

Incidence and morbidity of hospital-presenting corneal infiltrative events associated with contact lens wear

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Aim: To determine the incidence and morbidity (visual loss) of hospital-presenting corneal infiltrative events (CIEs) associated with the wearing of current generation contact lenses.

Methods: All contact lens wearers presenting with any form of corneal infiltrate/ulcer to a hospital centre in Manchester, UK, were surveyed in this 12-month, prospective, hospital-based epidemiological study. A clinical severity matrix was used to quantify the overall severity of presenting signs and symptoms. The size of the hospital catchment population and the wearing modalities (daily wear [DW] or extended wear [EW]) and lens types used in that population were estimated from relevant demographic and market data to facilitate the calculation of incidence. We also attempted to ascertain, from their eye care practitioners, the visual acuity (VA) of patients suffering from CIEs prior to and at about six months following attendance at the hospital.

Results: During the survey period, 118 patients presented with CIEs of varying severity. The annual incidence (cases per 10,000 wearers) for all wearing modalities and lens types is 21.3 (95 per cent confidence interval 17.8 to 25.5). The incidence of CIEs for each wearing modality and lens type is: DW rigid, 8.6 (3.9 to 18.7); DW hydrogel daily disposable, 14.0 (9.3 to 21.0); DW hydrogel (excluding daily disposable), 20.4 (15.9 to 26.2); DW silicone hydrogel, 55.9 (9.9 to 309.6); EW rigid, zero (0.0 to 1758.8); EW hydrogel, 144.6 (66.4 to 311.8) and EW silicone hydrogel, 118.6 (75.2 to 186.7). The risk of developing a CIE with EW lenses was 8.1 (5.3 to 12.5) times greater than that with DW lenses ($p < 0.0001$). Although there was no difference between EW hydrogel and EW silicone hydrogel lenses with respect to the risk of developing CIEs, the clinical severity of CIEs was greater with EW hydrogel lenses ($p = 0.04$). Results of VA for pre- and post-hospital attendance were obtained from 38 patients, none of whom lost more than one line of VA. For the study population, zero patients (95 per cent CI: 0 to 9.2 per cent) suffered a significant loss of VA as a result of developing a CIE.

Conclusions: Overall, there is an eight times higher incidence of CIEs in wearers who sleep in contact lenses compared with wearers who use lenses only during the waking hours. For those who choose to routinely or intermittently sleep in soft contact lenses, silicone hydrogels are the lens of first choice because CIEs are less clinically severe with this lens type compared with hydrogel lenses. The rate of significant visual loss as a result of developing a CIE is low.

Key words: contact lens, cornea, corneal infiltrative events, incidence, keratitis, morbidity relative risk, vision loss

Health care practitioners benefit from knowledge of the likely rate of occurrence of the various conditions that fall within their clinical remit. The situation is no different for eye care practitioners, especially with respect to the occurrence of contact lens-associated keratitis, which is the only contact lens complication that can potentially lead to permanent visual loss.^{1,2} There have been substantial advances in contact lens manufacturing and material technology over the past 15 years, with the most notable being the development of processes for the mass production of contact lenses (whereby daily lens disposability is now prominent in the market³) and the introduction of hyper-oxygen transmissible silicone hydrogel lenses.⁴ Notwithstanding the overall benefits of these advances, recent case reports have appeared in the literature of severe sight-threatening keratitis in patients wearing daily wear daily disposable lenses^{5,6} and extended wear silicone hydrogel lenses.⁷

In all progressive fields of health care, there is a constant need to redefine the safety of various treatment options. Clearly, this also applies to the contact lens field. While previous epidemiological studies have documented the incidence of contact lens-associated keratitis with disposable hydrogel lenses,^{8,9} and non-planned replacement lenses before that,¹⁰ the recent advances deem it necessary to re-examine the rate of occurrence of keratitis with respect to new-generation rigid and soft lens products, including daily disposable and silicone hydrogel lenses.

