The Role of the Eye Care Professional in Maximizing Safety for Contact Lens Wearers

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**Introduction**

There are many factors that contribute to the safety of contact lens wear, beginning with the research and development team who create the products through to the marketing team who promote the products to potential wearers. Relevant issues include optimizing oxygen transport to ensure that no oxygen deficit occurs to the cornea, ensuring product biocompatibility with the ocular surface and any associated care system, and providing consumers with recommendations on how to appropriately wear and care for their lenses. The eye care practitioner’s role is to ensure the patient is a good candidate for lenses, determine the most appropriate lens through careful fit and evaluation, and prescribe the lens and solution combination to meet the needs of the patient. It is the eye care practitioner’s responsibility to continually encourage the safe use of contact lenses through meaningful instruction regarding contact lens wear time, replacement schedule, and by reinforcing compliance to lens hygiene and lens storage case care. Every patient encounter provides the opportunity to promote the adherence to recommendations, thereby establishing improved contact lens hygiene habits and maximizing the safety of contact lens wearers. A recent Contact Lens Leadership Summit concluded that, “contact lenses are a safe, effective, very useful, and, for many, an essential way of giving sight to some 120 million people around the world.” For this reason, it is vital to maximize the safe use and care of this medical device.

**FDA’s Role**

The US Food and Drug Administration (FDA) regulates contact lenses, for vision correction as prescription devices and as decorative purposes, and lens care products through the Federal Food, Drug, and Cosmetic Act. Pre-market and post-market public safety are the primary concerns of the agency. The MedWatch program processes adverse
event reports from the consumer and industry\textsuperscript{24}. The Federal Trade Commission (FTC) regulates advertising and marketing of devices to protect consumers from injury\textsuperscript{11}.

**Contact Lens Modalities**

There are many contact lens modalities to choose from. It is the eye care practitioner’s responsibility to select an appropriate lens/solution combination to meet the patient’s needs based on a comprehensive history. With each contact lens modality there is a required wear time and replacement schedule prescribed by the eye care practitioner that must be followed to ensure safe, comfortable vision. This maintenance schedule is part of safe contact lens care and compliance.

**Soft Contact Lenses (SCL)**

There have been many advances made in soft contact lens materials that provide healthier, safer options for contact lens wearers. Many believe the lenses made of high oxygen-permeable silicone hydrogel material are the lenses of choice for most eyes,\textsuperscript{2} due to the decreased signs of corneal hypoxia, regardless of whether the lenses are worn on a daily wear basis or overnight. This lens material is selected when patients use their lenses in an extended wear modality, and are typically replaced every month. However, it is ultimately the eye care practitioner who decides the replacement schedule on a case-by-case basis.

**Conventional SCL Wear**

Contact lenses are worn during the day only and removed for sleep. This requires an appropriate cleaning and lens storage regimen, which is prescribed by the eye care practitioner.
Disposable Contact Lenses

Daily disposable (inserted, removed, and discarded daily) and extended wear disposable (inserted, slept in for a period, removed, and discarded) lenses are a convenient, safe option because the patient can avoid cleaning and storage of the lenses when the patient follows the safety rule of never re-inserting a used lens. These lenses are used for a limited time before discarded; therefore, they have decreased safety concerns. People with sensitivities to solutions or buildup on lenses can safely return to daily disposable contact lens wear. It is important to note that overnight wear of contact lenses increases the risk of contact lens related complications. Another safety risk is taken when a patient chooses to over wear disposable lenses for any reason (i.e. economical interest), thereby putting the health of the eyes at risk.

Extended Wear (EW), Continuous Wear (CW) and Flexible Wear

EW is approved for overnight use up to 6 consecutive nights (7 days). It is important to remove the lens one night a week. The FDA has approved continuous wear (CW) contact lenses for up to 30 nights (31 days) of consecutive wear without removal. Flexible wear is considered sleeping in approved EW or CW lenses occasionally, but lenses are worn predominately on a daily wear basis. Each time lenses are removed they must be properly cleaned and disinfected before reinsertion. EW lenses were first approved for the treatment of aphakia and later for non-aphakic ametropia.

Gas Permeable (GP) and Specialty Lenses

An often over-looked option over the past 10 years, particularly for new lens fits, relates to the use of gas permeable lenses. It is estimated that only 10% of lens fits now occur with this modality. It is a healthy, extremely safe choice because of the lens material’s
high oxygen permeability and transmissibility, and low rate of deposition of tear film components. Several studies have demonstrated that GP lenses result in reduced corneal binding of bacteria to corneal epithelial cells than soft contact lenses. GP lens materials have the lowest prevalence of microbial keratitis infections (1.48/10,000 eyes annually) compared to all other types of contact lenses, under both daily and extended wear conditions.

