Topical Review: Contact Lens Eye Health and Safety Considerations in Government Policy Development

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SIGNIFICANCE: As new federal or state policies are introduced in the United States to shape the evolving contact lens market, it has never been more important to amplify the importance of patient health and safety during contact lens wear and promote the value of the eye care professional–patient relationship.

Within the United States, contact lenses are regulated by the Food and Drug Administration as class II or III medical devices that require additional regulatory and professional oversight to keep consumers safe. The contact lens market and broader eye health landscape are rapidly changing. Recently, the U.S. Federal Trade Commission finalized its 10-year review of the Contact Lens Rule, implementing new policies that will shape the contact lens market in the United States for years to come. The purpose of this clinical perspective was to compile and review key data regarding contact lens–related adverse events, including their economic impact on the health care system, to inform government policy development. Although contact lenses provide many benefits to the wearer, a variety of complications can occur ranging from asymptomatic events or mild discomfort to severe sight-threatening adverse events such as microbial keratitis. Patients who do not routinely visit their eye care professional or do not receive the lenses prescribed to them are at a greater risk of contact lens–related adverse events. Nearly 1 million people in the United States experience ocular infections or inflammation annually, resulting in significant health care costs. The economic burden of contact lens–related microbial keratitis in the United States has been estimated to be approximately $175 million annually. The importance of eye care professional oversight of contact lens wear cannot be emphasized enough to key stakeholders, including lawmakers, government regulators, contact lens manufacturers and distributors, and the broader eye health community.

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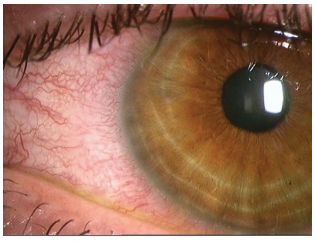

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Within the United States, contact lenses are regulated by the Food and Drug Administration as class II or III medical devices that require additional regulatory and professional oversight to keep consumers safe. Class II devices are considered to pose moderate risk to the patient/user, whereas class III devices pose the highest risk.[1] Examples of class II contact lenses include daily wear hydrogel, rigid gas-permeable, hybrid, and scleral contact lenses. Class III contact lenses include extended (overnight) wear soft, rigid gas-permeable, and orthokeratology contact lenses and daily wear myopia control lenses.

The contact lens market and broader eye health landscape are changing. Recently, the U.S. Federal Trade Commission finalized its 10-year review of the Contact Lens Rule, implementing new policies that will shape the contact lens market in the United States for years to come.[2] The Contact Lens Rule was originally implemented in 2004 and included a requirement for patients to be provided with a copy of their contact lens prescription upon completion of the contact lens fitting process.[3] Contact lens sellers were also required to obtain a copy of the prescription or verify the prescription with the original prescriber.[3] During the recent 10-year review of the Contact Lens Rule, issues regarding increasing competition in the contact lens marketplace and consumer access to contact lenses were considered, as well as the release and portability of contact lens prescriptions. The updated Contact Lens Rule requirements now include patient acknowledgement of prescription receipt after fitting and revised definitions of illegal and legal alteration of a contact lens prescription.[2]

As the contact lens field continues to rapidly evolve, with new lens designs, materials, technologies, manufacturers, and sources of supply being introduced, it has never been more important to amplify the importance of patient health and safety. There are an estimated 45 million contact lens wearers in the United States,[4] consisting of approximately 84% soft, 7% rigid gas permeable, and 9% other (presumably scleral, hybrid, etc.) lens wearers.[5] These contact lens wearers benefit from a marketplace that supports their preferences for accessing their lenses, without compromising the role of the eye care professional–patient relationship. Patients who do not routinely visit their eye care professional or do not wear the actual contact lenses prescribed to them are at a greater risk of developing contact lens–related adverse events, including sight-threatening infection and inflammation.[4,6,7]

The purpose of this clinical perspective was to compile and review key data regarding contact lens–related adverse events, including their economic impact on the health care system. These data underscore the importance of eye care professional oversight of contact lens wear to key stakeholders including lawmakers,

government regulators, contact lens manufacturers and distributors, and the broader eye health community.