In an attempt to more accurately describe and/or differentiate various forms of keratitis, especially (but not exclusively) those associated with contact lens wear, researchers and clinicians have adopted a variety of descriptors to precede the term 'keratitis', such as microbial,⁸ infiltrative,¹¹ ulcerative,¹⁰ infectious,⁶ suppurative,¹² infective¹ and sterile.¹³ For many clinicians, the term 'keratitis', when used without one of these descriptors, has the connotation of a severe form of the disease. To avoid any potential ambiguity and to encapsulate other terms that have been used to describe symptomatic forms of keratitis, such as 'contact lens peripheral ulcer'¹⁴

and 'contact lens acute red eye',¹⁵ we shall adopt the term 'corneal infiltrative event' (CIE), as used by Sweeney and colleagues,¹⁶ as a phrase that embraces all forms of keratitis.

Justification for the approach outlined above is found in Dorland's *Medical Dictionary*,¹⁷ which defines 'keratitis' as 'inflammation of the cornea', and defines 'inflammation' as being characterised by '... leukocytic migration into the inflammatory focus'. Therefore, the terms 'keratitis' and 'corneal infiltrative event' can be considered as being essentially synonymous, as both terms imply an infiltration or migration of cellular elements into the cornea. Use of the latter term is preferred as it is consistent with our approach of considering all forms of contact lens associated CIEs as being part of a continuous spectrum of disease (see below). As this paper is concerned only with CIEs that occur in association with contact lens wear, the term 'contact lens-associated' will not be repeated throughout this paper.

Previously, we reported the incidence of 'non-severe' and 'severe' keratitis among contact lens wearers¹⁸ using the same data set as is used in this paper. While that approach served the useful purpose of allowing our data—especially those regarding severe keratitis—to be compared to earlier reports of the incidence of so-called microbial^{8,9} or ulcerative¹⁰ keratitis, such a binary division of keratitis severity can be problematic for a number of reasons. True differentiation of microbial versus sterile keratitis is dependent on proof of microbial infection, which is usually sought by scraping the cornea and culturing for evidence of pathogenic micro-organisms. The difficulty with this procedure is that on up to 50 per cent of occasions when a corneal scrape is taken from a patient with presumed microbial keratitis (based on clinical signs and symptoms), the result turns out to be culture-negative.^{8,10,18} It is difficult to interpret such a negative result because it is not possible to determine whether this indicates that micro-organisms were truly absent or whether micro-organisms were present but simply not picked up in the course of the scraping procedure. Also, a positive culture may

indicate the presence of potentially pathogenic micro-organisms that were cultured coincidentally and were unrelated to the CIE under investigation.

Differentiation of ulcerative versus non-ulcerative keratitis is similarly problematic as this distinction depends on the criteria for corneal ulceration. This difficulty has been discussed in some detail by Stein and associates,¹³ who attempted to define a corneal ulcer in terms of its size and shape, the presence or absence of overlying corneal staining, and whether or not the ulcer was found to be culture-positive. These authors documented considerable overlap in these diagnostic indices for conditions presumed to be infected versus sterile, which served to further highlight the difficulty in clinically differentiating such conditions.

We believe that it is clinically useful to consider all forms of symptomatic corneal infiltrative events as being part of a disease continuum. Putting aside the small minority of extremely serious cases requiring hospital admission and/or intensive medical therapy, we have observed little difference in the clinical journey of patients suffering from symptomatic CIEs of different levels of severity, including those who were most likely to have been diagnosed traditionally as suffering from microbial keratitis.¹⁸ All patients had to take time off work (or time off from pursuits in which they would otherwise have been engaged); it was necessary to seek advice from a health care professional (often in a hospital setting) and be subjected to an ophthalmic examination, sometimes involving corneal scrapes; most patients were required to temporarily suspend lens wear and resort to alternative modes of vision correction (typically spectacle wear); and patients often had to access various therapeutic or prophylactic topical and systemic medications either on prescription from their attending clinician or as over-the-counter products. All of these factors probably served to heighten the anxiety of the vast majority of patients fearing a potentially permanent loss of sight.

In view of the above, we sought to determine the incidence and morbidity (permanent visual loss) of hospital-presenting

CIEs, considering the various levels of severity of this condition as a continuous spectrum of disease. As far as we are aware, this is the first time that such an approach has been adopted in the contact lens field.