The safety of overnight orthokeratology GP lenses for the correction of myopia is discussed in the literature with expressed concern for more research. The issue that requires investigation is if the epithelial barrier is compromised when the corneal reshaping mechanism induces central epithelial thinning. Many patients can benefit from this treatment. However, the concern involves the safety risk associated with a compromise in the epithelial barrier and that this device of myopia management is targeted toward the adolescent population.

A recent study found Menicon Z material GP lens for the treatment of aphakic infants and children to be safe and effective with no observable increase in the rate of infection during the six month study period while lenses were being worn on a one-week EW basis.

**Decorative (Plano) Contact Lenses**

Decorative contact lenses, or cosmetic lenses, are not intended to correct vision but to alter the appearance of the eye. In the past, these contact lenses have been obtained without a prescription and have been used without the supervision of an eye care practitioner. This poses a serious public safety concern for the increased risk of contact lens related adverse events. The FDA issued a health notice in 2002 informing consumers of the
risk involved when using unapproved decorative contact lenses and advised consumers to seek a qualified eye care professional for all contact lens needs\textsuperscript{13}.

**Adverse Events**

The most serious adverse event eye care practitioners would prefer to avoid is an infection causing microbial keratitis (MK), as it is the most serious complication with potentially severe ocular morbidity. Microbial keratitis can occur while wearing any contact lens modality\textsuperscript{19,28} but typically is more prevalent with overnight wear of soft contact lenses made from low oxygen permeable material\textsuperscript{10}. Additional risk factors reported in association with MK are lens hygiene practices, smoking, overnight wear and male gender\textsuperscript{28}.

Unfortunately, advances in the development of silicone hydrogel material and daily disposable contact lenses have not reduced the incidence of this potentially sight-threatening event\textsuperscript{26}. A major investigation, The Australian and New Zealand Microbial Keratitis Study, recently reaffirmed the infrequency of contact lens related infections: 4/10,000 daily wear and 20/10,000 extended wearers annually\textsuperscript{20,28}. Overnight contact lens wear increases the risk of MK by approximately four times\textsuperscript{19}.

Other non-sight threatening contact lens related complications include inflammatory, mechanical, or hypoxic events such as: contact lens–induced peripheral ulcer (CLPU), infiltrative keratitis (IK), contact lens-induced acute red eye (CLARE), vascularized limbal keratitis (VLK), asymptomatic infiltrates (AI), asymptomatic infiltrative keratitis (AIK), and conjunctival papillary reactions.
**CL Care and Handling**

Contact lenses are contaminated through handling, storage, and lens wear. A study in Australia\textsuperscript{32} reported that recommendations for contact lens case hygiene are inconsistent and inadequate among sources responsible for providing this safety information to contact lens wearers. However, the contact lens industry, the FDA, and optometrists are more consistent regarding instruction and recommendations for adequate contact lens disinfection\textsuperscript{32}. This finding is an important reminder for contact lens authorities to reduce the confusion regarding recommendations for contact lens case hygiene and to highlight the necessary steps to achieve improved safety, comfort, and success for contact lens wearers.

**Hand Washing**

Proper hand washing is a prerequisite to safe contact lens handling. The objective is to decrease the transmission of microorganisms from the hands, to the lens, and into the eyes. A rule of thumb is to avoid touching eyes, handling contact lenses, and the storage case, without washing hands thoroughly. The CDC recommends washing hands with soap and clean running water. Begin by rubbing hands together and scrub all surfaces with lathered soap for 20 seconds. Rinse hands well under running water and dry hands completely [preferably with a lint-free towel for contact lens wearers]. Finally, use the towel to turn the faucet off\textsuperscript{4}. This established hand-washing technique is recommended to be performed by all health care practitioners and contact lens wearers before handing lenses to prevent the spread of infection.
Disinfecting Soft Contact Lenses: Multi-Purpose Solution and Hydrogen Peroxide Solution

There are two types of solutions on the market: Multi-Purpose Disinfecting Solution (MPS) and a hydrogen peroxide solution. Most contact lens wearers favor the MPS solution because it is convenient and does not require a neutralization period before insertion of lenses.