CONTACT LENSES ARE COMPLEX AND NOT INTERCHANGEABLE

Contact lenses are complex medical devices that interact directly with the eye, including the cornea, tear film, and eyelids. Contact lenses differ from each other, based not only on material, which affects oxygen permeability, tear film structure and interaction, water content, lubricity, and lens surface deposition—just a few factors that play a role in ocular biocompatibility—but also on other common parameters such as base curve, power, and diameter.[8,9] Furthermore, even when contact lenses have similar base curves and diameters, the eyes' physiological reaction can differ because contact lenses also vary in other characteristics such as modulus (stiffness), center thickness, sagittal height, wettability, and edge design.[9–11] Inappropriately increasing lens thickness, for example, can reduce oxygen transmissibility (especially in higher prescriptions) and cause increased eye redness, neovascularization, and corneal swelling, as well as reduced lens comfort.[9] An increased risk of infection may also occur if the lenses are worn overnight because of reduced oxygen transmissibility.[9]

Importantly, contact lenses do not simply differ across manufacturers, including large commercial and custom laboratories, but they also even vary within the same brand of lenses. For example, the entire Johnson & Johnson Vision ACUVUE Brand portfolio of soft lenses encompasses more than 12 different brands and more than 12,000 stock-keeping units in the United States to meet the individual needs of each patient. In 2020, CooperVision calculated the number of silicone hydrogel stock-keeping units available in the United States from the four major contact lens manufacturers and reported 32,191 (CooperVision), 12,327 (Bausch + Lomb), 10,409 (Johnson & Johnson Vision Care), and 5332 (Alcon) stock-keeping units, respectively.[12] The physiology of the eye and visual demands change over time.[13] As such, material and lens design parameters that are unique and proprietary to each manufacturer are designed to address different patient physiological needs and lifestyle preferences.

The ocular response to each contact lens may be significantly different and can lead to a variety of physiological reactions, such as corneal staining (Fig. 1A), neovascularization, conjunctival staining, and increased redness (Fig. 1B),[9,14] even when fitting the same patient with various lenses.[10] In addition, reusable contact lenses require lens care solutions for cleaning, rinsing, and disinfection. These must be compatible with both the patient's ocular surface and the lens material to avoid complications such as solution-induced corneal staining, discomfort, and corneal infiltrative events.[15–17]

To date, no single type of contact lens has been shown to provide a clinically acceptable healthy ocular response for every single patient, and contact lenses are not freely interchangeable because each one interacts differently with an individual patient's ocular surface.[18] The fit of each particular contact lens and the ocular response to that lens (and lens care solution if applicable) must be evaluated over time, to provide healthy vision correction that minimizes the risk of potentially sight-threatening complications.[19] As such, the prescribed brand of contact lenses that an eye care professional works closely with the patient to determine should not be freely substituted by sellers and/or contact lens wearers. Similarly, lens care solutions also should not be substituted without professional oversight.

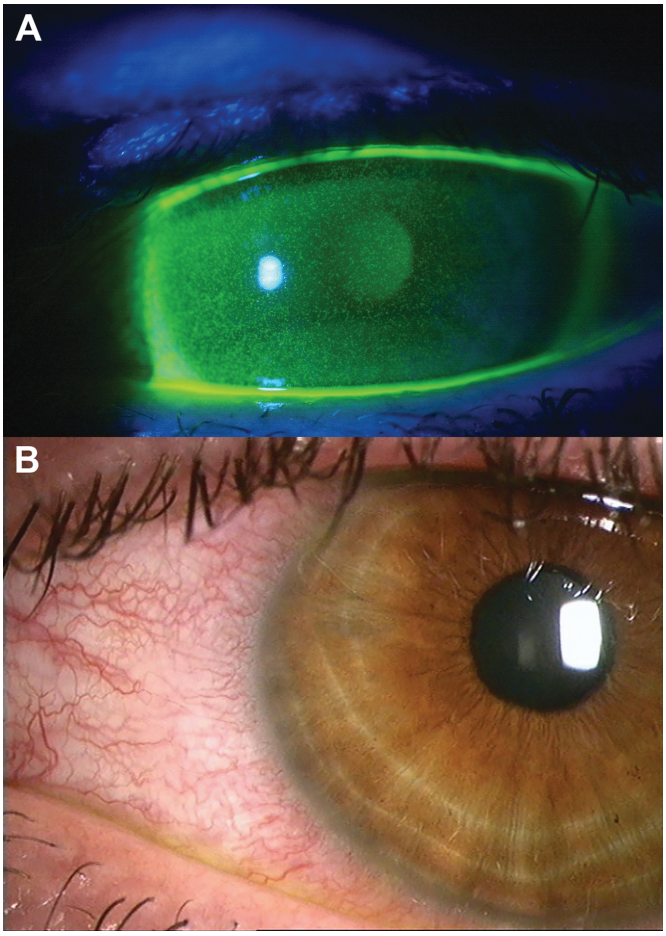

FIGURE 1. Examples of adverse events that can occur during contact lens wear include (A) corneal staining and (B) conjunctival redness. Reprinted with permission from Davies I, Meyler J, Sulley A, eds. *A Handbook of Contact Lens Management*. 3rd ed. Livingston, United Kingdom: Johnson & Johnson Medical Ltd.; 2011.