METHODS

Study setting

A prospective survey was conducted between January 25 2003 and January 24 2004 of all patients who were wearing contact lenses (irrespective of the primary reason for presentation) and attending the acute service of the Royal Eye Hospital, Manchester, United Kingdom.

This research followed the tenets of the Declaration of Helsinki. Informed consent was obtained from all patients surveyed in this study. Ethics approval to conduct this study was obtained from the Local Research Ethics Committee (Central) of Manchester Health Authority.

Survey procedure

All presenting patients who habitually wore contact lenses completed a patient questionnaire,¹⁸ which gathered information such as personal details, whether or not they slept in lenses (wearing modality), lens type (defined in terms of the material from which the lens was fabricated and/or the lens replacement frequency), lens care system used and their reason for attending the study centre.

If a corneal infiltrate or ulcer was noted on ocular examination, the attending clinician completed a survey form that gathered clinical information relevant to this study. An important feature of this form was a 'clinical severity matrix', as described by Aasuri, Venkata and Kumar¹⁴ (with minor textual adaptations). This matrix was used by the clinician to score the severity of each of the following signs and symptoms on a zero to 3 scale: level of ocular discomfort, lid swelling, conjunctival redness, infiltrate size, infiltrate shape, fluorescein staining, surrounding corneal haze, endothelial debris, hypopyon and the effect of lens discontinuation. The cumulative score for each event—the 'clinical severity score'—was between 2

(the minimum score relating to the criterion for this study of only including patients exhibiting an infiltrative response) and 22, whereby the higher the score, the more clinically severe the event.

Hospital catchment population

Calculation of the incidence of infiltrative events necessitated an estimation of the catchment population of the hospital. We applied the technique of Bailey (reported by Senn and Sampson¹⁹) to the demographic details of the 24,630 patients with all forms of ocular problem presenting to the acute service of the hospital during the survey period. Essentially, this involved determining in which of the 14 National Health Service Primary Care Trusts (urban geographic regions) within Greater Manchester the patients were resident. The small number of patients living outside Greater Manchester was factored into this analysis. Assuming that the rates of ocular problems were similar for all areas of residence, a weighted population size was calculated for each area and the total of these was determined to be 1,071,503—the hospital catchment population.

Determination of lens wearing modality

We have conducted annual surveys on contact lens prescribing trends in the United Kingdom between 1996 and 2003.²⁰ This data set comprises information relating to 8,833 contact lens fittings by 977 practitioners. From these data, we could determine the proportion of each of the four lens types described below that are prescribed for daily wear versus extended wear.

We categorised contact lens types as follows:

1. rigid: lenses made from silicone-containing rigid gas-permeable materials
2. hydrogel daily disposable: single use hydrogel lenses (excluding silicone hydrogel lenses) that are discarded after each daily use
3. hydrogel: all forms of hydrogel lenses (excluding daily disposable and silicone hydrogel lenses)
4. silicone hydrogel: silicone-containing hydrogel lenses; during the time of this

survey, only two such materials were available in the United Kingdom (balafilcon A and lotrafilcon A).

Determination of number of lens wearers

Information on the number of contact lens wearers in the United Kingdom in each of the above categories was accessed from data on lens sales collected by the United Kingdom Association of Contact Lens Manufacturers for 2003. Using these data as well as data from our prescribing surveys relating to wearing modality²⁰ and assuming a total UK population of 59,050,800,²¹ we were able to estimate the number of wearers within the hospital catchment population using each lens type on a daily wear versus extended wear basis. The above analyses assume that lens usage in the hospital catchment population is the same as that for the United Kingdom as a whole.

Assessment of morbidity

With the consent of the patient, we attempted to contact the eye care practitioner of each contact lens wearer examined in this study about six months after attending the hospital. The practitioner was asked to provide, from his or her own clinical records, measures of visual acuity (VA) in the affected eye of the hospital attendee before and after the hospital visit.

