are normally used in conjunction with finger rubbing(sometimes called digital rubbing) or mechanical cleaning, i.e. with the aid of a mechanical device (agitator, stirrer, ultrasonic bath or 'swisher').

The rubbing step is always followed by a rinsing step. The former dislodges lens contaminants while the rinsing step removes the displaced contaminants as well as any residual lens cleaner.

9

5L397716-10

## Surfactant Cleaners

- Daily cleaners.

  Cleaners contain friction-enhancing agents/polymeric beads. These are small, solid particles that behave as a mild abrasive but which do not affect lens surfaces (Phillips and Czigler, 1985). They also contain alcohol (to dissolve lipids) and/or more conventional constituents in varying concentrations. Some products in this category are marketed for use by laboratories or practitioners only.

  Examples of daily cleaners include: Allergan LC 65, B&L Sensitive Eyes Daily Cleaner, etc.

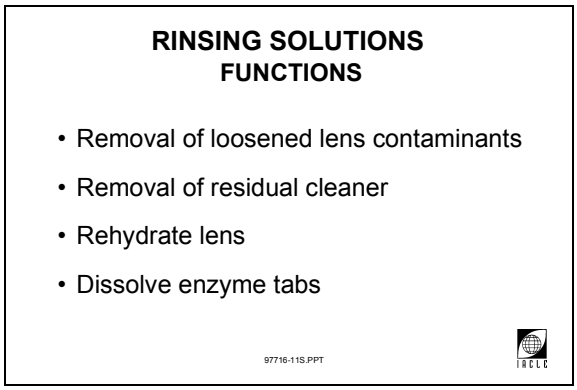
  Examples of 'extra-strength' daily cleaners include: Alcon Opticlean, Polyclens II, B&L Concentrated Cleaner, CIBA Miraflow.

- Weekly cleaners.

  Weekly cleaners are usually formulated for protein removal. They are sometimes referred to as enzymatic cleaners because most contain one or more proteolytic enzymes. Some also contain other types of enzymes that target mucins, lipids and other tear fluid components which may also be deposited on lenses.

## II.B Rinsing Solutions

10

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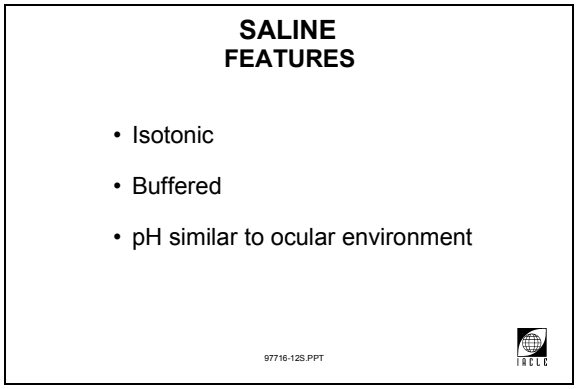
### Functions

All lenses, regardless of lens type and the lens care regimen applied to them, must be rinsed following the cleaning step.

Before insertion, and after the disinfection cycle, it is useful to rub and rinse lenses, particularly if they have been stored for several days.

The most common and most economical rinsing solution is saline. However, even if a one-bottle system (multi-purpose/multi-action) is used, a rinsing step is still required because of the debris created by rubbing as well as the action of the solution's surfactant(s).

11

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### Saline

If saline is required as part of a lens care regimen, it is normally isotonic. Isotonic saline is used because the parameters of a lens equilibrated in such a solution approximate the on-eye parameters. Further, any isotonic saline carried into the eye on the lens will not usually cause ocular discomfort because of the absence of any significant osmotic imbalance. However, some unbuffered salines may produce some discomfort. This is because of their low pH caused by absorption of atmospheric carbon dioxide.

Isotonic saline can also be used:

- As a medium for enzyme treatment in some regimens.
- To elute unbound adsorbed or absorbed lens contaminants.
- To rehydrate lenses.

Studies of the effectiveness of lubricating drops (comfort drops) often use saline as the 'control' solution. Frequently these studies show that, while both can deliver symptomatic relief, there were no clinically significant differences in their performance. See for example Efron *et al.*, 1990, regarding comfort drops *versus* saline.

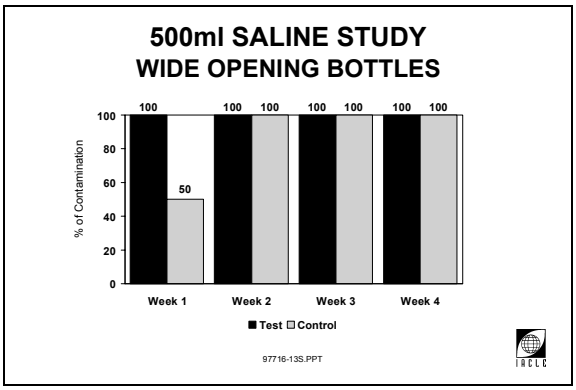
12

5L30633-91

## Saline Solution Studies

Sweeney *et al.* (1992) conducted a study to investigate contamination of saline solution after opening. The saline packaging used is shown in slide 12.

13

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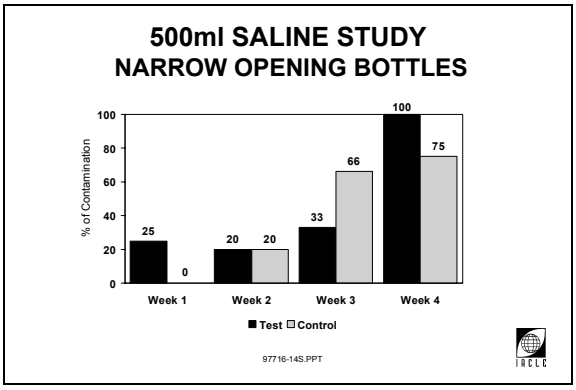
Their study found that saline bottles with wide openings showed 100% contamination after one week of use.

14

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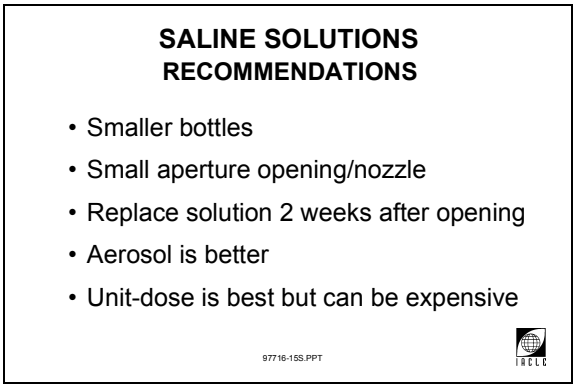
By comparison, saline bottles with narrow opening showed less contamination in the first two weeks of usage and significant increases in the number of bottles contaminated after two weeks.

Containers with smaller apertures reduce the risk of the solution becoming contaminated by airborne micro-organisms.

15

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Saline in aerosol containers should be dispensed in the near vertical position (maximum tilt: 45 degrees) to avoid depleting the reserves of propellant before the solution itself is exhausted.

16

5L30232-97

Unit-dose vials (ampoules) are a safe, portable and convenient, albeit expensive form of packaging for isotonic saline. A possible role for saline packaged in this form is as an emergency rinsing, cleaning, lubricating and hydrating solution to be carried by wearers at all times.

## II.C Disinfection

17

**WHY IS DISINFECTION REQUIRED ?**

Contact lenses may:

- Inhibit the washing action of tear film
- Introduce micro-organisms
- Compromise the epithelial barrier function

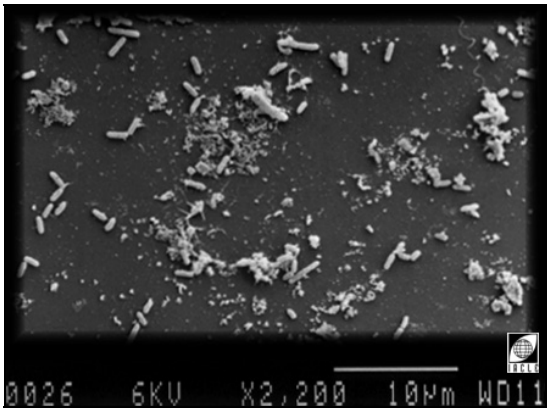
97716-16S.PPT

5L397716-16

### Disinfection

The purpose of disinfecting soft CLS is to reduce/eliminate the microbial load in order to minimize the risk of inflammation and infection when lenses are worn.

18

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### Micro-Organisms

Micro-organisms such as bacteria can adhere to deposits on the surface of contact lenses.

19

**DISINFECTION SYSTEMS**

- Thermal (heat)
- Chemical
  - conventional
  - polymeric
  - tablet
- Hydrogen peroxide

97716-18S.PPT

5L397716-18

## II.C.1 Thermal Disinfection

20

**THERMAL DISINFECTION**

Original form of disinfection.
High temperatures kill micro-organisms by:

- Denaturation of cell components
- Disruption of plasma membranes
- DNA damage

97716-19S.PPT

5L397716-19

### Thermal Heat Disinfection

Thermal disinfection was the most common form of soft contact lens disinfection until the mid-70s. Initially, hydrogen peroxide was the only other system readily available. Once reliable and relatively trouble-free chemical systems were introduced, thermal disinfection, and to some extent in some markets the use of hydrogen peroxide, declined in popularity.

Thermal disinfection:

- The oldest form of disinfection.
- Highly effective.
- Denatures tear protein deposits on lenses.
- Economical.
- Can be made preservative-free.

21

**THERMAL DISINFECTION METHOD**

- Clean and rinse lenses
- Place lenses in fresh saline in lens case
- Secure lid(s) and place lens case in thermal disinfecting unit
- After heat cycle allow lenses to cool before use

97716-20S.PPT

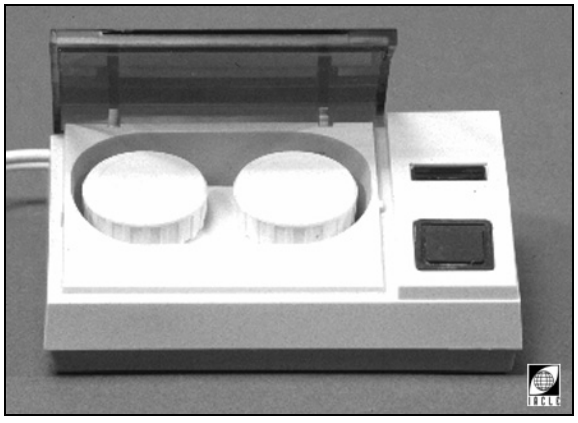
5L397716-20

### Thermal Disinfection

Disinfection follows the rubbing and rinsing steps. It is essential that fresh solutions are used for rubbing, rinsing and disinfection.

There are two main methods of applying heat to lenses in a lens storage case, 'wet' and 'dry'. Wet heating methods include immersing the lens case in water at or near its boiling point, or placing the lens case above boiling water (i.e. a steam bath). Dry heat involves the direct heating of the lens case by a matching, snug-fitting, electrically-heated device, an example is shown in slide 22.

22



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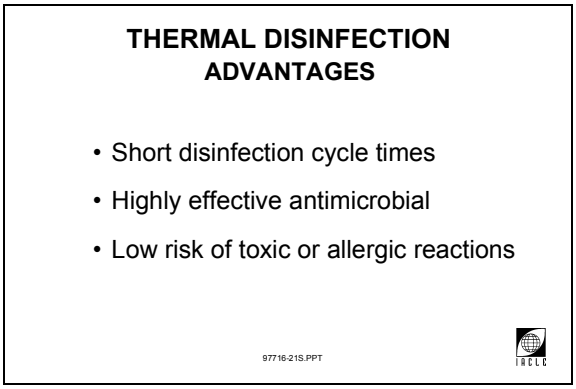
Should cracks develop in lens cases that are wet-heated, contaminants from the surrounding environment can be drawn into the case during the cooling phase of their disinfection cycle. Similarly, lens case cracks used with dry heating may result in the 'ingestion' of airborne contaminants during the cooling phase.

The use of a saucepan on a stove as a heat disinfection procedure should be discouraged since:

- The temperatures developed are excessive.
- The control of the process is poor (e.g. the duration).
- The risk of boiling the saucepan dry with subsequent melt-down of the case and lenses is high.

Liubinas *et al.* (1987) concluded that exposure to temperatures ∑ 80° C for ∑ 20minutes was excessive and suggested an alternative of >70° C but < 80° C (at the lens) for five minutes as being adequate to disinfect soft contact lenses. Some thermal units operate at higher temperatures (80 to 99° C) and for longer times depending on the manufacturer, the model and any relevant national regulatory requirements.

23

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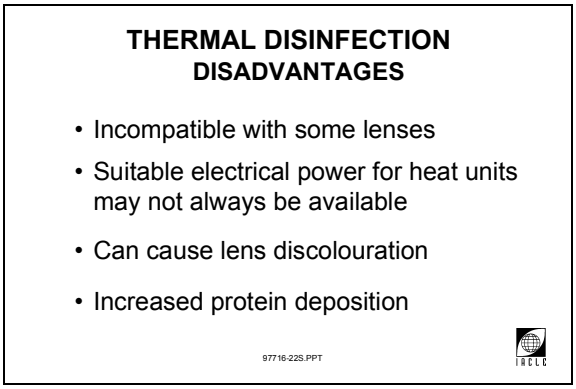
## Thermal Disinfection

### Advantages

- Short disinfection cycle times (10 - 30 minutes) are faster than four hour to overnight chemical disinfection soaking times.
- Heat is very effective in destroying micro-organisms; bacteria, fungal spores, *Acanthamoeba* cysts, etc.
- When unpreserved saline is used, the risk of lens care product-induced ocular irritation is virtually nil.

24

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### Disadvantages

- Incompatible with some lenses (usually higher water content lenses).
- Can be inconvenient with unreliable local power supplies or when travelling to other countries (different voltages, different and incompatible plug and socket configurations).
- Lens discolouration (especially yellowing) arising from:
  - denaturation of protein
  - thermally-altered lens contaminants

  - sorbic acid-preserved saline
  - thimerosal-preserved saline
  - PVA uptake from PVA-containing solutions (including ocular pharmaceuticals).
- High temperatures cause protein to denature and bind more tightly to contact lenses thereby increasing the risk of Giant Papillary Conjunctivitis (GPC) or CLPC.

While heat is highly effective against most micro-organisms there are some which are heat resistant to temperatures above 100° C for considerable periods of time. Unfortunately, the performance of a species is often difficult to categorize because micro-organisms of the same nominal genus and species often demonstrate disparate susceptibilities to heat, e.g. *Bacillus subtilis*, *Clostridium welchii* (Russell, 1965).

## II.C.2 Chemical Disinfection

## II.C.2a Conventional Chemicals

25

**CHEMICAL DISINFECTANT**
**CONVENTIONAL**

- Thimerosal
- Chlorhexidine
- Sorbic Acid
- ATAC
- Isopropyl alcohol

EDTA often used as antimicrobial enhancer

97716-26S.PPT

5L397716-26

### Chemical Disinfection: Conventional Chemical

Conventional chemical disinfectants and preservatives for soft lenses appear in the slide opposite.

Commonly, EDTA is also included as a preservative enhancing agent. However, EDTA *per se* is bacteriostatic at best.

Most of the disinfectants containing conventional chemicals are used as soft lens storage solutions, i.e. disinfection occurs during storage. The lenses are cleaned and rinsed normally. Then they are immersed in the disinfecting solution for a minimum recommended period, usually four or more hours, overnight being preferred.

It is prudent to recommend a lens rinse in sterile saline before lens insertion to minimize the eye's exposure to the solution's chemistry.

26

**ALCOHOL**

Used in:

- Cleaners (isopropyl alcohol and ethanol)
- Disinfection (isopropyl alcohol)

97716-27S.PPT

5L397716-27

### Alcohol

While ethanol (ethyl alcohol) is a good antimicrobial agent, it is only used in low concentrations in cleaners or conventional chemical disinfectants. This is because of the deleterious effects that significant levels of alcohol have on the anterior eye.

Examples: PBH-WJ Cleaner #4, Hexidin

Isopropyl alcohol, until recently used in cleaners only, e.g. CIBA Miraflow, is now also used in a disinfecting solution. Example: CIBA Vision QuickCare or InstaCare. Both the cleaner and disinfectant contain large concentrations of alcohol (20 and 17% respectively).

In the InstaCare product (17%) the alcohol is kept from the eye by having preserved saline rinses and preserved saline storage interposed between disinfection and lens insertion.

## II.C.2b Chemical Disinfection: Toxicity/Sensitivity

27

**DISINFECTANTS/PRESERVATIVES**
**KNOWN OCULAR IRRITANTS**

- Thimerosal
- Chlorhexidine
- Sorbic Acid

97716-23S.PPT

5L397716-23

### Chemical Disinfectants/Preservatives

These disinfectants, which are also used as preservatives in other lens care products, are chemicals with the potential to cause ocular irritations or induce a hypersensitivities if used in high concentrations or for prolonged periods as described in Unit 5.2.

Alternatives to these chemical entities should be used where possible.

28

**DISINFECTANT SENSITIVITY**

| SYMPTOMS | SIGNS |
|---|---|
| • Sudden decrease in ocular tolerance | • Conjunctival redness (general/localized) |
| • Decreased wearing time (2-4 hours) | • Epithelial damage (diffuse corneal staining) |
| • Burning, gritty, dry sensation | • Corneal inflammation (if severe) |

97716-24S.PPT

5L397716-24

29

**DISINFECTANT SENSITIVITY**
**INCIDENCE: 5 - 30%**

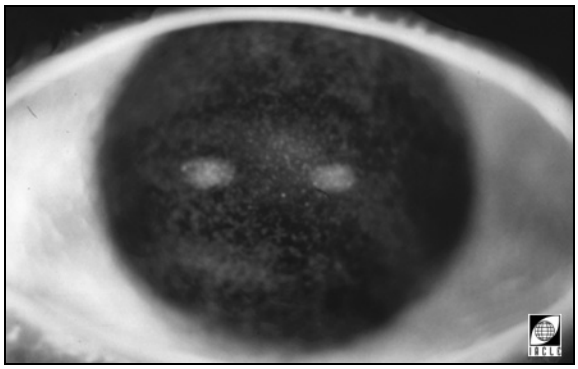
Depends on:

- Preservative type
- Preservative concentration
- Lens materials
- Soaking time
- Lens age
- Patient susceptability

97716-25S.PPT

5L397716-25

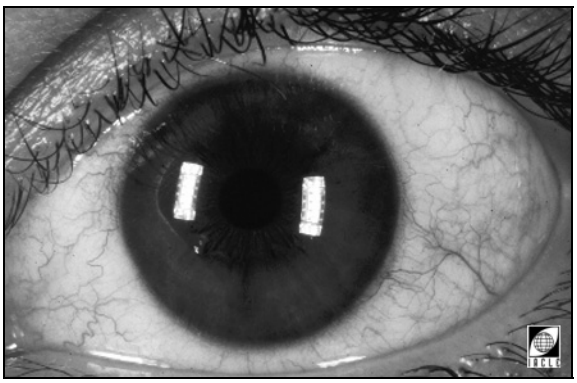
30



5L10816-91

Slide 30 shows diffuse corneal staining resulting from a reaction to a disinfectant or a preservative. Typically, staining is bilateral, approximately equal in each eye, diffuse and superficial.

31

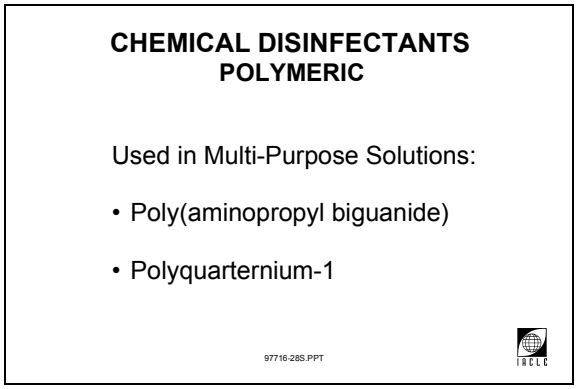


5L51039-91

A mild red eye (conjunctival hyperaemia) due to sensitivity to a solution component, usually the disinfectant.

## II.C.3 Polymeric Disinfectants

32

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### Chemical Disinfection: Polymeric Conventional

This is a relatively recent class of disinfectants which are either direct descendents or close relatives of conventional disinfectants.

The most common examples include:

- Poly(hexamethylene biguanide) (PAPB, PHMB, Polyhexanide, Trischem). A relative of chlorhexidine which is also a biguanide.
- Polyquaternium-1. A polymeric (large molecule) quaternary ammonium compound.

This new generation of polymeric chemical disinfectants causes significantly fewer and less serious reactions by having an apparently lower toxicity. Most are now used in multi-purpose (all-purpose, multi-function) solutions which are used in place of a series of single-purpose solutions. Multi-purpose solutions form the basis of one-bottle lens care systems (OBSs). OBS products are marketed on the basis of their convenience and ease of compliance.

The lower complication rate is at least partially due to the large molecular size of these new-generation compounds. Their molecular size prevents them from entering, or being absorbed by, hydrogel lens materials, leaving the eye to contend with residual surface solution only. This reduces the amount of chemical being carried by the lens into the eye at insertion.

Examples: B&L Multi Purpose Solution/ReNu, Alcon Opti-Free, Allergan Complete, Ciba SOLO-care Soft, Abatron Quattro.

33

**POLYMERIC DISINFECTANTS**
**DISADVANTAGES**

- Reduced disinfecting 'power'
- Rub/rinse still required
- Compliance more important

97716-29S.PPT

5L397716-29

**Polymeric Chemical Disinfectants: Disadvantages:**

- Reduced disinfecting 'power'. This is particularly so for fungi and *Acanthamoeba sp.*, especially in the encysted form.
- Rub/rinse step still a prerequisite for effective cleaning prior to disinfection.
- Compliance is more important. This is due to their reduced safety margin resulting from their lower disinfecting 'power'. It is absolutely essential that users use fresh solution for each lens care cycle.

It has been shown that multi-purpose solutions containing polymeric chemical disinfectants clean lenses as well as single-purpose cleaners, provided they contain a surfactant (Franklin, 1997).

34

**EFFICACY* AGAINST BACTERIA**
Lowe *et al*., 1992, Reinhardt *et al*., 1990

| GOOD | POOR |
|---|---|
| Heat (80°C, 10 mins) | Softab (4 hrs) |
| 3% $H_2O_2$ (10 mins) | |
| AOSept (6 hrs) | |
| 0.002% Thimerosal (4 hrs) | |
| 0.00005% Dymed (4 hrs) | |
| 0.001% Polyquad (4 hrs) | |

*within recommended soaking time

97716-30S.PPT

5L397716-30

Lowe *et al.* (1992) and Reinhardt (1990) investigated the efficacy of seven SCL disinfection systems against various micro-organisms (bacteria, fungi an *Acanthamoeba*) using the manufacturer's recommended methods and soaking times.

Their relative bactericidal performances (in order of decreasing efficacy) are listed in slide 34.

35

**EFFICACY* AGAINST FUNGI**
Lowe *et al*., 1992, Reinhardt *et al*., 1990

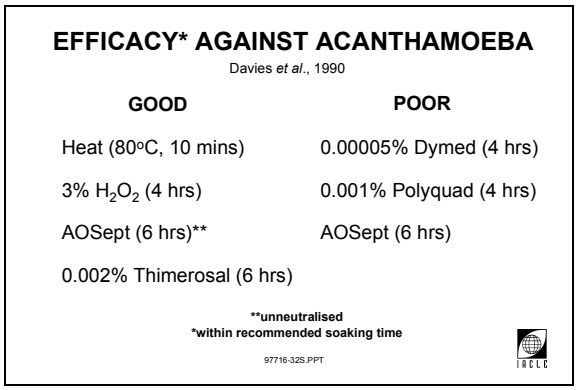
| GOOD | POOR |
|---|---|
| Heat (80°C, 10 mins) | 0.00005% Dymed (4 hrs) |
| 3% $H_2O_2$ (60 mins) | 0.001% Polyquad (4 hrs) |
| AOSept (6 hrs)** | AOSept (6 hrs) |
| 0.002% Thimerosal (4 hrs) | Softab (4 hrs) |

**unneutralised
*within recommended soaking time

97716-31S.PPT

5L397716-31

36




5L397716-32

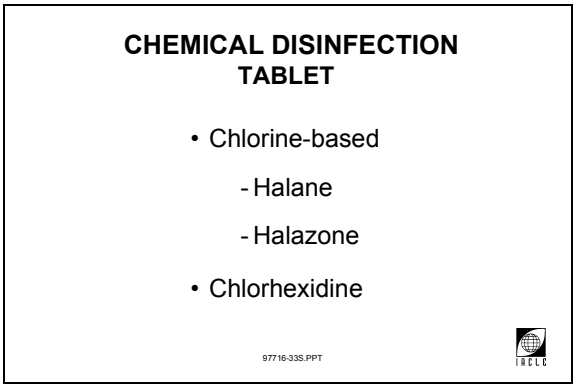
The effect of the seven solutions against *Acanthamoeba* are presented here. As can be seen, the newer generation of disinfectants are less effective.

The AOSept product appears twice in this slide because it was tested with and without its catalytic disk neutralizer in place. As can be seen, when used with the disc, its performance is significantly reduced and, like several other 'convenience' products, it does not perform well against fungi and *Acanthamoeba*.

*Note:* In some literature the word *mycotic* may be used in place of *fungal,* e.g. mycotic challenge in place of fungal challenge (see Lowe *at al.*, 1992).

## II.C.4 Tablet-Based Systems

37

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### Chemical Disinfection: Tablet-Based Systems

A relatively early lens care system developed in the UK in the 1970s was based on the production of chlorine or related chemistries from a tablet dissolved in unpreserved saline. The developers were ultimately responsible for two conceptually similar chlorine tablet systems. These are:

- Halane (sodium dichloroisocyanurate).
- Halazone (poly(dichlorosulphamoyl) benzoic acid).