Illegal substitution is a concern in today's marketplace. A 2015 survey commissioned by Johnson & Johnson Vision found that one in four online consumers reported having received a different brand of contact lenses than those they ordered, without being given advance warning.[20] Recently, the online contact lens company Hubble Contacts was fined $3.5 million by the U.S. Department of Justice and the Federal Trade Commission for violating the Contact Lens Rule by illegally substituting contact lenses with their own brand of lenses.[21] In addition to the fine, Hubble was also issued a court order to cease altering contact lens prescriptions and other deceptive practices.[21] Maintaining and enforcing the current requirements that prescribers must include the specific contact lens brand and product name, in addition to other necessary information on a patient's contact lens prescription, and prohibiting substitution are absolutely necessary to minimize the risks of contact lens wear.[10]

COMPLICATIONS ARISING FROM CONTACT LENS WEAR

Contact lenses have become widely used as technologies have evolved to include new lens modalities and materials,[22–24] with

more than 140 million contact lens wearers now worldwide,[24] compared with 70 million in the late 1990s (Fonn D, Sweeney DF. Contact Lenses: The Last 30 Years. CL Spectrum 2016;31 (9):22–7). It is difficult to estimate the number of new wearers annually, but global market growth has been reported to be approximately 5 to 6% per year (Nichols JJ, Starcher L. Contact Lenses 2019. CL Spectrum 2020;35(1):18–9, 21–5). The expanded application of contact lens technologies, such as for myopia control (Nichols JJ, Starcher L. Contact Lenses 2019. CL Spectrum 2020;35(1):18–9, 21–5) and drug delivery,[25] could contribute to an increase of contact wearers worldwide, including more children wearing lenses. Because there are significant and serious complications that can arise from contact lens wear, these have the potential to impact thousands of patients each year. Therefore, eye care professional oversight is necessary to ensure safe and successful lens wear.

Wearing any type of contact lens can lead to a variety of complications, from mild discomfort to moderate/severe adverse events that may be sight-threatening such as inflammation and, most seriously, corneal infection.[14,26] For example, a tight lens fit, as a result of reduced lens movement, can be extremely comfortable for a wearer but can affect tear film exchange and lead to a significantly increased risk of inflammation or infection. Ozkan et al.[27] showed that for every 0.1-mm decrease in silicone hydrogel lens movement there was a 1.8 times increased risk of developing a corneal inflammatory event. It is not always possible to just rely on symptoms to determine if a contact lens is fitting appropriately.

Up to 26% of soft contact lens wearers experience corneal inflammatory events/infiltrative keratitis, which may be symptomatic or asymptomatic (Fig. 2).[28,29] Risk factors for corneal inflammatory events include younger age (age 15 to 25 years),[30] smoking,[31] previous history,[29,32] extended wear,[30,33] and silicone hydrogel material.[30,33] Although contact lens–related inflammation is generally not considered to be as serious as infection, current research suggests that corneal inflammation and infection are on a continuous spectrum[34] and the U.S. Food and Drug Administration recognizes corneal inflammatory events as a surrogate for infection in establishing the safety of contact lenses.[35]

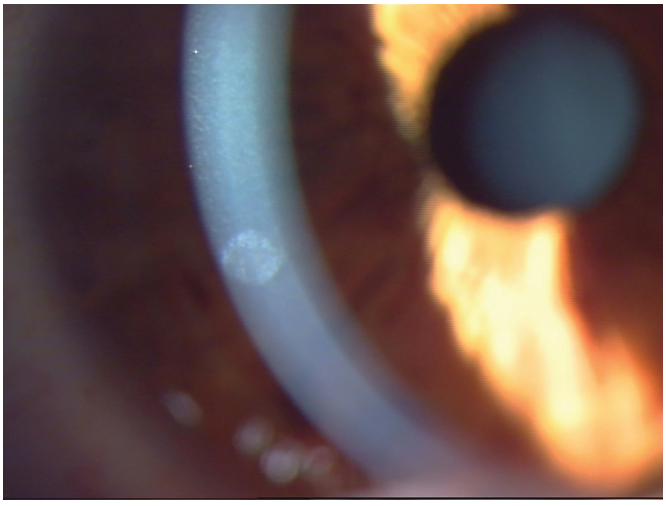

FIGURE 2. A corneal scar from a contact lens peripheral ulcer, a type of contact lens–related corneal infiltrative event. Reprinted with permission from Davies I, Meyler J, Sulley A, eds. A *Handbook of Contact Lens Management*. 3rd ed. Livingston, United Kingdom: Johnson & Johnson Medical Ltd.; 2011.

