History of Contact Lens Care

Evolution of SCL Lens Care

circa 1971

Heat disinfection with components:
- daily cleaner
- saline rinse (homemade!)
- steam disinfection
- weekly cleaners (enzymes)
**Evolution of SCL Lens Care chemical systems**

<table>
<thead>
<tr>
<th>Chemical disinfection:</th>
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</thead>
<tbody>
<tr>
<td>• daily cleaners</td>
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<tr>
<td>• saline rinse</td>
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<tr>
<td>• overnight chemical disinfection (e.g. thimerosal, chlorhexidine)</td>
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<tr>
<td>• morning saline rinse</td>
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<tr>
<td>• weekly cleaners</td>
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</table>

**Evolution of SCL Lens Care chemical MPS**

<table>
<thead>
<tr>
<th>All-in-One Multipurpose solutions: clean, rinse and disinfect in one step</th>
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<tbody>
<tr>
<td>• Patients were told they no longer needed to ‘rub and rinse’ their lenses</td>
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**Contact Lens Care Product Associated Non-infectious inflammations**

- Hypersensitivity
  - Cell mediated, T-cell dependent reaction
  - May develop in predisposed individuals following prolonged exposure

- Cytotoxicity
  - Acting as a poison
  - Causes irritation and tissue damage
  - Dose related
  - Preservatives, cleaners, disinfectants

**Corneal Staining**
Toxic/inflammatory Reaction
Lens Care Product

Toxic Reactions to MPS
• Early or late onset of S&S
• Often a history of recurrent low-level irritation/redness that resolves post d/c CL wear and returns when CL wear resumes; +/- multiple treatments with Ab & anti-inflammatory meds
• Injection and SEIs tend to present early at superior limbus, then more diffuse

Comparative Toxicity of Preservatives on Immortalized Corneal and Conjunctival Epithelial Cells

• Conclusions
  • All multidose eye drops and CL care products use some form of solution preservation
  • Even at low concentration, these agents will cause some degree of ocular tissue damage

Decreasing order of toxicity:
  • Thimerosal
  • BAK
  • Chlorobutanol
  • Methyl paraben
  • sodium perborate
  • EDTA

Label: No Rub
Message: No Care
This ‘no care’ concept has led to dangerous complacency among patients and practitioners as regards to disinfection, comfort and lens functionality

Rub Vs No Rub
• The No Rub label was approved by replacing rubbing with extra rinsing
• FDA requires a 5-sec/side/ lens rinse with MPS to pass FDA challenge tests
• Either rub it off or hose it off
• Si-H lenses need to be digitally cleaned to prevent
  • lipid build up (decreases wettability, blurs vision), and
  • denatured protein build-up (increases inflammations)

Rinse it off or rub it off?
Silicone Hydrogel properties / characteristics

Si-H lens chemistry makes them behave differently:
• Very high gas permeability
• Material stiffness
• Lower water content; higher bound water
• Low levels of total protein uptake, but higher binding of denatured proteins
• Higher levels of lipid uptake
• Less dehydration

Lipid Deposition on Si-H (vs. HEMA)
Jones and Senchyna

The End of No Rub?

• Lack of proper lens care and hygiene play a significant role in MK
• “Rub & Rinse” significantly decreases debris & microbial load on CL surfaces
• Complacency from “No Rub” label likely plays a role in MK

Dry Eye

Unfortunately, a significant number of CL wearing patients are lost each year due to dryness-perceived discomforts

New Formulations

• Industry responded by introducing new product formulations to address lens drying concerns
• Lubricants/humectants/osmotics were added to lens care products to reduce lens dehydration

2004-2006 MPS Formulations
Looking for the Silver Bullet

- The key to preservative/disinfection use is to have sufficient concentrations for antimicrobial efficacy, yet low enough to prevent toxicity.
- Toxicities are dose-related events.
- All preservatives are toxic if used in excess concentrations.

It is always a balance between toxicity and antimicrobial efficacy.

Infection

- Infection: Invasion by microorganisms with associated inflammatory response and tissue damage.

Fungal Keratitis

- Fungal Keratitis: Cases of fungal keratitis associated with ReNu with Moisture Loc were reported in sub-tropics of South Asia and later in the USA & other countries.

