

Ulcerative Keratitis from Overnight Contact Lens Wear Compared with Other Life Risks

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Wearers of extended wear contact lenses are at increased risk for ulcerative keratitis compared with daily wear contact lens users. Using incidence rates, we compared ulcerative keratitis in contact lens wear with other diseases and serious life risks. "Comparative risk," a theoretical construct for this paper, is a framework through which the incidence rates are compared. Although the risks of ulcerative keratitis in extended wear are greater than with daily wear contact lenses, the risks of extended soft contact lens wear are 2–10 times less than the risks for non-fatal, serious and disruptive occurrences in a general population. Contact lens associated ulcerative keratitis is in the range of 10–20 times greater than the incidence of common causes of death in a low risk, middle-age population.

Introduction

During the late 1980s ulcerative keratitis among extended wear soft contact lens wearers strongly influenced the field. Earlier published reports¹⁻⁴ recognized complications, but the numbers of patients and patient years of wear were very small. The first reports in the mid 1980s were from tertiary referral centers and hospital emergency rooms⁵ where ulcerative keratitis had significantly increased and was largely attributed to extended wear soft contact lens use. Incidences and relative risks for different contact lens modes in the general population were first defined in US epidemiologic studies by Poggio, Schein, and associates⁶⁻⁸ and in the United Kingdom by Dart and associates.⁹⁻¹¹ The incidence of ulcerative keratitis varied from 41 per 100,000¹ for daily wear soft contact lenses to 209 per 100,000 wearing population for extended wear soft contact lenses. (To facilitate the comparison of statistics presented herein, all incidence or prevalence statistics are expressed in occurrences per 100,000 population. Poggio and colleagues expressed these in occurrences per 10,000 population.) Poggio and associates,⁶ in a case control study, determined relative risks for wearing extended wear soft contact lenses on an overnight basis to be 10–15 times greater than daily wear users who removed their lenses nightly. Dart and associates¹⁰ reported a relative risk of 20.8 times greater for extended wear soft contact lenses than for daily rigid gas permeable lens wear. MacRae¹² analyzed the clinical data on 22,739 patients participating in clinical investigations and gave comparative results for adverse reactions for different

categories of contact lens wearers. Corneal ulcers and severe adverse reactions occurred two to four times more often among users of extended wear soft and rigid gas permeable contact lenses compared with daily wear soft contact lens users.

Disposable and frequent replacement soft contact lenses were expected to reduce the occurrence of complications by minimizing the potential risk factors of patient handling, spoiled lenses, and solution and accessory contamination. However, controlled studies^{13,14} have been equivocal and have found a possible increase in complications compared with non-disposable extended wear. Buehler and associates¹⁵ reported an odds ratio (relative to daily wear soft wear) of 14.34 (5.47–37.63, 95% confidence intervals) for disposable lenses compared with 1.87 (0.61–5.71) for extended wear soft contact lenses. Schein¹⁵ and Poggio¹⁶ report lower odds ratios for overnight wear compared with daily lens removal through greater specificity of controls but did not find significant differences between disposable and extended wear lenses used in overnight wear.

For purposes of this paper, the cohort study reported by Poggio⁶ for primarily incidence of extended wear soft contact lens complications (209 cases per 100,000 population) was used for subsequent comparisons.

Contribution of epidemiologic techniques

Epidemiologic advancements have improved our understanding of diseases, accidents, and occurrences.¹⁷ Statistically we can express reliable incidences and confidence limits, as well

as define the effects of risk factors.¹⁸ Epidemiologic terms used in this article are incidence, risk factors, and relative risks. "Incidence" defines the number of newly diagnosed cases in a defined population for a particular period. A "risk factor" is an independent condition that influences an event or disease. They can be volitional as in smoking or sun exposure, or predetermined by genetics, age, or other non-controllable factors. "Relative risk" is the ratio of the incidence of a condition with and without the presence of a specific risk factor.

