

Incidence of Corneal Adverse Events in Children Wearing Soft Contact Lenses

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Objectives: There is increasing interest in fitting children with soft contact lenses, in part due to the increase in prescribing of designs to slow the progression of myopia. This literature review summarizes large prospective and retrospective studies that include data on the incidence of microbial keratitis and corneal infiltrative events (CIEs) in children wearing soft contact lenses.

Methods: Peer-reviewed prospective and retrospective studies that report contact lens-related complications in children with at least one year of wear and at least 100 patient years of wear were identified.

Results: Seven prospective studies published between 2004 and 2022 were identified representing 3,752 patient years of wear in 1,756 children, nearly all of whom were fitted at age 12 years or younger. Collectively, they report one case of microbial keratitis and 53 CIEs, of which 16 were classified as symptomatic. The overall incidence of microbial keratitis was 2.7 per 10,000 patient years (95% CI: 0.5–15), and the incidence of symptomatic CIEs was 42 per 10,000 patient years (95% CI: 26–69). Two retrospective studies were identified representing 2,545 patient years of wear in 1,025 children, fitted at age 12 years or younger. One study reports two cases of microbial keratitis giving an incidence of 9.4 per 10,000 patient years (95% CI: 0.5–15).

Conclusions: Accurate classification of CIEs is challenging, particularly in retrospective studies. The incidence of microbial keratitis in children wearing soft lenses is no higher than in adults, and the incidence of CIEs seems to be markedly lower.

Key Words: Soft contact lens—Incidence—Children—Complications—Corneal infiltrative events—Microbial keratitis.

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Interest in fitting children with contact lenses continues to increase, in part due to the availability of modalities and designs that help slow the progression of myopia in children.^{1,2} Numerous

optometry and ophthalmology bodies around the world have developed guidance documents in favor of intervening to slow myopia progression using optical or pharmaceutical methods.^{3–7} The efficacy of different modalities has been reviewed in detail elsewhere.^{1,2} Overnight orthokeratology slows axial elongation by 0.25 mm—equivalent to around 0.6 D⁸—over two years regardless of patient age,² lens design, or patient race.⁹ Dual-focus, soft contact lenses slow myopia progression and axial elongation over three years by around 0.7 D and 0.3 mm, respectively.¹⁰ Multiyear studies of soft multifocal designs, be they intended for myopia control, or not, also show significant, albeit lower, slowing of progression.^{11–13} Although the focus of these and other studies of myopia control is efficacy,² safety is an important consideration for eye care professionals (ECPs), parents, and regulators.¹⁴

Historically, ophthalmology has had reservations about the safety of fitting children with contact lenses.^{15–17} Specifically, the concern was that the risk of microbial keratitis may not outweigh the improved quality of life or other perceived benefits offered by contact lens wear.¹⁶ Recent analyses have demonstrated that the risks of contact lens wear are clearly outweighed by the potential reduction of visual impairment associated with lowering a patient's ultimate level of myopia.^{18,19} Nonetheless, although microbial keratitis is a rare event and vision loss only results in a small percentage of all cases, its consequences can be devastating.²⁰

Most soft contact lens-related complications are constrained to the lids and conjunctiva, but corneal lesions have the potential to be sight threatening, particularly when there is inflammation coupled with the presence of infiltrates. Corneal infiltrative (or inflammatory) events (CIEs) include contact lens peripheral ulcer and infiltrative keratitis.²¹ The most severe CIE is microbial keratitis, sometimes called infectious keratitis, but this usually only accounts for around 5% of all CIEs.^{22,23} Microbial keratitis may be defined as one or more corneal stromal infiltrates greater than 1 mm in size with pain more than mild, and one or more of the following: anterior-chamber reaction more than minimal, mucopurulent discharge, or positive corneal culture²⁴ although variations are common. As discussed later, these definitions and their application can affect estimates of incidence for these rare events. Because of its low incidence, microbial keratitis is unlikely to be observed in prospective studies and best studied in case-control studies or creating a registry.²⁵

Most contact lenses cleared by the US Food and Drug Administration (FDA) for daily wear carry no age restriction but are only intended for the correction of ametropia. By contrast, MiSight 1 day is “indicated to slow the progression of myopia in children between the ages of 8 and 12 years at the initiation of treatment” and remains the only FDA-approved

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intervention for controlling the progression of myopia in children in the United States. Even in the absence of age restrictions, the FDA may still require studies to provide further assurance of safety.²⁶ In other markets, including the European Union, MiSight 1 day and other soft lenses are approved for myopia control.