Outbreak of Fusarium Keratitis

- Chang et al. (USA):
  - Case-control
  - 164 confirmed cases
  - 154 associated with RML
- Khor et al. (Singapore):
  - 68 cases
  - Associated with poor contact lens hygiene and RML.

Acanthamoeba Keratitis

- Acanthamoeba Keratitis:
  - This action followed reports and data from CDC regarding an increase of Acanthamoeba keratitis.

References:
- Chang et al., JAMA 23:2006
- Khor et al., JAMA 295:2006
Acanthamoeba Keratitis CDC data

- 138 cases of culture + AK since January 2005
- Initial analysis of 46 patients:
  - 39 wore SCL (85%)
  - 3 wore RGP (7%)
  - 4 no CL wear (9%)
  - 35 (83%) reported showering while wearing CL
  - 16 (38%) wore CL while swimming
  - 56% reported using CMP
  - 16-fold greater risk of AK if using CMP

WHY DON’T WE SEE MORE CONTACT LENS ASSOCIATED MICROBIAL KERATITIS?

Ocular Defenses

- Decreased ocular temperature
- Mechanical action of blinking
- Tear film; Constant irrigation by lacrimal secretions
- Intact epithelial surface

Antimicrobial activity of resident microbes
- Tear lysozyme
- Immunoglobulins and complement in tears
- Anti-microbial peptides on ocular surface, TLRs

Ocular Microbiota

The normal flora will change (quantitatively and qualitatively) with environmental conditions, such as humidity, temperature and substrate availability...and contact lens wear
Symbiosis

- Three types of symbiotic relationships:
  - commensalism
  - mutualism
  - parasitism
- Mutualism - these bacteria receive a place to live and feed while keeping other harmful microbes from taking up residence.

Microbial Keratitis

- Microbial keratitis is the most feared complication of contact lens wear
- Categorically, bacteria are the most rapidly destructive of any infectious microbes
- More MK is caused by *Pseudomonas* sp. than any other organism

Pseudomonas
the most common organism in CLaMK

- *Pseudomonas* is a g-negative rod
- *aerobic/ facultative anaerobic
- *P. aeruginosa*: opportunistic pathogen
  - ubiquitous water & soil organism
  - nosocomial infections, abrasions, contact lens associated corneal ulcers
  - proteolytic enzymes block eukaryotic cell functions => necrosis
  - virulence factors => rapid destruction of cornea

Inducible enzymes

- Bacteria react to changes in their environment through changes in patterns of structural proteins, transport proteins, toxins, enzymes, => virulence

Inflammatory Response

- Epithelial cell TLRs recognize bacterial invaders, activate cytokines & chemokines, which recruit PMNs & other WBCs
- Excessive stimulation of the host immune response leads to corneal tissue destruction

biofilm - glycocalyx; polysaccharide slime scaffold
- increases attachment; persistent survival
- protects from antibodies, complement, disinfectants, antibiotics
CL-a-Microbial Keratitis

- Pseudomonas
- Staphylococcus
- Streptococcus
- Fungi
- Amoeba

Risk Factors for Microbial Keratitis

- #1: Sleeping in contact lenses
- Wearing CL during water activities
- High ametropias
- < 25 years of age, and new wearers
- Ordering CLs on line (4.8 X)
- Poor hygiene; smoking

Lessons from the Keratitis Outbreaks

- As reported by The Ophthalmic Devices Panel of the Medical Devices Advisory Committee, 2008


New Testing Methods should include:

- Silicone hydrogel CL
- More diverse and representative set of infectious organisms, including Acanthamoeba
- “Real world” scenarios
  - Noncompliant care/ solution evaporation
  - Clinical isolates
- Contact lens and case

Limitations of the current regulatory testing methods:

- Stand Alone: no lens or case
- Regimen: only 2 lens types:
  - One Group I
  - One Group IV

U.S. Food and Drug Administration (FDA) Activities
Research


Solution Components

• Surfactants/Cleaning agents
• Chelating/Sequestering agents
• Buffers
• Antimicrobials/Biocides/Disinfectants/Preservatives
• Salts
• Demulcents
• Lubricants/Wetting agents