Microbial keratitis is an infection of the cornea and the most serious complication of contact lens wear, as it can result in permanent loss of vision from corneal scarring. Corneal trauma is the leading cause of microbial keratitis globally[36]; however, contact lens wear is also a major risk factor for microbial keratitis.[36–38] Risk factors for microbial keratitis include male sex, extended wear, smoking, tap water exposure, and poor case hygiene.[39] The *Fusarium* and *Acanthamoeba* keratitis outbreaks that occurred in the 2000s were associated with the use of contact lens multipurpose solutions.[40,41] Poor compliance with contact lens care and maintenance procedures is a major risk factor for a number of complications, including both microbial keratitis and contact lens–related inflammatory events.[37,39] The annualized rates of microbial keratitis in soft contact lens wear are estimated to be 2 to 4 per 10,000 in daily wear per year (0.02 to 0.04%, ~1/2500 wearers) and 20 per 10,000 in extended wear per year (0.2%, ~1/500 wearers).[42] When you consider these data in relation to the sheer number of contact lens wearers in the United States today, 45 million, they are not insignificant. Nearly 1 million people in the United States experience eye infections or eye inflammation annually, of which approximately 25% are due to contact lens wear.[37]

In an epidemiological study of 278 soft and rigid gas-permeable contact lens–related microbial keratitis cases in Australia and New Zealand, 24% were categorized as mild, 49% severe without vision loss, and 16% severe with two or more lines of vision loss and/or surgical intervention.[43]

Although patients may experience obvious symptoms during lens wear and subsequently remove their lenses, several asymptomatic adverse events from mechanical events to infiltrative keratitis can occur without the patient knowing.[29,44] These can have important consequences for future eye health and contact lens wear. For example, a previous history of a corneal inflammatory event can result in an up to six times greater risk of having reoccurring inflammation that may lead to a more severe sight-threatening event.[29]

Routine examinations also provide an opportunity for patient reeducation, as compliance decreases over time and information on best practices with contact lenses and lens care changes as new science emerges and the field evolves.[45] In a recent study of 202 asymptomatic soft contact lens wearers presenting for annual routine eye examinations, Chen et al.[46] found that 52% of wearers had at least one ocular health complication (systemic, ocular, and/or contact lens–related) that was previously undiagnosed. Seventy percent of these wearers had contact lens–related ocular complications, 52% had non–contact lens–related ocular health issues, and 4% were found to have undiagnosed systemic diseases such as diabetes and hypertension.[46] When contact lens fit issues and lens care noncompliance were included in the overall complication prevalence rate, the complication rate increased from 52 to 72% in the asymptomatic wearer population.[46] Therefore, symptoms cannot be relied upon alone for maintenance of eye health during contact lens wear. This study further demonstrated the importance of routine monitoring of contact lens wearers by an eye care practitioner, irrespective of symptoms.

Even in the most optimal environment, complications can still arise. As Dr. Jennifer Cope, a medical epidemiologist at the Centers for Disease Control and Prevention, stated, "Contact lenses can provide many benefits, but they are not risk-free—especially if contact lens wearers take shortcuts and don't take care of their contact lenses and supplies."[47] Only eye care professionals can best determine, after a comprehensive eye examination, what the most appropriate lenses are for the patient and can work closely with

patients to reduce occurrences of adverse events and address compliance issues.