Examples: Alcon Softab, Sauflon Aerotab.

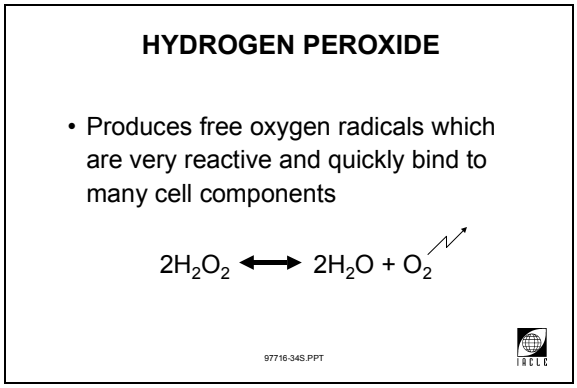
Another more recent tablet system is based on chlorhexidine. The product is intended for use in quality tap water and includes compounds to 'condition' the water, an agent to render the resulting solution isotonic and chlorhexidine for disinfection.

Example: OptimEyes.

This product, when used with high water content lenses, may cause adverse reactions (corneal and conjunctival staining and conjunctival injection) in a significant number of wearers.

## II.C.5 Hydrogen Peroxide

38

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### Chemical Disinfection: Hydrogen Peroxide

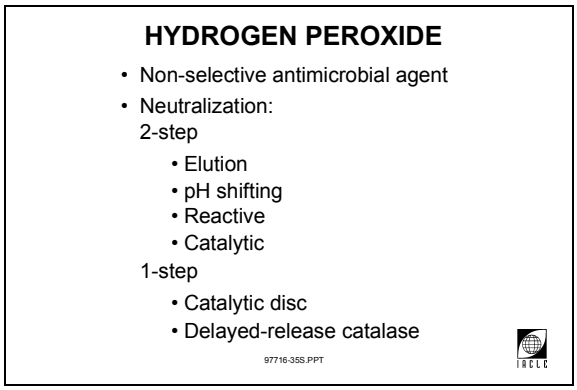
Hydrogen peroxide, along with thermal disinfection, is one of the earliest SCL disinfection methods. Its roles in medicine and oral hygiene (now largely abandoned) facilitated its acceptance as a useful lens care product. The need to eliminate residual peroxide from lenses was accepted from the beginning. However, the methods of achieving this have varied over time.

One of the principal attractions of hydrogen peroxide has always been the inherent acceptability of its decomposition products, namely water and oxygen.

Hydrogen peroxide:

- Produces free oxygen radicals which are very reactive and quickly bind to many cell components.
- Decomposes to water and oxygen. $H_2O_2 \Leftrightarrow 2H_2O + O_2$
- Requires neutralization.
- Can be formulated preservative-free.
- Can be supplied in one-step form.
- Must be stabilized.

39

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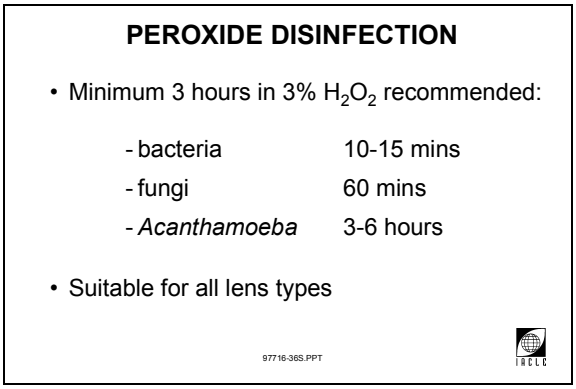
### Hydrogen Peroxide: Neutralization

Hydrogen peroxide is a non-selective antimicrobial agent normally used at 3% concentration (0.6% has also been used in a system on the basis that any 0.6% solution entering the eye unintentionally will cause less damage). When a second solution or step is required for neutralization, the system is called a 2-step system. A 1-step system requires the combination of both the disinfection and neutralization steps using either a catalytic disc, or a coated delayed-release catalytic neutralizing tablet.

40

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Initially, single or serial elution with normal saline was used for neutralization. This was followed by a pH-shifting approach using sodium bicarbonate. Bicarbonate raised the pH of the peroxide solution to levels at which the peroxide was relatively unstable. Decomposition, albeit slowly, followed.

Later, a stoichiometric (reactive) approach was taken using sodium thiosulphate, sodium sulphite or sodium pyruvate. The reaction that followed did not release oxygen.

More recently, catalytic methods have found favour and most current systems use either biological or metallic catalysts for neutralization. Catalytic neutralization liberates a significant volume of oxygen which must be vented safely from the lens case without the risk of microbial contamination of the case and contents.

**Hydrogen Peroxide: Use**

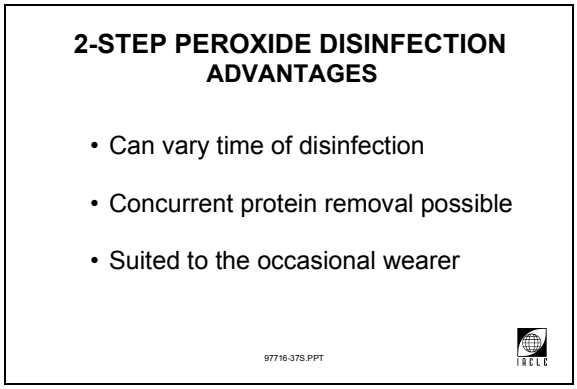
The time for peroxide to effectively inactivate bacteria, fungi and *Acanthamoeba* varies (see slide 40).

It is recommended that lenses should be soaked overnight or a minimum of six hours in 3% $H_2O_2$.

Claims have been made that no cleaning (rubbing /rinsing) is required when using $H_2O_2$ system. While the agitation caused by liberated oxygen may be somewhat beneficial to the 'cleaning' process the actual gains are small. Therefore, these claims should be rejected. The cleaning step prior to disinfection (any method or chemistry) is necessary.

It is important when using $H_2O_2$ lens care systems not to mix components of different brands as some contain pH and osmolality-adjusting agents required by their own system but not by others.

41

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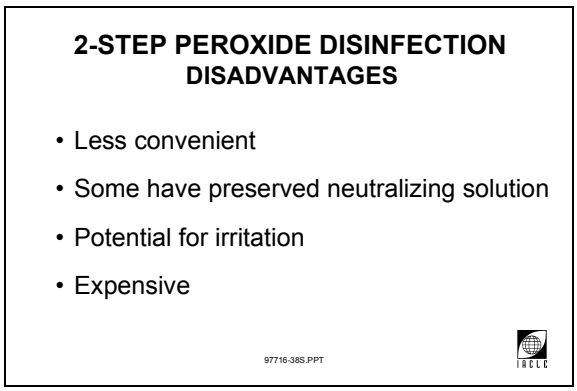
## 2-Step Hydrogen Peroxide Systems: Advantages

Some of the advantages of a 2-step system are summarized in the slide opposite. Enzymatic protein removers suitable for use in hydrogen peroxide (1 and 2-step systems) are also available. However, not all enzymatic protein removers are suitable for use in peroxide systems.

By not neutralizing the peroxide, lenses can be stored for extended periods of time (up to six months?). While high water ionic hydrogels may take some time to re-equilibrate to 'normal' conditions (i.e. regain their original parameters) any changes induced are reversible. Occasional wearers should be advised to store their lenses in unneutralized hydrogen peroxide. They should be advised against lens storage in neutralized peroxide or one-bottle chemical systems.

42

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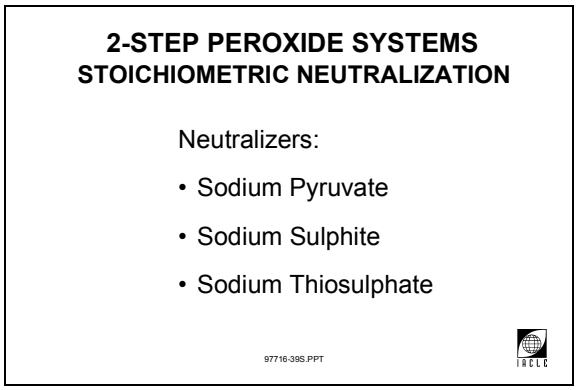


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## 2-Step Hydrogen Peroxide Systems: Stoichiometric (also called Reactive) Neutralization

The following chemicals neutralize hydrogen peroxide by a straightforward chemical reaction: (adapted from Stewart-Jones *et al.*, 1989):

- Sodium pyruvate.

  Sodium pyruvate is a naturally occurring compound which reacts with hydrogen peroxide to produce water, sodium acetate and carbon dioxide.

44

**2-STEP PEROXIDE SYSTEMS**
**STOICHIMETRIC NEUTRALIZATION**

- Longer neutralization/equilibration times required
- Vented lens case not required
- No 'activity' visible

97716-40S.PPT

5L397716-40

$NaC_3H_3O_3 + H_2O_2 \rightarrow NaC_2H_3O_2 + H_2O + CO_2$

The carbon dioxide gas is not liberated since it readily dissolves in the solution.

- Sodium sulphite.

  Sodium sulphite and peroxide produce sodium sulphate and water.

  $Na_2SO_3 + H_2O_2 \rightarrow Na_2SO_4 + H_2O$

- Sodium thiosulphate.

  When sodium thiosulphate and peroxide react they produce sodium tetrathionate and caustic soda (sodium hydroxide). The latter, which is highly deleterious to the cornea, is not produced in sufficient quantities to be problematic. In fact, sodium hydroxide and hydrochloric acid are regularly used in the production of lens care products and ocular pharmaceuticals to adjust pH on a custom basis.

  $2Na_2S_2O_3 + H_2O_2 \rightarrow Na_2S_4O_6 + 2NaOH$

45

**2-STEP PEROXIDE SYSTEMS**
**CATALYTIC NEUTRALIZATION**

Neutralizers:

- Catalytic disc in second lens case
- Catalase solution or tablet

97716-41S.PPT

5L397716-41

**2-Step Peroxide Systems: Catalytic Neutralization**

Peroxide systems using a catalytic disc and two or more steps have longer neutralization times. In such systems, soft lenses have adequate time in which to re-equilibrate with their environment and for their parameters to be restored.

For 2-step systems utilizing catalase in either tablet or solution form, neutralization and equilibration (lens parameter restoration) times of 10 - 15 minutes are generally adequate for low water content lenses. However, high water SCLs, especially if ionic, require longer times of up to one hour.

Neutralization times are not directly related to the rapidity of the chemistry. They are governed by the time taken for the peroxide already inside the lens to exit, under the influence of the osmotic

gradient generated by peroxide neutralization in the surrounding solution.

46

**1-STEP PEROXIDE DISINFECTION**
**ADVANTAGES**

- Convenient
- Preservative-free
- Concurrent protein removal now possible

97716-42S.PPT

5L397716-42

47

**1-STEP PEROXIDE DISINFECTION**
**DISADVANTAGES**

- Inflexible neutralization time
- $H_2O_2$ concentration decreases rapidly (3% to 1% in <10mins)
- Not effective against some fungi and Acanthamoeba sp.
- Catalytic disc needs regular replacement
- Potential for irritation
- Possible recontamination

97716-43S.PPT

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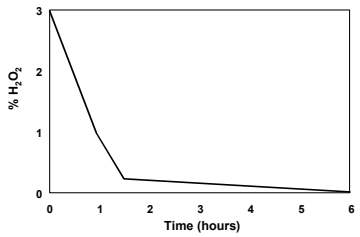
48

**PEROXIDE CONCENTRATION OVER TIME**
**1-STEP $H_2O_2$ WITH CATALYTIC DISC**

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## 1-Step Peroxide Systems

In systems using platinum-based catalytic discs, disc efficacy decreases over time as disc surfaces become contaminated by eye, tear, finger and LCP residues. Paradoxically, the poorer the performance of the catalyst, the greater the efficacy of disinfection, since neutralization occurs more slowly.

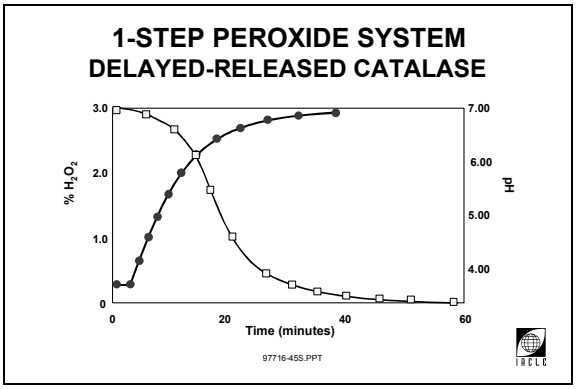
Any residual $H_2O_2$ left by a disinfection cycle can irritate some users. The peroxide level required to cause discomfort is subject to individual variation and depends on the source. If a solution is involved (pulse dose) the minimum required (95.45% probability) is 188ppm, while lens-borne peroxide (sustained release dose) requires 144ppm (data derived from Chalmers and McNally, 1988). Similar figures are quoted by Janoff (1990).

If patients experience irritation upon lens insertion, they should be advised to rinse their lenses prior to insertion. Such irritation is more likely to be caused by pH rather than peroxide (Harris *et al.*, 1988) because catalase-based systems have residual levels of the order of < 2 ppm and disc-based systems < 20 ppm (see Gyulai *et al.,* 1987) depending on the condition of the disc.

Once neutralization is complete, the remaining solution is unpreserved (and therefore unprotected). Viable organisms residing in any lens case biofilm, unkilled organisms or organisms introduced by opening the case after disinfection or because the case is poorly sealed, can lead to recontamination.

In systems using a catalytic disc, whenever $H_2O_2$ is in contact with the disc, the hydrogen peroxide concentration is decreasing. A significant time (approximately 4 - 6 hours) is required for most of the $H_2O_2$ to be neutralized. Exposure to the catalyst is aided by the process of diffusion through the solution

49

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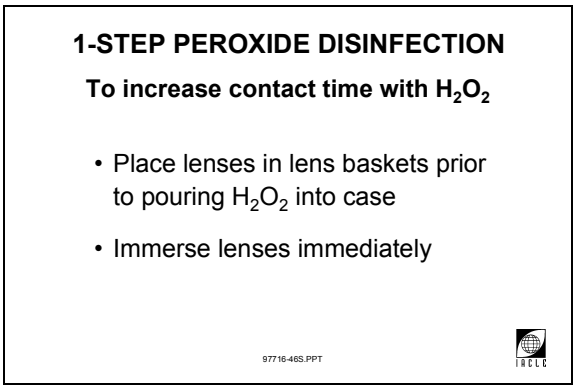


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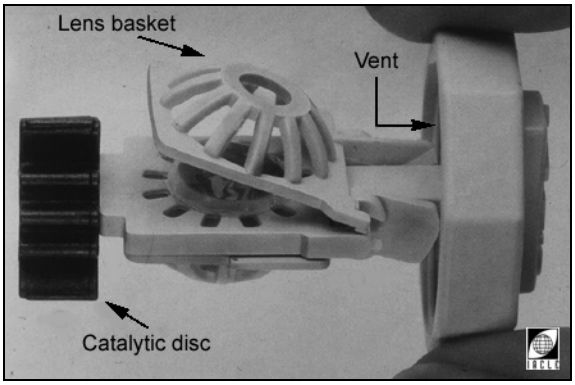
51



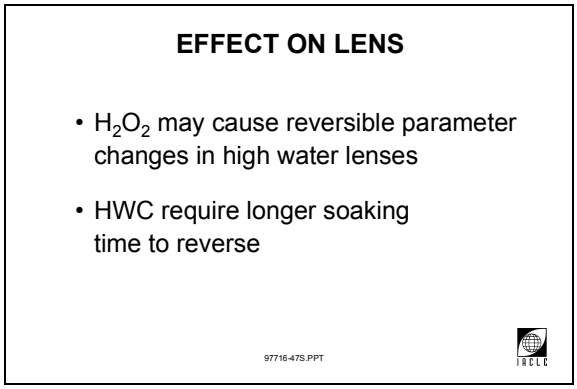

5L31546-92

and agitation by the bubbles of liberated oxygen.

Users of disc-based 1-step systems should be instructed to place their lenses in the lens baskets before pouring peroxide solution into the case. If users do not follow this directive, i.e. they fill the case first and then place the lenses in their baskets, disinfection in a $H_2O_2$ concentration <1% (slide 48) is being attempted since much of the peroxide is neutralized by exposure to the disc before the lenses are immersed. This is not as important in tablet-based 1-step systems because of the significant delay in catalase release (see slide 49).

A case design in which the catalytic disc is attached to the lens basket addresses this potential problem (slide 51).

52

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## Hydrogen Peroxide: Effect on Lens Parameters

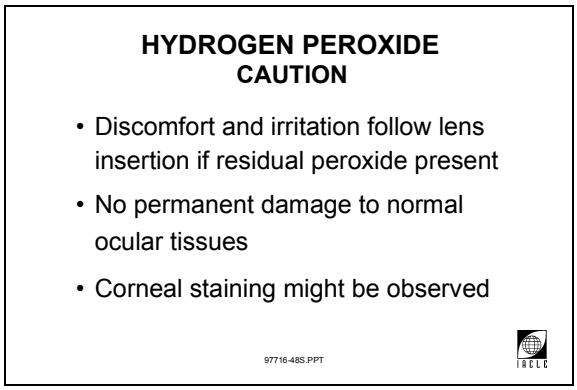
Any effects of a solution on lens parameters can be due to its osmolality, pH or chemistry or combinations of these.

Some 1-step systems are isotonic and of almost normal pH (e.g. AOSept, EasySept) while others are very hypotonic and of very low pH (e.g. OmniCare 1-Step, Oxysept 1-Step or UltraCare). In the latter system the delayed-release tablet contains a colour indicator to confirm neutralization and agents to adjust osmolality and pH to normal levels once the 'release' of tablet contents is complete (see slide 49).

The characteristics of a material also influence its behaviour. This is especially true of high water ionic hydrogel materials (FDA Group 4).

- $H_2O_2$ causes parameter and hydration changes (Harris *et al.,* 1989).
- High water content lenses require longer neutralization/soaking time to reverse effects of soaking in non-isotonic acidic solutions (Holden, 1990, Jones, 1993).

53




5L397716-48

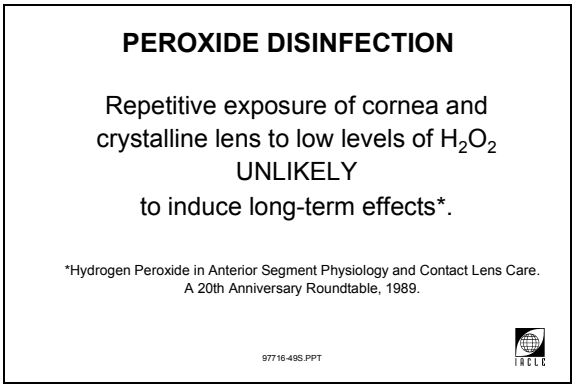
## Hydrogen Peroxide: General

Caution:

- Discomfort and irritation may result if lenses are inserted with either unneutralized hydrogen peroxide or > 150 ppm peroxide remaining in and on the lens.
- While peroxide exposure can be quite unpleasant, no permanent damage to normal ocular tissue has been reported (Grant, 1986).
- When an unneutralized lens is inserted, significant corneal staining results.

Ocular tissue is equipped with its own anti-oxidant defence mechanisms which are capable of addressing the problem of the anterior eye being directly exposed to hydrogen peroxide. The anterior eye has the following peroxidative enzymes

54




5L397716-49

(Chalmers *et al.,* 1989):

- Catalase (conjunctival and corneal epithelia).
- Superoxide dismutase (corneal epithelium).
- Glutathione peroxidase (corneal epithelium).

The internal eye also has these three mechanisms. However, it is unlikely that they would be called upon to deal with exogenous peroxide. Riley and Kast (1991) concluded that up to 680 ppm peroxide did not affect the endothelium or anterior chamber, provided the epithelium was intact. Further, it has been shown that the external eye systems are rapidly effective (< 1 minute) at neutralizing realistic (40 - 50 ppm) concentrations of hydrogen peroxide carried by soft contact lenses (Chalmers *et al.,* 1989).

A roundtable meeting convened in 1989 to discuss $H_2O_2$ and anterior segment physiology and contact lens care concluded that repetitive exposure of cornea and crystalline lens to low levels of exogenous $H_2O_2$ is unlikely to induce long-term effects (see Supplement to the CLAO Journal 16(1): Jan/Mar., 1990).

## II.C.6 Unconventional Disinfection Methods

55

**OTHER CLEANING/DISINFECTION METHODS**
**ULTRASONIC**

- Results not superior to conventional method
- Rub and rinse step still necessary
- Expensive

97716-50S.PPT

5L397716-50

56

5L31539-92

### Other Cleaning/Disinfection Methods

### Ultrasonic

A partial explanation of the poor efficacy of ultrasonic devices was presented by Fatt (1991). Fatt found that for ultrasound to be effective the interface between the irradiated 'solid' (the lens) and the immersion medium (saline) must be significant acoustically. The fact that the physical properties of a hydrogel lens and saline are 'so closely alike' means that little energy is released at the lens/saline interface. Therefore, it seems unlikely that current soft lens materials can be 'cleaned' ultrasonically.

Some devices could behave as microbial incubators rather than antimicrobial devices. Some of their temperature settings warm the solution, not sufficiently to kill micro-organisms but potentially increasing population growth rates.

Experience has shown that, as yet, there is no substitute for rubbing contact lenses with the fingers using a suitable lens care product.

Another uncommon device is the Aquasteril™ (from France). This ultrasonic device also has an ozone-generating UV source in the lid. Unfortunately, no attempt has been made to seal the hinged lid to the lens wells. This leaves them open to contamination after the disinfection cycle is complete.

57

**OTHER CLEANING/DISINFECTION METHODS**
**MICROWAVE** (Harris *et al*., 1990)

- Similar principle to heat/thermal disinfection
- Needs vented lens container
- Convenient and effective for large number of lenses simultaneously
- Effect of long-term repeated microwave irradiation on lens parameters unknown

97716-51S.PPT

5L397716-51

## II.C.7 In-Office Trial Set Disinfection

58

**IN-OFFICE HYDROGEL TRIAL LENS DISINFECTION**

(Callender *et al*., 1992)

- Inventory trial lenses should be disinfected at least once per month
- Thermal disinfection is safest
- If using chemical disinfection, vials and lenses should be cleaned periodically and solution changed regularly

97716-52S.PPT

5L397716-52

### In-Office Hydrogel Trial Lens Disinfection

The use of convenient one-bottle systems for trial lens storage is not supported by the data of a study (Callender *et al.,* 1992) which showed the highest level of contamination occurred when such sytems were employed. Heat, especially when used in conjunction with a preserved saline, was clearly superior to all other methods examined.

Note: Thermal disinfection is neither recommended, nor possible, with many high water content lenses. Storage, including long-term storage, of such lenses is possible in unneutralized hydrogen peroxide (preferably in a peroxide which is isotonic and of normal pH). However, trials with these lenses necessitate timely neutralization before use. The peroxide solution should be changed at least every six months and the case lids must be secured firmly. No metal should be in contact with lenses so stored as it may decompose the peroxide catalytically, leading to case rupture caused by excess pressure generated by liberated oxygen.

59

**IN-OFFICE HYDROGEL TRIAL LENS DISINFECTION**

**RECOMMENDATION**

- Use thermal disinfection for low water content
- Clean lenses with alcohol-based cleaner prior to storage
- Use unneutralized peroxide on high water lenses
- Use disposable lenses where possible

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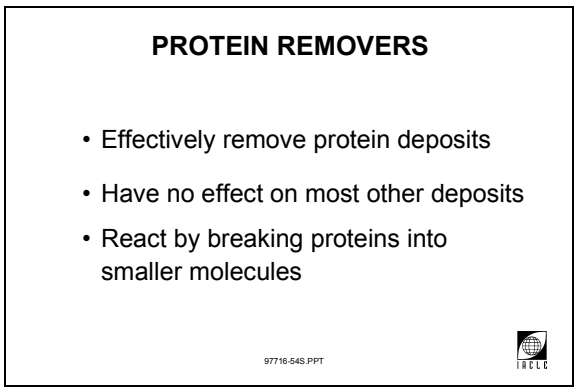
## II.D Protein Removers

60

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### Protein Removers

While most protein removers are based on enzymes, not all are enzymatic. Some are based on inorganic chemicals while others may be organic but not enzymatic.

- Enzymatic cleaners work by having substrate-specific enzymes (biochemical catayst) break down their target molecules, thereby facilitating their removal. For example proteases target proteins, lipases target lipids while amylases target polysaccharides.

  The enzymes work by breaking down their targets into smaller molecules. They cleave peptide bonds within the protein molecules, creating lower molecular weight, more soluble molecules which are more easily removed (Weinstock, 1989).

- Enzymes can also remove other types of deposits if they are incorporated in the protein deposits.

- Enzymes may also break bonds between the lens material and proteins (Fletcher *et al.,* 1994).

- Enzymatic cleaning does not replace the disinfection step.

Hydrogen peroxide is believed to be capable of breaking disulphide bonds in the protein lysozyme. Therefore, it was postulated that a combination of hydrogen peroxide and a proteolytic enzyme is potentially an effective protein 'treatment'. A study of this possibility found that, compared to a papain-based enzyme treatment it was true for light deposits only and papain was superior for heavy deposits (Larcabal *et al.,* 1989).

61

**PROTEIN REMOVER**
**GENERAL PROCEDURES**

- Used regularly, *after* the daily cleaner and rinsing step
- Lenses should be soaked in enzyme dissolved in solution/saline for 15mins to overnight, depending on manufacturer
- Lenses should be thoroughly rubbed and rinsed *again* afterwards

97716-55S.PPT

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## Protein Remover: General Procedures

The procedures usually followed for protein removal are presented in the slide opposite.