Data analysis

For each wearing modality/lens type combination investigated in this 12-month study, the annual incidence of CIEs was determined by dividing the number of cases of each of these conditions by the estimated number of wearers for each wearing modality/lens type combination within the hospital catchment population. In common with previous practice in this field,⁸⁻¹⁰ we have expressed incidence data as the number of cases per 10,000 wearers per year. The 95 per cent confidence intervals (CI) for all incidence and morbidity estimates were calculated according to the method of Wilson.²²

The data are also expressed in terms of relative risk, which is the ratio of annual incidence of a given condition to a 'refer-

ent' condition.²³ Relative risk was calculated for all possible paired combinations of wearing modality/lens type. A p-value of less than 0.05 was taken to indicate a significant difference in the risk of developing a CIE between two wearing modality/lens type combinations.

The Mann Whitney U test was used to examine any difference in clinical severity scores in patients suffering from CIEs who were wearing extended wear hydrogel and extended wear silicone hydrogel lenses. This non-parametric test was adopted because the small number of data points within these two categories precluded an assumption of normally distributed data.

RESULTS

Over the 12-month survey period, 415 patients who were wearing contact lenses presented to the study centre. All except one of these patients agreed to complete a survey form. Five forms were unintelligible and therefore were not analysed in this study. The remaining useable forms provided details of 118 patients who were observed to have a corneal infiltrate or ulcer.

The number of patients who presented with CIEs (the numerator of the incidence equation), the estimated number of wearers in the hospital catchment population (the denominator of the incidence equation) and the calculated incidence of CIEs are presented in Table 1 with respect to each of the two wearing modalities and four lens types. Figure 1 shows the distribution of clinical severity scores for the 118 patients included in this analysis, stratified by wearing modality and lens type. The distribution of data was tested for normality against an arbitrary reference set of normal data using the Kolmogorov-Smirnov test. This analysis confirms that the data are normally distributed ($\chi^2 = 4.3$, $p = 0.23$). The average clinical severity of CIEs for the population was 7.7 ± 2.9 (mean \pm standard deviation).

Table 1 documents three CIEs in patients wearing hydrogel daily disposable lenses on an 'extended wear' basis. Although such lenses are self-evidently

Wearing modality	Lens type	Number of CIEs	Number of wearers in HCP*	Incidence of CIEs**
Daily wear	Rigid	6	6,996	8.6 (3.9 to 18.7) [†]
	Hydrogel daily disposable	23	16,413	14.0 (9.3 to 21.0)
	Hydrogel	61	29,876	20.4 (15.9 to 26.2)
	Silicone hydrogel	1	179	55.9 (9.9 to 309.6)
	All daily wear lenses	91	53,464	17.0 (13.9 to 20.9)
Extended wear	Rigid	0	18	0.0 (0.0 to 1758.8)
	Hydrogel daily disposable	3	§	§§
	Hydrogel	6	415	144.6 (66.4 to 311.8)
	Silicone hydrogel	18	1,517	118.6 (75.2 to 186.7)
	All extended wear lenses	27	1,950	138.4 (95.3 to 200.7)
All wearing modalities and lens types		118	55,414	21.3 (17.8 to 25.5)

* hospital catchment population
 ** number of cases per 10,000 wearers per year
 † incidence (95% confidence limits)
 § unknown (that is, the number of persons who routinely sleep in daily wear daily disposable lenses has not been determined)
 §§ indeterminable because the denominator is unknown

Table 1. Determination of incidence of CIEs

prescribed for daily wear, in these three cases the patients admitted to being non-compliant by way of sleeping in lenses immediately prior to presentation at the hospital. Therefore, data relating to these cases are entered as extended wear incidences.

Figure 2 displays the incidence of CIEs for those wearing modality/lens type combinations with six or more data points. In this figure, the level of severity of CIE for each of the wearing modality/lens type combinations depicted is indicated in the form of colour banding. The apparent difference in the distribution of severity between hydrogel and silicone hydrogel extended wear lenses, such that there appears to be a greater proportion of severe forms of CIE with hydrogel extended wear lenses, was confirmed by the Mann Whitney U test ($Z = 2.1$, $p = 0.04$).

The relative risk of developing a CIE for various pairs of combinations of wearing modality/lens type are displayed in Table 2. The category of extended wear rigid lenses is excluded from this table because

this category had an incidence of zero, thus precluding a calculation of relative risk. The category of extended wear daily disposable lenses is also excluded from this table because the incidence of developing a CIE with this wearing modality is indeterminable (due to an unknown denominator). Patients wearing lenses on an extended wear basis had an 8.1 times greater risk (95 per cent confidence interval 5.3 to 12.5) of developing a CIE than patients wearing lenses on a daily wear basis ($p < 0.0001$).