The Centers for Disease Control and Prevention has recommended a number of efforts to prevent infection and inflammation.[37] These include increased surveillance, improving the estimates of disease burden, and targeted health promotion activities for both eye care professionals and contact lens wearers. For microbial keratitis in particular, increased surveillance capacity, including obtaining more data directly from optometrist office visits, has been recommended.[37] Eye care professionals are encouraged to promptly report contact lens or lens care adverse events through the Food and Drug Administration Safety Information and Adverse Event Reporting program, irrespective of severity (https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program).[48] Other surveillance opportunities include more post-market surveillance and "real-world" populations studies, to generate data to supplement controlled clinical trials.[49]

REGULATORY FRAMEWORKS AND CONTACT LENS–RELATED CORNEAL INFECTION RATES DIFFER AROUND THE WORLD

Contact lens regulatory frameworks differ around the world. In many Asian countries, patients do not need prescriptions for contact lenses, and as a result, higher infection rates are reported.[7,50,51] Contact lenses can be the leading cause of corneal infections in markets where contact lens prescriptions are not mandatory, such as in Taiwan.[52] In other Asian markets, where contact lens prescriptions are usually required, there are lower percentages of contact lens–related microbial keratitis compared with trauma-related microbial keratitis, for example, India (0.8% contact lens vs. 42% trauma), Philippines (12.6% contact lens vs. 66% trauma), and Hong Kong (26% contact lens vs. 55% ocular surface disease or trauma).[51,53] In markets where a prescription is not mandatory, contact lenses are often identified as the leading cause of microbial keratitis, for example, Taiwan (43% contact lens vs. 16% trauma), Singapore (68% contact lens vs. 9% trauma), and Japan (26% contact lens vs. 18% trauma).[51] In two studies of patients hospitalized with contact lens–related microbial keratitis cases in Iran, it was found that 80.8% (21 of 26)[54] and 85.7% (12 of 14)[55] of cases were wearing lenses without consultation with an ophthalmologist. A case series of corneal ulcers in patients using plano colored contact lenses in India found that 100% of patients (13 of 13 patients) had obtained their lenses without professional oversight, either without a prescription, from friends/relatives, or from the garbage.[56] In France, contact lens wear is one of the major risk factors for microbial keratitis,[57] and a recent study found a 1.4 times greater risk of microbial keratitis if contact lens fitting and evaluation/oversight were not performed by an ophthalmologist.[6] These examples from countries outside the United States demonstrate that, when contact lenses are regulated and subject to oversight by eye care professionals, the risk of contact lens–related microbial keratitis is reduced.

ECONOMIC IMPACT

Nearly 1 million people in the United States experience ocular infections or inflammation annually,[37] resulting in significant health care costs. In 2010, according to the most recent published data available for the United States, total economic burden for keratitis (including infectious and noninfectious) with contact lens–related diagnostic codes was $174.9 million on the U.S. economy, including $58 million for Medicare patients and $11.9 million for Medicaid patients.[37]

In 2010, the average cost of a doctor's office visit for a keratitis-related diagnostic code was $151, compared with $587 for an emergency department visit. That year alone, approximately 230,000 doctor's office and outpatient clinic visits and 19,000 emergency department visits for contact lens–related corneal disorders occurred, with 70% resulting in antimicrobial prescriptions.[37] This is of significant concern because such practices may promote antimicrobial-drug resistance,[58,59] which also has a major economic impact. The U.S. Centers for Disease Control and Prevention estimated the annual cost of infections caused by antibiotic-resistant microorganisms to be in the order of $55 billion annually.[60] If antibiotic resistant bacteria were to continue to increase in such cases of contact lens–related microbial keratitis, it could potentially lead to poorer patient outcomes, such as higher rates of central corneal scarring, permanent loss of best-corrected visual acuity, and/or corneal transplants,[61,62] which would have even more detrimental impacts to patient quality of life and the health care system.

Also in 2010, Smith and Orsborn[63] calculated the economic burden of contact lens–related corneal infiltrative events in soft contact lens daily wear in the United States. Corneal infiltrates were categorized as severe or nonsevere, and both direct (such as medical visits and drugs) and indirect costs (such as lost productivity) were estimated. Total annual economic burden was estimated to be $58 million, with the cost of each severe and nonsevere contact lens–related corneal infiltrative event to be $1496.00 and $1002.90, respectively.[63] This study again highlights the significant economic burden of contact lens complications, including less severe infiltrative events that can still impose a substantial burden on both patients and the health care system.

CONCLUSIONS

Even with today's well-defined regulatory framework, which promotes the value of the eye care professional–patient relationship in monitoring patients' contact lens wear and helping to mitigate the risks of adverse events, complications can still arise. Contact lens wearers can experience mild to severe complications including contact lens–related infection and inflammation. It is therefore imperative to maintain and enforce the existing U.S. regulatory framework to ensure that patients can continue to wear their contact lenses successfully and safely, as prescribed by their eye care professional, while promoting patients' access to their lenses no matter where or how they choose to purchase them.

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