Because all *lens care* enzymes are 'foreign' proteins (non-human and not from the wearer), it is important to remove all traces of them from contact lenses before lens insertion. They all have the potential to induce an ocular hypersensitivity reaction in the user.

62

5L30948-92

Slide 62 shows some enzymatic protein removers.

63

**ENZYMATIC PROTEIN REMOVERS**

Contain one of the following:

- Papain
- Pancreatin
- Subtilisin A or B

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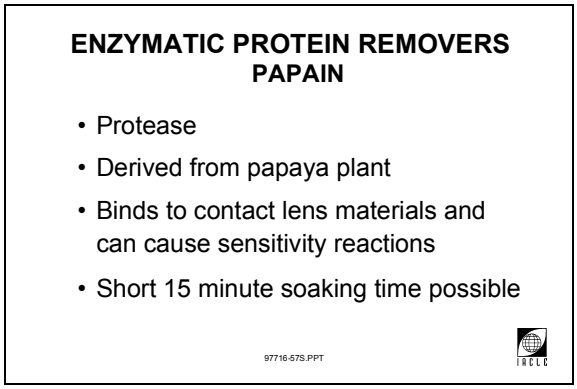
## Enzymatic Protein Removers

Most enzymatic protein removers currently available contain one of four enzymes listed opposite.

64

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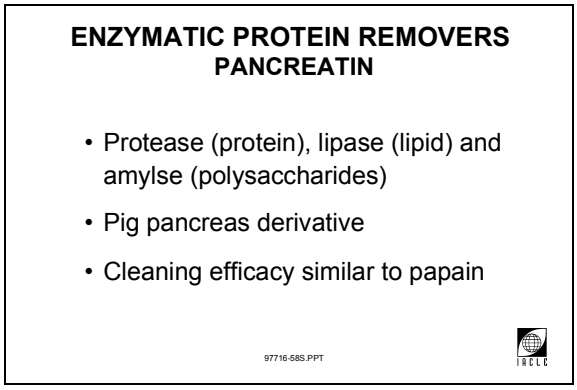
## Enzymatic Protein Removers: Papain

Papain**:**

- Is a protease, i.e. an enzyme that acts on proteins specifically.
- Is derived from the pawpaw/papaya plant (*Carica papaya)*.
- Preparations containing it usually have a slightly unpleasant odour due to the inclusion of cysteine (used as an enzyme stabilizer).
- Binds to soft contact lens materials and may cause sensitivity reactions. In an attempt to decrease the frequency of sensitivity reactions soaking time was reduced from two hours to just 15 minutes.

Examples: Allergan's Soflens Enzymatic Cleaner or Profree.

65

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## Enzymatic Protein Removers: Pancreatin

Unlike papain, pancreatin is an animal (porcine) derivative.

Pancreatin:

- Has three separate enzyme activities: Protease (protein), lipase (lipid) and amylase (polysaccharides and mucus-like (glycoproteins) debris).
- Derived from the pancreas of the pig.
- Unfortunately, the lipase and amylase enzymes do not seem to improve the performance of products containing pancreatin. The performance of such products is similar to papain or subtilisin-containing products (Begley

*et al.,* 1990) or even inferior on all but light deposits (Kurashige *et al.,* 1987).

Examples: Alcon Optizyme, Polyzym, Opti-Free Enzymatic Cleaner.

66

**ENZYMATIC PROTEIN REMOVERS**
**SUBTILISIN - A & B**

- Proteases
- Derived from Bacillus bacteria
- Low toxicity, used in food products
- Less specific binding characteristics
- May be more effective than papain

97716-59S.PPT

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**Enzymatic Protein Removers: Subtilisin A & B**

Subtilisin A (from *Bacillus subtilis* ) and Subtilisin B (from *Bacillus lichenformis* ).

- More effective than papain and pancreatin due to less specific binding characteristics. These enable them to break a wider variety of protein bonds.
- Subtilisin A is formulated specifically for use in hydrogen peroxide lens care systems.
- Subtilisin B is formulated for use in conventional chemical and thermal systems.
- In comparative studies, all enzyme systems (papain, pancreatin, subtilisin A & B) performed similarly with one (subtilisin B) almost reaching a statistically superior performance (Begley *et al.,* 1990). The thermal formulation of subtilisin B was not tested.

Examples: B&L Sensitive Eyes Thermal Protein Removal Tablets, Sensitive Eyes Protein Removal Tablets (Subtilisin B), Allergan Ultrazyme (Subtilisin A), PBH Softmate Enzyme Plus.

## II.E Re-Wetting/Lubricating Drops

67

**RE-WETTING/LUBRICATING DROPS**

Used for:

- Alleviating symptoms of dryness/ discomfort
- Flushing irritating particles from eye and lens
- Rehydrating lenses

97716-60S.PPT

5L397716-60

68

5L31692-91

69

**RE-WETTING/LUBRICATING DROPS**

Useful for:

- Marginal dry eye patients
- A dry environment or windy conditions
- Tired eyes
- Alleviating allergy symptoms

97716-61S.PPT

5L397716-61

### Re-Wetting/Lubricating/Comfort Drops

Dryness and discomfort can be caused by abnormalities of the tear film and lowered relative humidity. Relative humidity can be influenced by climate and air conditioning.

Any decrease in the lubricity of the tear film has the potential to decrease ocular comfort especially in contact lens wearers. Further, tear film abnormalities and/or abnormal amounts of tear film 'drying' on the lens surfaces have the potential to increase lens deposition. Additionally, lowering the level of lens hydration can adversely affect the Dk/*t* of contact lenses (Paugh, 1992).

In the interests of solution contamination control, and possible cross infection of the eyes, it is important to caution the patient not to touch the dispensing nozzle (jet) to the lids, lashes or external eye.

Re-wetting/lubricating drops should *not* be used prior to soft contact lens removal because they may make removal more difficult. Some are hypertonic which can tighten the lens fit and all contain surfactants which make the lens 'slippery'. The latter effect can also be exaggerated by the use of viscosity-enhancing agents which are also common in such products.

## III Lens Wear Categories and Care Regimens

70

**SCL CARE AND MAINTENANCE**
**OCCASIONAL & INFREQUENT WEARERS**

Storage

- Lenses should be stored in disinfecting solution when not in use

97716-62S.PPT

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71

**SCL CARE AND MAINTENANCE**
**OCCASIONAL WEARERS**

**UNSUITABLE Long-Term Storage:**

- Multi-purpose solution (low concentration of preservative)
- 1-step peroxide (concentration of peroxide decreases rapidly, no preservation)

97716-63S.PPT

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72

**SCL CARE AND MAINTENANCE**
**OCCASIONAL & INFREQUENT WEARERS**

- Clean and disinfect lenses again prior to use
- Replace the storage solution at least every week when lenses not worn
- Use preserved saline for rinsing (sensitivity problem is unlikely if only used for rinsing)

97716-64S.PPT

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73

**SCL CARE AND MAINTENANCE**
**OCCASIONAL & INFREQUENT WEARERS**
**LENS CARE REQUIREMENTS**

- Surfactant cleaner is a must
- Select appropriate disinfection system
- Protein removal when needed

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### Care Regimen Guidelines for Occasional and Infrequent SCL Wearers: Storage

For regular wearers this will involve overnight storage (approximately 8 - 10 hours), and for occasional wearers storage for days (>24 hours).

Stronger solutions increase adsorption by the lens material. However, solutions containing weak preservatives increase the risk of lens contamination during long-term (>7 days) storage.

Multi-purpose solutions and 1-step peroxide systems are unsuitable to long-term contact lens storage.

If a cold chemical system is used, the solution should be replaced weekly.

The requirements for lens care are summarized in slide 73.

The frequency of protein removal should be based on the number of times the lenses are worn and the frequency of wear. A factor in protein denaturation is the age of the protein involved. If lens wear is infrequent, it is probable that a recommendation to remove protein every five lens uses may be prudent.

74

**CARE AND MAINTENANCE**
**OCCASIONAL & INFREQUENT WEARERS**
**HEAT/THERMAL DISINFECTION**

- Low water content lenses
- Lens storage case is airtight and sealed properly after disinfection
- Infrequent use will not damage lenses
- Clean and disinfect prior to and after each use

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## Care Regimen Guidelines for Occasional and Infrequent Wearers

Preserved or unpreserved saline can be used. If preserved saline is used, the lenses can be stored in the preserved solution.

However, if unpreserved saline is used, the risks of contamination are much greater once the bottle is opened and has been in use for a few days.

75

**CARE AND MAINTENANCE**
**OCCASIONAL & INFREQUENT WEARERS**

One-Step Hydrogen Peroxide:

- Disinfection and neutralization period depends on brand
- Platinum disc neutralizes hydrogen peroxide solution into preserved saline
- Air vent allows release of gas

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76

**CARE AND MAINTENANCE**
**OCCASIONAL & INFREQUENT WEARERS**

Two-Step Hydrogen Peroxide:

- Store lens in 3% peroxide when not in use
- Neutralize before wear
- Better system if neutralizer unpreserved

97716-68S.PPT

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## Care Regimen Guidelines for Occasional and Infrequent Wearers

### One-Step Hydrogen Peroxide

While occasional and infrequent wearers are able to disinfect their lenses for the maximum period recommended, one-step systems present potential problems in some situations.

One-step peroxide systems neutralize their solutions using either a platinum disc or delayed-release catalase tablet, a process requiring up to six hours. Their breakdown product is basically unpreserved saline (the liberated oxygen is ventilated). Unpreserved saline is a solution entirely *unsuited* to long-term lens storage.

A possible solution is to have a discless cup (for disc-based systems) or to withhold the delayed-release neutralizing tablet (tablet-based systems). In this way the lenses are stored in unneutralized hydrogen peroxide, a safe procedure. The disadvantage of such storage is the need for neutralization immediately prior to lens usage. This presupposes a knowledge of when the lenses are required.
It is also important to remind patients that vented storage cases are not ideal for lens carrying because of their potential for leakage and contamination, especially if they topple over.

### Two-Step Hydrogen Peroxide

Two-step hydrogen peroxide systems provide a better long-term storage

alternative since the lenses can be stored in a 3% hydrogen peroxide solution between lens uses.

Neutralization is performed prior to lens wear. Longer soaking times are required for lenses with higher water content. A preservative-free neutralizer is ideal. It is important to realize that neutralization is not just a process involving the solution in which the lens is stored. For neutralization to be complete, the peroxide content of the lens must also be converted to compatible by-products. This takes longer because of diffusion into, and out of, the lens.

## IV Lens Case Care

77

**CARE FOR LENS CASES**

- Scrub with a new toothbrush and CL cleaning solution weekly
- Rinse with saline or disinfecting solution
- Air dry upside-down
- Replace regularly

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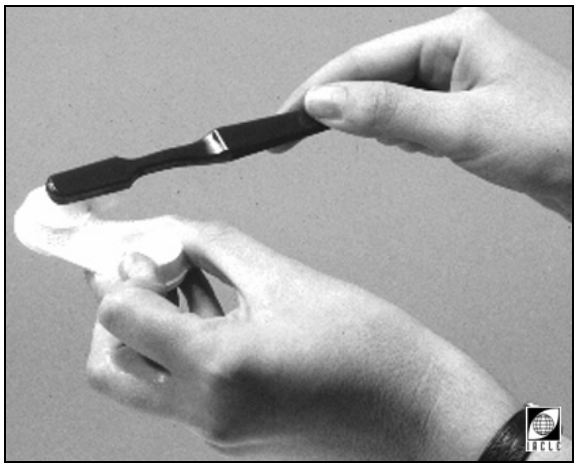

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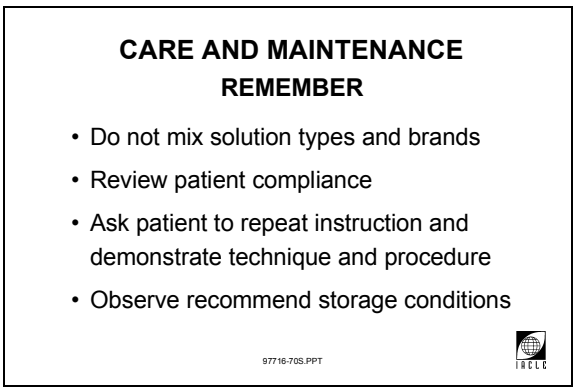
## V Summary

79

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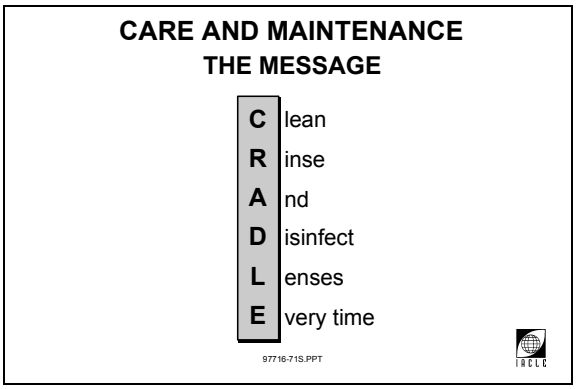


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# Tutorial 5.3

(2 Hour)

# Review of Soft Contact Lens Care Systems

# Tutorial

## Session 1:

Examination of a comprehensive array of soft contact lens care products

## Session 2:

A discussion of soft contact lens care products, their components and functions

## Tutorial Session 1:

A comprehensive array of soft contact lens care products needs to be assembled for the student group to examine and familiarize themselves with. It is suggested that all products readily available in the local lens care market be included. A list of lens care products from the major global manufacturers is provided below. Many countries also have indigenous manufacturers and/or local variations of major products. The product list should be tailored to match the local lens care market. A starting point for such a product list is also provided.

## SOFT CONTACT LENS CARE PRODUCTS

For each product the following aspects/features should be ascertained by the students.

**PRODUCT NAME:**_____

(a) Manufacturer _____

(b) Intended purpose _____

(c) Preservative/disinfectant(s) & concentration(s) _____

(d) Other components & their concentrations _____

(e) Procedures for use _____

(f) 'Discard-after' period _____

**PRODUCTS LIST** (adapt as appropriate to local circumstances and market place)

**Products from major global manufacturers ( in ALPHABETICAL order)**

**ALCON:**

Adapettes
Clerz II Lubricating & Rewetting Drops
Flexcare
MiraSept Disinfecting Solution
MiraSept Rinsing & Neutralizing Solution
Opti-Clean
Opti-Free
Opti-Free Enzymatic Cleaner
Opti-Free Express
Opti-Free Rewetting Drops
Opti-One Multi-Purpose Solution
Opti-One Rewetting Drops
Opti-Tears
Opti-Zyme Enzymatic Cleaner
Pliagel

Polyclens II (Opti-Clean II)
Polyzym
Preflex
Saline for Sensitive Eyes
Supra-Clens Daily Protein Remover
Unisol/Unisol 4/Unisol Plus

**ALLERGAN:**

Barnes Hind Saline Solution
Complete Brand Lubricating & Rewetting Drops
Complete Brand Multi-Purpose Solution
Complete Enzymatic Cleaner
Consept 1
Consept 2
Enzymatic Contact Lens Cleaner
Hydrocare Cleaning and Disinfecting Solution
LC 65 Daily Cleaner
Lens Plus
Lens Plus Daily Cleaner
Lens Plus Rewetting Drops
Oxysept 1
Oxysept 2
Soft Mate Comfort Drops for Sensitive Eyes
Soft Mate Hands Off Daily Cleaner
Ultracare (OmniCare 1-Step) (Oxysept 1-Step)
Ultrazyme Enzymatic Cleaner

**BAUSCH & LOMB:**

EasySept
ReNu Effervescent Enzymatic Cleaner
ReNu MultiPlus Disinfecting Solution
ReNu Multi-Purpose Disinfecting Solution
ReNu One-Step Enzymatic Cleaner
ReNu Rewetting Drops
Sensitive Eyes Daily Cleaner
Sensitive Eyes Drops
Sensitive Eyes Enzymatic Cleaner
Sensitive Eyes Plus Saline Solution
Sensitive Eyes Saline Solution

Sensitive Eyes Saline Solution
Sensitive Eyes Sterile Saline Spray
Sensitive Saline/Cleaning Solution
Sterile Daily Cleaner
Sterile Preserved Saline

**CIBA VISION:**

AODisc Catalytic Disc
AOSept Disinfection/Neutralization Solution
CIBA Vision Cleaner
CIBA Vision Lens Drops
CIBA Vision Saline
Clerz
InstaCARE (Quick-Care) Finishing Solution
InstaCARE (Quick-Care) Starting Solution
Miraflow (Miraflow Extra-Strength Cleaner)
Pure Eyes Cleaner/Rinse
Pure Eyes Disinfectant/Soaking Solution
SoftWear Saline
SOLO-care Soft (Solo-care Multi-Purpose Solution)
Unizyme Enzymatic Cleaner

**LOCAL VARIATIONS OF MAJOR PRODUCTS:**

**PRODUCTS FROM INDIGENOUS MANUFACTURERS:**

# Tutorial Session 2:

The educator should lead a group discussion on the practical and formulations aspects of soft contact lens care products. Particular attention should be paid to the following:

- Preservative *versus* preservative-free solution formulations and packaging.
- Classes of disinfectants.
- Classes of preservatives.
- Hydrogen peroxide neutralization chemistry.
- Recommended disinfection times of the various systems.
- Expiry dates.
- Discard-after time periods.
- Lens case designs.
- Comparing and contrasting the leading systems in local markets.

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# Unit 5.4

(3 Hours)

**Lecture 5.4:** Care and Maintenance of RGP Lenses

**Tutorial 5.4:** Review of RGP Contact Lens Care Systems

# Course Overview

### Lecture 5.4: Care & Maintenance of Rigid Gas Permeable Contact Lenses

I. Solutions: Cleaning, Disinfection, Wetting (conditioning) and Re-wetting.
II. Trial Lens Disinfection.

### Tutorial 5.4: Review of RGP Contact Lens Care Systems

- A quiz and discussion about the components of various RGP contact lens care systems

# Lecture 5.4

(1 Hour)

# Care and Maintenance of RGP Lenses

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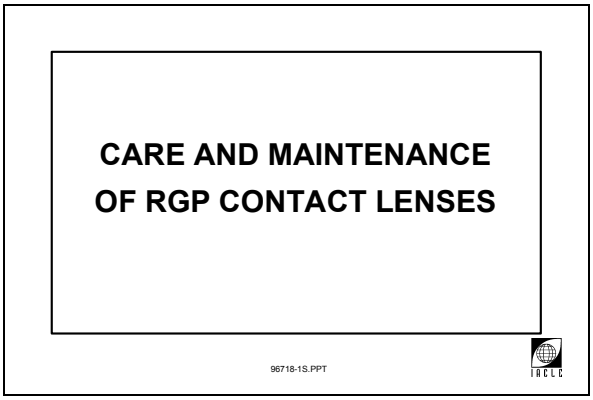
## I RGP Lens Care and Maintenance: Introduction

1

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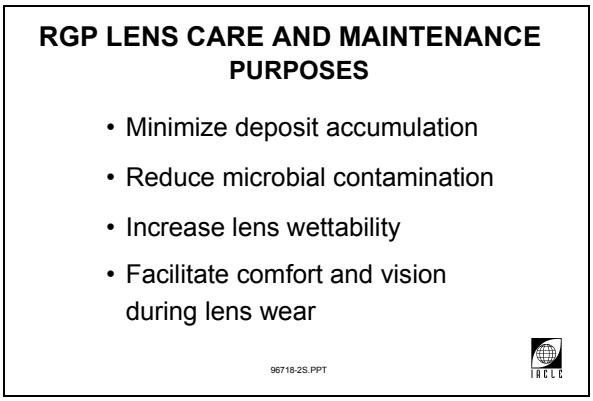
### Care and Maintenance of RGP Contact Lens

The care and maintenance of RGP lenses is only slightly different from that of SCLs. One difference is that while SCL disinfecting solutions primarily have a single role, RGP disinfecting solutions are used for both disinfection and enhancement of lens wettability.

2

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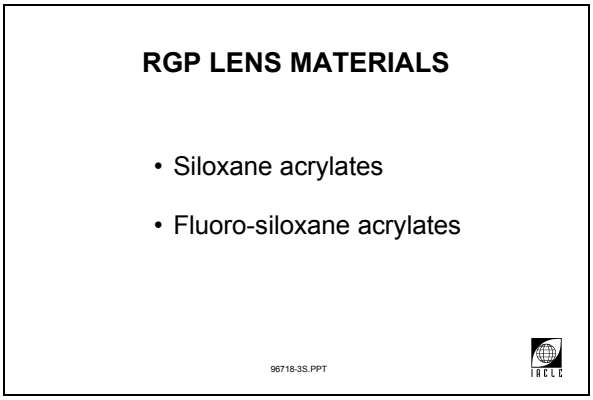


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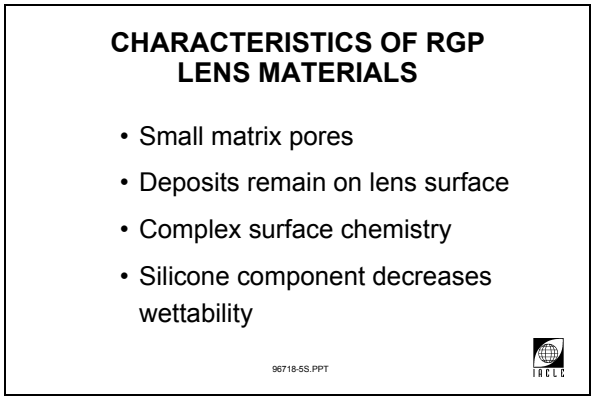
### RGP materials

The characteristics of these materials are very different from those of SCLs. The materials therefore require different care and maintenance products. However the care and maintenance procedures themselves differ little.

Unless advice to the contrary is provided by the manufacturer, lens care products intended for one type of contact lens should *not* be used on the other.

4

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**Hydrophobic Lens Surfaces:**

- Components of RGP lens materials used to enhance oxygen permeability (especially siloxanes) can also result in a less wettable or even hydrophobic surface.
- The reduced wettability of a lens surface decreases the lubricity of the tear film. This can increase the mechanical effects of the lens on the lids.
- A hydrophobic surface increases lens deposits. The surface attracts lipids, proteins and other organic compounds from the tears as well as tear film contaminants. Surface drying may increase the deposition rate of these contaminants.
- Sometimes the lens surface is treated during manufacture to improve its characteristics.

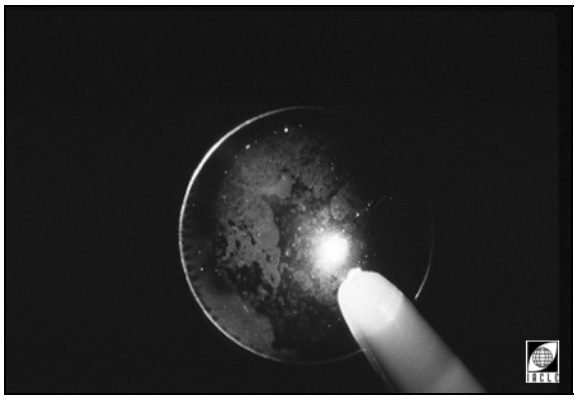
Additional characteristics of RGP materials include:

- Small matrix pores (at the molecular level).

  Since deposits cannot penetrate the lens matrix, they remain on the lens surface.
- Complex surface chemistry which can be altered during the manufacturing process. For example, exposure to inappropriate chemicals or excessive polishing during manufacture (resulting in local heat generation) can affect surface wettability and other surface properties.

## II Deposits

5



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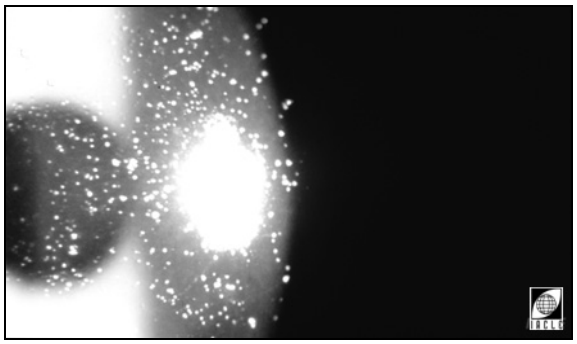
### RGP Materials: Deposits

RGP materials containing:

- Siloxane are more prone to protein deposits.
- Fluorine are more susceptible to lipid coating.

6



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### RGP Deposits: Appearance

Slide 6 is an example of lipid deposits on a lens surface. This appearance has been described as 'pearlescent' or 'soft and shiny' (Sulaiman and Cornish, 1989)

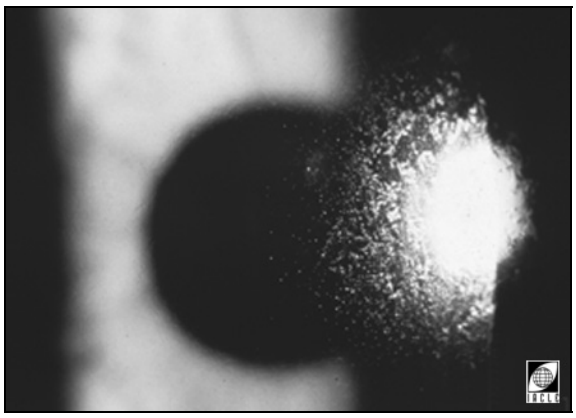
In addition to the spotty appearance, a film may also be present. These deposits usually build upon a non-wetting area on the lens surface.

The deposits can produce an irregular, raised surface which leads to a less wettable surface and a shorter tear break up time (TBUT).

They are usually easy to remove from the lens surface by rubbing (with a surfactant cleaner). If extensive, an alcohol-based surfactant cleaner may prove to be more effective.

Generally, patients are asymptomatic and comfort remains unaffected.