TABLE I Annualized incidence rates of life risks compared with contact lens ulcerative keratitis

Ocular conditions	Relative risks	Incidence rates [†]	Comparative risk [*]
Contact lens-associated ulcerative keratitis			
Cosmetic EWSC wearers [§]		209	1.0 [†]
Cosmetic DWSC wearers [§]		41	5.1
Cosmetic EWRGP wearers [‡]		239	0.87 (-1.1)
Cosmetic DWRGP wearers [‡]		68	3.0
Ocular industrial injuries/industrial population		660	0.32 (-3.16)
Keratoconus [§]		20.0	1.04
Hospitalized ocular trauma [‡]		13.2	15.8
Color deficiency, ^{‡§} Caucasian males		8,000	0.026(-38.2)
Caucasian females		800	0.26(-3.8)
Blindness diabetes ^{§§}		500	0.418(-2.4)
Health related statistics			
Death rate from head injury ^{‡§}		16.9	12.4
Death rate from all cancers ^{‡§}			
35-44 years		18.3	11.4
65-74 years	0.17 (-6.0)	109	1.9
Death rate from heart disease ^{‡§}			
25-44 years		21.1	9.9
45-64 years	0.07 (-14.6)	308	0.68 (-1.5)
Death rate from breast cancer ^{‡§}			
35-44 years, females		18.3	11.4
55-64 years, females	0.23 (-4.4)	80.9	2.6
Incidence/squamous cell skin cancer ^{‡§}			
(females compared with males)	3.4	29.8	7.1
Residential fire injury ^{‡§}		8.1	26
Residential fire death ^{‡§}		2.1	100
Death rate from motor vehicles		19.9	10.5
Death rate from air/space accidents ^{‡§}		0.5	418
Disabling motor vehicle accidents		1,860	0.12 (-8.9)
Suicides ^{‡§}		12	17.4
Non-health related statistics			
Murders ^{‡§}		11.8	17.7
250,000 city compared with 10,000 city		6.4	
Robberies ^{‡§}		220	0.95 (-1.1)
Burglary ^{‡§}		1,309	0.6 (-6.3)
Lightning strike ^{‡§}		0.17	1,229
IRS audit/taxpayer ^{‡§} population		1,300	0.16 (-6.3)
audit under \$10,000 income		400	0.52 (-1.9)
audit over \$50,000		3,500	0.06(-16.7)

*Comparative risk = $\frac{\text{Incidence - EWSC Wear}}{\text{Incidence - other occurrence}}$
 When this is less than one, the reciprocal is given in parentheses and is further designated as a negative number.
[†]Comparative risk is by definition 1.0.
[‡]per 100,000 population.
[§]Blindness occurring within 4 years of onset and diagnosed before age 30.

The volume of information and sometimes conflicting results hinder the consumer and the professional in interpreting the results. Unfortunately, epidemiologic data comparisons cannot be made with dangers that are immediately recognizable. How significant is an incidence of 209 per 100,000 population compared with other diseases and occurrences? Relative risks may not be comprehended without understanding whether the incidence of the disease is exceedingly common, or rare.¹⁹ For example, are the increased risks of ulcerative keratitis in extended wear compared with daily wear a meaningful risk or is the incidence so low as to be extremely improbable? Since every activity we perform either has a risk or is a risk factor, how do we compare the many risks to which we are exposed?

Actual versus perceived risks

Actual risks differ from perceived risks.²⁰ Consumer and practitioner perception of risks can be influenced by the actual frequency of the incident, the severity of the outcome, and other available alternatives. Perceived risks are weighed heavily by subjective factors and complex value judgments. The professional is likely to look at the public health and legal consequences. The consumer may react to the concerns of the moment. For example, the fear of flying after air terrorist incidents may dissuade large numbers of people from flying, although they may select automobile transportation, which is statistically a far more risky transportation alternative.

Extended wear soft contact lenses compared with other epidemiologic data

Table I represents the annualized incidence, relative risks, and comparative risks of a number of events subdivided into ocular, health, and non-health occurrences. Many of the statistics are from recognized primary sources including the National Center for Health Statistics, National Safety Council, and the Federal Bureau of Investigation. In general these are statistical reports on conditions relating to a wide spectrum of diseases and life risks known to the patient and/or ophthalmic practitioner. Either the practitioner or the patient, with his/her value system, can place into perspective the risks of contact lens wear compared with other situations. All data are expressed in annualized form; i.e., the number of new cases per 100,000 population each year.

Comparative risks are a theoretical construct for this paper, because a review of the statistical literature yielded no similar concept to make a quantitative comparison.

$$\text{Comparative risk} = \frac{\text{Incidence}_{\text{occurrence}}}{\text{Incidence}_{\text{EWSC wear}}}$$

Comparative risk is the ratio of incidence in extended wear soft contact lens wear to the incidence of the compared occurrence and can be expressed as above. For example, the comparative risk for death from cancer from all causes for an individual in a 35-44 age group is 11.4, which means that ulcerative keratitis in extended wear soft contact lens use is 11.4 times more likely to happen over a time period than fatal cancer.