Biotrue (Bausch + Lomb)

• Matches the pH of healthy tears
  • sodium borate and boric acid (7.4-7.6)
• Utilizes lubricant naturally found in eye
  • hyaluronic/hyaluronic acid
  • glycosaminoglycan (mucopolysaccharide)
• Keeps beneficial tear proteins (lysozyme and lactoferrin) active
  • Enhances antimicrobial activity
• Dual disinfection:
  • Polyhexamethylene biguanide (PHMB)
  • Polyquaternium-1 (PQ-1)

RevitaLens OcuTec (Abbott Medical Optics)

• Dual disinfection:
  • Aldexine dihydrochloride (biguanide)
  • Polyquaternium-1 (PQ-1)
• Sodium borate (buffer)
• Tetronic 904 (block copolymer surfactant) → lubrication
• EDTA (chelant) → decreases deposit formations
  • EDTA (chelant) → decreases deposit formations

OPTI-FREE PureMoist (Alcon)

• Same as RepleniSH:
  • Cleaning (Citrate/Tetronic 1304)
  • Disinfecting (POLYQUAD .001%)
• New:
  • Disinfecting (Aldox .0006% vs .0005)
  • Chelating (added EDTA)
  • Wetting Agent (poly-[(oxyethylene)-poly (oxybutylene)])
Ocusoft Lens Care System
(Ocusoft, Inc./Essentia Pharma, LLC)

- 3% hydrogen peroxide
- Lubricating agent
- No added preservatives
- Limited retail availability:
  - dispensing from doctor’s office
  - direct patient order: www.ocusoft.com
- Same composition as OneStep

KeraSoft IC (UltraVision CLPL, Bausch + Lomb, Art Optical)

- Digitally rub between fingers
- Recommended products:
  - Any MPS or hydrogen peroxide system
- If chemically disinfected with MPS, rinse thoroughly with fresh, sterile rinsing solution prior to placement on the eye

NovaKone (Alden Optical)

- “compatible with any of the soft contact lens solutions on the market”
- Recommendations:
  - peroxide system
  - ClearCare
  - Oxysept
  - Sauflon
  - daily cleaner
  - enzymatic cleaner

Hydrogen Peroxide
Mode of action

\[ \text{H}_2\text{O}_2 \rightarrow \text{H}_2\text{O} + \text{O}_2 \]

- produces free radical superoxide, which is toxic to microbes;
- damages DNA
- strong oxidant
- not affected by organic matter
- removes proteins & lipids from lens surfaces

D - Values for 3% hydrogen peroxide
Hydrogen Peroxide Disinfection Systems

- Catalase enzyme neutralized (Oxysept)
  - full 3% strength for >20min; delayed neutralization
- Catalytic disc neutralized (AOSept, ClearCare, Sauflon)
  - decreasing peroxide concentration
  - age of disc determines if neutralization occurs in a few minutes or several hours

Peroxides

- Very effective, and preservative free
- For daily use; not for occasional CL wearers
- Caution patients not to store ‘spare lenses’ in neutralized peroxides
- Most common problem is toxicity from non/insufficiently neutralized H₂O₂

What’s in the “Brown Bottle”?

- cleared by the US FDA for ophthalmic use
- extensive clinical trial testing as well as analytical (preclinical) testing, which includes shelf-life stability and disinfection efficacy
- not micro-filtered, purified or sterile
- may also contain heavy metals or stabilizers not suitable for ophthalmic use and may discolor contact lenses; these impurities and stabilizers remain after neutralization

Brown Bottle H₂O₂

- May vary in %
- No neutralization
- Hypotonic, which may cause lenses to bind to the cornea upon insertion
- Not buffered: pH can be as low as 3.5
  - disinfection and neutralization may be inconsistent or inadequate:
    - burning, stinging, lens discoloration, and other problems
- Does not contain surfactants: aid in the cleaning and comfort of contact lenses

Contact Lens Solutions and Air Travel

- United States Transportation Security Administration (TSA)
- will not pass through 3 ounces of solution in a 12 oz. bottle

Don’t Let Your Patients...