Contact lens wearers who use hydrogen peroxide disinfection modality suffer less solution-related adverse events than those who use MPS solution. Hydrogen peroxide is the solution of choice for patients with chemical sensitivities because the solution is self-preserving (no added preservative) and the resultant products after the neutralization period are water and oxygen. For this reason, hydrogen peroxide disinfecting solution is the safest and most effective disinfection system. If contact lenses have been stored for a week or more without being worn, it is advisable to repeat the disinfecting process completely before wearing lenses again.

The ‘rub and rinse” technique of lens care continues to be an important part of decreasing contact lens contamination. In 2008, the Center for Devices and Radiological Health (CDRH), Ophthalmic Devices Panel Advisory Committee, issued a letter in response to the recent outbreaks of Fusarium and Acanthamoeba infections to the contact lens care product corporations reinstating, “that there is improvement in lens care when using a "rub-and-rinse" regimen as compared to a "rinse alone" regimen. This is because "rub-and-rinse" regimens help prevent microbial adhesion to the contact lens, help prevent formation of biofilms, and generally reduce the microbial load on the lens and the lens case.” It is highly recommended to rub and rinse lenses before and after lens disinfection and storage with the disinfection solution. The rub and rinse step should be done with a sterile saline solution before and after disinfecting lenses with hydrogen peroxide.
Never ‘top up’ old solution in the contact lens storage case with new solution; always use fresh solution with each disinfection procedure. Be mindful to rinse and rub, and disinfect lenses thoroughly every time the contact lens is removed. Any bacterial contamination introduced through handling, storage, or wearing the contact lenses will be greatly reduced by carefully following these recommended guidelines for contact lens care and hygiene.

**Disinfecting Gas Permeable Lenses**

Gas permeable lens care requires more steps than SCL care. Every time the GP lens is removed it should be cleaned with daily cleaner to remove deposits, stored in disinfecting solution, then rubbed and rinsed with saline or disinfecting solution before insertion. Do not use tap water for rinsing, nor storing GP lenses. It is strongly advised not to use tap water in conjunction with children’s lens care. The objective is to avoid contamination of the lens by microorganisms commonly found in potable water. The eye care practitioner may suggest an enzyme treatment to be used once a week to remove allergy-inducing protein deposits. Before inserting the lens a wetting solution may be used to aid in comfort.

**Contact Lens Storage Case Care**

Contact lens case hygiene is an often over-looked component of safe contact lens wear. Cases can be a major source of contact lens contamination, which could lead to serious infection. A recent literature review found the main pathogenic microorganisms that contaminate contact lens cases include: *Pseudomonas, Serratia, Staphylococcus, Acanthamoeba* and *Fusarium*. Hall and Jones recommend patients to clean and disinfect lens cases daily, avoid using tap water, replace cases regularly, and to consider where (i.e. as far away from the toilet as possible) and how cases/lids are stored while lenses are being worn.
Bathrooms are a known source of microorganisms; therefore, patients should be counseled to store their lenses, cases, and care products in a clean, dry environment\textsuperscript{16}.

Recent, updated recommendations for case care is to rub and rinse the case with the MPS solution, dry with a clean lint-free cloth, and store the case and lids upside down on a clean tissue while not in use\textsuperscript{16,28}. Frequent replacement of the lens storage case is important to minimize contamination\textsuperscript{32}. Replacement suggestions for a contact lens case range from monthly to every 6 months, or replacement with each new bottle of solution.

The latest innovation is an antimicrobial lens storage case, which is impregnated with silver (CIBA Vision, Duluth, GA) for use with Aquify Multi-Purpose Solution (CIBA Vision); this technology can decrease lens case contamination, especially microbial biofilms formed on the case walls\textsuperscript{31}. This system performs best when the lid is recapped when it is not in use, i.e. avoid air-drying\textsuperscript{32}.

**Solution and Contact Lens Material Compatibility**

Not all lens types and solution combinations are compatible\textsuperscript{17}. The corporations who receive FDA approval assume responsibility for producing a product that is compatible with all lenses on the market or to make available to the public the product's restrictions\textsuperscript{2}. Likewise, the eye care practitioner must be aware of these interactions to prescribe an appropriate MPS solution with prescribed silicone hydrogel lenses. Hydrogen peroxide is very safe and causes the least corneal staining with silicone hydrogel lenses compared to any MPS solution\textsuperscript{28}.