Comparative risks of less than one are expressed in two ways in the Table. The first is according to the above definition. The second, shown in parentheses, is the reciprocal of the above formula, with the addition of a minus sign. For example, the comparative risk of a disabling motorized vehicle accident is 0.12 or expressed perhaps in a more useful way, -8.9. This means that an individual is 8.9 times less likely to have ulcerative keratitis in extended wear soft contact lens use than a disabling motorized vehicle accident in an identical time interval.

Figure 1 plots the comparative risks with the incidence for each life risk on a log scale. The graph is a convenient way to display both the qualitative and a more quantitative ranking relative to the incidence of extended soft lens wear. Extended wear was used as the baseline, rather than daily wear which is more common in contact lens comparative studies, because extended wear soft contact lens use has evoked the most concern.

To summarize a large number of these comparative risks, the comparative risks of ulcerative keratitis in extended wear is from 2 to 10 times less risky than certain non-fatal occurrences, including disabling industrial eye injuries (-3.2), a disabling motor vehicle accident (-8.9), burglary (-6.3), or being audited by the IRS with an income under \$10,000 (-1.9). Extended wear soft contact lens use is in the range of 10-20 times more risky than some of the common causes of death in a 35-55 year old population. Examples include death from all cancers for 35-44 year old population (11.4); death for 35-44 year old females

from breast cancer (16.7); and death rate from motor vehicle accidents (19.7).

Caveats

Shortfalls for comparing incidences of unrelated conditions are that we do not know the definitions, study design, limitations, and confidence limits for the statistics. For example, the definition of "ulcerative keratitis" used by Poggio and associates⁶ is an "ulceration of the corneal epithelium with an underlying inflammation of the corneal stroma." Any other definition (e.g., hospital admission, or positive culture) would alter the incidence rate. Similarly, variability in the definitions of other diseases, occurrences, or populations will also affect incidence.

The base populations for each of these statistics also differ. When compared to the contact lens wearing population, populations in the other life risk groups do not necessarily have the same exposure, perceptions, and risk avoidance to these diseases and occurrences.

The design of the studies affects the results, as well as the interpretation. The companion studies of Poggio, Schein and coworkers^{6,7} produced two different relative risks. The prospective study found 5.1 times greater risk of ulcerative keratitis in extended wear compared with daily wear, and the case control study reported 10 to 15 times greater risk. The range of relative risks for the latter may have resulted from two different control

