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Contact Lens Health Week — August 22–26, 2016

August 22–26, 2016, marks the third annual Contact Lens Health Week. In collaboration with partners from clinical, public health, industry, and regulatory sectors, CDC is promoting healthy contact lens wear and care practices to reduce the risk for eye infections among the approximately 41 million persons in the United States who wear contact lenses. Research after outbreaks of rare but serious eye infections in the United States have indicated that these infections occur most often in contact lens wearers who do not take proper care of their contact lenses, indicating a need to promote safer wear and care (*1*,*2*).

A report in this issue of *MMWR* analyzed 1,075 contact lens–related eye infections reported to the Food and Drug Administration's Medical Device Report database. Nearly 20% of the reports described a patient who had eye damage, and approximately 25% of the reports described potentially modifiable factors that might have put patients at risk for a contact lens–related corneal infection, such as sleeping in lenses or wearing lenses for longer periods than prescribed.

Although most contact lens wearers receive the benefits of vision correction, contact lenses can pose an infection risk, especially if they are not worn and cared for properly. Practicing proper contact lens hygiene and regularly visiting an eye care provider are important actions for keeping contact lens wearers' eyes healthy. Additional information on Contact Lens Health Week and the proper wear and care of contact lenses is available at http://www.cdc.gov/contactlenses.

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Contact Lens–Related Corneal Infections — United States, 2005–2015

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Keratitis (inflammation of the cornea) can result from contact lens wear or other causes. Keratitis from all causes, including contact lens wear, results in approximately 1 million clinic and emergency department visits annually, with an estimated cost of $175 million in direct health care expenditures in 2010 (*1*). Approximately 41 million U.S. residents wear contact lenses, and in 2014, >99% of contact lens wearers surveyed reported at least one behavior that puts them at risk for a contact lens–related eye infection (*2*). The Center for Devices and Radiological Health at the Food and Drug Administration (FDA) regulates contact lenses as medical devices, and certain adverse events related to contact lenses are reported to FDA's Medical Device Report (MDR) database. To describe contact lens–related corneal infections reported to the FDA, 1,075 contact lens–related MDRs containing the terms "ulcer" or "keratitis" reported to FDA during 2005–2015 were analyzed. Among these 1,075 reports, 925 (86.0%) were reported by a contact lens manufacturer and 150 (14.0%) by an eye care

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provider or patient. Overall, 213 (19.8%) reports described a patient who had a central corneal scar, had a decrease in visual acuity, or required a corneal transplant following the event. Among the reports, 270 (25.1%) described modifiable factors known to be associated with an increased risk for contact lens–related corneal infections, including sleeping in contact lenses or poor contact lens hygiene; the remainder did not provide details that permitted determination of associated factors. Continued efforts to educate contact lens wearers about prevention of contact lens–related eye infections are needed.

FDA's MDR database contains reports submitted by mandatory reporters (manufacturers, importers, and device user facilities*) and voluntary reporters (health care professionals, patients, and consumers). FDA uses MDRs to monitor device performance, detect potential device-related safety issues, and develop benefit/risk assessments of these devices. An MDR contains standardized device and patient problem codes, as well as a narrative description of the adverse event. A contact lens MDR was included in this analysis if it was submitted by a U.S. reporter during 2005–2015 and contained the terms "ulcer" or "keratitis" anywhere in the MDR; these terms were selected after reviewing a subset of MDRs indicating that these terms reliably identified reports of apparent microbial keratitis. Each MDR narrative was reviewed by at least two reviewers, and data pertaining to modifiable risk factors, outcomes, and etiologic agents were abstracted. Discrepancies related to data interpretation were discussed by the study team and resolved by consensus. Frequencies of modifiable risk factors, outcomes, and etiologic agents were calculated for both standard variables and variables created from abstracted narrative data.

The final data set included 1,075 MDRs, representing 62% of all contact lens MDRs from U.S. reporters during 2005–2015. Overall, 925 (86.0%) MDRs were reported to FDA by contact lens manufacturers, and 150 (14.0%) were reported by an eye care provider or patient. A total of 615 (57.2%) reports were associated with soft daily wear lenses,† 381 (35.4%) with soft extended-wear lenses,§ 36 (3.3%) with daily disposable lenses,¶ and 43 (4.0%) with rigid gas-permeable lenses.** Thirty-three (3.1%) reports were associated with decorative or cosmetic lenses.†† Sixteen (1.5%) reports indicated purchase of lenses without a prescription, from an unapproved source such as a flea market or costume shop. One hundred thirty

* A device user facility is a hospital, ambulatory surgical facility, nursing home, or outpatient facility (including urgent care clinics and emergency departments).