We managed to obtain estimates of VA pre- and post-hospital attendance from the eye care practitioners of 38 of the 118 patients suffering from a CIE. The average clinical severity of CIEs suffered by these 38 patients was 7.7 ± 3.0 (mean \pm standard deviation). The elapsed time between the hospital visit and the measurement of VA following the hospital visit was 173 ± 132 days (mean \pm standard deviation). Estimates of VA were generally reported using Snellen notation. Compared to VA prior to developing a CIE, three per cent of

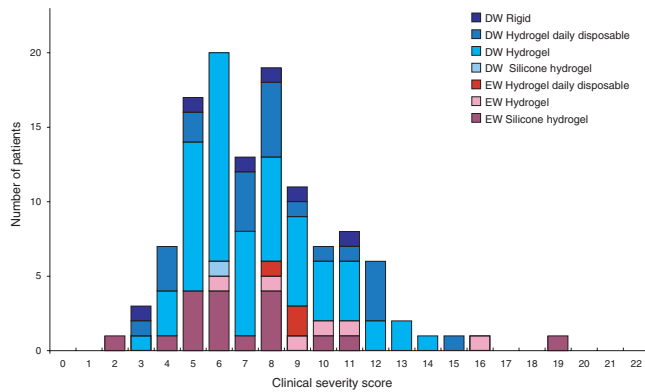


Figure 1. Distribution of clinical severity scores for corneal infiltrative events with respect to wearing modality and lens type

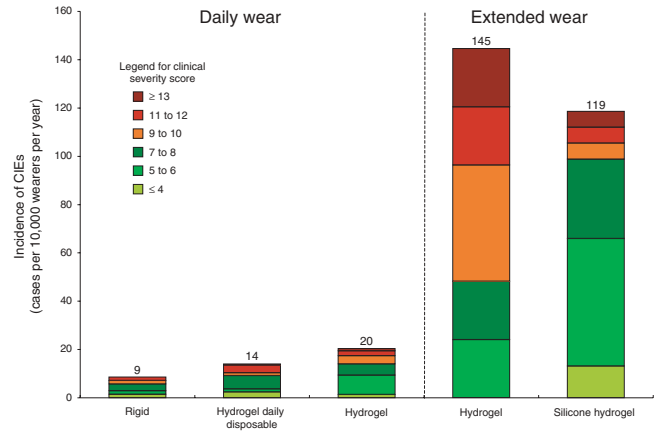


Figure 2. Incidence of corneal infiltrative events with colour banding indicating the distribution of clinical severity scores

Referent	Variable				
	Daily wear hydrogel daily disposable	Daily wear hydrogel	Daily wear silicone hydrogel	Extended wear hydrogel	Extended wear silicone hydrogel
Daily wear rigid	1.63 (0.67 to 4.01)* p = 0.284	2.38 (1.03 to 5.50) p = 0.043	6.51 (0.79 to 53.83) p = 0.082	16.86 (5.46 to 52.04) p < 0.0001	13.84 (5.50 to 34.80) p < 0.0001
Daily wear hydrogel daily disposable		1.46 (0.90 to 2.35) p = 0.124	3.99 (0.54 to 29.36) p = 0.175	10.32 (4.22 to 25.20) p < 0.0001	8.47 (4.58 to 15.65) p < 0.0001
Daily wear hydrogel			2.74 (0.38 to 19.63) p = 0.317	7.08 (3.08 to 16.29) p < 0.0001	5.81 (3.44 to 9.81) p < 0.0001
Daily wear silicone hydrogel				2.59 (0.31 to 21.34) p = 0.377	2.12 (0.29 to 15.82) p = 0.462
Extended wear hydrogel					0.82 (0.33 to 2.05) p = 0.673

* relative risk (95 per cent confidence limits)

Table 2. Risk of a variable developing a CIE compared with that of a referent

patients gained one line of VA, eight per cent had no change in VA, 71 per cent had no change in VA, five per cent lost half a line of VA and 13 per cent lost one line of VA. Taking a change of two lines of VA measured in routine clinical practice as representing a significant change in vision,^{24,25} it can be said that no patients in this study suffered significant visual loss (95 per cent CI: 0 to 9.2 per cent).

