Epidemiology of Ulcerative Keratitis in Northern California

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Objective: To determine the incidence and associated risk factors for ulcerative keratitis in northern California.

Methods: In this large-population, retrospective, cohort study, all medical records with diagnosis coding for corneal ulcers during a consecutive 12-month period were reviewed. Incidence rates were calculated using a dynamic population model. Multivariate relative risk regression was conducted to evaluate potential risk factors for ulcerative keratitis.

Results: Within the target population of 1,093,210 patients, 302 developed ulcerative keratitis. The incidence of ulcerative keratitis was 27.6 per 100,000 person-years (95% confidence interval, 24.6-30.9). The incidence of corneal ulceration in contact lens wearers was 130.4 per 100,000 person-years (95% confidence interval, 24.6-30.9), with an adjusted relative risk of 9.31 (7.42-11.7; \( P < .001 \)) compared with non-contact lens wearers, who had an incidence of ulcerative keratitis of 14.0 per 100,000 person-years (11.7-16.6). Seven of 2944 people known to be infected with human immunodeficiency virus developed ulcerative keratitis, with 5 being contact lens wearers. The incidence of ulcerative keratitis in human immunodeficiency virus–positive patients was 238.1 per 100,000 person-years (95% confidence interval, 95.7-490.5), with an odds ratio of 9.31 (7.42-11.7; \( P < .001 \)) compared with human immunodeficiency virus–negative patients, who had an incidence of ulcerative keratitis of 27.1 per 100,000 person-years (24.1-30.3).

Conclusions: The incidence of ulcerative keratitis in this population is higher than previously reported. This may be owing to the increasing prevalence of contact lens wear.


Despite the serious risks of ulcerative keratitis, current knowledge of the incidence of and risk factors for this condition is limited. The only US population-based study, to our knowledge, occurred in a racially homogeneous, rural-county population. The authors found that the incidence rates of ulcerative keratitis had increased from 2.5 per 100,000 people in the 1950s to 11.0 per 100,000 people in the 1980s. Another study has estimated that ulcerative keratitis affects between 27,000 and 30,000 individuals in the United States annually.

Studies describing the spectrum of ulcerative keratitis and its risk factors have been reported from subspecialty and academic practices. These findings are affected by the referral bias of each practice and may not be representative of the general population. In addition, the population size from which these ulcerative keratitis series are drawn cannot be accurately determined.

The purpose of this study is to determine the incidence rate of and risk factors for ulcerative keratitis in northern California using a large-population, cross-sectional approach. The study population was drawn from the Northern California Kaiser Permanente (KP) Health Care Program, which cares for approximately 30% of the 9 million people living in the 14 northern California counties (data available on request).

The KP Health Plan provides comprehensive care to a large, relatively stable population that encompasses all ages, a wide range of socioeconomic levels, a diverse racial mix, and urban and suburban members. Prepaid care is provided by a closed panel of physicians, including comprehensive and specialty ophthalmologists in outpatient and inpatient settings; patient care is recorded in a system-wide computerized database. The database allows an accurate count of the denominator population served by the outpatient clinics and medical center and provides age-stratified and sex-stratified data on a quarterly basis.
A retrospective incidence cohort study using a dynamic population model for calculation of incidence was performed. Nine KP medical facilities in 8 KP communities in northern California were chosen for this study: Fremont, Hayward, Milpitas, Oakland, Redwood City, Richmond, San Francisco, Santa Clara, and South San Francisco. The size of each of the 9 medical facility study populations was defined by the KP Division of Health Statistics as the number of active KP Health Plan members who use each of these facilities as their site for outpatient clinical services. During the study period, the Northern California KP Health Care Program consisted of 35 medical facilities in 17 KP community service areas: 23 of the 35 medical facilities had ophthalmologists on site with at least 1 facility in each of the 17 KP communities providing ophthalmologic care.