† Soft daily wear lenses are contact lenses made of soft, flexible, plastics that allow oxygen to pass through to the cornea. They are worn daily and removed, cleaned, and stored prior to sleeping.

§ Soft extended wear lenses are contact lenses made of soft, flexible plastics that allow oxygen to pass through to the cornea. They can be worn overnight or continuously for up to 30 days.

¶ Daily disposable lenses are contact lenses that are worn once and discarded daily.

** Rigid gas-permeable lenses are contact lenses made of durable materials resistant to deposit buildup.

†† Decorative or cosmetic lenses are contact lenses that change the look of the eye but might not correct vision. These lenses can be daily disposable, soft daily, soft extended wear, or rigid gas permeable lenses.

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(12.1%) reports described patients who went to an emergency department or urgent care clinic for their condition, and 25 (2.3%) reported patients who were hospitalized. Eye damage, defined as having a central corneal scar or a decrease in visual acuity, or needing a corneal transplant, was indicated in 213 (19.8%) reports (Table 1).

Two hundred seventy (25.1%) reports described potentially modifiable factors that might have put the patient at risk for a contact lens–related corneal infection. Extended wear of lenses (defined as routine wearing of lenses continuously or overnight, whether prescribed for extended wear or not) was noted in 121 (11.3%) reports, and often prompted the provider to discontinue their use. Other behaviors reported included occasional overnight wear or napping in lenses (7.0%), overwear of lenses (wearing lenses for longer than the prescribed period) (7.9%), using expired lenses or products (0.7%), storing lenses in tap water (0.8%), and wearing lenses while swimming (0.9%) (Table 2). The pathogen causing the infection was reported in 137 (12.7%) MDRs. The most commonly mentioned pathogens were, in order of frequency, *Pseudomonas* (48, 4.5%), *Acanthamoeba* (34, 3.2%), *Fusarium* (24, 2.2%), and *Staphylococcus* species (15, 1.4%). Analysis of narrative sections of reports of patients who ultimately recovered revealed frequent visits to their eye care provider (sometimes daily), frequent administration of prescribed treatment (including hourly administration of eye drops), and missed work or school during the acute phase of their infection.

TABLE 1. Number and percentage of patients with contact lens–related eye infections (N = 1,075), by selected characteristics and outcomes — Food and Drug Administration's Medical Device Report Database, 2005–2015

Characteristic	No. (%)
Female sex (n = 960*)	637 (66.4)
Type or source of lens	
Daily disposables	36 (3.4)
Soft daily wear	615 (57.2)
Soft extended wear	381 (35.4)
Rigid gas permeable	43 (4.0)
Decorative or cosmetic lens†	33 (3.1)
Purchased from unlicensed source (i.e., flea market or costume shop)	16 (1.5)
Outcome	
Emergency department or urgent care clinic visit	130 (12.1)
Hospitalized	25 (2.3)
Eye damage§	213 (19.8)
Corneal transplant	47 (4.4)

* Sex was unknown for 115 patients.
† Decorative or cosmetic lenses can include any type of lens (i.e., daily disposables, soft daily wear, soft extended wear, or rigid gas permeable).
§ Having a central corneal scar or a decrease in visual acuity, or requiring a corneal transplant.

TABLE 2. Modifiable factors known to increase the risk for contact lens–related eye infections mentioned in reports of patients with infectious keratitis (N = 1,075) — Food and Drug Administration's Medical Device Report Database, 2005–2015.

Risk factor*	No. (%)
Any modifiable risk factor	270 (25.1)
Extended wear†	121 (11.3)
Occasional sleeping in contact lenses	75 (7.0)
Overwear (i.e., longer than the prescribed period)	85 (7.9)
Using expired lenses or products	8 (0.7)
Storing lenses in tap water	9 (0.8)
Wearing lenses while swimming	10 (0.9)
Unspecified hygiene problem	12 (1.1)

* These categories are not mutually exclusive.
† Defined as routine wearing of lenses continuously or overnight, whether the use is prescribed or not.