DISCUSSION

This paper reports the incidence of all symptomatic forms of hospital-presenting CIEs; as such, the incidence values for given wearing modality/lens type combinations reported here are expected to be considerably higher than those reported previously for microbial/ulcerative keratitis (that is, severe forms of CIEs only).

Indeed, this is the case. Taking extended wear hydrogel lenses as an example—the annualised incidence of microbial/ulcerative keratitis per 10,000 wearers reported by Poggio and colleagues,¹⁰ Cheng and co-workers⁸ and Lam and associates⁹ of 20.9 (95 per cent confidence interval 15.1 to 26.7), 20.0 (10.3 to 35.0) and 9.3 (confidence intervals not reported), respectively, are significantly lower than the figure of

144.6 (66.4 to 311.8) reported here.

The normal distribution of severity scores in Figure 1 lends support to the notion that CIEs represent a continuous spectrum of disease; that is, CIEs are less likely to represent a binary division of microbial/sterile or ulcerative/non-ulcerative keratitis, or an agglomeration of differentiated sub-types of disease. If either of the latter scenarios were to represent the true situation, a bimodal or multimodal distribution might have been revealed. Consideration of CIEs as a continuous spectrum of disease obviates the need to differentiate the various proposed sub-types according to aetiology, especially with respect to the less severe manifestations; however, we recognise the clinical value of attempting to identify the causative microbial agent in the case of severe disease. For example, utilising corneal scraping and culturing^{8,10,18} and occasionally employing confocal microscopy to confirm the presence of *acanthamoeba*²⁶ will often yield results that have a crucial bearing on the management of the condition.

The risk of developing a CIE is 8.1 times higher for all extended wear lenses versus all daily wear lenses. This reaffirms previous data^{8,9,27,28} of the increased risks of sleeping in hydrogel contact lenses. We found that this increased risk is also apparent with respect to the specific case of sleeping in silicone hydrogel lenses. Thus, despite the optimised physiological status of the eye as a result of the increased levels of corneal oxygenation when sleeping in such lenses,²⁹ daily wear of all forms of hydrogel and rigid lenses still constitutes a reduced risk for the development of CIEs. This suggests that factors other than corneal oxygenation—such as post-lens tear film dynamics,³⁰ mechanical lens effects³¹ and the sub-clinical inflammatory nature of the closed lid environment³²—may also be of relevance in the aetiology of CIEs in patients who sleep in silicone hydrogel lenses.

The failure to demonstrate a statistically significant difference in the incidence of CIEs between hydrogel and silicone hydrogel lenses, when worn on an extended wear basis, indicates that hypoxia may not

be a significant factor in the initiation of such an event when soft lenses are worn overnight. Increased corneal oxygenation with silicone hydrogel lenses is probably responsible for the overall lower levels of clinical severity of CIEs compared with that of hydrogel lenses, making silicone hydrogel lenses a safer option for extended wear.

At the time of our survey, only two silicone hydrogel lenses were available, lotrafilcon A and balafilcon A, and both of these lenses were promoted for use primarily on an extended wear basis. As a result, few contact lens wearers were using such products on a daily wear basis and only one such patient presented to the hospital with a CIE during our survey. Similarly, a very small number of people had been fitted with rigid lenses on an extended wear basis in the hospital catchment population and our survey did not record any patients wearing such lenses presenting with a CIE. The resultant wide 95 per cent confidence range for daily wear silicone hydrogel lenses (10 to 310 cases per 10,000 wearers per year) and extended wear rigid lenses (0 to 1,759) precludes any meaningful comparative analyses incorporating these wearing modality/lens types. Future surveys capturing data relating to daily wear silicone hydrogel lenses³³ that are now entering the market are likely to provide more accurate incidence data relating to such lenses. Although the same notion theoretically applies to extended wear rigid lenses, our analysis of international contact lens usage³ suggests that the prescription rate for such lenses has been low and constant over the past five years and we believe that this situation is unlikely to change.