Contact Lens Case (Contact Solution)

- Holds “up to 3 weeks” of “your favorite brand solution” inside the case
- Patented “one-touch design” dispenses solution from inside the case
- “TSA-approved” for air travel
- “Provides microbial protection”
What Your Patients Can Do:

- Purchase travel-sized bottle:
  - RevitaLens Ocutec (Abbott Medical Optics), OptiFree PureMoist and RepleniSH, Clear Care, Opti-Free GP (Alcon), BioTrue, ReNu, Boston Simplus, and Boston Advance Comfort Formula (Bausch + Lomb)
- Request a sample care kit from your office
- Declare MPS as an “over-the-counter medication,” bypassing the 1 quart bag altogether
- Check it through

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Private Label Contact Lens Solutions

What’s in the Bottle?

Recent History of the Alcohol-based daily cleaner

- MiraFlow (CIBA) d/c January 2010
- CVS brand d/c 2011
  - Sereine Extra-Strength Daily Cleaner (Optikem International)
  - Walgreens Extra Strength Daily Cleaner (Optikem International)
  - Lens Fresh (Orion Vision Group, formerly Marietta)
  - Sof/Pro2 Extra-Strength Daily Cleaner (Lobob)

GP Lens Care

- Surface cleaning/debulking of debris
- Rinsing
- Disinfection
- Surface cushioning/conditioning
- Wetting/rewetting
- Lens storage case care
Surface Cleaning

- Removing Debris & Deposits
  - Tear debris
  - Make up
  - Facial/hand creams
  - Inadequate cleaning
    - Hydrophobic
    - Irregular surface
    - Debris attachment cycle

More Daily Cleaners

- Abrasive
  - Boston Cleaner

- Mildly Abrasive
  - Alcon Opti-Free
  - Boston Advance

- Non-Abrasive
  - Optimum by Lobob Extra Strength Cleaner

What should be used to rinse daily cleaners?

- Water
- Tap
- Bottled
- Distilled
- MPS
- Saline
- Unit dose
- Aerosol

Disinfection

Chemical vs Peroxide

- Optifree Daily Cleaner, Opti-Clean II
  - abrasive polymeric beads, PQ-1
- Miraflo Equivalents

- Of note:
  - Detergents
  - Solvents
  - Abrasives
  - +/- preservatives
Chemical Gas Permeable Lens Care Products

Care System or All-in-One MPS?

Multipurpose All-in-one Solutions

Cleaning, disinfecting, soaking, wetting
- Simplus (B+L)
- Unique pH /
  - Opti-Free GP (Alcon)

Unique pH (Menicon) Opti-Free GP (Alcon)

- multipurpose solution
- Polyquaternium-1 preserved @ 0.0011% & EDTA
- Hydroxypropyl guar, PEG, PG, boric acid
- viscosity adjusts with pH
  - ↑pH = ↑viscosity
  - ↓pH = ↓viscosity

Boston Simplus (B+L)

- Contains poloxamine to remove dirt & repel deposits from lens surfaces
- Hydroxyalkylphosphate (HAP) for protein removal
- Chlorhexidine & PAPB for disinfection
- Glucam-20 & Hydroxypropylmethyl Cellulose (HPMC)
  - Cushioning on insertion
  - Uniform wetting
  - No evening rub; + Morning rub n rinse

GP Care Systems

- Boston
- Boston Advance
- Optimum
  - ESC, CDS, WRW
- Menicon
  - CDS, WRW

Optimum (Lobob)

- 3 part system
- Separate:
  - Extra strength cleaner
  - Cleaning, soaking, disinfecting
  - Wetting/Rewetting
Optimum (Lobob)

- Extra Strength Cleaner = ESC
  - cocoamphodiacetate and glycols
- Cleaning/Disinfecting/Storage = CDS
  - benzyl alcohol 0.1%, disodium edetate 0.5%, surfactants
- Rewetting Drops = WRW
  - benzyl alcohol 0.1%
  - disodium edetate 0.5%
  - sorbic acid 0.05%
  - PVA, PVP, mc

Menicare (Menicon/Lobob)

Boston Advance Conditioning Solution

- PAPB 0.0005%
- Chlorhexidine 0.003%
- Polyquaternium 10
- PVA, EDTA, buffers, salts

Soaking/Disinfecting/Storage

- Chemical disinfection
- Surface conditioning
- Deposit resistance
- Wetting
- Storage
  - Change, daily, weekly, or store dry?