7



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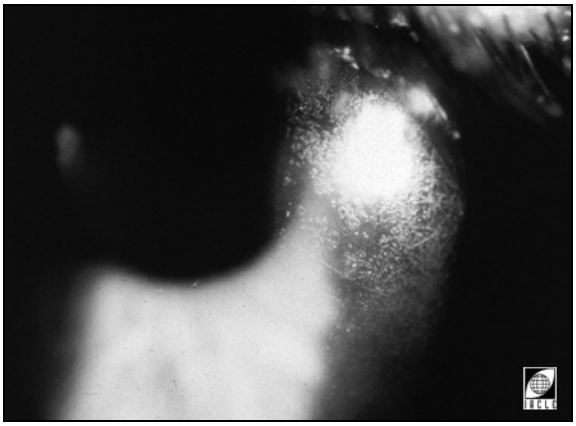
The deposit on an RGP shown in slide 7 is denatured protein which is also sometimes described as plaque. It:

- Has a hard matte appearance and will invariably decrease wettability.
- Can be difficult to remove. Use of a cleaning pad or even lens polishing compound may be required.
- Is likely to adversely affect lens comfort and may cause CLPC and/or corneal staining.

8

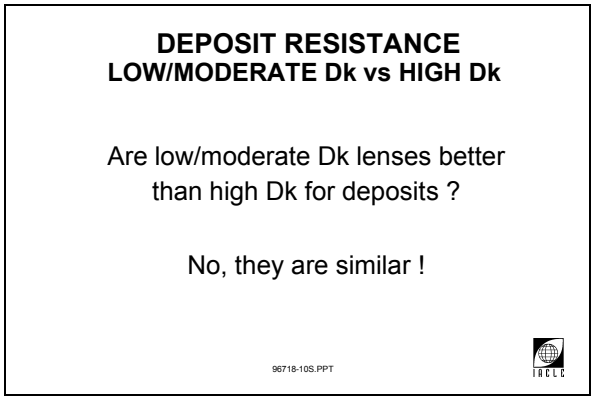


5L51648-91

As can be seen in slide 8, the lens surface deposits (visible after the tear film breaks up) exhibit a granular appearance. It is recommended that an RGP lens with this type of deposit be replaced annually to prevent the possible development of upper eyelid problems.

This deposit can be removed by laboratory polishing but it is preferable to replace the lenses before this type and amount of deposit develops.

9

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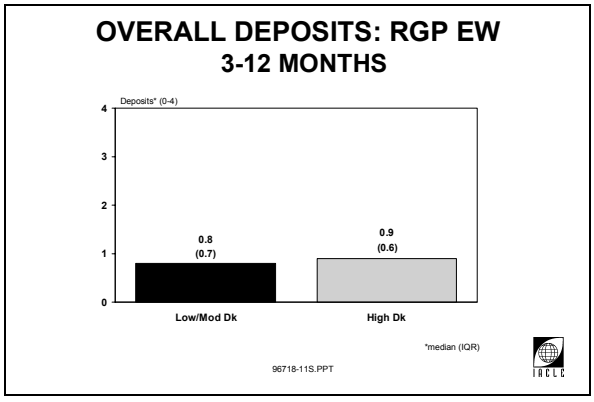


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## Which RGP Materials?

Frequently, practitioners choose low Dk over high Dk RGP materials despite the benefits of higher oxygen transmissibility. It is claimed that high Dk RGP lenses are more susceptible to lens surface deposits than their low to moderate Dk counterparts.

A study comparing RGP materials with low, moderate and high Dks found that when the lenses were produced by the same manufacturer, the amount of deposits was similar for low and high Dk lenses for up to one year of wear.

The rate of increase of deposits with lens wear in low and high Dk lenses was found to be similar.

When RGP lenses are used for extended wear, there are no clinically significant differences in the level of deposits between low/moderate Dk lenses and high Dk lenses. This finding also holds true for daily wear (provided lenses are cleaned daily, as recommended, rather than weekly).

In general, deposits can be controlled by the care regimen.

## III RGP Lens Care: Product Categories

11

5L596718-17

### RGP Lens Care: Product Categories

There are two forms of cleaners: daily surfactant and protein removers (tablet or liquid form).

RGP disinfecting/soaking solutions, sometimes referred to as conditioning solutions, can be classified as multipurpose because they fulfill the functions of disinfection, soaking and wetting.

Lubricants are designed to be instilled in the eye while the lenses are being worn. These are designed to re-wet and rehydrate the lenses *in situ.*

## III.A RGP Lens Care: Cleaning

12

**RGP LENS CLEANING**

- Daily surfactant
- Enzyme
- Polish (as necessary)
- Cleaning pad ?

96718-18S.PPT

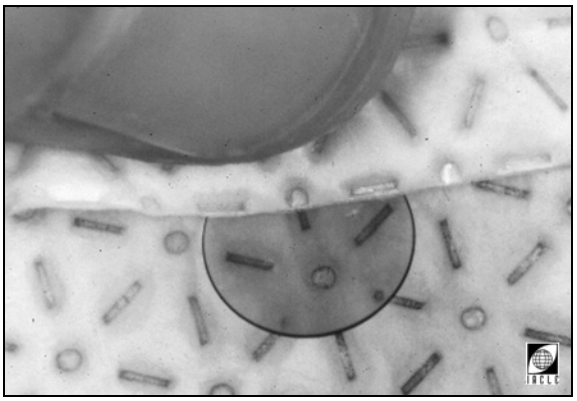
5L596718-18

### Cleaning RGP Contact Lenses

Daily surfactant cleaners for RGP lenses are similar to their SCL counterparts. An alcohol-based cleaner is well suited to fluoro-siloxane lenses which tend to acquire lipid deposits.

Patients should be cautioned against soaking RGP lenses in alcohol-based cleaners. Further, they should be advised to rinse their lenses thoroughly immediately after using such cleaners because they have been shown to alter lens parameters if allowed to remain in contact with the lenses (Lowther, 1987).

13



5L51552-91

While enzyme cleaners (tablet or liquid form) are recommended for protein removal in deposit-prone wearers, their use in other wearers is worth considering as a prophylactic measure. The effectiveness of an enzymatic cleaner on RGP lenses is subject to significant individual variation.

Surface polishing can be done as required. This may be necessary for lenses over 12-18 months old (i.e. lenses at or near the end of their service life).

A cleaning pad may be effective in removing some deposits from RGP lenses (slide 13).

14

**RGP LENS CLEANING**
**TECHNIQUE**

Avoid:

- Vigorous rubbing
- Excessive pressure on the lens
- Prolonged cleaning with mildly abrasive cleaners

96718-19S.PPT

5L596718-19

### RGP Cleaning Technique

RGP lens materials are softer and more flexible than PMMA and consequently should be handled more carefully.

Aggressive cleaning may damage or scratch the lenses over time, and in some cases, even change their power and/or decrease their thickness These outcomes are more likely when a mildly 'abrasive' cleaner (i.e. one containing particulate matter) is used.

15

**RGP LENS CLEANING**
**RECOMMENDED TECHNIQUE**

- Place lens in the palm of the hand
- Rub lens with finger for minimum of 10 seconds
- Rinse with saline or tap water approved for drinking

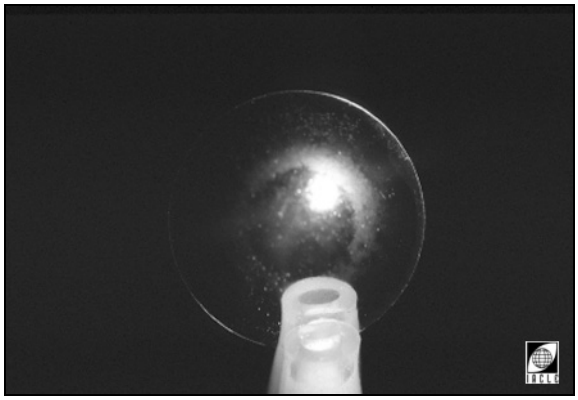
96718-20S.PPT

5L596718-20

Tap water has no place in an SCL cleaning regimen and should be used with extreme caution on RGP lenses. Even then, such water must be of high quality and approved for human consumption. Regardless of water quality, the final lens rinse should be with the *soaking/storage* solution normally used with contact lenses.

Cleaning the lens between the thumb and forefinger is not recommended as this technique increases the likelihood of lens breakage or distortion.

16

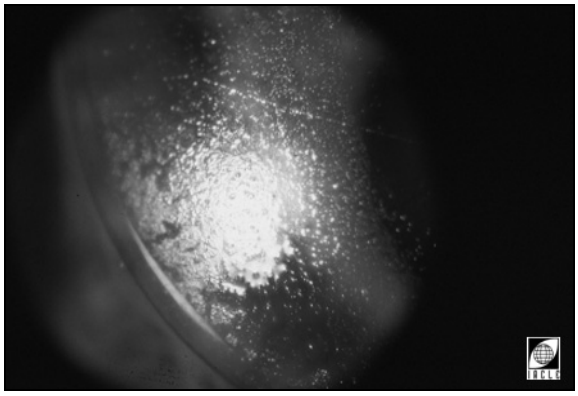


5L50170-93

Lenses with medium to high plus Rxs also present a problem in that it is often difficult to clean the space above the first front curve junction, adequately because of the 'bridging' that occurs when the finger or palm passes over the area. A 'ring' deposit results (see slide 16).

When giving cleaning instructions it is important to emphasize the need to roll and rock the lens-manipulating finger, while rubbing backwards and forwards and left to right to ensure the lens periphery is also cleaned. Failure to manipulate the lens correctly will result in inadequate cleaning of the peripheral third of the lens.

17



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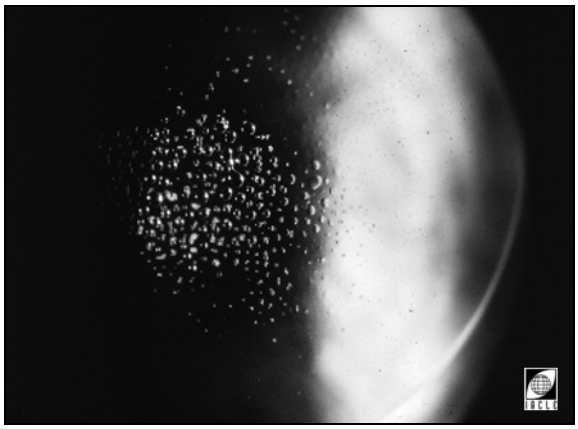

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**RGP Care and Maintenance: Aerosols**

*Caution*: When using an aerosol saline for rinsing, the propellant can create small bubbles in the saline dispensed. These may cause 'dimple veiling' if the lens is applied to the eye immediately after rinsing. Dimple veiling may result in the patient complaining of blurred vision.

## III.B RGP Lens Care: Disinfection

19

**RGP LENS CARE & MAINTENANCE**
**DISINFECTION**

- Micro-organism can attatch to deposits
- Use chemical disinfection systems
- Soaking time 4 hours to overnight or as recommended
- Preservatives incorporated

96718-21S.PPT

5L596718-21

### RGP Care and Maintenance: Disinfection

- Although micro-organisms cannot readily attach to RGP lens surfaces, they can attach to the deposits formed on the lens surfaces.
- Only chemical systems should be used to disinfect RGP lenses. RGP materials should not be thermally disinfected as this can cause warpage.
- Soaking time is usually four hours to overnight, or as recommended by the manufacturer.
- Preservatives used include: thimerosal, phenylmercuric nitrate, benzalkonium chloride, chlorhexidine, poly(aminopropyl biguanide) and polyquaternium-1.

Even though hydrogen peroxide is suitable for all types of contact lenses, it is not normally used on RGP lenses. One reason is the lack of any significant wetting function. Therefore, hydrogen peroxide disinfection of RGP lenses would require the addition of a wetting step after disinfection. The simplicity and efficacy of the RGP care systems available has resulted in almost no peroxide system usage on RGPs.

Unlike SCLs, peroxide systems have been shown not to have any significant effect on RGP parameter stability (Picolo *et al.,* 1990, Boltz *et al.,* 1993*).*

20

**RGP LENS WETTING & SOAKING SOLUTIONS**

- Also known as *conditioning* solutions
- Functions - disinfection
  - wetting
  - storage

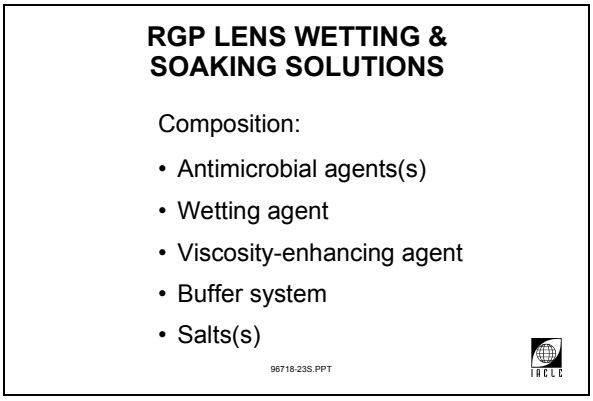
96718-22S.PPT

5L596718-22

### RGP Care and Maintenance: Wetting and Soaking

If RGP lenses are stored dry, parameters such as the back optic zone radius (BOZR) will invariably flatten and the lens surfaces may not wet optimally. It takes some time after re-immersion in a soaking/storage solution for the lens parameters and surface properties to be restored. Wet storage also improves initial 'on-eye' comfort and greatly assists microbial control of lens storage conditions. It is therefore better for

21

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regular RGP lens wearers to wet-store their lenses. It is logical to combine the essential disinfection step with a procedure that enhances wettability. Solutions which combine the disinfecting, wetting and soaking functions are sometimes called *conditioning* solutions.

RGP wetting and soaking solutions contain:

- Antimicrobial agent(s) (i.e. disinfectant) to disinfect the lenses and to preserve the solution after initial opening.
- Wetting agent(s) to improve lens wettability.
- Viscosity-enhancing agent(s) to 'thicken' the formulation.
- Buffer system to adjust and maintain solution pH.
- Salt(s) to adjust solution osmolality (usually to be isotonic with the tears because they come into contact with the eye).

Dry storage of RGP trial set lenses is quite common however, because of the need to replace storage vial solutions regularly.

## III.C RGP Lens Care: Wetting

22

**RGP LENS CARE & MAINTENANCE**
**WETTING AGENT**

Improve the wetting characteristics of the lens surface:

- Convert hydrophobic surface to hydrophilic
- Assist tear film to spread more easily and evenly on lens surface
- Increase comfort on insertion

96718-24S.PPT

5L596718-24

### RGP Care and Maintenance: Wetting Function

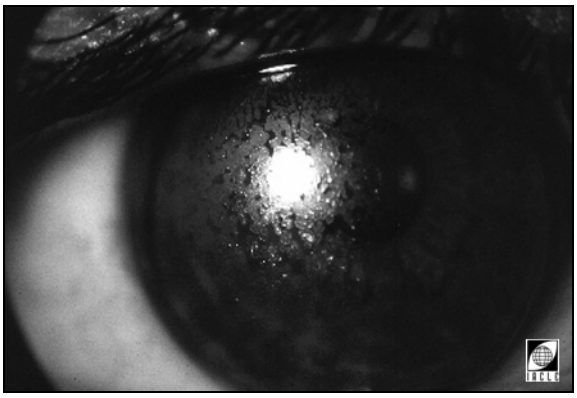
While less common now, separate wetting solutions are available. The function of a wetting solution are listed opposite.

Better wetting results in better vision (better optical quality due to a more regular tear film) and greater comfort (an intact tear film is more lubricious).

Saliva must never be used to wet contact lenses of any description because of its microflora and fauna.

Examples of wetting agents include: poly(vinyl alcohol), poly(vinyl pyrrolidone), Polysorbate. Interestingly, both compounds are also used in the formulations of various SCL polymers.

23



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### RGP Contact Lenses: Non-Wetting

Slide 23 shows a non-wetting RGP lens surface.

Failure of RGP contact lenses to wet may be due to:

- Deposits.
- The manufacturing process.

  Inappropriate manufacturing procedures may 'burn' the surface of the lens resulting in areas which fail to wet. These areas may be extensive or localized.
- Polishing compounds.

  Residual polishing compound may lead to local areas of hydrophobicity. Further, the use of inappropriate polishing compounds such as the domestic polishing suspension, Silvo, can alter the surface properties of a lens. While used commonly on PMMA lenses Silvo is not recommended for use on any RGP materials because it contains ammonia which may be absorbed into the material and leach out when the lens is worn, causing discomfort.
- Surface contamination.

24

**RGP LENSES: NON-WETTING**

Non-wetting areas can be due to:

- Deposits
- Manufacturing process
- Polishing compounds
- Surface contamination

96718-26S.PPT

5L496718-26

Surface contaminants include: eye make-up, hand lotion, hairspray, oils, soaps, finger grease, etc.

## III.D RGP Lens Care: Rinsing

25

**RGP LENS CARE & MAINTENANCE**

- Rinsing Post-disinfection/soaking usually not necessary before insertion
- Blurring on insertion - change to a less viscous solution
- Stinging on insertion - change solution

96718-27S.PPT

5L596718-27

26

**RGP MULTI-PURPOSE SOLUTIONS**

- One-bottle system (OBS)
- Combination of cleaning, disinfecting and soaking functions
- Convenient

96718-28S.PPT

5L596718-28

### RGP Care and Maintenance: Rinsing

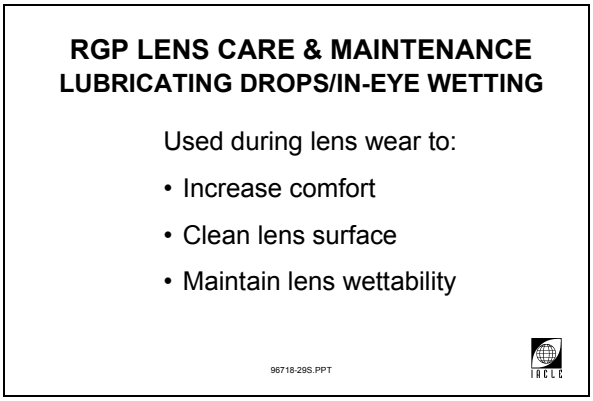
Generally, RGP lenses can be inserted directly into the eye after soaking in appropriate wetting/soaking solutions. If patients experience blurring due to the viscosity of the solution, or stinging on lens insertion, it may be necessary to change to a less viscous solution or one with a different chemical basis. Rinsing with saline is not recommended as it will decrease surface wetting.

The development of RGP all-purpose/multi-purpose solutions is a simplification of RGP lens care. These solutions are similar in concept to SCL multi-purpose solutions, and combine the cleaning, disinfecting and soaking functions. Such convenient one-bottle combination solutions are sometimes referred to as one-bottle systems (OBS).

Examples include: Allergan Total, Boston Simplicity, CIBA SOLO-care-Hard.

## III.E RGP Lens Care: Lubricating Drops

27

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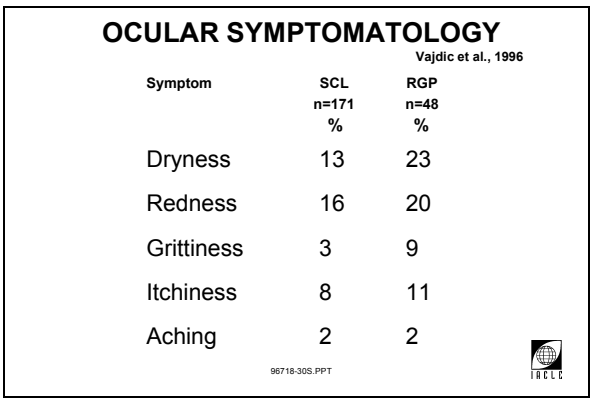
### RGP Care and Maintenance: Lubricating Drops

Lubricating drops normally contain polymers and a viscosity-enhancing agent or agents to:

- Reduce friction between the cornea, eyelids and contact lens surface.
- Provide additional viscous fluid to the anterior eye.
- Remove debris from behind the lens (partially by the increased lens movement facilitated by the instillation of the drops).

28

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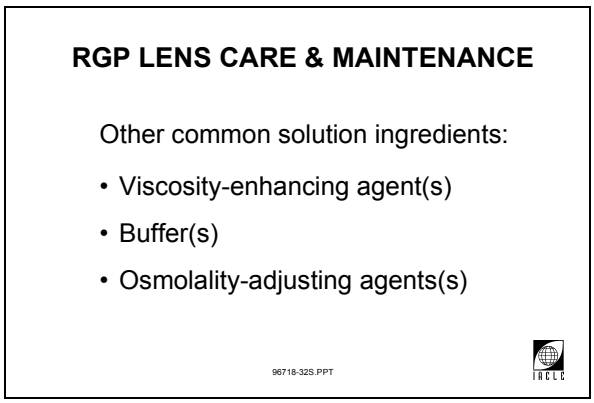
### Ocular Symptomatology

A study conducted by Vajdic *et al.* (1996) on ocular symptomatology, found that RGP lens wearers can be differentiated from SCL wearers by the dryness and redness symptoms they reported.

Therefore it is important to ensure that patients who have dryness problems are provided with an 'in-eye' wetting/re-wetting solution (comfort drops) to improve comfort and minimize dryness.

## III.F RGP Lens Care: Other Solution Ingredients

29

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### RGP Care and Maintenance: Other Ingredients

- Viscosity-enhancing agent(s): These agents 'thicken' (increase the viscosity of) the formulation to increase the 'stay time' (residence time) of the product on the lens and ocular surfaces.
- Buffer(s): These agents maintain the pH of the solution within the limits desired.
- Osmolality-adjusting agent(s): These agents alter the osmolality of a solution. As with buffers, solutions which do not normally come in contact with the eye do not have to be isotonic with the tears.

## IV RGP Care and Maintenance: Complications

30

**RGP LENS CARE & MAINTENANCE**
**COMPLICATIONS**

- Solution toxicity: rare
- Punctuate corneal staining: uncommon
- Viscous solution:
  - ➡ blurry/fluctuating vision on lens insertion
  - ➡ may leave residue on lashes

96718-33S.PPT

5L596718-33

### RGP Care and Maintenance: Complications

- Solution toxicity is uncommon as preservatives are not normally absorbed by RGP lenses. It is noteworthy that most RGP care products which use ingredients common to SCL care products, usually contain these compounds in higher concentrations. If lens cleaner is used inadvertently on the eye, a severe toxic reaction will occur (diffuse corneal staining)
- Punctate corneal staining can occur. However it is not common.
- With viscous soaking solution, adherence may occur and wearers may complain of blurry/fluctuating vision and a sticky sensation upon lens insertion. A dehydrated solution residue may be left on the eyelashes.

31

**RGP LENS CARE & MAINTENANCE**
**LENS REPLACEMENT**

- Replace lenses at least annually
- Residual deposits can irritate lids, especially the upper lids
- Resurface (polish) lenses annually as an alternative to replacement

96718-34S.PPT

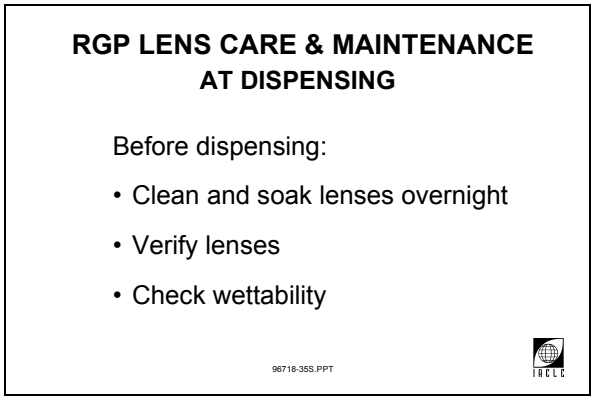
5L596718-34

### RGP Care and Maintenance

Annual replacement of RGP lenses is recommended. Regular replacement helps prevent problems which may be due to residual deposits on the lens surfaces. These deposits can irritate the lids, especially the upper lids. Programmed lens replacement schemes are now becoming available.

In some cases lenses may need to be replaced more often (e.g. six-monthly intervals is suggested by Woods and Efron, 1996) if the patient is wearing lenses on an EW basis and/or is a heavy depositor. The susceptibility of the lenses to deposits should also be taken into account when prescribing a replacement regimen.

32

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## RGP Care and Maintenance

It is important to clean and soak new lenses in conditioning solution for a few days before dispensing them.

This ensures that any residue from the manufacturing process is removed and lens wettability will be optimal when dispensed to the patient (generally, custom lenses are shipped dry-stored).

Upon receipt from the lab:

- Clean and soak lenses overnight prior to verifying the parameters.
- To ascertain that the lens is wetting, observe the lens *in vitro* with a slit-lamp, microscope or magnifier prior to dispensing.