Five years ago, Bullimore¹⁴ reviewed the literature on the safety of soft contact lenses in children. Since then, a number of large prospective and retrospective studies of contact lens wear in children have been published.^{27–31} Soft contact lenses are the most frequently fitted lens type to children³² and safety remains at the forefront in decision making for both ECPs managing pediatric patients and parents considering contact lens options for myopia management. This update to the previous literature review¹⁴ further summarizes the incidence of microbial keratitis and CIEs—both symptomatic and asymptomatic—in children wearing soft contact lenses.

FREQUENCY OF SOFT CONTACT LENS FITTING IN CHILDREN

A summary of 13 years of survey data from US ECPs³³ showed that patients 15 years and younger accounted for 11% of 7,702 contact lens fits. Similar data were reported for the global community.³² Based on 105,734 fits between 2005 and 2009, children (6–12 years) accounted for 1.6% of all fits and teenagers (13–17 years) represented 11.5%. Children had the highest proportion (>25%) of newly prescribed daily disposable lenses, consistent with the view that this replacement frequency is especially suited to children and teenagers.³⁴ However, in 2014, daily disposable soft lenses still only accounted for 27% of all soft lens fits in the United States.³³ More recently, 401 of 783 children (51%) at seven US eye care clinics were first fitted with daily disposable soft lenses.²⁹ Daily disposable contact lens wear is defined by the FDA as a single-use product (types of contact lenses. Food and Drug Administration, United States Department of Health and Human Services. <https://www.fda.gov/medical-devices/contact-lenses/types-contact-lenses>. Published 2018, accessed May 17, 2022). A recent report presents information from 66 countries from 2011 to 2018, presumably from the above data.³⁵ Among 23,830 contact lens fits in children, a small but increasing number were for myopia control. This proportion had risen from 0.2% in 2011 to 6.8% in 2018. Thus, despite the substantial growth of fits for myopia control, over 90% of myopic children were still being fitted with contact lenses that will not help slow myopia progression.

PROSPECTIVE STUDIES OF THE SAFETY OF CONTACT LENSES IN CHILDREN

Soft contact lens wear elevates the risk of microbial keratitis, but it is still a rare event, similar to that of dying in a motor vehicle crash in the United States (<https://injuryfacts.nsc.org/all-injuries/preventable-death-overview/odds-of-dying/> Accessed May 18, 2022). These low probabilities are easier to digest and compare when presented in cases per 10,000 patient years of wear rather than a percentage. Equally important is the 95% confidence interval (CI) which indicates the precision of the estimate and will be broader for smaller samples. There have been a handful of short-term studies published demonstrating the feasibility of fitting chil-

dren as young as seven years with soft contact lenses.^{36–39} Although they all report data on adverse events, they are not included here because of their short-term nature and low number of patient years of wear. Seven publications report contact lens–related complications in children with at least one year of wear and at least 100 patient years of wear. These are described below and summarized in Table 1.

Walline et al.³⁴ randomly assigned 116 US children aged 8–11 years to wear rigid gas-permeable or two-week replacement hydrogel lenses (CIBA Focus 2, CIBA Vision, now Alcon, Fort Worth, TX) in a three-year clinical trial of myopia progression. Of the 57 children randomized to soft lenses, 53 completed the trial (93%). No cases of microbial keratitis or CIEs were reported (95% CI: 0–233 per 10,000 patient years).