The Outpatient Diagnostic Database of the Northern California KP Health Care Program was used to identify all patients coded with the diagnosis of corneal ulcer during a consecutive 12-month period from September 1, 1998, through August 31, 1999. All identified medical records were screened based on specific inclusion and exclusion criteria. For inclusion, patients were required to have their initial visit for a newly diagnosed case of ulcerative keratitis during the study period and to have medical record–documented examinations meeting the clinical definition of ulcerative keratitis: the presence of a corneal epithelial defect with an underlying stromal infiltrate and inflammation attributed to bacterial, fungal, or parasitic infection. Patients with culture-positive and culture-negative results were included. Excluded were patients with epithelial breakdown or stromal infiltrates clinically due to immune-mediated causes, such as staphylococcal hypersensitivity or various rheumatologic diseases, or to viral causes, such as herpes simplex virus, neurotrophic ulceration, or ulcerations secondary to vernal or atopic keratoconjunctivitis. Patients who were not treated with topical antibiotic eyedrops were also excluded.

The cause of the ulcerative keratitis was based on medical record descriptions and drawings, as well as culture findings. If the medical record was incomplete or unclear as reviewed (by 1 of us [B.H.J., D.C.G., A.B.K., or D.S.H.]), the patient's data were excluded. All medical records coded as corneal disorder NOS (not otherwise specified) and keratitis at 1 of the 9 facilities were also reviewed to estimate the number of actual cases of ulcerative keratitis that would be overlooked by not reviewing all medical records at all facilities with these diagnoses.

Age, sex, potential risk factors for ulcerative keratitis (including contact lens wear, ocular trauma, and ocular surface disease), and human immunodeficiency virus (HIV) status were abstracted. Any relevant information with regard to these risk factors (eg, type of contact lens wear, wearing habits, duration of wear, and contact lens solutions used) was also recorded whenever it was present in the medical records. The date of presentation was recorded to identify possible seasonal variation among patients.

Incidence rate calculations were determined using a dynamic population model, based on quarterly age-stratified and sex-stratified data from the KP Division of Health Statistics. In a dynamic population model, the number of person-years accumulated each quarter are calculated and then added. Because of the detailed quarterly data available, this model gives a more accurate measure of the person-years accumulated over time, in contrast with calculating the number of person-years based on the mean of the population at the beginning and end of the study period (midperiod population) or a single measure at 1 point in time. Using the data available, all calculations were performed stratifying for age and sex. This model does not contain confounders or interaction variables because it is simply a way to calculate the number of person-years accumulated by a study population.

Incidence rates were stratified for sex and age and placed in groups spanning 15 years each, except that patients younger than 10 years and older than 85 years were separately grouped together. The US Census 2000 data were used to estimate the number of cases of ulcerative keratitis annually in the United States, adjusting for age and sex.

The risks of ulcerative keratitis related to contact lens wear and the possible confounding effects of having HIV infection were studied. The number of individuals with HIV infection in the study population in 1999 was obtained from the KP Division of Health Statistics. The overall number of contact lens wearers and the subset of contact lens wearers in the HIV-infected population were estimated using the data from the KP Business Strategy and Operations Support Division (available on request), which closely tracks contact lens dispensing at each medical center.

Statistical analysis, including Poisson confidence intervals (CIs) and relative risk, was performed using the Stata statistical software program (StataCorp LP, College Station, Texas) and the R software package for Apple Macintosh. Multivariate relative risk regression was conducted using the Relative Risk package for R (command estrr); interaction was tested using the Wald test for the coefficient of the interaction term at the 0.1 level. Models without evidence of interaction were refit without the interaction terms. Kaiser Foundation Research Institute's institutional review board approved the protocol for this study.

### RESULTS

#### GENERAL EPIDEMIOLOGY AND THE INCIDENCE OF ULCErATIVE KERATITIS

Of the 468 patients coded with the diagnosis of corneal ulcer, 302 patients (173 females and 129 males) fulfilled the inclusion criteria. The reasons for exclusion of 166 patients included staphylococcal hypersensitivity marginal keratitis (95 [57.2%]), insufficient information to make a definitive diagnosis (31 [18.7%]), epithelial defects without stromal infiltration (12 [7.2%]), herpes simplex viral keratitis (10 [6.0%]), and other reasons (18 [10.8%]), including cases of eyes ultimately found to have corneal scars, rheumatoid mils, neurotrophic ulcers, dellen, phlyctenules, and vernal shield ulcers. Patient ages ranged from 4 to 100 years (mean age, 42.8 years; median age, 40.0 years). On average, females were younger than males (40.1 vs 46.5 years, P = .03). The age and sex-stratified distribution of patients with ulcerative keratitis is given in [Table 1](#).