Dr. Andrasko has produced an online reference tool called, “Andrasko’s Corneal Staining Grid” to aid the eye care professional in selecting a biocompatible contact lens material/brand and multipurpose solution. The results from his grid are based on small studies that demonstrate the average corneal staining area at two hours. This staining grid
is accessible online at www.staininggrid.com. The purpose of this biocompatibility study is to determine which lens/solution combinations do not cause excessive corneal staining. A second goal of this study is to establish if corneal staining affects lens comfort1. Another grid available online is called the Itoi Grid (www.staininggrid-japan.com).

**Ophthalmic Drops**

**Artificial Tears, Rewetting Drops**

Contact lens wear may exacerbate asymptomatic dry eye; a lubricating drop may be indicated to prevent corneal desiccation with soft contact lenses. There are numerous rewetting drops on the market approved for use with contact lenses, in alphabetical order: Aquify Comfort Drop (CIBA Vision, Duluth, GA), Boston Rewetting Drops (Bausch &Lomb, Rochester, NY), Blink Contacts (AMO Abbott, Santa Ana, CA), Clerz Plus (Alcon, Fort Worth, TX), Complete Blink-N-Clean (AMO Abbott, Santa Ana, CA), Complete Lubricating and Rewetting Drop (AMO Abbott, Santa Ana, CA), Opti-Free Express Rewetting Drop (Alcon, Fort Worth, TX), and ReNu Rewetting Drop (Bausch & Lomb, Rochester, NY). Drops indicated for use with soft contact lenses can be safely used with GP lenses, but GP lens rewetting drops are not recommended to be used with soft contact lenses. There are many lubricating drops that are not compatible with contact lenses. It is imperative for the safety, clarity of vision, and longevity of the lens, that an appropriate rewetting drop is prescribed with contact lens wears. Eye care practitioners may consider offering a sample when dispensing lenses to encourage the use of a drop that is compatible with contact lenses.

**Ocular Therapeutic Drops**

In some instances it is desirable to increase contact time of a medication on the ocular surface, thereby benefitting from the uptake and release properties of a SCL.
However, most therapeutic ocular drops are not to be used concomitantly with soft contact lenses because SCL are permeable and may absorb the medication or preservative in the drop. The uptake property of the SCL effectively increases the concentration of the eye drop in the contact lens, which may provoke an ocular toxicity reaction. The alternative is that the lens may draw in the medication and delay the onset of the action of the drug, thereby decreasing its effectiveness. An additional risk is that some hydrogel contact lenses deform in the presence of therapeutic drops and can become a safety concern to the cornea\(^\text{18}\). A recent study measured the uptake of two ophthalmic drops with hydrogel soft contact lenses; the study found that zwitter ionic SCL are, “highly safe for wear with concomitant use of eye drops based on its high contour stability and low uptake of substances applied to the eye.”\(^\text{18}\)

**Daily Considerations**

**Tap Water**

Tap water hosts a variety of bacteria, some of which can be dangerous for the eye. Patients should be instructed to close their eyes tightly in the shower (or remove lenses) and while washing their face\(^\text{28}\). Leak-proof goggles should be worn in swimming pools, lakes, and hot tubs.

**Make-up**

Cosmetics can be a source of ocular infection or irritation, and cause dirty, deposited contact lenses. Some suggestions to avoid cosmetic-related complications with contact lens wear include: apply makeup after the insertion of contact lenses, do not borrow or lend cosmetics to others, wash or replace application brushes frequently, do not apply eyeliner to lid margins, and do not apply cosmetics to a red, swollen, infected eye.
**Seasonal Allergies and Contact Lens Use**

Daily wear disposable contact lenses are ideal for allergy sufferers, as allergens that build up on the lens during the day are tossed away and a fresh lens is inserted the next morning.

**Spectacles**

It is imperative that contact lens wearers also have a pair of current prescription spectacles to use in the event of misplaced contact lenses, and illness. Contact lenses should be removed if lenses are associated with symptoms of pain, discomfort, redness, or decreased vision.

**Monovision**

It is important to warn monovision patients to be aware of decreased stereopsis with this presbyopic correction option. FDA recommends prescribing driving spectacles to meet the state Department of Motor Vehicles requirements.