## V Trial Set Disinfection/Storage

33

**RGP**
**TRIAL LENS DISINFECTION**

- Clean with alcohol-based cleaner immediately after use
- Place in clean vial (suspending lens if possible)
- Wet-store in disinfecting/storage conditioning solution when not in use use (change regularly)
- Clean lenses again immediately before next use

96718-36S.PPT

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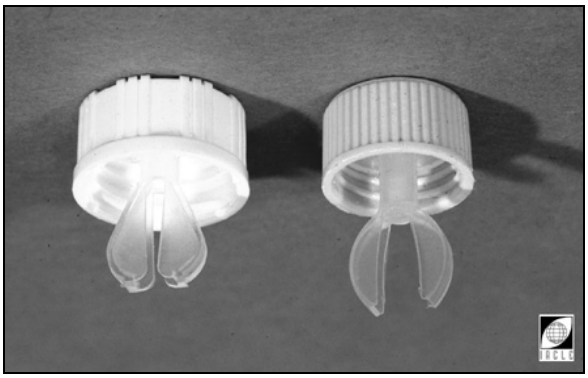

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### RGP Trial Lens Disinfection

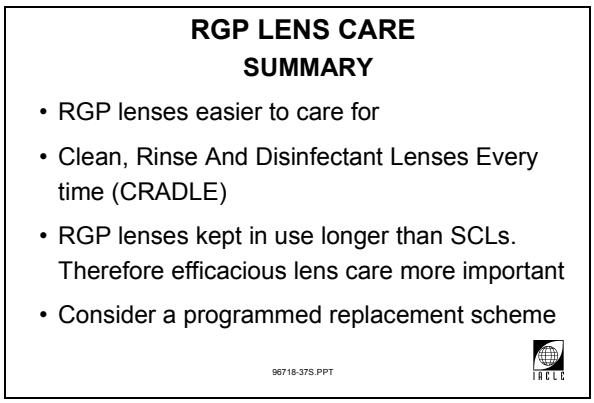
The method recommended is:

- Clean with alcohol-based cleaner immediately after use (Ghajar *et al.,* 1989). With short exposure times and thorough rinsing, RGP lens stability will not be affected by the use of such cleaners (Lowther, 1987).
- Place in a clean container. A container which *suspends* (slide 34) the lens without stress is recommended. However if one is not available the lens should be placed 'concave-up' in a flat container. This orientation is preferred to prevent the lens attaching to the floor of the container ('sucking' on).
- Wet store in a soaking solution when lens is not being used.
- Change the storage solution periodically (e.g. monthly).
- Clean lenses again immediately before their next use on a prospective RGP wearer.

Dry storage is another option for RGP trial lenses. Dry storage is convenient because there are no solutions requiring regular replacement, a necessary step if microbial growth is to be prevented. Further, dry storage removes all potential media for microbial growth provided the lenses and cases are truly clean and dry. However, lenses that are 'dry' stored may not wet as well during the trial fitting.

## VI Summary

35

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### RGP Care and Maintenance: Summary

Because of their non-absorbent nature, surface properties, rigidity and durability, RGP contact lenses are easier to care for than soft lenses. However, as most RGP lenses are currently kept in use longer than the average modern SCL, it is incumbent on both the wearer and their practitioner to ensure proper lens care is pursued rigorously if ocular health and safety are to be maintained. Programmed replacement of RGP lenses is an important factor in maintaining ocular health.

# Tutorial 5.4

(2 Hours)

# Review of RGP Contact Lens Care Systems

# Tutorial

## Session 1:

Examination of a comprehensive array of RGP lens care products

## Session 2:

Discussion of RGP contact lens care products, their components and functions

# Tutorial Session 1:

A comprehensive array of RGP lens care products needs to be assembled for the student group to examine and familiarize themselves with. It is suggested that all products readily available in the local lens care market be included. A list of lens care products from the major global manufacturers is provided below. Many countries also have indigenous manufacturers and/or local variations of major products. The product list should be tailored to match the local lens care market. A starting point for such a product list is also provided.

## RGP CONTACT LENS CARE PRODUCTS

For each product the following aspects/features should be ascertained by the students.

**PRODUCT NAME:**_____

(a) Manufacturer _____

(b) Intended purpose _____

(c) Preservative/disinfectant(s) & concentration(s) _____

(d) Other components & their concentrations _____

(g) Procedures for use _____

(h) 'Discard-after' period _____

**PRODUCT LIST** (adapt as appropriate to local circumstances and market place)

**Products from major global manufacturers ( in ALPHABETICAL order).**

**ALCON:**

Enzymatic Cleaner for EW Lenses
Opti-Plus Active Cleaner
Opti-Soak
Opti-Soak Conditioning Solution
Opti-Soak Soothing Drops
Opti-Tears
Optizyme Enzymatic Cleaner
Polyclens II (Opti-Clean II)
Soaclens
Supra-Clens Daily Protein Remover

**ALLERGAN:**

Barnes Hind Comfort Care GP Dual Action Daily Cleaner
Barnes Hind Comfort Care GP Wetting & Soaking Solution
Barnes-Hind Comfort Care Comfort Drops
Barnes-Hind GP Daily Cleaner

Clean-N-Soak Solution
Duracare
Duraclean

**ALLERGAN Continued…..**

LC 65 Daily Cleaner
Liquifilm Wetting Solution
ProFree/GP Weekly Enzymatic Cleaner
Resolve GP
Total
Wet-N-Soak & Wet-N-Soak Plus
Wet-N-Soak Re-wetting Drops

**BAUSCH & LOMB:**

Concentrated Cleaner
Conditioning Solution
Sensitive Eyes Lens Lubricant
Wetting and Soaking Solution

**BOSTON:**

Boston Advance Cleaner
Boston Advance Comfort Formula Conditioning Solution
Boston Cleaner
Boston Conditioning Solution
Boston One-Step Liquid Enzyme Cleaner
Boston Re-wetting Drops
Boston Simplicity Multi-Action

**CIBA VISION:**

CIBA Vision Lens Drops
Clerz
InstaCARE (Quick-Care) Finishing Solution
InstaCARE (Quick-Care) Starting Solution
Miraflow
SOLO-care Rigid

**MENICON:**

$O_2$Care Solution
Progent Intensive Cleaner

**LOCAL VARIATIONS OF MAJOR PRODUCTS:**

**PRODUCTS FROM INDIGENOUS MANUFACTURERS:**

## Tutorial Session 2:

The educator should lead a group discussion on the practical and formulations aspects of RGP contact lens care products. Particular attention should be paid to the following:

- Preservative *versus* preservative-free solution formulations and packaging.
- Classes of disinfectants.
- Classes of preservatives.
- Recommended disinfection times of the various systems.
- Expiry dates.
- Discard-after time periods.
- Lens case designs.
- Comparing and contrasting the leading systems in the local market.

## 🕮 References

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# Unit 5.5

(4 Hours)

## **Lecture 5.5:** Contact Lens Deposits

## **Tutorial 5.5:** Identification of Deposits on Contact Lenses

# Course Overview

**Lecture 5.5: Contact Lens Deposits**

I. Mechanism of Contact Lens Deposits
II. Examination of Contact Lens Deposits
III. Types of Contact Lens Deposits
IV. Managing Contact Lens Deposits

**Tutorial 5.5: Identification of Deposits on Contact Lenses**

- Deposit Type
- Appearance
- Origin
- Severity
- Prognosis
- Treatment Methods
- Should the lens be replaced?

# Lecture 5.5

(1 Hour)

# Contact Lens Deposits

# Table of Contents

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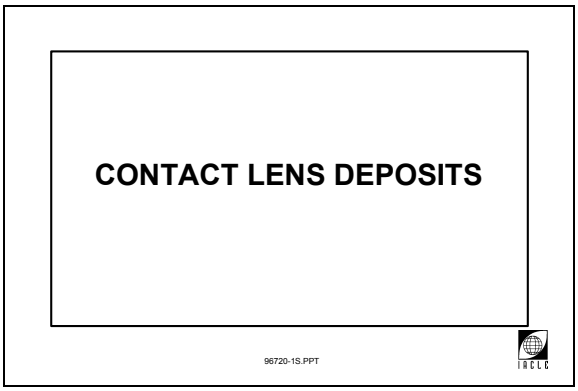
IV.F Lens Discolouration ..... 226
**V Summary of Deposit Management ..... 231**

## I Mechanisms of Deposit Formation

1

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### Contact Lens Deposits

One definition of a deposit is:

'..any lens surface coating or lens matrix formation which is *not* flushed or rinsed from the lens by the tears during blinking'. In effect, anything that remains on the surface despite blinking is a 'deposit'.

A more rigorous definition might add '...and is not removed by routine lens care procedures'.

Deposit formation, absorption (in) and adsorption (on) contact lenses have spurred investigations and research into preventive measures and the development of deposit resistant materials.

From a clinical point of view, the care regimen should be patient-specific and dependent on the type of lens prescribed. As an adjunct to the lens care regimen decision-making process, the following are relevant:

- An understanding of the mechanisms of deposit formation.
- A knowledge of deposit types and their characteristics.
- Some familiarity with deposit identification techniques.
- A knowledge of deposit management strategies.

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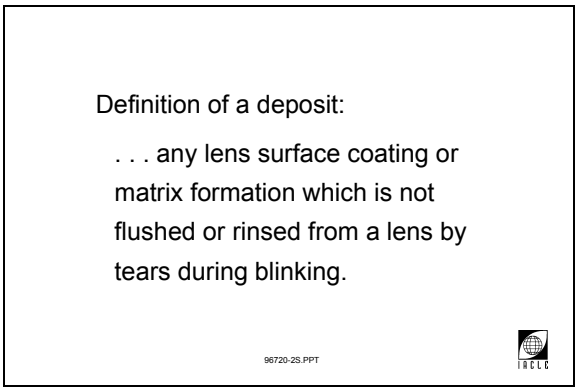


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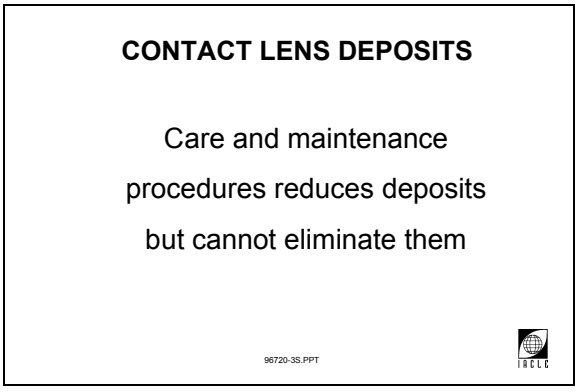


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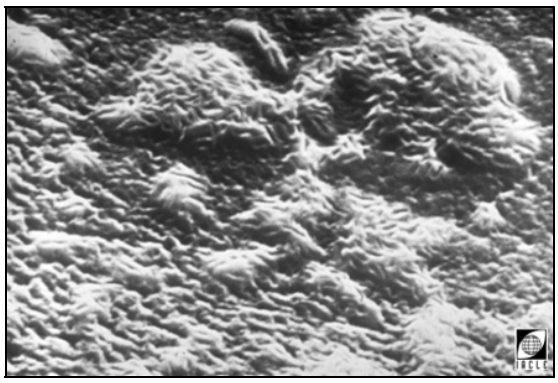
### Deposit Formation

The very nature of lens materials and the complexity of the tear film, makes deposits virtually unavoidable.

As soon as a lens is placed on an eye, the depositing process commences. Lens care and maintenance procedures reduce deposits and resist deposit accumulation but do *not* eliminate them.

Several studies have shown that lens material ionicity is a significant factor in deposit formation (Minarik and Rapp, 1989; Minno *et al*., 1991; Bleshoy *et al*., 1994).

4



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Minarik and Rapp (1989) isolated water content and ionicity from all other possible factors that might influence protein deposition, and showed water content to be the primary factor.

Using the FDA classification system for soft contact lens materials, Group I (low water, non-ionic) lenses showed the greatest deposit resistance and Group IV (high water, ionic) showed the least.

5

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**The Ideal Lens Surface**

The ideal lens surface can be represented by an unworn contact lens which is:

- Clean.

  A contact lens free from any contaminants on or within its material matrix.

- Wettable.

  A contact lens must be able to hold and maintain a complete and stable tear film over the whole of its surface. A good tear film is important to the maintenance of the optical properties of the lens, good vision and deposit minimization.

- Comfortable.

  A lens that is wet and clean, and which does not interfere with blinking, will ensure comfort. Such a lens mimics the normal corneal surface.

- Safe for long-term wear.

  As contact lenses are worn continuously for many hours, biocompatibility is a major factor in choosing a lens/lens material.

When prescribing the care and maintenance regimen, the aim is to maintain the contact lenses in optimum condition.

6

**DEPOSIT FORMATION**

- Tear proteins (e.g. lysozyme) are attracted to the lens
- Tears evaporate and leave residues on the lens
- After protein is deposited, other components of the tear film (such as mucin) may adhere to the protein
- Over time, layers build up and structural changes take place (e.g. denaturation)

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7

Factors influencing lens deposition:

- Individual difference in tears
- Lens material
- Care system
- Wearing schedule
- Environment
- Patient hygiene

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## Deposit Formation

Since the development of hydrogel and rigid gas permeable lenses, the question of deposit formation has been the subject of many studies.

Generally, theories on the role of *ionicity* present deposition as being the result of the interaction of tear proteins (particularly lysozyme) with the surface charge of the lens material. As tears evaporate, they leave a bound residue on the lens surface. Later, other components adhere to this initial deposit resulting in a build-up of lens surface contaminants.

On a contact lens, the initial deposit layer formed may be beneficial in making the lens more comfortable and compatible with the external ocular environment. However, when deposit layers build up, structural changes occur within the proteins and they denature over time. This can lead to an allergic, or an allergic-like, response such as Contact Lens-related Papillary Conjunctivitis (CLPC).

### Factors Influencing Deposit Formation

- Some individuals are more susceptible than others, i.e. individual variation.
- Some types of lens materials attract characteristic types of deposits.
- Incompatibilities between some lens care constituents and some lens materials can predispose or aggravate lens deposition.
- Extended wear (EW) might induce more deposits than daily wear (DW).
- Sometimes patients exhibit lens contamination related to their environment, e.g. rust spots seen on lenses of metal workers exposed to ferrous metals.
- A patient's general attitude to personal and lens hygiene is also very important.

8

**DEPOSIT SUSCEPTIBILITY:**
**SCL MATERIALS**

Generally:

- Low water materials deposit less than high water materials
- Non-ionic materials deposit less than ionic materials

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## Deposit Susceptibility: SCL Materials

A SCL can be described as having some sponge-like characteristics. It contains water and has molecular pores through which water can pass freely enabling rapid deposition in and on the lens. Note that *free* water only can pass, as bound water is not so labile). Rapid deposition of proteins onto a surface also occurs with other implantable biomaterials (e.g. artificial hearts and heart valves, artificial blood vessels).

9

**DEPOSIT SUSCEPTABILITY:**
**RGP MATERIALS**

- Deposits form on lens surface only

Reasons:

- No water to permeate lens
- Small pore size (limited polymer-free space)

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RGP lens deposits are different fundamentally in that they are usually limited to lens surfaces only. The reasons are summarized in the slide opposite.

10

**CONSEQUENCES OF DEPOSIT ACCUMULATION**

- Non-wetting lens surface
- Alteration in lens shape
- Degradation of lens polymer

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## Lens Deposits: Consequences

Perhaps most importantly, deposits serve as a culture medium and substrate for micro-organisms. Micro-organisms which may be unable to attach to a lens normally, may, by adherence to surface deposits, be able to colonize a lens and increase the possibility of ocular infection.

11

**CONSEQUENCES OF DEPOSIT ACCUMULATION**

Problems that can be caused by deposits:

- Decrease in:
  - Vision
  - Comfort
  - Wearing time
  - Lens wettability
  - Lens Life
- Ocular reactions

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## II Examining Lenses for Deposits

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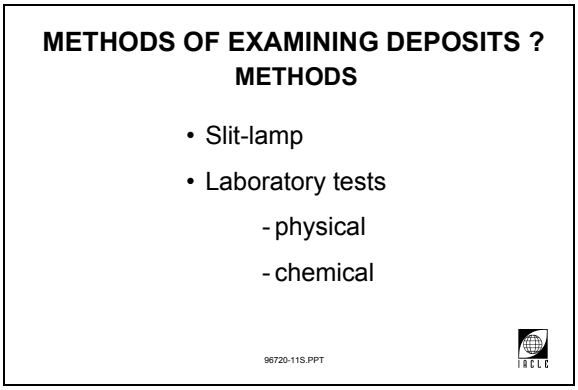


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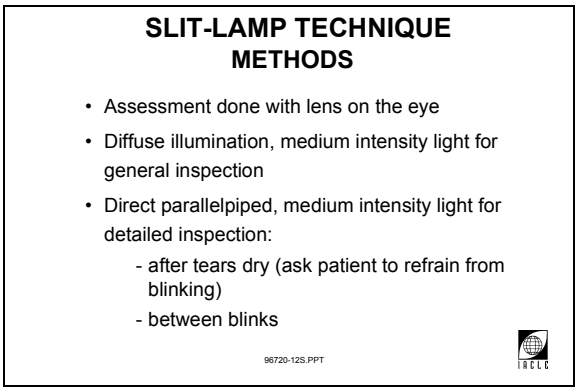
### Methods of Examining Deposits

- Slit-lamp.
- Laboratory tests (after Ruben, 1978, Minno *et al*., 1991, Ruben and Guillon, 1994):
  - physical:
    - dark-field, phase contrast or interference microscopy
    - polarization (plane and circular)
    - confocal and LASER scanning confocal microscopy
    - Scanning and Transmission Electron Microscopy (SEM & TEM)
    - UV, IR and X-ray spectroscopy or spectrometry
    - Attenuated Total Reflectance-infrared spectroscopy (ATR)
    - ion-probe SEM and electron probe microanalysis
    - atomic absorption and emission spectrophotometry.
  - chemical (and histochemical):
    - staining and surface chemical techniques
    - protein and amino acid analysis;
    - Poly(Acrylamide) Gel Electrophoresis (PAGE)
    - radiochemical techniques
    - immunological techniques.

13

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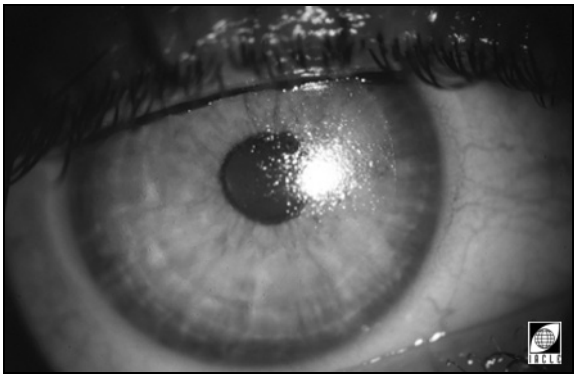
### Methods of Deposit Examination

### Slit-Lamp Techniques

Due to its ready availability in a consulting room, a slit-lamp is the most common instrument used to examine a lens surface for the presence of deposits.

- Deposit assessment is usually made while the lens is still on the eye.
- The slit-lamp is also used as an *in vitro* dark-field microscope by providing a black or dark backdrop to a lens suspended/mounted from the instrument's brow rest/chin rest/vertical

14



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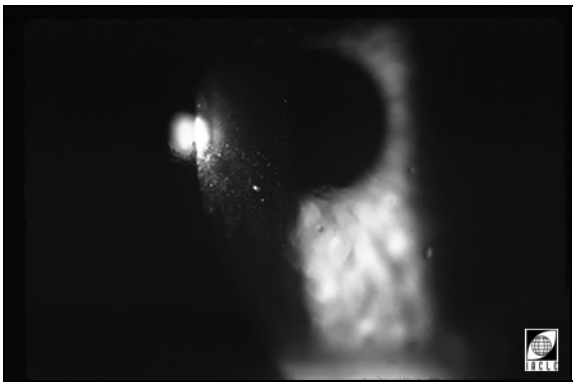

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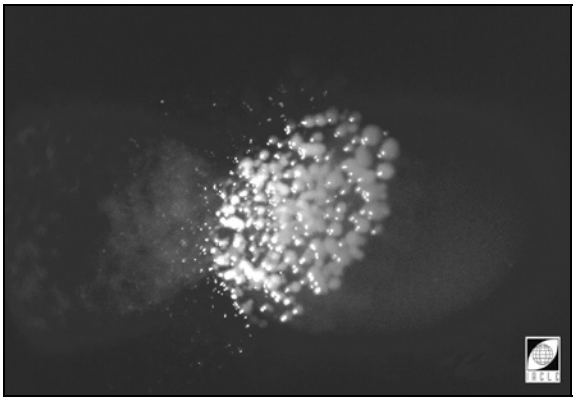
stays.

- Usually, deposits are rendered more conspicuous if the lens surface is allowed to dry, or is blotted dry, before inspection.
- Diffuse illumination of medium intensity is used to view the lens surface generally.
- Direct parallelepiped illumination of medium intensity is used to view the appearance of the lens surface in detail. This is done:
  - after the tears dry on the lens surface (the patient needs to refrain from blinking)
  - between blinks, i.e. when the tear film is normal and transparent on the lens surface.
- Higher magnification may assist the identification of any deposits observed.

Slide 14 shows a deposited lens *in situ.* The alterations to the specular reflection from the pre-lens tear film are obvious and typical of a surface build-up. Additionally, a degree of change in surface wettability is apparent. Slide 15 is similar and also shows deposits in direct and marginal retro-illumination

When assessing RGP lenses *in situ,* all observations should be made *before* sodium fluorescein is instilled for lens fit assessment.

16



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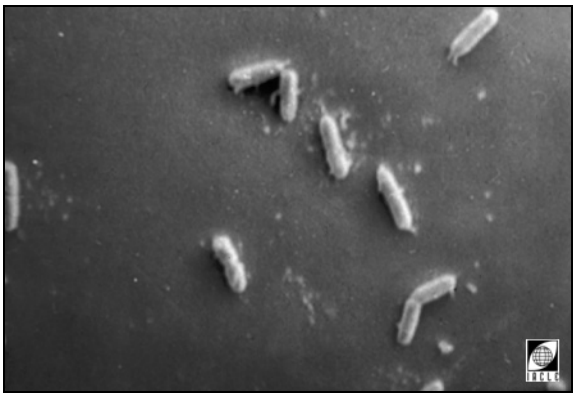
**Bacteria and Viruses**

The propensity for bacteria and other micro-organisms to use contact lens deposits as a culture medium, or as an aid to adhesion is a concern. Microbial contaminants may:

- Adhere to deposits.
- Cause ocular infections.

Such colonization is not normally visible to an observer even with the aid of a slit-lamp.

17



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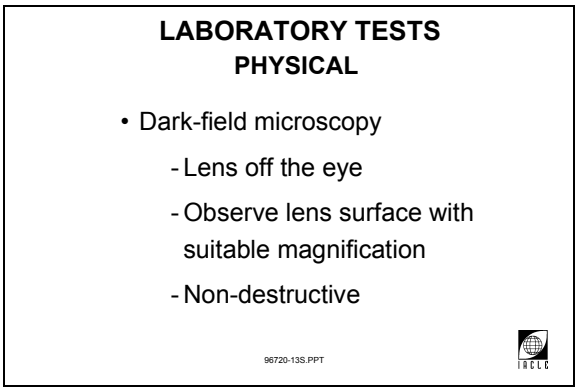
Disinfection of the lenses on a regular basis is essential if ocular complications are to be prevented.

Slide 16 shows bacterial colonization of a contact lens.

Slide 17 shows *Pseudomonas aeruginosa* (a bacteria) on the surface of an RGP lens.

18

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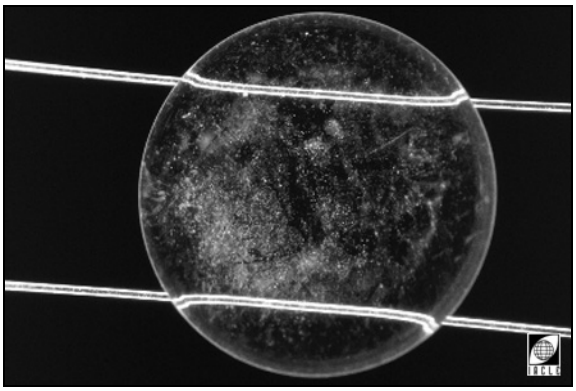
## Laboratory Tests: Physical

Dark-field microscopy is the most commonly used and practical (clinically) of all the *in vitro* laboratory techniques. However, regardless of the methods used, visual typing techniques (e.g. Rudko deposit type) are poor quantitative measures of deposited proteins (Minno *et al.,* 1991).

It is important for the practitioner to handle the lenses appropriately. Use plastic tweezers (or tweezers with siloxane rubber tips) when handling the lenses to ensure they are not physically damaged and are not contaminated with hand oil, creams, hand-borne micro-organisms, etc.

19



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An example of lens deposits viewed using a dark-field technique is illustrated opposite (slide 19). The contrast between the light deposits and the dark background results in a full disclosure of the extent (total area affected) of the deposit and the severity (optical density) of the deposition. However, this technique does *not* identify the *type* of deposit seen.

**Preparing a lens for dark-field inspection.**

RGP:

- Rub and rinse the lens in cleaner and saline respectively.
- Dry the lens with a lint-free tissue.
- Inspect with a dark-field microscope.

SCL:

- Rub and rinse the lens in normal saline.
- Place lens in a wet-cell (either an open-type with a dipping, windowed lid or a cuvette-style cell with flat parallel glass sides) and fill cell with saline until lens is immersed fully.
- Inspect with a dark-field microscope.

20

**LABORATORY TESTS**
**CHEMICAL**

- Lens off the eye
- Uses stain to identify the type and quantity of deposits on and in lens matrix
- Usually destructive

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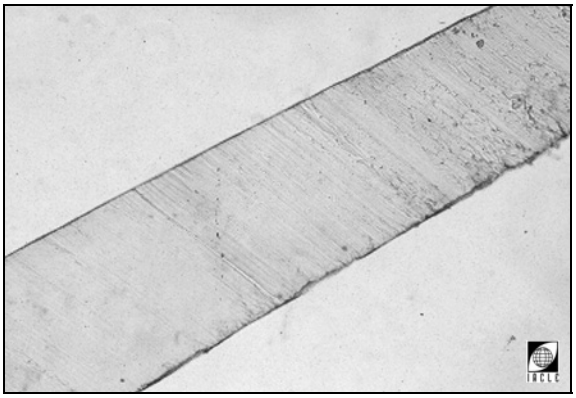
**Laboratory Tests: Chemical**

Various methods ranging from simple stains and stain-quantification systems to complex electron microscope-based techniques can be used to identify the types of deposits present on the lens surfaces and in the lens matrix. Many techniques allow the quantity and type, as well as location (e.g. on or near the surfaces), to be determined.

This test usually involves the destruction of the lens.

21



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This slide shows a complete cross-section of a soft lens at high magnification. It can be seen from the density of the stain that deposits have formed in the lens matrix (absorption) but are heavier at the surface (adsorption).