The number of patients with ulcerative keratitis seeking treatment each month during the study period ranged from 15 (October) to 33 (May). No seasonal variation in the number of patients with ulcerative keratitis was observed. During the rainy season (November 1998...
through April 1999), there were 145 patients with ulcerative keratitis compared with the 157 patients with ulcerative keratitis seen during the drier season (P = .46).

The incidence of ulcerative keratitis was 27.6 per 100 000 person-years (95% CI, 24.6-30.9). Extrapolating this figure using an estimated total population of 281 421 906 for the United States in 2000, an estimated 71 000 new cases of ulcerative keratitis occur annually nationwide. Females had a higher incidence of ulcerative keratitis than males (30.8 vs 24.2 per 100 000 person-years), but the difference was not statistically significant. After adjusting for multiple comparisons, the 25- to 39-year age group was the only group in which there was a statistically significant difference in incidence rates between males (27.8 per 100 000 person-years) and females (30.8 per 100 000 person-years) (P = .02).

Of the 23 medical records coded as “corneal disorder NOS” or “keratitis” examined at 1 facility, only 1 true case of ulcerative keratitis was found. No further medical records coded in this manner were reviewed for this study.

**MICROORGANISMS RECOVERED FROM CULTURES**

Of the 302 patients with ulcerative keratitis diagnosed by clinical examination, 60 had cultures taken, with 29 (48.3%) yielding positive results. *Staphylococcus aureus* was the most commonly recovered organism (8; 27.6%) (Table 2).

### Table 1. Age and Sex Stratification of Patients With Ulcerative Keratitis

<table>
<thead>
<tr>
<th>Age Range, y</th>
<th>No. of Patients</th>
<th>Incidence per 100 000 Person-years (95% Confidence Interval)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Females</td>
<td>Males</td>
</tr>
<tr>
<td>0-9</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>10-24</td>
<td>27</td>
<td>16</td>
</tr>
<tr>
<td>25-39</td>
<td>68</td>
<td>36</td>
</tr>
<tr>
<td>40-54</td>
<td>40</td>
<td>37</td>
</tr>
<tr>
<td>55-69</td>
<td>21</td>
<td>26</td>
</tr>
<tr>
<td>70-84</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>≥85</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Total</td>
<td>173</td>
<td>129</td>
</tr>
</tbody>
</table>

**Table 2. Microorganisms Recovered From 29 Positive Corneal Cultures**

<table>
<thead>
<tr>
<th>Organism</th>
<th>Cultures, No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Staphylococcus aureus</em></td>
<td>8 (27.6)</td>
</tr>
<tr>
<td>Coagulase-negative <em>Staphylococcus</em></td>
<td>7 (24.1)</td>
</tr>
<tr>
<td>Moraxella species</td>
<td>6 (20.7)</td>
</tr>
<tr>
<td>Diphtheroids</td>
<td>3 (10.3)</td>
</tr>
<tr>
<td>Streptococcus viridans</td>
<td>2 (6.9)</td>
</tr>
<tr>
<td>Gemella morbillorum</td>
<td>2 (6.9)</td>
</tr>
<tr>
<td><em>Proteus mirabilis</em></td>
<td>1 (3.4)</td>
</tr>
<tr>
<td><em>Streptococcus pneumoniae</em></td>
<td>1 (3.4)</td>
</tr>
<tr>
<td>Enterococcus species</td>
<td>1 (3.4)</td>
</tr>
<tr>
<td>Candida parapsilosis</td>
<td>1 (3.4)</td>
</tr>
<tr>
<td>Yeast (otherwise unidentifiable)</td>
<td>1 (3.4)</td>
</tr>
<tr>
<td><em>Phialophora</em> species</td>
<td>1 (3.4)</td>
</tr>
<tr>
<td><em>Pasturella multiflora</em></td>
<td>1 (3.4)</td>
</tr>
<tr>
<td>Normal flora</td>
<td>1 (3.4)</td>
</tr>
</tbody>
</table>

**PROBABLE PREDISPOSING FACTORS**

One hundred sixty-six patients (55.0%) were contact lens wearers, with 123 (74.1%) of them wearing soft lenses. The mean age of contact lens wearers was 34.5 years, with more females wearing contacts than males (107 vs 59, P = .005). Ocular trauma occurred in 36 patients (11.9%).