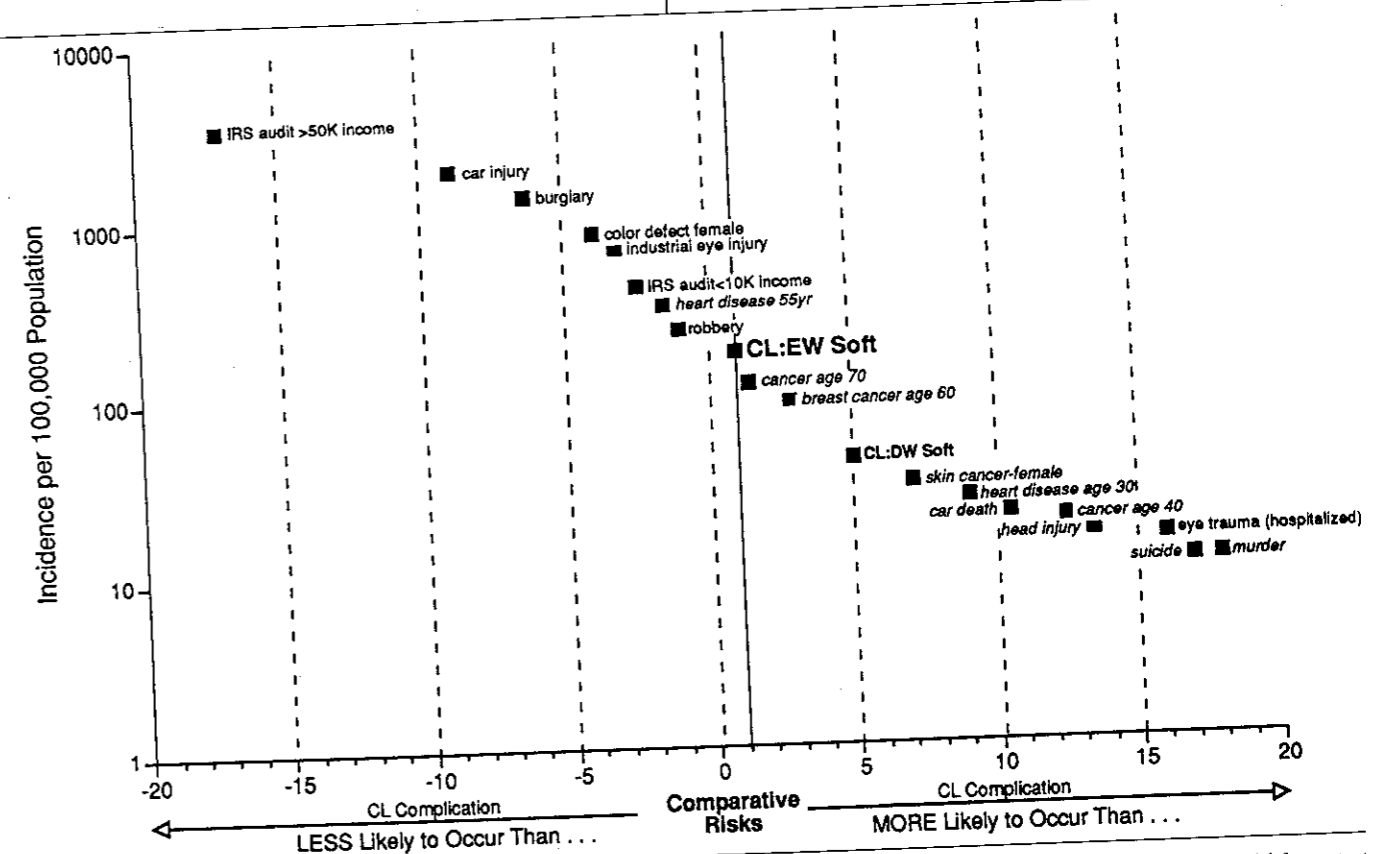


Figure 1 A comparison of the incidence of different life risks. The graph demonstrates a relative order of life risks, and how much greater or less is the risk for contact lens associated ulcerative keratitis. (Mortality statistics are in italics.)

groups, a population-based and a hospital-control group. Another difference in the case-control study was in separating those with extended wear and daily wear lenses whose wearing schedules did not match the lens type.

Also, patient populations and epidemiologic techniques yield certain confidence limits for incidences or relative risks when the sample results are interpolated to the general population. For example, the study by Schein and associates⁶ reported the incidence of ulcerative keratitis among soft extended wearers as 209 per 100,000 population, but the 95% confidence range was between 151-267. The relative risk of 5.15 for extended wear soft contact lens use compared with daily wear soft contact lens use had a 95% confidence interval of 3.47-7.65.

Comparative risks are one aspect of risk analysis, with the other being a risk-benefit consideration. The practitioner or the patient may have different opinions of extended wear risks, considering the alternative is daily wear. Similar determinations of benefits are made in all other areas. Yet the two are intertwined because we are not likely to undertake an activity such as bungy jumping, even if one variation is less risky, for example, jumping off a derrick compared with the walls of a canyon.

Lastly, there is a valid criticism to comparing such diverse situations as contact lens complications with injuries and death from a wide range of causes. Not only are there the unknowns of study design, but perceived benefits and outcomes are so different. However, the generalities derived from comparing incidences of contact lens complications to common injuries and death occurrences provide a perspective for extended wear contact lens wear in the hierarchy of life risks.

Conclusions

The risks of ulcerative keratitis in extended soft contact lens wear are 2-10 times less than the risks for non-fatal, serious and disruptive occurrences in a general population. Contact lens associated ulcerative keratitis is in the range of 10-20 times greater than the incidence of common causes of death in a low risk, middle-age population.

The comparisons herein should not minimize the public health significance of extended wear complications of contact lens wear, but are intended to clarify the relationship of ulcerative keratitis to other life risks. Through informed consent, potential extended wear soft contact lens patients should be provided the alternatives, relative risks, and risk factors.

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