The following list indicates published papers on various techniques.

*Protein* (particularly lysozyme) assessment:

- Ninhydrin assay for adsorbed protein (Minno *et al.,* 1991.
- Modified Lowry assay; extraction of proteins from the lens, their reaction with a colourant followed by a spectrophotometric assessment at a fixed wavelength (typically 700nm) (Sack *et al.,* 1987, Jones *et al.,* 1997).
- Amido black; a protein-disclosing agent which also stains lenses to varying degrees.
- $^{14}C$ labelling of protein (Stone *et al,*

1984).

- Electrophoresis or gradient polyacrylamide gel electrophoresis (Wedler, 1977, Holly and Hong, 1982).
- IR absorption (Castillo *et al.,* 1985).
- Attenuated Total Reflectance (ATR) spectroscopy (Mitzutani *et al.,* 1988).
- UV and visible spectroscopy (Kleist, 1979).
- Amino acid analysis (Kleist, 1979, Mitzutani *et al.,* 1988).
- Silver staining (Wedler *et al.,* 1987).
- Bio-Rad Protein Assay (Jung and Rapp, 1993).
- Million's reagent histological stain (Abbott *et al.,* 1991).
- Coomassie Brilliant Blue R-250 (Tan *et al.,* 1997).
- Colloidal Coomassie (Jones, 1990)
- Texas Red, fluorescein isothiocyanate (FITC) and Tetramethylrhodamine isothiocyanate (TRITC) (Meadows and Paugh, 1994).

*Lipid* assessment:

- Fluorescence spectrophotofluorimetry; the fluorescence of lipids following excitation with UV light(Jones *et al.*, 1997).
- IR absorption or Fourier Transform IR spectroscopy (FT-IR) (Castillo *et al.,* 1984 – 1985, Mitzutani *et al.,* 1988).
- Histochemical stains (Kleist, 1979).
- High performance Thin Layer Chromatography (TLC) (Mitzutani *et al.,* 1988, Bontempo and Rapp, 1994).
- High Performance Liquid Chromatography (HPLC) (Franklin *et al.,* 1991).
- Fluorescence spectroscopy (Franklin *et al.,* 1991).
- Nile red stain and oil red O stain (the former is better) (Caroline *et al.,* 1985,

Abbott *et al.,* 1991, Mirejovsky *et al.,* 1991).

*Mucin* (glycoproteins and muco-polysaccharides) assessment:

- Histochemical staining technique (Gachon *et al.,* 1985, Sack *et al.* 1987, Abbott *et al.,* 1991).
- IR absorption (Castillo *et al.,* 1986).
- Alcian blue/Periodic Acid-Schiff's (AB/PAS) reagent staining and SDS-PAGE gels (Sodium Dodecyl Sulphate-PolyAcrylamide Gel Electrophoresis (Wedler *et al.,* 1987).
- Bio-Rad Protein Assay (Jung and Rapp, 1993).
- AB/PAS and Müller's reagent (colloidal iron stain) (Klein, 1989).
- Mucicarmine histological stain (Abbott *et al.,* 1991).

*Albumin* and prealbumin (proteins) assessment:

- Immunochemical staining technique (Sack *et al.* 1987).
- IR absorption (Castillo *et al.,* 1984).
- Silver staining (Wedler *et al.,* 1987).
- Radiolabeling with $Na^{125}$Iodine (Garrett and Milthorpe, 1996).
- Bio-Rad Protein Assay (Jung and Rapp, 1993).

*Immunoglobulins* A, G, E (IgA, IgG, IgE) assessment:

- Immunochemical staining technique (Sack *et al.* 1987).
- Immunocytochemical/TEM technique (Versura *et al.,* 1988).
- Immunofluorescence microscopy (Gudmundsson *et al.,* 1985).

*Lactoferrin* (a protein) assessment:

- Immunochemical staining technique (Sack *et al.* 1987).
- Immunofluorescence microscopy (Gudmundsson *et al.,* 1985).
- Silver staining (Wedler *et al.,* 1987).
- Bio-Rad Protein Assay (Jung and Rapp, 1993).

*Fibronectin* (a large glycoprotein) assessment:

- Modified Enzyme-Linked ImmunoSorbent Assay (ELISA) (Baleriola-Lucas *et al.,* 1997).

*Inorganic deposits* particularly those containing calcium, phosphorous, iron and mercury:

- Electron microprobe equipped SEM (Kleist, 1979, Reidhammer, 1980).
- SEM and Energy Dispersive X-ray analysis (EDX) (Begley and Waggoner, 1991).
- X-ray fluorescence (Caroline *et al.,* 1985).
- Von Kossa's stain (Abbott *et al.,* 1991).

## III Deposits: Grading and Classification

22

**CLINICAL CLASSIFICATION SYSTEM**

Assessment of surface:

- Appearance classification: Rudko
- Deposit categories and types: Tripathi
- Grading systems: Josephson & Caffery, Hart

Results may be influenced by:

- Lens wettability
- Surface drying time

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**RUDKO CLASSIFICATION**
**CATEGORIES**

I = No deposit visible on wet or dry lens with 15 x magnification
II = Deposit visible in wet cell with 15x magnification
III = Deposits visible on dry lenses without magnification
IV = Deposits visible on wet lenses without magnification

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### Rudko Classification

An early attempt to classify deposits was presented by Rudko in 1974 (Rudko and Proby, 1974, Rudko and Gregg, 1975).

This system was later modified to include coding for:

- The type of deposits (crystalline, granular, filmy, plaque, coating, etc.).
- The extent of the deposits (how much of the lens surface area was covered).

Variations of this general scheme are still in use.

24

**TRIPATHI**
**CATEGORIES AND TYPES**

- Appearance description
- Deposit types:
  - organic deposits
  - inorganic
  - mixed
  - micro-organisms

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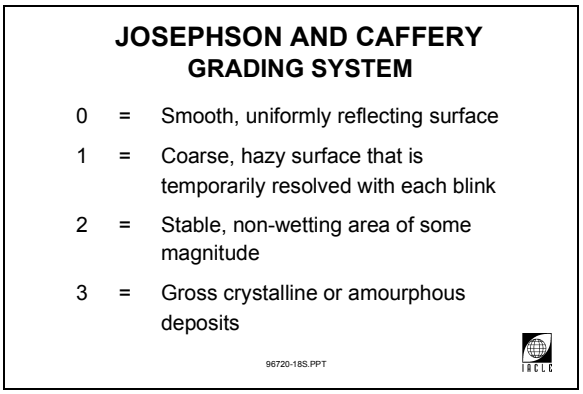
### Tripathi: Categories and Types

Tripathi *et al.* (1988) presented a series of categories into which alterations to contact lenses can be placed.

- Appearance description, e.g. clear film, grainy, hazy, stringy materials, non-wetting areas, discolouration, discrete, elevated, white spots, crystalline deposits, particles.
- Deposit types
  - organic
  - inorganic
  - mixed.
- Micro-organisms cultured.

Tripathi *et al.* (1994) presented a more detailed classification system which classified heaviness, type and extent of deposits separately.

25

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## Josephson and Caffery: Grading system

Josephson and Caffery (1989) developed an *in situ,* slit-lamp biomicroscopic grading system for contact lens deposits.

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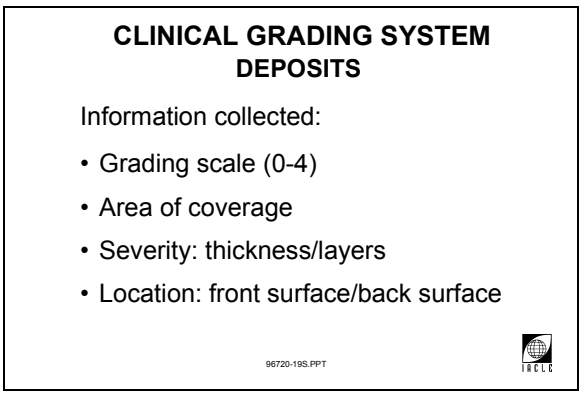


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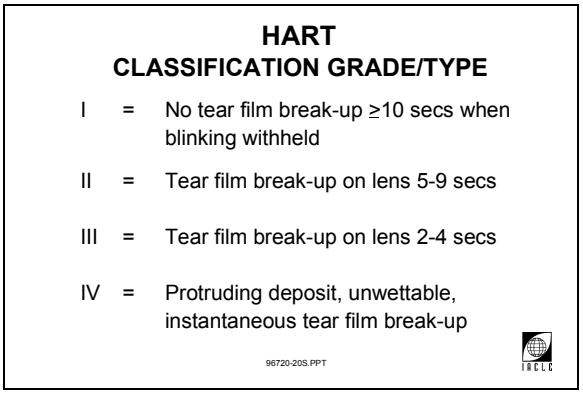
## Clinical Grading System: Deposits

When undertaking clinical research involving contact lenses, a grading system for deposits is required. A subjective scale has been developed which not only grades deposits but also classifies their type based on researcher observations. Several clinical research organizations have such scales. Most have limited compatibility. Should it become necessary to make comparisons between scales it is probable that a 'none, mild, moderate, severe' breakdown would have to be made.

27

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## Hart - Classification Grade/Type

A more recent method using a slit-lamp was proposed by Hart (presented in Phillips and Stone, 1989).

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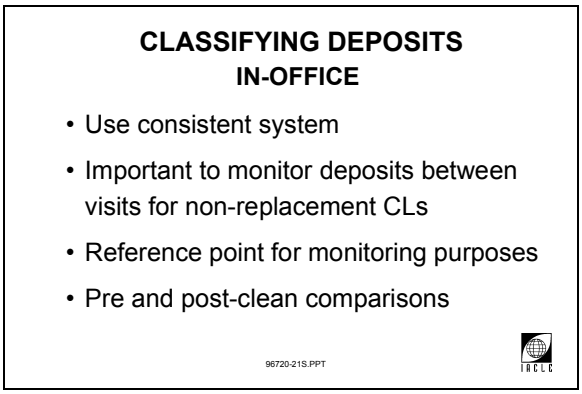


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## In-Office (in CL Practice): Grading System

An in-office grading system is extremely useful.

It is essential to apply the system developed, consistently. Erratic application of a rating system invalidates data generated using it.

It is useful in monitoring levels of deposits between visits for conventional (non-replaced) CLs.

Ratings given are a sound basis for comparisons over time and are suitable for reference purposes.

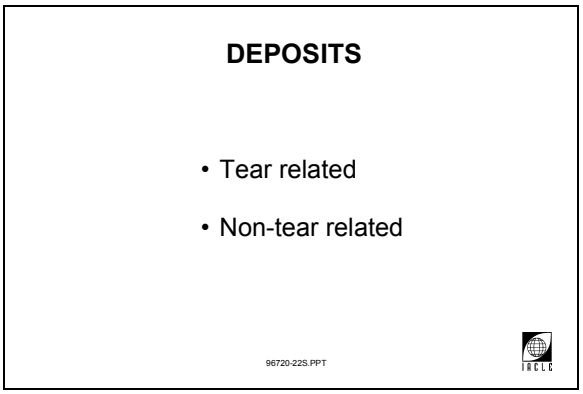
The efficacy of any lens care procedure, particularly cleaning or enzyme treatments, can only be measured by comparing deposit ratings before and after the procedures.

In the clinical office setting, it is important that practitioners use a system with which they are familiar.

In an office where there is more than one practitioner, steps to standardize the procedures and ratings by comparing figures regularly (preferably of the same observations), may need to be taken. Only in this way can ratings from several observers be regarded as comparable, especially over time.

## IV Types of Deposits: Introduction

29



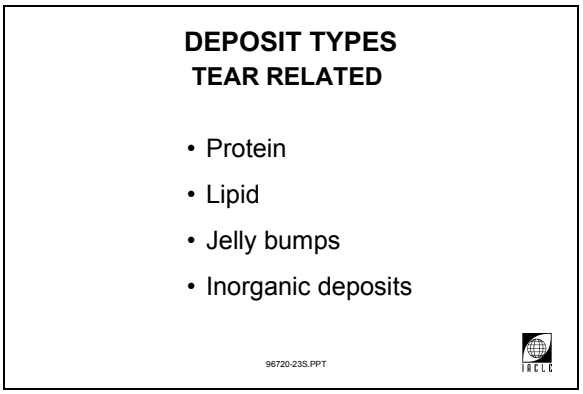

5L596720-22

### Deposits

Based on their origin, deposit types can be classified as:

- Tear-related deposits.
  Tear-related deposits are the result of tear components such as lysozyme, lipids, albumin, mucin, immunoglobulins (A, G and E), lactoferrin, fibronectin and calcium adhering to the lens. Deposits may be inorganic or organic.
- Non-tear related deposits.
  This type of deposit is believed to be environmental in origin. Such deposits can vary from foreign particles embedded in the lens matrix to a build-up of rust on the lens surface resulting from iron particles oxidizing *in situ*.

30




5L596720-23

### Deposit Types

All used lenses are coated with glycoprotein (mucin) and varying amounts of protein. Few lenses yield albumin in deposit assays (Sack, 1985).

Apart from the usual 'flat' or film-like protein and lipid deposits, another tear-related deposit is 'jelly' bumps (also referred to as mulberry spots or bumps, lens calculi and 'barnacles'). These deposits are called jelly bumps because of their similarity to a molded jelly desert or mulberry bumps because of their similarity to the rounded facets of the fruit of the mulberry tree (*Morus nigra*). Jelly bumps are covered in more detail in section III.C.

Commonly, a combination of deposit types is seen rather than one type in isolation. In some cases, one type of deposit precedes and facilitates the formation of subsequent deposits of a different type (see IV.C: Jelly Bumps).

Deposits tend to accumulate much more on the front surface of contact lenses than the back surface.

31

**DEPOSIT TYPES**
**NON-TEAR RELATED**

- Fungi
- Lens discolouration
  - mercurial deposits
  - cigarette residues
  - Surface contamination: make-up, lotion
- Rust spots

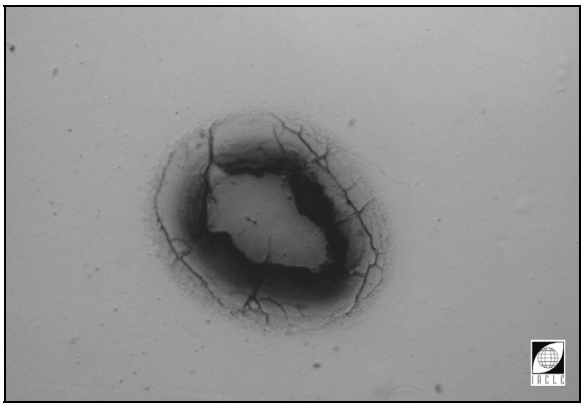
96720-24S.PPT

5L596720-24

Deposits may also be unrelated to tear film components. Usually, they are derived from lens care products or the environment including components of cosmetics/make-up.

Fungi can be acquired from water (pools, saunas, hot-tubs), soil (farmers, gardeners) or the atmosphere.

32

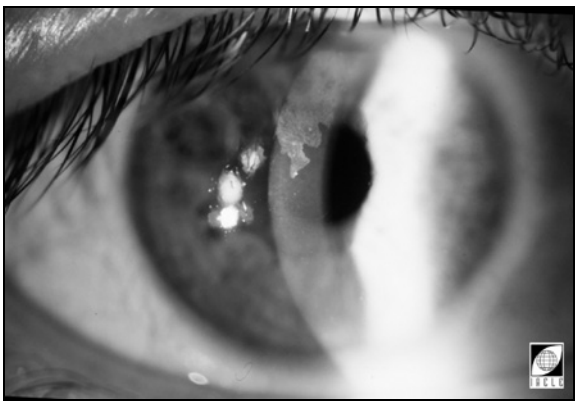


5L5009B-16

A rust spot is shown in slide 32.

## IV.A Protein Deposits

33



5L51587-95

### Protein

Slide 33 illustrates a typical soft lens protein deposit *in vivo* viewed in direct illumination.

Protein deposits:

- Are a semi-opaque or translucent film - usually thin, whitish and superficial (Tripathi and Tripathi, 1984). In extreme examples protein films have a frosted-glass appearance (see slide 36).
- May cover lens surface partially or fully.
- Consist of denatured lysozyme.
- Cause the lens surface to become hydrophobic.
- Can crack and peel if thick.
- Can result in significant discomfort when film is peeling.

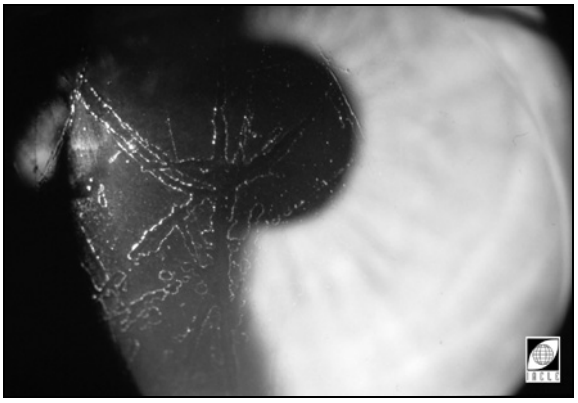
Factors favouring a build-up of protein on a contact lens include:

- Short BUT (Hathaway and Lowther, 1978).
- Ionic-binding capacity (Sack *et al.,* 1987, Hamano *et al.,* 1993, Sack *et al.,* 1996, Jones *et al.,* 1997).
- Inadequate cleaning, especially of the lens periphery (Heiler *et al.,* 1991).
- Intersubject susceptibility (Jones *et al.,* 1997).
- Heat disinfection (now uncommon).
- Altered blinking (Tripathi and Tripathi, 1984).
- Tear deficiency or altered tear composition (Tripathi and Tripathi, 1984).
- Chronic allergies and GPC (and CLPC?) (after Tripathi and Tripathi, 1984).

Factors decreasing protein deposition:

- Closed-eye lens wear (Sack *et al.,* 1996).

34



5L50439-92

- Limited tear lysozyme levels, e.g. initially, a new high water ionic lens will accept as much lysozyme as the tears can deliver until a steady state is eventually reached (Sack *et al.,* 1996).

Slide 34 shows a flat, almost transparent protein film on an RGP lens.

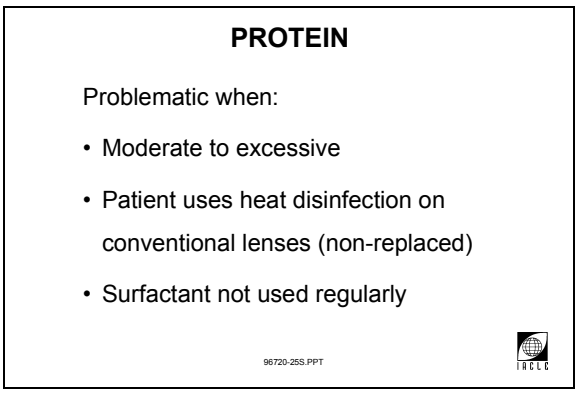
35

5L5008B-10

Slide 35 shows an almost opaque incomplete protein film on an RGP lens.

Interestingly, Lever *et al.* (1995) found no correlation between lens protein levels and patient comfort ratings for a large population sample involving all FDA lens groupings. They suggested that lens-bound protein is not the sole or primary factor determining lens comfort or lens intolerance.

36



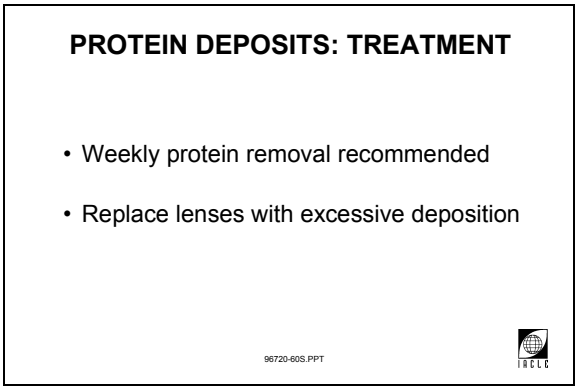

5L596720-25

**Protein**

Problematic when:

- The quantity is moderate to excessive. It can lead to reduced visual acuity and ocular surface trauma.
- Patients use heat disinfection on conventional lenses (non-replaced), especially if regular prophylactic protein removal is not undertaken.
- A surfactant cleaner is not used regularly.

37

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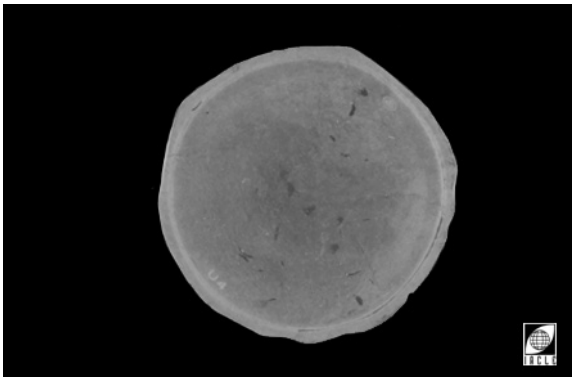
Patients with thick protein deposits will usually complain of eye and lid irritation. This is often the result of the upper lid passing over the rough lens surface resulting from a deposit build-up. If this continues over an extended period of time, patients can develop Contact Lens-related Papillary Conjunctivitis (CLPC) or Giant Papillary Conjunctivitis (GPC).

While both lens surfaces are subject to deposits, the front surface is usually more severely affected. This may be because of drying of the exposed front surface.

If the back surface of the lens has significant bound protein, the corneal surface may be affected by the mechanical effects of the irregular posterior lens surface. Corneal damage which stains with fluorescein may result.

Weekly use of an enzymatic cleaner is recommended to avoid a build-up of deposits. Excessive deposition will ultimately necessitate lens replacement.

38



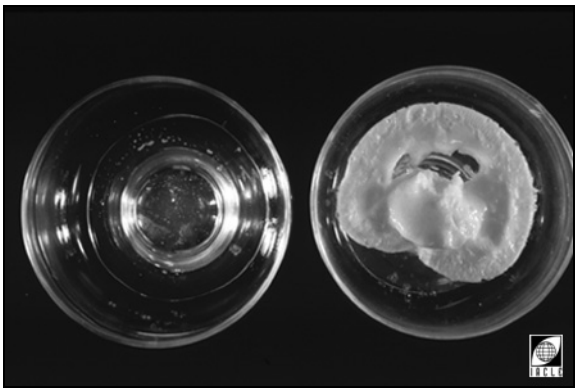
5L50816-93

**Protein Denaturation**

Slide 38 shows an extreme case of a protein-deposited lens whose surface has become opaque due to denaturation of the protein by heat over time. However, heat is not the only 'polymerizer' of lysozyme. The interfacial tension between lens and tear film is also believed to be an effective polymerizer (Sack *et al.,* 1987, Jones, 1990).

Lysozyme changes its structure typically from an alpha-helix to a beta sheet configuration once the protein is polymerized at, and attached to, the lens surface (Jones, 1990 quoting Castillo *et al.,* 1984).

39

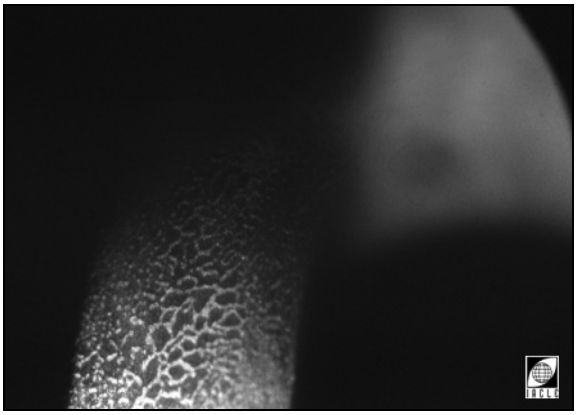


5L50138-92

The work of Sack *et al.,* (1987) also suggests strongly that the ionic nature of a lens plays a significant role in the conformation (i.e. natural or denatured) of the protein deposited. Their results showed that non-ionic materials were associated with the most denatured tear protein and ionic materials with the least.

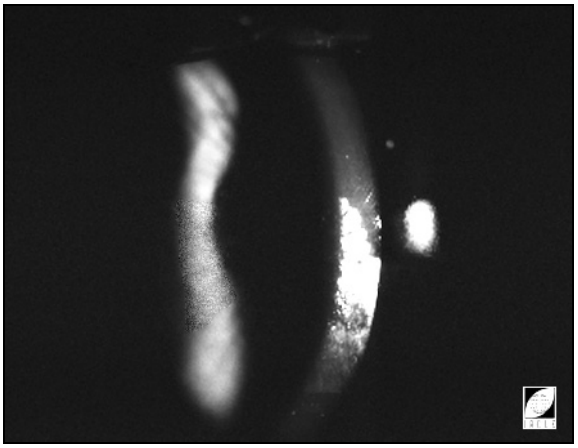
They also reported protein deposit

40



5L51964-91

41



5L50197-97

differences according to lens ionicity. Anionic lenses (i.e. ionic lenses with a negative surface charge, –ve) attracted a thick, loosely-bound layer of lysozyme, much of which retained its conformational integrity (i.e. remained natural).

The non-ionic hydrogel deposit was thinner and was a mixture of mainly denatured tear proteins.

Sack *et al.,* (1987) and Holly and Hong, (1982) claimed that only lysozyme was sufficiently positively charged (+ve) to have a marked affinity for the negatively charged ionic (anionic) lens material. At physiological pHs, all other tear proteins are negatively charged which may explain why they are poorly represented in lens deposits.

Further, it is possible that those deposits which do include some of the negatively charged species, may require some other deposit to be laid down as a prerequisite or interface to the similarly charged lens. In heavy depositors, mucin deposition requires a tear protein layer to be laid down first (Wedler *et al.,* 1987). While some lenses are referred to as non-ionic, such lenses do have charged sites *within* their molecules. Ionic lenses have a *surface* charge in addition to the charged sites within their molecules.