The mean age of these patients was 46.9 years, with 27 males vs 9 females having ocular trauma (P < .001). Ocular surface disease was present in 54 patients (17.9%), with blepharitis accounting for the largest proportion (18; 33.3%) of cases of surface disease. The mean age of patients with ocular surface disease was 54.1 years, with more males than females having ocular surface disease (29 vs 21, P = .02). Of the patients with ocular surface disease, bulbar keratopathy was present in 4 patients with ulcerative keratitis, with a mean age of 79 years. None of these 4 patients had previously been wearing bandage soft contact lenses, and all patients developed central ulcers. Seropositivity for HIV was found in 7 patients with ulcerative keratitis.

Because age and sex data were not available for those HIV patients and contact lens wearers who did not develop ulcerative keratitis, relative risk regression was conducted for ulcerative keratitis as an outcome using only HIV seropositivity and contact lens wear (and their interaction) as predictors; we found that the interaction of HIV seropositivity and contact lens wear (and their interaction) was not statistically significant.

The estimated incidence of ulcerative keratitis in contact lens wearers was 130.4 per 100 000 person-years (95% CI, 111.3-151.7), whereas the incidence of ulcerative keratitis in non–contact lens wearers was 14.0 per 100 000 person-years (11.7-16.6). The relative risk (adjusted for HIV status) of developing ulcerative keratitis in contact lens wearers compared with nonwearers was 9.31 (95% CI, 7.42-11.7; P < .001) (Table 3).

Of the 7 HIV-positive patients with ulcerative keratitis, 5 were contact lens wearers. The overall incidence of ulcerative keratitis in HIV-infected individuals was
The present study may have estimated a greater incidence of contact lens–related ulcerative keratitis because it studied a general population treated by subspecialists and comprehensive ophthalmologists rather than individuals treated in an academic referral practice. The decreasing number of patients with contact lens–related ulcerative keratitis cared for in an academic referral practice may be owing to improved treatment of ulcerative keratitis in the community since the introduction of topical fluoroquinolones in the 1990s.20,22-23 The large proportion of contact lens–related ulcerative keratitis in this community-based study supports this hypothesis.

RISK FACTORS

The risks of ulcerative keratitis related to contact lenses are well known, and several studies20-23 have reported its increased incidence among contact lens users. For discretionary contact lens use, the annual incidence of ulcerative keratitis caused by bacteria depends on the type of contact lens used: 4.4 to 15 per 100,000 persons for rigid lenses, 22 to 41 per 100,000 persons for daily-wear soft contact lenses, and 93 to 209 per 100,000 persons for extended-wear soft contact lenses. For wearers of aphakic contact lenses, the overall annual incidence of ulcerative keratitis for all lens types is estimated to be 520 per 100,000 persons.30

The type of contact lens or wearing schedule could not be reliably determined by medical record review in 27 (16.2%) contact lens–related ulcerative keratitis cases in this study. In addition, although 123 contact lens wearing patients (74.1%) in this study wore soft contact lenses, the wearing schedule of 99 contact lens wearers (59.6%) could not be determined by medical record review. Given these statistics, this study’s overall incidence rate of ulcerative keratitis of 130.4 per 100,000 persons in contact lens wearers may be similar to those reported in earlier studies.

Another important risk factor associated with ulcerative keratitis in this study was a history of trauma to the eye unrelated to any surgery, occurring in 36 (11.9%) of all 302 patients with ulcerative keratitis. This result is lower than that in other published series20,30,31 in the United States citing nonsurgical trauma as accounting for between 16% and 27% of all cases of ulcerative keratitis.