When worn on a daily wear basis, hydrogel lenses are associated with a 2.4 times higher risk of developing CIEs than rigid lenses. The enhanced performance of rigid lenses in this regard may be due to the inert nature of rigid lens materials and their lower propensity to develop protein deposits.³⁴ The greater movement and tear exchange on blinking with rigid lenses^{35,36} also reduces the propensity for tears and debris to stagnate beneath the lenses or for micro-organisms to become attached to the cornea (the necessary precursor for

infection), thus minimising the risk of physical, physiological or immunological compromise of the ocular surface.

It might have been expected that wearing daily wear daily disposable lenses would carry a reduced risk of developing CIEs compared with wearing daily wear hydrogel lenses that are replaced on a less frequent basis. The latter lens type is typically maintained by a daily care procedure, comprising surfactant cleaning and overnight soaking in a disinfecting solution. Despite such maintenance procedures, protein and lipid deposits can accumulate over the life of the lens³⁷ and these deposits may become denatured,³⁸ probably as a result of exposure to the solutions used for lens maintenance. The ocular surface may develop an adverse immunological reaction to the denatured proteins on the lens surface, which can result in ocular compromise and possibly predispose the cornea to the development of a CIE. Although the incidence of CIEs associated with the wearing of daily wear daily disposable hydrogel lenses was numerically lower than with all other forms of daily wear hydrogel lenses, which are replaced less frequently, the difference was not statistically significant. It is unclear whether this is due to a true lack of difference or to a lack of statistical power in our data set.

A significant proportion of any visual loss at the time of the hospital visit may have been transient as a result of acute but reversible tissue inflammation. Our strategy of measuring vision about six months after the patients visited the hospital, after any acute inflammation had subsided, ensured a true measure of morbidity. The matching clinical severity scores of the subgroup of 38 patients in whom morbidity was assessed (7.7 ± 3.0), compared with that of the 118 contact lens wearers who suffered from a CIE during the survey period (7.7 ± 2.9), suggests that this subgroup constituted a representative sample of the parent body. Our finding that zero per cent (95 per cent CI: zero to 9.2 per cent) of patients suffered clinically significant visual loss as a result of CIEs is consistent with the analysis of Holden and co-workers.²⁵

The reason for the low rate of visual loss after experiencing a CIE can be explained in terms of the size, density and location of any residual scar following such an event. A CIE can occur at any location in the cornea but only those occurring within the pupillary area can leave a scar that is capable of interfering with vision. Only 13 per cent of the CIEs documented in this study fell within the central four-millimetre zone of the cornea.³⁹ For the small proportion of CIEs within the central corneal zone, the density of any residual scar will have a bearing on the degree to which it interferes with vision. However, it is possible that residual corneal scarring in the central or mid-peripheral cornea could still adversely affect the quality of vision, if not VA, by inducing glare due to light scatter.

Our data can be extrapolated to the population of lens wearers generally. Assuming that a CIE is the only potential cause of visual loss among contact lens wearers and taking the 'worse case' scenario of our 95 per cent confidence interval for visual loss (9.2 per cent of CIE patients losing two or more lines of VA), we have calculated that up to 0.02 per cent of all contact lens wearers will suffer visual loss per year. To put this finding into a broader perspective, it has been estimated that two to six per cent⁴⁰⁻⁴² of patients suffer visual loss of two or more lines of VA following laser refractive surgery. Assuming an average wearer uses contact lenses for 10 years, the risk of visual loss with contact lenses is at least 10 to 30 times lower than that with laser refractive surgery.

The incidence of hospital-presenting CIEs for all wearing modalities and types of contact lenses was found to be 21.3 cases per 10,000 wearers per year. Thus, if a given clinic were responsible for the ongoing care of, say, 1,000 contact lens wearers, it would be expected that about two patients each year would suffer from a symptomatic form of CIE requiring hospital/medical attention. Patients who suffer from a CIE can be reassured that the likelihood of significant loss of vision is low. While the clinical severity matrix used in this work was applied in a research context, we believe that clinicians might find

this to be a useful adjunct to their clinical decision-making. It is our view that CIEs constitute a continuous spectrum of ocular disease and an overall assessment of the level of severity of the condition can be useful in formulating an appropriate clinical management plan.

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