Additional Cleaners

Enzymatic Cleaners

- Papain (papaya)
  - no longer available
- Pancreatin (porcine protease)
  - Supraclens
- Subtilisin A (endopeptidase from B.subtilis)
  - Ultrazyme, Boston one-step liquid enzyme, Unizyme
Progent (Menicon)

A = sodium hypochlorite
B = potassium bromide

Mix A and B doses in the Progent vial

- Soak the lenses for 30 minutes (soaking over 30 minutes may discolor lenses)
- Rinse the lenses and vial thoroughly for at least 15 seconds with Menicare Plus

Scleral Contact Lens Care

- Surfactant cleaning / rinse
- ≥ 2 hour soak in H$_2$O$_2$, followed by neutralization
  - Alternative: use commercial H$_2$O$_2$
- Dry storage
- Clean / rinse / wet prior to reuse

Scleral Lens Solution Survey

- No current standard of care
- Soaking: 72% GP solutions, 48% hydrogen peroxide, 17% SCL solutions
- Rinsing: 7% GP solutions, 7% SCL solutions, 7% preserved saline, 28% other (AT)
  - 72% nonpreserved saline
  - Off-label in U.S.
  - Careful with contamination: unit-dose 0.9% NaCl
  - Inhalation/irrigation: nonpreserved saline supplied in 3 or 5 ml. vials

Prior to Insertion:

- Filling the bowl:
  - Nonpreserved saline least toxic
  - Nonpreserved AT for lubrication
  - Can add Refresh Celluvisc (Allergan)
  - Prevents spillage
  - All off-label in U.S.
- Fill the entire lens to edge, not just the “bowl”
  - Prevents air bubbles that occur upon insertion

Gromacki S.J. Handling and Care of Scleral GP Contact Lenses, Part 1, Contact Lens Spectrum 2011;27(10):27
Care

- Clean manually with daily cleaner suitable with GP lenses
- Rinse with nonpreserved saline
- Disinfect with GP conditioning/disinfection solution
- MPS OK for minimal depositors
- Sensitive eyes:
  - Rinse with nonpreserved saline prior to insertion (less wettable) and/or:
  - Clear Care (Alcon) (may need larger case from Dry Eye Zone)

Contact Lens Care

Piggyback

- For SCL/GP combined Tandem system:
  - Remove GP, clean with GP daily cleaner, rinse and store in MPS or peroxide
  - Do not use Boston Cleaner on Menicon or other surface treated materials
  - Remove SCL, clean, rinse and store in MPS or peroxide
  - In the morning, rinse & wet both lenses with MPS or PFAT prior to placing on eye
  - Do Not Allow GP Solutions to Come in Contact with SCL materials

Hybrid Contact Lenses

Duette™ (SynergEyes)

SynergEyes “highly recommends”:
- Clear Care®

Duette™ also approved for use with:
- Aquify
- Express/Replenish
- Complete
- ReNu
- GP cleaners and solutions contraindicated
- Replace lenses q 6 mos.

ClearKone™ and UltraHealth™ (SynergEyes)

- Daily Cleaner
- Rinsing: only preservative-free saline, e.g. Unisol®4 (Alcon)
- Disinfection:
  - Clear Care® (Alcon)
  - Oxysept® Ultracare® Formula (AMO)
PuriLens
• 15-min. cycle
• short wavelength UV irradiation
• subsonic shear
• UV radiates solution, not lenses or certain areas of case/lens holder
• uses 4oz non-preserved saline

Contact Lens Wear
• Contact lens wear is not a sterile event, but it should be a clean one
• Consider:
  • Our eyes are not sterile
  • Our fingers are not sterile
  • Only new lenses are sterile – until they are touched

Biofilms
• "a microbial community" that can aid in bacterial adhesion and colonization by secreting substances that act as a scaffold
• May contain multiple species of organisms and can render resistance to the biocide properties of lens care products
• Relevance for CL wearers:
  • Case contamination
  • CL surface contamination