In 1990 Cheng *et al.* showed lysozyme (after one day) and an unidentified larger protein (after two days) in deposits on ionic high water lenses (etafilcon A, 58% water). The larger molecule was identified by Scott and Mowrey-McKee (1996) as being a dimer of lysozyme, i.e. the polymerization of two molecules of lysozyme into a larger molecule of twice the molecular weight of the base molecule. Such lysozyme dimers do not occur in the tear film, rather they are the result of lysozyme and lens polymer interaction.

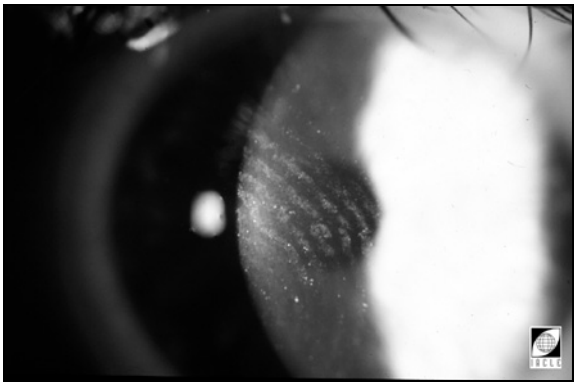
Slide 39 shows the denaturation of a protein (egg white) in response to heat. This is the equivalent of tear proteins on a lens disinfected by heat.

Should a protein film be allowed to continue to build, it will eventually crack as a result of lens flexure. Slide 40 illustrates the result.

Less dramatic presentations such as in slide 41 are more likely to be seen in practice. This slide shows a protein coating in direct retro-illumination (to the left of the main slit image). The image shows the translucent/transparent nature of the deposit as well as the refractile irregularities introduced by the deposit. The reduction in lens wettability is confirmed by the thin-film interference effect shown to the right of the main slit image. The direct illumination and/or specular reflection of the main slit image reveals the surface irregularity of the protein film as well as its extent.

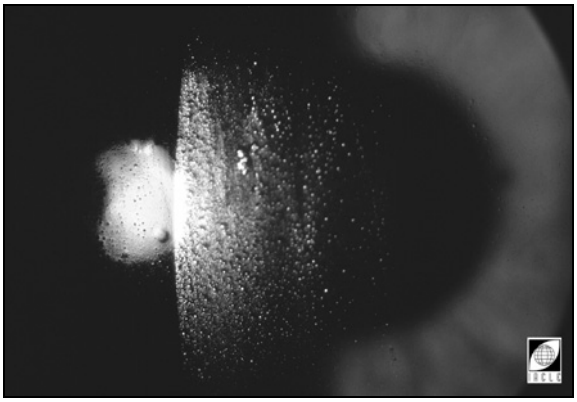
## IV.B Lipid Deposits

42



5L51618-95

43



5L50627-97

44

**APPEARANCE OF LIPID DEPOSITS**

- Minute droplets loosely bound to the lens surface making it hydrophobic
- Best observed between blinks
- Varies with individual patients
- Appears as a thick, oily coating

96720-26S.PPT

5L596720-26

### Lipid Deposits: Appearance

Lipid deposits appear as greasy, smooth and shiny adherent films on both RGP and soft contact lenses. Frequently, they form an incomplete film which looks like a fingerprint (Tripathi and Tripathi, 1984) especially if the lens is allowed to dry out a little (see slide 42 which shows a lipid deposit on an RGP lens with a typical fingerprint pattern).

The lipids involved include: phospholipids, neutral fats, triglycerides, cholesterol, cholesterol esters and fatty acids (Tripathi and Tripathi, 1984).

Because the films are not of uniform thickness or transparency, they affect adversely the wearer's vision.

The lids and blinking smear the film over the lens front surface (see slide 43 which shows a lipid deposit on a soft contact lens).

45

**ORIGIN OF LIPID DEPOSITS**

Lipids are mainly from the Meibomian glands
(lipids reduce tear film evaporation)

96720-27S.PPT

5L596720-27

## Source of Lipid Deposits

Lipids are derived mainly from the Meibomian glands whose outlet ducts are located along the upper and lower lid margins. The blinking action of the lids stimulates the Meibomian gland's secretory function.

The sweeping action of the upper lid spreads the lipid layer over the pre-corneal (or pre-lens) tear film, effectively 'resurfacing' it. This lipid layer serves to prevent evaporation of the tear film, particularly its aqueous phase. An intact tear film is central to the optical regularity and performance of the cornea-tear optical system. An intact tear film is partially responsible for the physiological well-being of the cornea and also has a lubrication role in lid movement over the eye and/or contact lens.

46

**LIPID DEPOSITS**
**PREDISPOSING FACTORS**

- Tear film quality
- Slow blink patterns
- Poor lens care compliance (particularly surfactants)
- Careless use of inappropriate cosmetics/lotions

96720-28S.PPT

5L596720-28

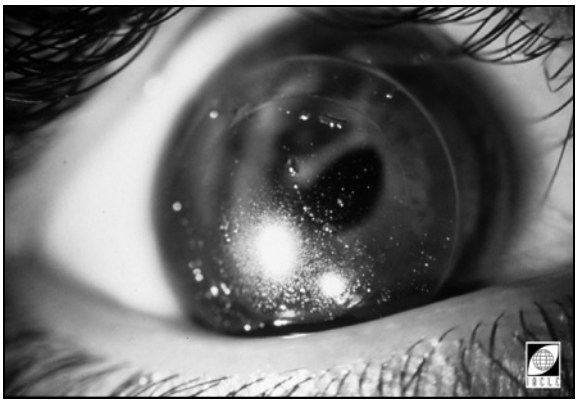
## Lipid Deposition: Predisposing Factors

Patients with oily tears and a thick lipid layer may be predisposed to higher levels of lipid deposition.

Some ocular conditions increase the lipid secretion rate from the Meibomian glands. Such conditions include: bacterial conjunctivitis, chronic blepharoconjunctivitis and meibomianitis

Exposure to a polluted environment can result in an accumulation of tear debris by virtue of the affinity of debris for tear lipids.

47



5L5008B-24

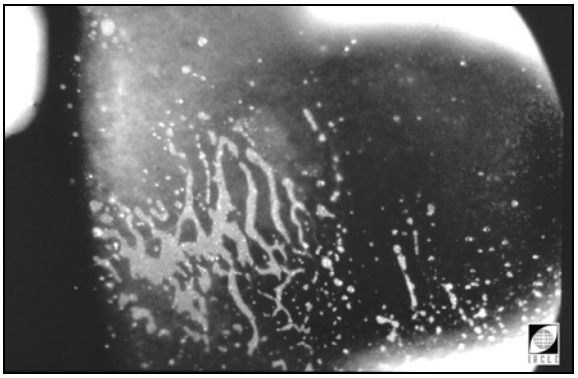
Therefore, regular surfactant cleaning of the lens, use of selected cosmetics and skin care preparations (preferably, oil-free or water-based formulations) as well as regular, frequent blinking to sweep away debris, should be practised to help prevent the deposition of lipids.

RGP lens surfaces that do not wet are more susceptible to lipid deposition. It has also been suggested that some RGP materials may be more prone to this type of deposit. However, there is no clear evidence of which materials fall into this category.

Soft lenses that are heavily deposited

with protein may also be more prone to lipid deposits because of surface dehydration.

48



5L5008F-6

More recently Jones *et al.* (1997) have demonstrated that the chemical composition of lens materials may also be a factor. They showed that, at least for the FDA group 2 (hi, non) and group 4 (hi, ion) materials tested, the vinyl pyrrolidone content was the predominant determinant of lipid deposition. The same study confirmed the suggestion that protein deposition was controlled by the ionicity of the lens material.

When an artificial tear solution was applied to new RGP and soft lenses, Bontempo and Rapp (1994) found that while lipids were deposited on all lenses tested, siloxane acrylate RGP lenses were two to three times more prone to lipid deposits.

They attributed this behaviour to the lipophilic-like character of the siloxane acrylate surfaces.

Fluoro-siloxane acrylates were not as lipid deposit-prone. This was attributed to the fluorine decreasing the lipophilicity of such lenses.

Conversely, siloxane acrylates with higher silicon contents were found to bind even more lipids because of their increased hydrophobicity.

Slide 47 shows extensive lipid deposition on an RGP lens.

Slide 48 shows a back surface combined lipid and mucus deposit on an RGP lens.

49

**LIPID DEPOSITS**

Problematic when:

- A thick, greasy coating decreases tear's ability to spread over lens surface
- Vision fluctuates

96720-29S.PPT

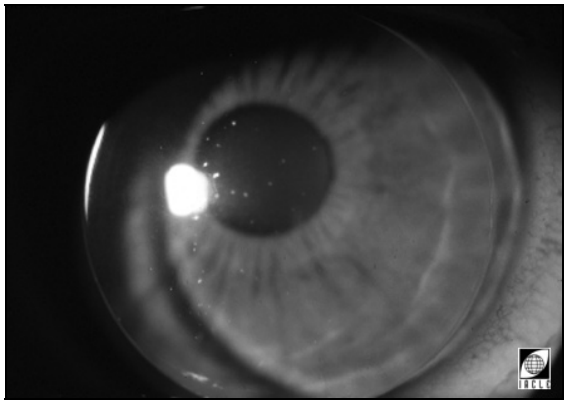
5L596720-29

**Management of Lipid Deposits**

Because lipid deposits form a thick, oily layer on the lens, fluctuating vision can result, especially as a direct result of a blink. The visual disturbance can be likened to looking through a grime-smeared car windscreen.

This type of deposit is easily removed using an alcohol-based surfactant cleaner which acts to prevent coalescence of lipid droplets on the lens surfaces.

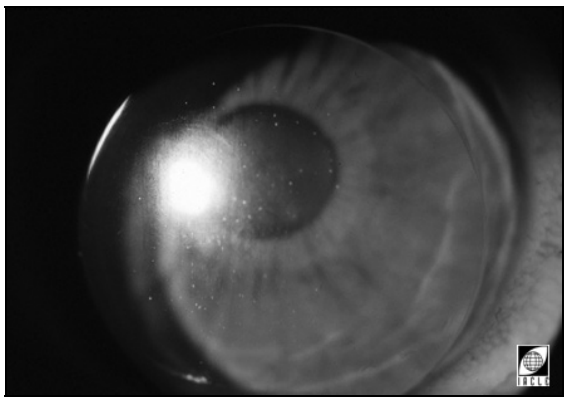
50



5L50198-97

Slide 50 shows an RGP lens immediately after a blink. A cursory examination of the tear film would pass it as being approximately normal. However, after a short period, in between blinks, the appearance changes. The real situation then becomes apparent, as shown in slide 51.

51



5L50199-97

## IV.C Jelly Bumps

52

**JELLY BUMPS**
**APPEARANCE**

- Appear as a clump of raised translucent mulberry-like deposits
- Typically form in inferior, exposed portion of lens

96720-30S.PPT

5L596720-30

53

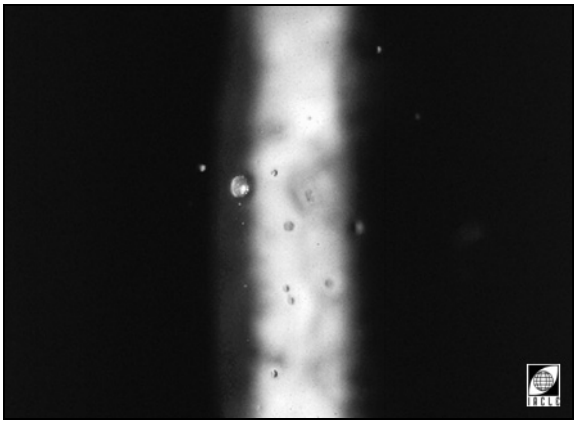
**JELLY BUMPS**
**FORMATION**

- Non-wetting area, interacting with tear constituents
- Tear lipids, proteins and occasionally calcium salts are involved
- Gradually builds into multi-layer deposit

96720-31S.PPT

5L596720-31

54



5L51199-92

### Jelly Bumps

Transparent or translucent jelly bumps occur more frequently on high water, ionic, EW lenses (Hart *et al.,* 1987). Their numbers can vary from one to many.

While they are predominantly lipid deposits they may also include:

- Calcium, protein or mucin (Tripathi and Tripathi, 1984).
- Calcium only as a minor component (Hart *et al.,* 1986, Hart, 1988).
- Lipid and lysozyme and calcium in varying amounts (Sabatine *et al.,* 1990).

Begley and Waggoner (1991) showed, using Energy Dispersive X-rays (EDX), that most such deposits did have calcium as well as polysaccharides (mucin) distributed finely throughout the nodules. Further, mucins and calcium were more obvious in the basal (closest to the lens) layers, suggesting that they may play a role in the early development of such deposits.

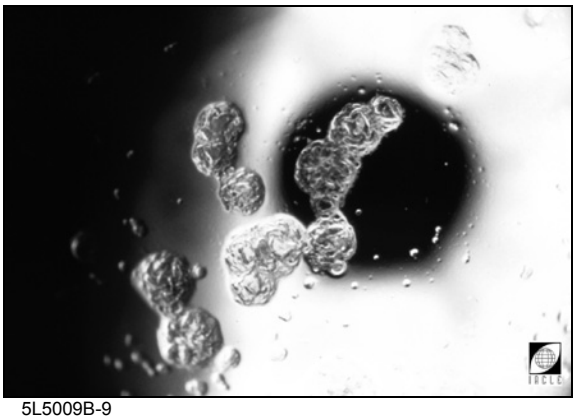
Tighe (1990) and Abbott *et al.* (1991) have suggested a similar mechanism. In discrete areas, the lens surface is preconditioned by unsaturated lipid material polymerizing at, and attaching to, the lens surface as a result of the tear film collapsing over the area. An elevated cholesterol-based lipid deposit builds on this polymerized layer. Free fatty acids that form the bulk of the subsequent 'deposit' can interact with calcium which may act as a stabilizing component. The latter assertion regarding the role of calcium has been cast into doubt by Abbott *et al.,* 1991.

Other factors implicated in the aetiology of jelly bumps are:

- Dietary factors such as cholesterol, protein and alcohol.
- Low tear-potassium levels induced pharmacologically (as experienced by diabetics and users of diuretics, anticholinergics or sympathomimetics)

(Hart *et al.,* 1987).

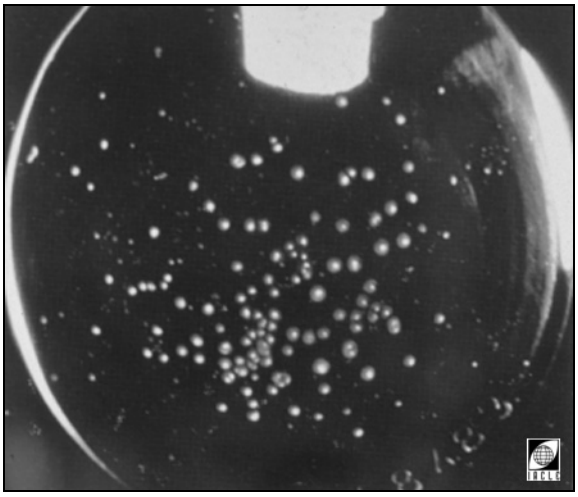
55



5L5009B-9

The typical appearance of jelly bump deposits on a lens surface is shown in the slide opposite. Usually, the discomfort (to the lids) caused by the protrusion of the deposit leads to cessation of lens wear. Therefore, it is rare to see large jelly bump deposits. The widespread use of disposable lenses has also made the clinical presentation of jelly bumps uncommon.

56

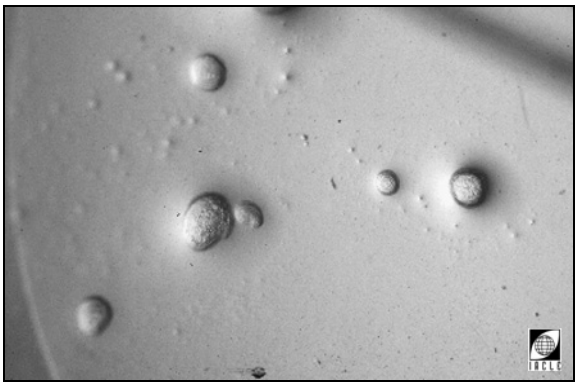


5L51450-91

Slide 55 shows a jelly bump deposit in retro-illumination. While relatively transparent, the refractile effects of the deposit can be seen clearly. The adverse effects on vision (refractive and diffusive) and comfort (elevated and not particularly smooth) are the usual reasons such deposits are reported by patients.

In advanced cases, the deposits are readily seen by the naked eye. Discomfort is usually experienced well before such a stage is reached. However, the ability of some wearers to 'ignore' the discomfort can be surprising.

57

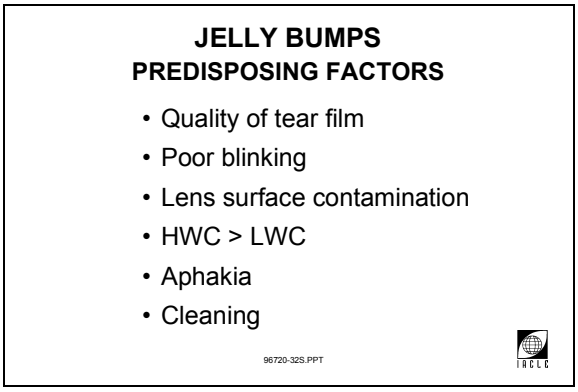


5L53113-93

Slide 56 shows numerous small lens calculi (jelly bumps) over much of the lens area.

A magnified view of jelly bumps on a lens surface showing reversed illumination (therefore they have a higher refractive index than the surrounding medium, i.e. the lens material).

58

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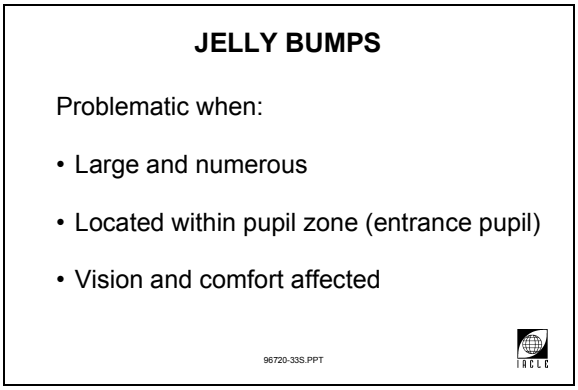
59




5L596720-33

## Jelly Bumps: Predisposing Factors

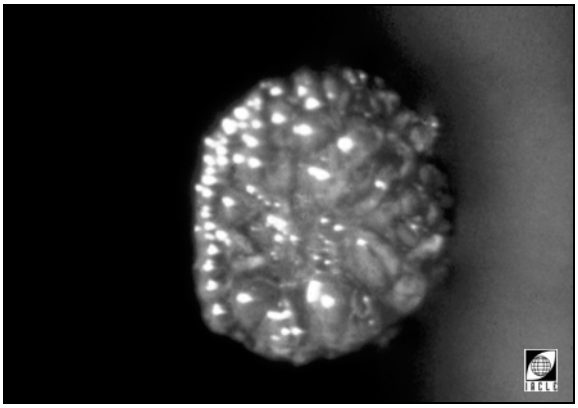
Susceptibility and predisposition to jelly bumps depends on:

- Quality of the tear film. Some patients exhibit a tendency for tear lipids and calcium salts to build up on the lens surface.
- Poor blinking, which allows drying of the tear film and adhesion of its constituents to the lens surface.
- Lens surface contamination. Jelly bumps require a lipid deposit as a prerequisite to their formation and 'growth'.
- The water content of the contact lens. High water content (HWC) lenses are more predisposed to jelly bump formation than low water content (LWC) lenses.
- Aphakic patients seem to have a higher incidence of this problem.
- Absence of, or poor, mechanical surface cleaning.

## Jelly Bumps: Consequences

- Large and numerous jelly bumps lead to wearer discomfort.
- Large deposits can cause the lens to attach to the upper lid so that each blink causes excessive lens movement.
- Visual acuity can fluctuate, especially when the jelly bumps are located within the pupillary area of the contact lens, interfering with the line of sight.
- Jelly bumps may also cause mechanical irritation of the tarsal conjunctiva.
- In extreme cases, jelly bumps may cause CLPC.

60



5L50187-97

## Management of Jelly Bumps

Removal of jelly bumps is impossible because their foundation forms within the lens matrix. Forced removal creates a pit in the lens which acts as a seed for rapid jelly bump re-growth. Regardless of whether the jelly bumps are removed or not, replacement is ultimately required and the eyes will benefit from lens replacement sooner rather than later.

Therefore, regular replacement of contact lenses is usually the most practical and convenient way to avoid problems and complications associated with jelly bump deposit build-up.

## IV.D Inorganic Deposits

61

**INORGANIC DEPOSITS**

- Inorganic films/salts
- Calcium carbonate deposits
- Calcium phosphate deposits

96720-34S.PPT

5L596720-34

### Inorganic Film/Salts

Inorganic films are insoluble accumulations of tear components on the surface and in the lens matrix. Such films can appear relatively rapidly (days/weeks as opposed to months).

These deposits, which normally do not occur in isolation, are generally covered by a protein film rendering rough surfaces smoother and the deposit more tenacious. As a result, removal can be even more difficult than for simple protein deposits.

Some controversy surrounds the role (if any) of calcium and calcium deposits in the formation of other deposits (Begley and Waggoner, 1991; Kleist, 1979; Hart, 1988). Nevertheless, the identification and differentiation of calcium deposits from other forms of deposits is important when planning their management.

62

**INORGANIC FILMS/SALTS**
**APPEARANCE**

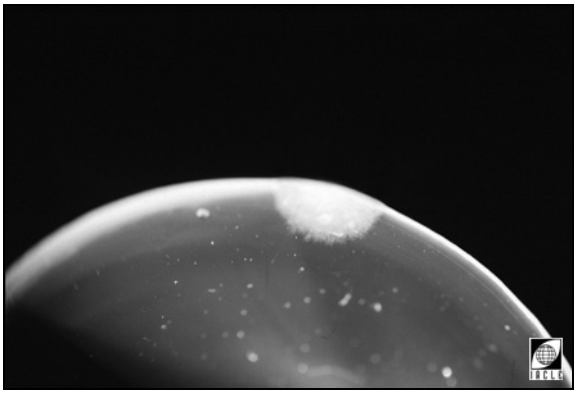
- White crystalline specks
- Can be small or large
- Rough surface
- Penetrate lens surface if severe

96720-35S.PPT

5L596720-35

The general appearance of inorganic deposits are summarized in the slide opposite.

63



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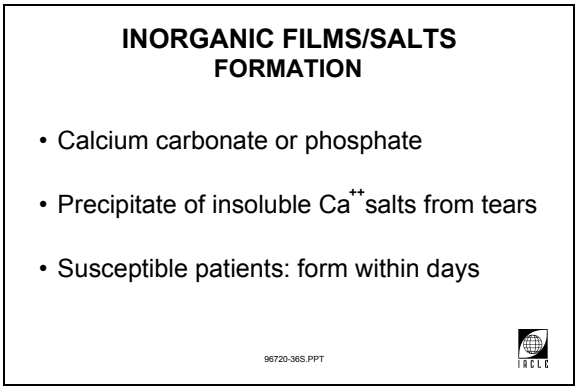
A typical calcium deposit is shown on slide 63.

64




5L596720-36

## Inorganic Films/Salts: Differentiation

Inorganic films are easily confused with protein films as their rough surface is covered by a protein film giving them a smooth texture. This is common amongst high plus lenses especially the lenses of aphakics. In the long term, this film can penetrate the lens in the form of crystalline deposits of inorganic salts.

### Causation

Inorganic films are formed by the precipitation and growth of calcium phosphate from the tears (Kleist, 1979).

Susceptible patients are those who are poor blinkers, have low tear break-up times and perhaps abnormal tear chemistry. In some cases the deposits form within days. There is also a greater tendency for these deposits to occur in patients with 'dry eye' or who are incomplete blinkers.

From various reports, it appears that inorganic deposits are more common with chemical disinfection (9 - 10%) than with thermal disinfection (1 - 4%).

There are also anecdotal reports that their incidence is higher when lenses are worn on an extended wear basis, especially if the lenses have a high water content.

Some lens materials may attract more calcium from the tears.

### Differentiating Deposits

Vehige and Sasai (1985) listed the differentiating characteristics for calcium phosphate and protein deposits:

| Calcium Phosphate | Protein |
|---|---|
| Visible with lens on eye | Not visible with lens on eye |
| Sharp, distinct borders | Indistinct borders |
| Pure white or milky blue off-white, | White or beige |
| Water-spot, finger print | No particular shape |

Granular, uniform texture Rough, non-uniform

Forms within matrix Forms on surface.

**Prevention**

- Avoid the use of tap water for cleaning or rinsing.
- Store the lenses in a non-phosphate buffered saline.

65

**INORGANIC FILMS/SALTS PROBLEM**

If heavily deposited:

- Damages lens surface
- Decreases comfort
- Decreases vision (if central)

Removal leaves pits in lens surface

96720-37S.PPT

5L596720-37

**Inorganic Films/Salts: Management**

Thermal disinfection may assist the removal of these deposits with patients prone to calcium deposits. While acetic acid may dissolve or reduce calcium phosphate deposits, it may also damage the lens.

As removal of such deposits leaves pits in the lens surface, prevention and replacement would seem to be the only effective method of management.

66

**CALCIUM CARBONATE CRYSTALS**

'Calcium carbonate deposits consist of crystalline growths that have a definite needle-like form when viewed under magnification'

96720-38S.PPT

5L596720-38

**Calcium Carbonate Crystals**

From the description opposite, it can be assumed that the rough texture of the lens will cause discomfort. This is common among extended lens wearers, with the crystals forming while the lens is still on the eye.