In this study, trauma may be lower because of the higher percentage of cases of contact lens–related ulcerative keratitis and possible referral bias in the other studies. In this
study, the opposite phenomenon, in which trauma patients may seek care directly at an outside tertiary care center, may exist, accounting for the lower figure, but we do not believe this is the case to any significant extent because patients within the KP system almost always seek care at a KP medical center before receiving authorization for referral to another hospital system. In this setting, even if the patients were ultimately referred outside the system, their data would still be captured because of their initial visit within the KP system.

The percentage of patients with ulcerative keratitis related to bullous keratopathy (1.3%) is less than the 6% to 9% reported in other series. Luchs and associates reported that approximately 4.7% of patients with bullous keratopathy experienced a corneal ulcer during a 10-year period. The smaller proportion of patients with ulcerative keratitis associated with bullous keratopathy in this study may be owing to a decreased incidence of bullous keratopathy since the 1980s with improved intraocular lenses and surgical techniques. Also, greater availability of donor tissue compared with the past may decrease the number of patients at risk.

Although cases of apparently spontaneous corneal infections in HIV-infected individuals have been previously reported, it was generally believed that HIV infection alone does not predispose a person to bacterial ulcerative keratitis. This study suggests that HIV infection is indeed a risk factor for ulcerative keratitis. This study assumed that the percentage of contact lens wearers in the HIV-positive population was the same as that in the general population. If this assumption was correct, the risk of developing ulcerative keratitis in HIV-positive individuals is nearly 9 times that in HIV-negative individuals.

Estimates of the prevalence of known HIV infection in the United States at the end of 2000, using an estimated 850 000 to 950 000 persons living with HIV, with 25% of these not knowing they were infected (leaving 637 500 to 712 500 persons with known HIV infection), and a population size of 281 421 906, yields a prevalence range of 0.23% to 0.25%. This range is in close comparison to the prevalence of known HIV infection in our study of 0.27%. Because the population that we considered HIV negative may encompass individuals who are unaware that they are HIV positive, our calculations of relative risk may underestimate the true relative risk that HIV infection carries with regard to ulcerative keratitis.

The individuals with HIV-positive status may be at greater risk of developing ulcerative keratitis because of HIV-associated keratoconjunctivitis sicca, anatomical eyelid abnormalities owing to Kaposi sarcoma and molluscum contagiosum, and the underlying immunodeficiency. In this study, CD4 T-lymphocyte counts and HIV-related disorders could not be reliably documented by medical record review. However, given that this study may have uncovered a suggestion that HIV disease may be a significant risk factor for the development of ulcerative keratitis, this possibility should be further studied.

In this study, the incidence of ulcerative keratitis with the different potential risk factors could only be estimated in the contact lens–wearing and HIV subgroups because these were the only subgroups for which we had accurate numbers with regard to those individuals who were nonwearers and were HIV negative. Our relative risk regression analysis found that there was no evidence of an interaction between HIV seropositivity and contact lens wear (P = .39); therefore, we modeled our analyses of these subgroups without interactions.

### STUDY STRENGTHS AND LIMITATIONS

The strength of this study is the ability to analyze a large, stable, and diverse population covering a vast geographic area. Approximately 30% of the overall population in northern California is insured by the KP Health Plan, and those insured come from a variety of socioeconomic backgrounds, including those participating in Medicare and Medicaid, as well as employer-based and self-pay programs. The large denominator size of more than 1 million provided substantial statistical power for this study, providing information on the general population and for subgroups. In addition, data from the 2003 California Health Interview Survey found that the KP membership is overall similar to the general population. Generalizing a study's findings to the overall population is sometimes not appropriate; however, the size, diversity, and similarity of this study's population with the general population make extrapolation of these data a reasonable choice when performed with the methods described herein.