Discussion

During the reporting period included in this analysis, 25.1% of MDRs that included the terms "ulcer" or "keratitis" mentioned a modifiable risk factor, including occasionally sleeping in contact lenses or extended wear of lenses, whereas few reports were associated with problems with the contact lens itself, such as the lens being ripped or torn. Other studies have shown that sleeping in contact lenses, whether occasionally or as part of a prescribed wearing schedule (i.e., extended wear lenses), increases the risk for contact lens–related eye infections by sixfold to eightfold (*3*,*4*). In addition, 19.8% of analyzed MDRs described eye damage after the contact lens–related infection. However, the actual proportion of contact lens–related infections that result in eye damage cannot be determined from the MDR database because of the passive nature of this surveillance system.

The MDR narratives reviewed for this analysis, which described frequent visits to eye care providers, frequent administration of prescribed treatments, and missed work or school give a more patient-focused view of the impact of microbial keratitis, qualitatively corroborating previous findings using large databases (*1*) and demonstrating substantial morbidity, even among patients who ultimately recover. MDR regulations mandate reporting of adverse events and product problems by manufacturers, importers, and device user facilities such as hospital emergency departments and urgent care facilities (*5*).

A high percentage of reports noted extended wear or sleeping in contact lenses. Habitual or occasional sleeping in contact lenses has been shown to increase risk for microbial keratitis (*3*,*6*). Conversely, wearers of daily disposable lenses have been shown to have a lower risk for eye infections (*3*), and in this analysis, daily disposable lenses were infrequently listed in reports for microbial keratitis.

The findings in this report are subject to at least four limitations. Although MDRs are a valuable source of information, they represent a passive surveillance system that includes the potential submission of incomplete, inaccurate, untimely, unverified, or biased information. Second, neither the

Summary

What is already known about this topic?

Approximately 41 million persons in the United States wear contact lenses, a safe and effective form of vision correction if worn and cared for as directed. Contact lenses are medical devices that are regulated by the Food and Drug Administration (FDA). Adverse events related to contact lenses are reported to FDA's Medical Device Report (MDR) database.

What is added by this report?

During 2005–2015, a total of 1,075 MDRs describing contact lens–related corneal infections were reported to the FDA MDR database. Approximately 20% of these MDRs described a patient who suffered eye damage. Approximately 25% of the 1,075 MDRs described potentially modifiable factors that might have put the patient at risk for a contact lens–related corneal infection, such as sleeping in lenses or wearing lenses longer than for the prescribed period.

What are the implications for public health practice?

Prompt reporting of adverse events can help the FDA identify and understand the health risks related to the use of contact lenses. Contact lens wearers can reduce their risk for contact lens–related infections by improving their hygiene behaviors, such as not sleeping in contact lenses unless prescribed and replacing their contact lenses as prescribed. If patients or eye care providers suspect or experience a problem with contact lenses or their care products, they are encouraged to file an MDR report through the FDA Safety Information and Adverse Event Reporting program

incidence nor prevalence of contact lens–related infections can be determined from this reporting system alone because of potential underreporting of events and lack of information regarding frequency of device use. Third, because cases involving patients with more severe outcomes are more likely to be reported, outcomes of infections reported to the MDR database are potentially more severe than typical contact lens–related eye infections. Finally, a small number of reports submitted to the system provided information about more than one patient or more than one problem per patient, and in other cases, multiple reports were submitted for one patient (one report for each eye or contact lens lot number involved). Therefore, the 1,075 reports cannot be interpreted as representing 1,075 cases of contact lens–related corneal infection.

Although contact lenses are a safe and effective form of vision correction if worn and cared for as directed, they pose an infection risk to wearers if not worn and cared for properly. Health promotion activities should focus on informing contact lens wearers of common behaviors that might put them at risk for eye infections, such as sleeping in contact lenses and exposing lenses to tap water, distilled water, or recreational water (*7*). Additionally, prompt reporting of adverse events can help FDA identify and understand the risks associated with the use of contact lenses. Patients or eye care providers who suspect or experience a problem with contact lenses or their care products, should file an MDR report through the FDA Safety Information and Adverse Event Reporting program at http://www.fda.gov/medwatch.

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