**Ultra-Violet Absorbing Contact Lenses**

UV absorbing contact lenses can be useful to help prevent the formation of cataracts, ARMD, and contribute to the general health of the eye. While not a replacement for sunglasses, UV blocking contact lenses that cover the limbus provide protection at least equivalent to wrap-around sunglasses or goggles.
Occupational Safety

National Institute for Occupational Safety and Health (NIOSH) recommends, “Workers be permitted to wear contact lenses when handling hazardous chemicals provided that the safety guidelines are followed and that contact lenses are not banned by regulation or contraindicated by medical or industrial hygiene recommendations. However, contact lenses are not to be used as an eye protective device, and wearing them does not reduce the requirement for eye and face protection”\(^6\). Therefore, it is imperative that CL wearers are educated regarding the necessity of safety eyewear while wearing contact lenses. Numerous studies have found additional safety benefits to contact lens wearers while using appropriate safety wear protection: contact lenses can provide some safety to the cornea in an eye splashed with chemicals, from ice/snow in cold environments, some forms of blunt trauma, and can offer protection from foreign body, or mechanical hazards\(^7\).

Education and (Non) Compliance

Eye care practitioners require regular continuing education regarding current guidelines for lens care, contact lens use, and maintenance to provide excellent patient-centered care. In the event of a contact lens complication, timely diagnosis and appropriate treatment will increase the likelihood of a positive outcome\(^19\).

Preventative medicine is taking measures to educate and instruct patients regarding CL safety. Patient compliance can be a reflection of the eye care practitioner’s clear, direct contact lens hygiene recommendations. Education should be simple, easy to remember, and direct. Patients prefer to have a reason why they must perform steps in lens care hygiene. It is helpful to have a contact lens care routine that has enough redundancy to safeguard the patient even when they are not compliant\(^8\). Spend time building relationship with patients to gain their trust and make suitable, informed choices by prescribing appropriate lenses.
for how they will be used. Patient lens care hygiene can be monitored effectively by using open-ended questions and asking the patient for a demonstration of their lens care routine. Each contact lens appointment should have some time allocated to review and monitor contact lens care and compliance. This is a good time to update the patient’s lenses to a newer technology material that provides a greater safety margin.

Noncompliance is a multifaceted problem that involves patient knowledge, attitudes and beliefs, and available resources. Variables that contribute to noncompliant behavior in contact lens wearers include: age, education, duration of time wearing contact lenses, wearing schedule, and the purpose for wearing contact lenses. Patients can develop a sense of self-assurance once comfortable in a routine and begin to ‘cut corners’ in lens care and case hygiene. Noncompliance in medical management varies from 24.8 – 44% and the rates for contact lens care noncompliance ranged from 50 – 99%. One study indicates that many contact lens wearers thought they were compliant but reported various noncompliant behaviors.

Remind patients to use extreme caution if purchasing contact lenses from someone other than an eye care professionals, for example over the internet. Contact lenses are regulated medical devices and are not to be purchased without a valid prescription. Do stress to the patient the importance of regular routine contact lens appointments whether the patient is symptomatic or not.

**Always and Never**

Encourage the contact lens wearing patient to always ask: “Do my eyes look good? Feel good? Can I see well?” If the patient answers ‘no’ to one of these questions they should remove their contact lens and talk to their eye care practitioner immediately. Patients should be instructed to never go to bed with a painful red eye but to seek help immediately.
**Future**

The Institute for Eye Research is investigating antibacterial contact lenses by embedding fimbrolides and selenium onto the surface of the contact lens.\(^{31}\) “By developing an antibacterial contact lens that prevents bacterial adhesion we are hoping to reduce the occurrence and severity of infection and inflammation caused by various microbes.”\(^{9}\) Further investigation needs to be done in developing new antibacterial surface technologies for contact lenses, and lens cases that circumvent patient contact lens hygiene non-compliance; these innovations are not a substitute for providing regular contact lens recommendations and exceptional education.

In the meantime, lens hygiene education by eye care practitioners, and marketing by industry, is of utmost importance for the continued safe use of contact lenses worldwide. Regular comprehensive eye exams and predetermined contact lens follow-up appointments lend themselves to regular opportunities to remind patients of the limitations and restrictions of safe lens use, and to review appropriate lens care habits. Based on studies, it is prudent to emphasize the increased risk of infections associated with poor case hygiene. During these discussions, the clinician can recommend safer contact lens modalities, particularly when patient compliance is questionable. Although, contact lens care presents a public health concern, it is important to keep in mind that contact lens wear is a safe, viable corrective lens option for most people. The wealth of contact lens knowledge continues to expand. Through the dedication of all those in the specialty field of contact lenses concern is evident in providing and updating safe contact lens options, and by elaborating on safe lens care practices. This is an exciting time for eye care practitioners to move forward with a gold standard in contact lens hygiene guidelines and with the united purpose of maximizing the safety of contact lens wearers.
REFERENCES