Misclassification bias could exist because of miscoding, resulting in a spuriously low estimate of disease in this study. The random sampling of medical records at 1 facility found that less than 5% of medical records coded as corneal disorder NOS or keratitis fit inclusion criteria. Misclassification bias in this study could have led to a lower or higher estimate compared with the true incidence of ulcerative keratitis, but the conservative and strict inclu-

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<tbody>
<tr>
<td></td>
<td>Overall, No. (%)</td>
<td>Male, No. (%)</td>
<td>Overall, No. (%)</td>
<td>Male, No. (%)</td>
<td>Overall, No. (%)</td>
<td>Male, No. (%)</td>
</tr>
<tr>
<td>0-14</td>
<td>60 253 375 (21.4)</td>
<td>212 938 (19.5)</td>
<td>30 854 207 (22.3)</td>
<td>108 777 (20.4)</td>
<td>29 399 168 (20.5)</td>
<td>104 158 (18.6)</td>
</tr>
<tr>
<td>15-24</td>
<td>39 183 891 (13.9)</td>
<td>133 932 (12.3)</td>
<td>20 078 816 (14.5)</td>
<td>65 053 (12.2)</td>
<td>19 105 073 (13.3)</td>
<td>68 879 (12.3)</td>
</tr>
<tr>
<td>25-34</td>
<td>85 040 251 (30.2)</td>
<td>352 440 (32.2)</td>
<td>42 568 327 (30.8)</td>
<td>174 363 (32.7)</td>
<td>42 471 924 (29.6)</td>
<td>178 077 (31.8)</td>
</tr>
<tr>
<td>35-44</td>
<td>61 952 636 (22.0)</td>
<td>275 595 (25.2)</td>
<td>30 142 586 (21.8)</td>
<td>132 238 (24.8)</td>
<td>31 810 050 (22.2)</td>
<td>143 357 (25.6)</td>
</tr>
<tr>
<td>45-64</td>
<td>34 991 753 (12.4)</td>
<td>118 308 (10.8)</td>
<td>14 090 625 (10.4)</td>
<td>52 789 (9.9)</td>
<td>20 582 128 (14.4)</td>
<td>65 199 (11.7)</td>
</tr>
</tbody>
</table>

a Percentages may not total to 100 because of rounding.

Table 4. Comparison of the Kaiser Permanente Study Population With the US 2000 Census Population for Age
sion criteria that we used may have led to underestimating of the true incidence. On the other hand, it is also possible that some patients with noninfective keratitis, especially in the setting of blepharitis, may have been included in the study, resulting in an overestimation of the incidence rates found in this study. Furthermore, we could have misclassified some contact lens wearers as control individuals because they did not obtain their lenses through the KP system, and this would result in an underestimation of the relative risk of developing ulcerative keratitis in contact lens wearers compared with nonwearers. We could have also misclassified some individuals who were not known to have HIV-positive status in the control group, which would result in an underestimation of the relative risk of developing ulcerative keratitis in individuals with HIV-positive compared with HIV-negative status. Thus, as with any study, the CIs are useful for determining where the truth may lie.

Because there were numerous treating subspecialty and comprehensive ophthalmologists involved with the care of these patients, there was no systematic routine for determining which cases of ulcerative keratitis were cultured and which were not. As such, the generalizability of the culture results and their interpretative value are limited.

The retrospective nature of this study also prevented some information, such as details regarding contact lens wear, from being collected. Other possible limitations of the study are that the study population included data only regarding people with health insurance, which would result in an underestimation of our incidence calculations. Uninsured people seek care at KP medical centers, but none had ulcerative keratitis during the target period. Although uncommon, some KP members may have sought initial and subsequent care for ulcerative keratitis outside the KP system and therefore were not included in the data set.

### CONCLUSIONS

From a public health perspective, it is important to recognize that the incidence of ulcerative keratitis in the United States is substantially higher than previously reported. Although it is well known that contact lens wear has been and continues to be a major risk factor for ulcerative keratitis, this knowledge has not effectively reduced the occurrence of the disease in contact lens wearers. Instruction in proper contact lens use and hygiene is an important public health task in which all providers of contact lens care must participate. In addition, discouraging patients from sleeping while wearing extended-wear contact lenses, despite the fact that those lenses are approved for overnight wear, may also decrease the risk of ulcerative keratitis. Although encouraging the use of daily disposable soft contact lenses may not further decrease the risk of ulcerative keratitis, vision loss is less likely to occur in users of these lenses compared with those who use reusable soft contact lenses.\(^{43}\)

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### REFERENCES