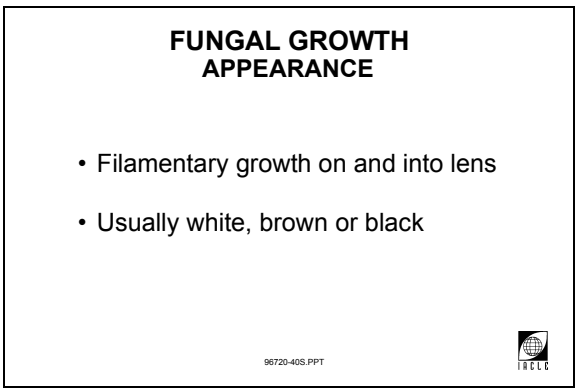
The small crystals are difficult to remove with chemical disinfection systems. however, they can be dissolved with thermal disinfection or the action of a dilute acid (e.g. hydrochloric acid).

As stated previously, removal leaves pits in the lens surface and ultimately lens replacement is required.

Abbot *et al.* (1991) studied surface-located white inorganic deposits on SCLs. The deposits were found to be structurally heterogeneous and composed of calcium phosphate-calcium carbonate overlaid on a lipid-rich organic layer to which it was not chemically bound. The organic layer contained elevated levels of cholesterol esters. This was attributed to the increased interaction of the lids with the rugous (rough or wrinkled) surface of the deposit.

## IV.E Fungal Deposits

67




5L596720-40

68

5L51439-93

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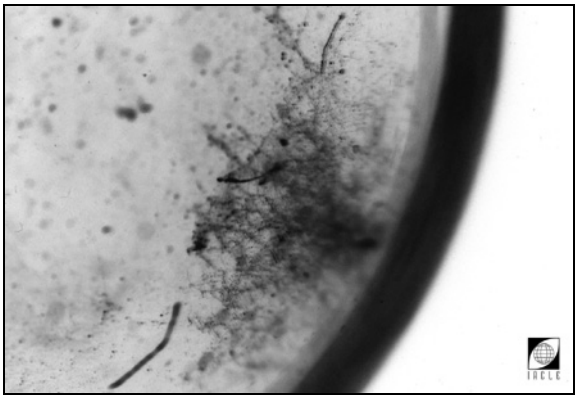

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### Fungal Growth

Fungi, in the form of yeasts (round cell fungi) or moulds, are usually found on the skin and mucous membranes. They have also been isolated in contact lens cases, therapeutic SCLs and conventional extended wear SCLs.

Hurtado *et al*. (1995) have identified several fungal genera found contaminating the surface or the matrix of SCLs. These include:

- *Penicillium sp., Aspergillus sp., Cephalosporium sp., Exophilia sp., Scopulariopsis sp., Scytalidium sp., Sclerotium sp., Rhinocladiella sp*.

Gray *et al*. (1995) have identified the following genera in lens cases:

- *Cladosporium sp., Candida sp., Fusarium solani, Aspergillus versicolor, Exophilia sp., Phoma sp*.

### Contamination Factors

The factors which predispose SCLs and lens storage cases to fungal contamination have yet to be investigated. From the Gray *et al.,* (1995) study neither proteolytic activity nor sensitivity to temperature are distinguishing characteristics of the list of fungi above. However, the incidence of biofilms in the lens cases used in the study was claimed to be a possible reason for a reduction in the efficacy of the disinfectants used.

A higher incidence of fungus penetrating lenses is also reported when unpreserved saline is used, especially home-made saline.

The sponge-like properties of SCL materials provide a medium and environment for fungal growth. Spores reach the surface of the lens via the atmosphere or the external eye. Fungus can then grow rapidly, both over the lens surface and into the lens matrix.

Fungal contamination of SCL is described as filamentary growths into the lens matrix (Ward, 1988). Sassani and

70

**FUNGUS FORMATION**

- Spores on lens surface from eye or environment
- Proliferates to large visible growth (filaments)
- Penetrates lens matrix
- Contact lens good medium for fungal growth

96720-41S.PPT

5L596720-41

Rosenwasser (1991) reported on fungal hyphae, simulating branching crystalline deposits in the lens matrix. The fungus was not identified by culture methods but by histologic examination using a scanning electron microscope.

Slide 68 shows a fungal growth on a soft lens as seen *in vivo.* Slide 69 shows a more extensive colonization of an SCL viewed *in vitro.*

71

**PREDISPOSING FACTORS**

- Improper lens care, e.g. prolonged storage in unpreserved saline without disinfection
- Susceptible patient, poor hygiene

96720-42S.PPT

5L596720-42

## Predisposing Factors

Yamaguchi *et al*. (1984) showed that the amount of fungal contamination (*Fusarium solani and Aspergillus flavus*) and depth of penetration is greater for high water content SCLs, which implies a need for better care and handling of such lenses. The same study showed that lenses with greater indentations (surface irregularities) allowed greater fungal colonization. Poor lens handling may make the patient more susceptible to fungal contamination.

The development of biofilms in lens cases is prevalent amongst patients who are non-compliant with lens care instructions. The importance of proper care of the lens case and its regular replacement is stressed in Unit 5.1.

72

**FUNGUS PROBLEMS**

- Fungal infection can damage the cornea
- Vision may be affected if growth is large and in pupil area

96720-43S.PPT

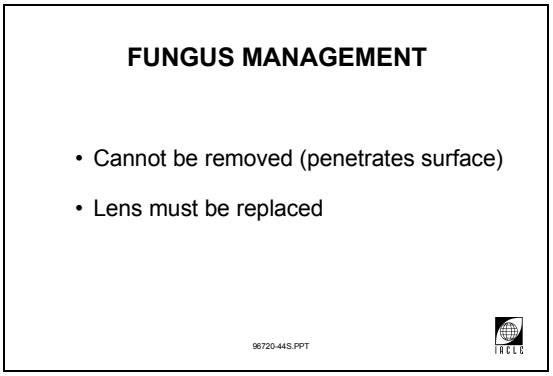
5L596720-43

## Fungal Infection and Healing

Corneal fungal infections can result in serious damage to the cornea. High levels of colonization can result in cytotoxic reactions and complications such as fungal keratitis (Wilhelmus *et al*., 1988) and even fungal ulceration in severe cases. Anterior eye fungal infections are very difficult to treat.

Filamentous fungal forms were seen amongst aphakics and cosmetic lens wearers while yeast forms were seen amongst therapeutic lens wearers. Healing can result in corneal scar formation and may interfere with vision if located in the pupillary zone.

73

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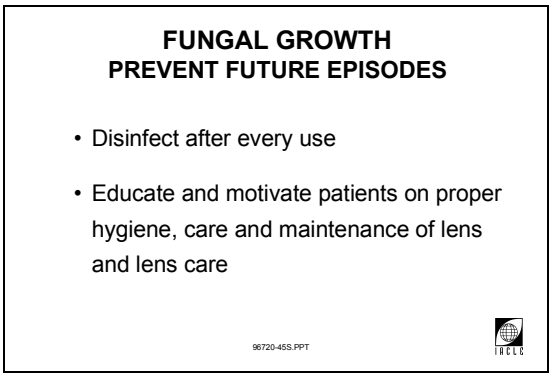


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## Management of Fungal Deposits

Fungus cannot be removed effectively from a contact lens, as it may have penetrated the lens matrix. Further, deep penetration of the lens matrix by fungal filaments helps to protect the fungus, especially in high water content SCLs. Therefore, fungal contamination necessitates lens replacement.

Patients susceptible to fungal contamination can benefit from using 3% hydrogen peroxide-based solutions (Lowe *et al*., 1992), preferably a two-step system (Gray *et al*., 1995) which allows a longer disinfection time.

For storage purposes, the peroxide should remain unneutralized until just before the lenses are to be worn.

## IV.F Lens Discolouration

75

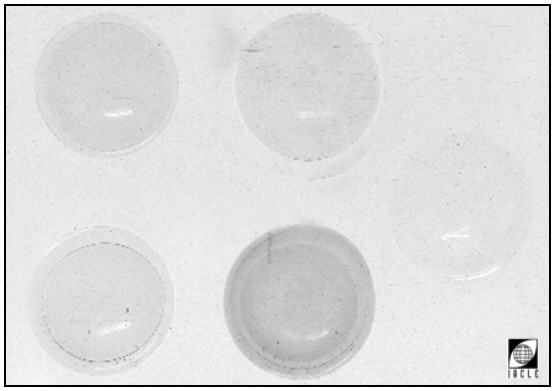
**LENS DISCOLOURATION**

- Natural lens ageing process
- Surface contamination
- Mercurial deposits

96720-46S.PPT

5L596720-46

76



5L50984-92

77

**LENS DISCOLOURATION**

- Colour dependent on the source of the problem
- Ranges from pink, yellow, brown, grey to blue haze
- More common in smokers

96720-47S.PPT

5L596720-47

78

**LENS DISCOLOURATION**
**MECHANISM**

- Foreign substance is absorbed into lens material
- Discolouration when concentration reaches a certain level

96720-48S.PPT

5L596720-48

### Lens Discolouration

Lens discolouration can result from:

- Natural lens ageing. An aged lens may appear to have reduced transparency and may be warped.
- Surface contamination. Contaminants such as pigment deposits, cosmetics, nicotine (cigarette smokers), iron (rust) and medications may be responsible.
- Mercurial deposits. These are usually due to the decomposition of mercury-containing compounds, e.g. thimerosal, phenylmecuric nitrate. Mercury deposits are usually grey to black in colour

Medications that contain epinephrine or phenylephrine can produce black, grey or brown discolouration. Such discolouration can be removed with an oxidizing agent (sodium perborate, sodium percarbonate, hydrogen peroxide with or without heat) Tetracycline can produce a yellow colour and phenolphthalein will usually produce a pink discolouration.

If patients are using ocular pharmaceuticals (eyedrops) they should be advised to instill them at least 10 minutes prior to lens insertion to avoid absorption of eyedrop constituents into the lenses. RGP lenses are less problematic in this respect.

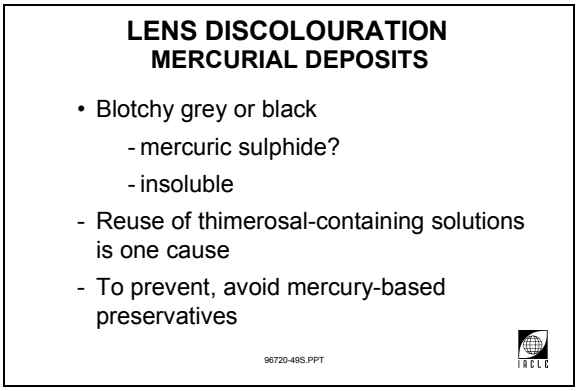
### Heat Disinfection

Heat disinfection can cause some lenses to yellow and may 'harden' (make more rigid) some soft lens materials. On those lenses for which thermal disinfection is approved, such effects are probably due to alterations of lens contaminants in and on the lens rather than alterations to the lens material.

### Sodium Fluorescein

Some lens yellowing may be due to inserting SCLs too soon after using sodium fluorescein to assess corneal integrity. Rinsing and soaking the lens in saline usually removes the dye. Generally, lenses which readily absorb fluorescein also readily allow its removal by leaching. Exceptions are usually ionic materials which may bind the sodium fluorescein within the lens matrix.

79




5L596720-49

### Lens Discolouration: Mercurial Deposits

Mercurial deposits appear as a blotchy greyish to black discolouration. The discolouration may come from insoluble compounds such as mercuric sulphide (Kleist, 1979), possibly a product of the interactions of mercurial compounds with sulphydryl groups in enzymes and other proteins (Stewart-Jones *et al.* 1989).

Reuse of thimerosal-containing solutions, mistreated lens cases and non-compliance with lens care instructions have been identified by practitioners and researchers as causes of this type of deposit.

Mercurial deposits are normally insoluble and are potentially toxic because of the concentration of mercury they represent. Rubbing and rinsing the lenses prior to storage, using fresh storage solution after every lens cleaning, and cleaning the lens case regularly are necessary. Use of lens cases that do not cause decomposition of thimerosal in the solution are important steps in the prevention of this form of deposition. Mercury-based lens care systems have persisted until quite recent times largely because of their anti-fungal properties. Avoiding mercury-containing solutions is the obvious answer to such problems, a step made easier by the contact lens industry which has now withdrawn most such products from the marketplace.

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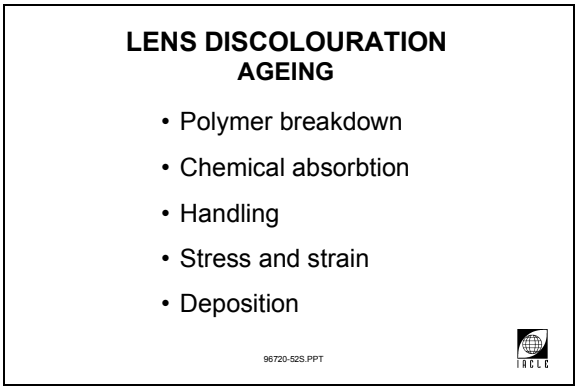


5L596720-52

## Lens Discolouration: Lens Ageing

Polymers change and break down over time and with use. The involvement of chemical absorption, handling, stress and strain factors and the effects of deposition all contribute to the ageing of a contact lens.

Lenses that age may develop a yellow discolouration and may even turn brown if the factors mentioned above are involved. Aged lenses may also be more brittle and develop a rougher surface texture (including scratches).

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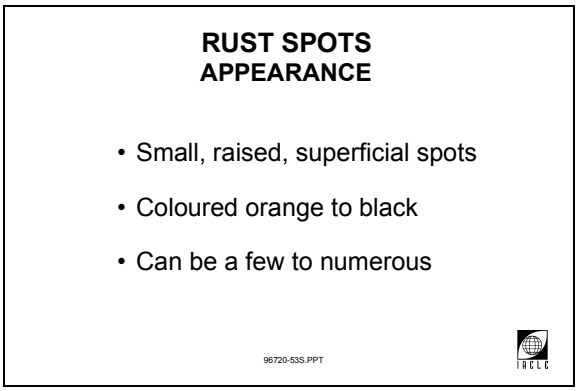


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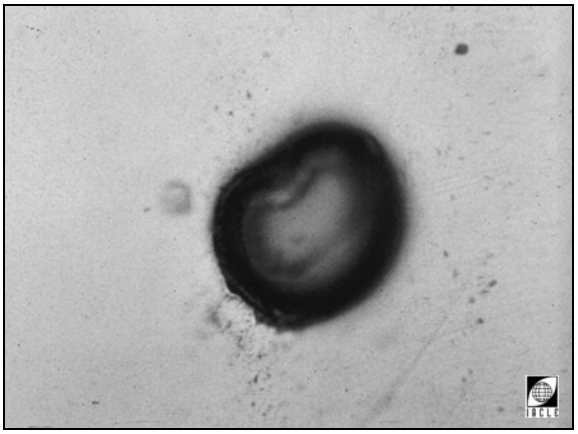
## Lens Discolouration: Rust Spots

Rust spots seldom affect comfort and are believed to be ferrous and ferric oxides (forms of oxidized iron) because they are usually on the front surface of the lens

These spots are often covered by a protein film and cause little discomfort. Enzymatic cleaning will remove the protein film but the orange rust spot remains.

Merindano *et al*. (1987) investigated the level of metallic cations, particularly iron, in new and used lenses of identical design and material. They confirmed the presence of iron compounds in contact lenses and showed they were mainly from the wearer/environment and not acquired during lens manufacture. Worn lenses were found to contain ferric cations, or ferrous or ferric oxides. Other metallic cations were also found in low concentrations including lead, magnesium, potassium and calcium. Some of these are physiological in origin. Improper lens handling was claimed to be a major cause of this type of contamination.

82



5L51112-92

Airborne iron particles once embedded in the lens, oxidize to form ferrous and ferric oxides which appear as blue or yellow/orange spots respectively (slide 82).

83

**SURFACE CONTAMINATION**

- Make-up,
  e.g. eye shadow, mascara
- Moisturizing lotion
- Hairspray
- Chemical fumes

96720-55S.PPT

5L596720-55

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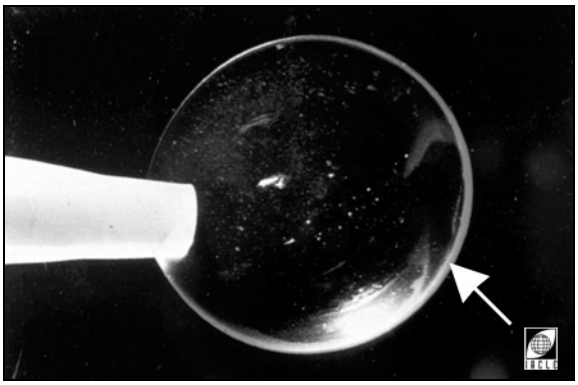

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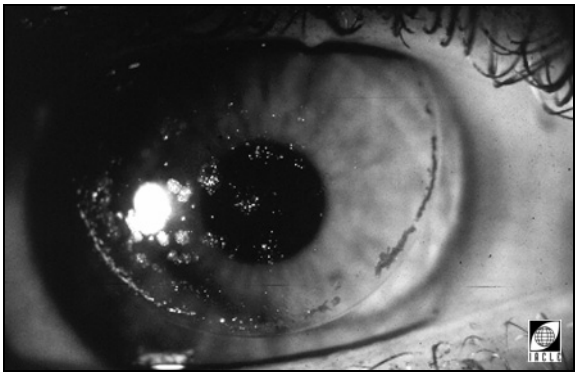

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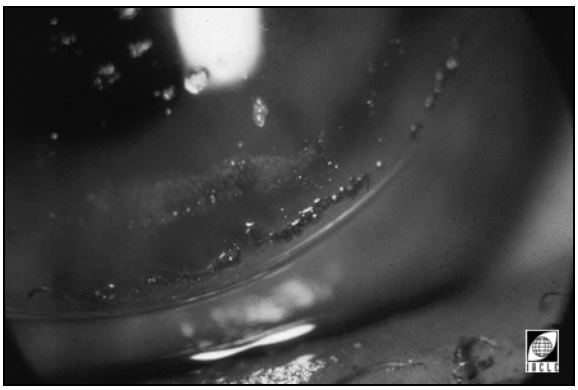

5L52516-93

## Lens Discolouration: Surface Contamination

Smears or scattered deposits on the lens may be the result of contamination by:

- Cosmetics: misapplied cosmetics such as makeup: eye shadow, mascara, hairspray (applied with eyes open?).
- Handling: moisturizing lotion, handling the lens after using hand lotion, soap, finger grease, dirt, nicotine, fingernail polish.
- Environment: chemical fumes, smoke, volatile chemicals, dust.

Contact lenses should be cleaned and rinsed to remove contamination. Patients should be advised on the proper use of cosmetics and other factors that may affect or damage CLs.

Slide 84 shows a typical contaminated surface which will affect lens wettability and tear break-up time.

While not clearly visible in this monochrome image, the colour and density of discolouration is best observed by examining the 'brighter' light-ring of the lens edge (an end-on or edge-on view of the lens interior, see arrow). Because of the exaggerated apparent thickness of this sectional view, even slight discolourations can often be detected.

Mascara and eyeliner can readily attach to contact lens surfaces, especially if the surfaces are already coated with protein or other contaminants. Water-based cosmetics, or cosmetics specifically formulated for use with contact lenses, are available and should be recommended.

Oil-based cosmetics, lotions and creams can coalesce as globules on the lens surface, creating non-wetting/non-wettable areas.

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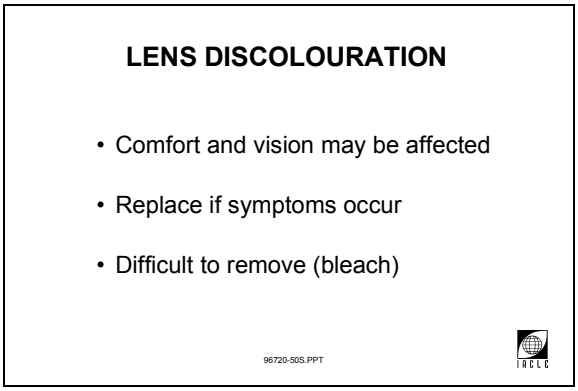


5L596720-50

**Management of Lens Discolouration**

In-office cleaning systems such as Liprofin™ (solution pH 9.5 to 11) can reduce the amount of deposition and make the lens look cleaner (bleaching). Other oxidising agents can be used, e.g. hydrogen peroxide with or without heat, especially at concentrations > 3%.

With the widespread popularity of regular replacement or disposable lenses, discolouration is no longer a significant problem.

88

5L596720-51

## V Summary of Deposit Management

89

**CONTACT LENS PRACTITIONER**

Must have the ability to:

- Identify deposits
- Recognise symptoms associated with deposits
- Determine whether deposits observed will cause problems
- Manage patients appropriately

96720-56S.PPT

5L596720-56

90

**DEPOSIT RELATED SYMPTOMS**

- Discomfort: irritation, dryness
- Fluctuating vision, variable with blink
- Decreased wearing time
- Redness of the eye

96720-57S.PPT

5L596720-57

### Deposit-Related Symptoms

Generally, the severity of symptoms relate to the level of deposits present on the lens.

As well as examining the lenses and discussing the symptoms with the patient, it is important to evert the upper lids to investigate any increase in papillae and/or redness.

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**HOW TO BEST MANAGE DEPOSITS**

- Proper care and maintenance
- Regular replacement before spoilage
- Good personal hygiene

96720-58S.PPT

5L596720-58

### How to Best Manage Deposits

Proper care and maintenance of contact lenses is the cornerstone of patient problem minimization unless lenses are replaced on a daily basis (i.e. no lens care is the ultimate answer).

As long as deposits are maintained at a clinically insignificant level, they will not usually create a problem. One obvious way to achieve this is to discard contact lenses before they become problematic. An alternative still being researched is the highly deposit-resistant contact lens.

While deposit-prone patients are obvious candidates for regular lens replacement and disposable lens programmes, it could be argued that since prevention is the aim of such programmes, all patients would benefit from such schemes.

Regardless of the lens care system and lens replacement regimen used, lenses still come in contact with the wearer's

| | |
|---|---|
| | hands. Therefore, good personal hygiene is essential if the incidence of eye infections and lens contamination, discolouration and deposits are to be minimized. |

# Tutorial 5.5

(1 Hour)

# Identification of Deposits on Contact Lenses

# Tutorial

## Session 1: Part A

Presentation of slides of deposited lenses

Description, identification and development of a management plan for contact lens deposits

## Session 1: Part B

Detailed discussion, by the educator, of the slides presented previously (part A)

Inspection of contact lenses with various types of deposits

## Session 2: Quiz and Discussion

Questions on lens care and a discussion of the answers

# Tutorial Session 1: Part A

**Deposits: Describing, Identifying and Managing**

A series of slides of deposited contact lenses is to be shown. The students are to:

- Describe what they see.
- Tentatively identify the likely cause and nature of the deposit(s).
- Describe what problems are likely to be experienced by the wearers of such lenses.
- Describe what can be done (if anything) to resolve or manage the problem in the interests of the patient.

## RECORD FORM

**SLIDE 1: DEPOSIT NAME:**

(a) Appearance _____

(b) Origin _____

(c) Severity _____

(d) Can this be removed? _____

(e) Recommended removal solution _____

(f) Prognosis _____

(g) Is lens replacement necessary? _____

(h) Symptoms patients may have _____

**SLIDE 2: DEPOSIT NAME:**

(a) Appearance _____

(b) Origin _____

(c) Severity _____

(d) Can this be removed? _____

(e) Recommended removal solution _____

(f) Prognosis _____

(g) Is lens replacement necessary? _____

(h) Symptoms patients may have _____

**SLIDE 3: DEPOSIT NAME:**

(a) Appearance _____

(b) Origin _____

(c) Severity _____

(d) Can this be removed? _____

(e) Recommended removal solution _____

(f) Prognosis _____

(g) Is lens replacement necessary? _____

(h) Symptoms patients may have _____

**SLIDE 4: DEPOSIT NAME:**

(a) Appearance _____

(b) Origin _____

(c) Severity _____

(d) Can this be removed? _____

(e) Recommended removal solution _____

(f) Prognosis _____

(g) Is lens replacement necessary? _____

(h) Symptoms patients may have _____

## Tutorial Session 1: Part B

The educator should repeat the slide presentation. For each slide they should provide a comprehensive review. While reviewing, any misconceptions and errors apparent from the student responses to the initial presentation should be corrected. The review should be as interactive as possible.

If suitable examples of deposited contact lenses are available these should be made accessible along with a suitable observation system (magnifier, stereo microscope or slit-lamp). If at all possible, RGP lenses should be included, since it is easy to convey the erroneous impression that deposits are only a soft lens problem.

# Tutorial Session 2

# Quiz and Discussion

**Name:**_____ **Date:**_____

**Instructions:** Having been presented with the lecture on contact lens deposits (Unit 5.5) and been shown slides on deposited contact lenses (Tutorial Session 1), and possibly real deposited lenses, the students should attempt to answer the questions below. Once completed, a discussion of the answers and an open forum should follow.

**Questions:**

**1. Name at least five methods of examining contact lens deposits.**

_____

_____

_____

_____

**2. What is the effect of the rejuvenation (restoration or deep cleaning) process on a deposited lens? Briefly describe the underlying principles of such a process.**

_____

_____

_____

_____

**3. Differentiate calcium salt deposits from jelly bumps or lens calculi.**

_____

_____

_____

_____

**4. Differentiate rust spots from mercurial deposits.**

_____

_____

_____

_____

**5. Which care regimen should be prescribed for patients with a history of protein deposition?**

## 🕮 References


Abbott JM *et al.* (1991). *Studies in the ocular compatibility of hydrogels.* J Brit Cont Lens Assoc. 14(1): 21 – 28.

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