Potential Problems
Ultraviolet Disinfection Systems
• Improper use (not removing lens case lids)
• No radiation to lens, lens holder, inside lid
• Cannot detect defective UV generating bulb
• Multidose non-preserved saline squeeze bottle prone to contamination; may re-contaminate if used to rinse after disinfection
• UV radiation may not penetrate established biofilm

Prevention
• However, just killing microbes is not the answer
• Proper handling and personal hygienic practices remain important aspects of prevention

Factors Affecting Bacterial Adhesion
• Temp/humidity/available nutrients
• Inverse correlation to lens material water content (prefers lower water content)
• Surface smoothness/debris, deposits (higher on worn lenses)
Factors Affecting Bacterial Adhesion

- Varies by genus/species; P. aeruginosa has greatest adherence
- Hydrophobicity of microbial cell and lens surfaces (greater adherence to SiHy materials)

Dutta, N Cole, M Willcox. Molecular Vision 2012(18) 14-21

Factors Affecting Bacterial Adhesion

- Inoculum size/density
- pH (highest at 7.0 for PBS media)
- Lack of floral microbes (Ps. cannot adhere as well if S.epi is present)

Dutta, N Cole, M Willcox. Molecular Vision 2012(18) 14-21

Bacterial Adhesion Stages

- 1 - temporary adhesion/loose; Van der Waals forces
- 2 - irreversible adhesion; no Brownian motion; cannot be washed off
- 3 - biofilm formation; stronger anchoring; slower activity

Dutta, N Cole, M Willcox. Molecular Vision 2012(18) 14-21

The Contact Lens Case


What’s growing there?

- >70% contaminated, 42% bacteria
- Biofilms (multicellular formations of organisms, including bacteria)
  - develop within 1 week
  - impart resistance to CL solutions
  - transfer from case to lens to eye
  - infection

Five steps to cleaner lens cases

- Always wash your hands before applying or removing CL, incl. open or close storage case
- Discard used solution immediately
- Rinse case thoroughly, incl. lids with disinfecting solution
- Air dry case with lids open
- Replace lens case at least four times/year.

Source: American Optometric Association
H₂O₂ Case Care

• 1X/week, fill case completely (pass line)
• Turn the lens case upside down to neutralize H₂O₂ on the inside of the cap
• Or, after removing the lenses, invert the lens case with fresh, un-neutralized peroxide to disinfect the inside cap; note that unless the case is full, there will still be unneutralized H₂O₂ remaining
• Separate and air dry

The Contact Lens Case

• Antimicrobial case
  • Pro-Guard (MicroBlock, CIBA)- polypropylene infused with silver ions
    • silver is gradually released as the case is exposed to moisture
    • interferes with DNA, cellular respiration, and enzyme conformation of pathogens
  • I-Clean cases (Amcon Laboratories)
    • In progress: antimicrobial material to coat CL cases
  • $300,000 Australian Research Council Linkage Grant, Brien Holden Vision Institute and the University of New South Wales, Sydney

Cases

• LensAlert (Watch Dog Group LC)
  • # days replace lenses
  • # days replace case
  • 2 cases included
  • Alarm

Adherence/ Compliance Rates and Consequences

Predicting Noncompliance

• The only independent significant factor predicting noncompliance with CL:
  • risk taking propensity
  • better predictor than age, gender and practitioner perception

Strategies to Improve Compliance


The Healthy Soft Contact Lens Habits Guide (AOCLE)

Prescribe a Solution

• “Prescribe,” not recommend
• Dispense a complimentary care kit
• Write your prescription on an Rx pad
• Provide a detailed written handout with the solution name
• Review the advantages of prescribed product
• "If you deviate from this solution, you run the risk of compromising comfortable, long-term wear."
• Communication is the key!

Recommendations

Lens Care:
• Wash hands
• Replace lenses as prescribed
• Do not store opened, old ‘spare’ lenses; spare lenses should be in unopened original containers
• Rub-n-rinse daily
• Use fresh solutions daily
• Do NOT top-off

Case Care:
• Empty, rub & rinse daily
• Clean case with mild detergent and hot water; alternatively H₂O₂
• Air dry daily
• Scald with freshly boiled water weekly
• Replace often

The Future is Bright!

Thank you!