Sankaridurg et al.⁴⁰ reported comprehensive data on 240 Chinese children aged 7–14 years enrolled in a prospective randomized clinical trial of daily wear of monthly replacement, silicone hydrogel lenses. Children were randomized to one commercial single-vision design and three experimental lens designs aimed at reducing myopia progression. All were manufactured in silicone hydrogel material lotrafilcon B (CIBA Vision, now Alcon, Fort Worth, TX) and worn on a daily wear, monthly replacement schedule. A total of 189 children completed one year of contact lens wear (79%), and 170 children completed two years (71%). There were no episodes of microbial keratitis, although 55 nonserious adverse events were observed: 16 cases of contact lens papillary conjunctivitis, six superior epithelial arcuate lesions, eight corneal erosions, 5 cases of symptomatic infiltrative keratitis, 7 cases of asymptomatic infiltrative keratitis, and 13 instances of asymptomatic infiltrates. Only the five cases of symptomatic infiltrative keratitis would meet the definition of symptomatic CIEs used in other studies,^{22,23,41} representing an incidence of 136 per 10,000 patient years (95% CI: 58–513). The incidence of all CIEs was 678 per 10,000 patient years (95% CI: 462–981).

Walline et al. randomized 584 myopic children aged 8–11 years at five clinical centers in the United States^{42,43} to spectacles or soft contact lenses: hydrogel daily disposable (1-Day Acuvue, Johnson & Johnson Vision, Jacksonville, FL) or hydrogel two-week replacement (Acuvue 2, Johnson & Johnson Vision, Jacksonville, FL). Daily disposable lenses were fitted in 93% of the children randomized to soft lenses. At the end of the three-year trial, 96% of the original cohort was examined including 241 subjects wearing contact lenses—224 originally assigned to contact lenses and 17 assigned to spectacles. Nine contact lens wearers (3.7%) experienced 13 adverse events, including six cases of “keratitis” (undefined) and all adverse events completely resolved. If the six cases of keratitis are assumed to be CIEs, it would represent an incidence of CIEs of 83 per 10,000 patient years (95% CI: 34–173).¹⁴

As described in a previous section, the TEMPO Study reported on 489 patient years of daily disposable silicone hydrogel wear and 471 patient years of daily disposable hydrogel wear.²¹ Overall, 82% of patients completed the 12-month survey. Although not stated in the original article, 202 children between 8 and 17 years were enrolled, accounting for 171 patient years of wear and no CIEs (95% CI: 0–220).^{14,25}

Cheng et al.²⁷ presented a summary of safety data from six randomized controlled trials, collectively of 581 myopic children wearing daily disposable hydrogel contact lenses (etafilcon A).

TABLE 1. Summary of Studies of Soft Contact Lens–Related Corneal Infiltrative Events (CIEs) in Children (Younger Than 18 years)

Authors (year)	Country	Age Range (years)	Duration (years)	Replacement Schedule	Material	N	Patient years	All CIEs	Symptomatic CIEs			Microbial Keratitis		
									Cases	Incidence	95% CI	Cases	Incidence	95% CI
Prospective studies														
Walline (2004) ³⁴	US	8–11	3	2W	H	57	159	0	0	0	0, 233	0	0	0, 233
Sankaridurg (2013) ⁴⁰	PRC	7–14	2	M	SiHy	240	369	25	5	136	50, 300	0	0	0, 103
Walline (2008) ⁴²	US	8–11	3	DD	H	247	723	6	6	83	38, 180	0	0	0, 51
Chalmers (2015) ²¹	US	8–17	1	DD	Both	202	171	0	0	0	0, 220	0	0	0, 220
Cheng (2020) ²⁷	Various	8–15	2–3.5	DD	H	581	816	2	0	0	0, 47	0	0	0, 47
Woods (2021) ²⁸	Various	8–12	6	DD	H	135	653	4	0	0	0, 58	0	0	0, 58
Gaume Giannoni (2022) ³¹	US	7–12	3	M	SiHy	294	861	16	5	58	25, 135	1	11.6	2, 65
Total						1,756	3,752	53	16	43	26, 69	1	2.7	0.5, 15
Retrospective studies														
Chalmers (2011) ²³	US	8–12	1.7	Various		243	411	4	4	97	31, 235	0	0	0, 93
Chalmers (2021) ²⁹	US	8–12	2.7	Various		782	2,134	16	16	75	46, 121	2	9.4	3, 34

Bold entries are based on the sum of the values above.

Where possible, the incidence of symptomatic corneal infiltrative events and microbial keratitis (per 10,000 patient years) is estimated based on the number of events, the number of patients, and the study duration.

Patient years based on study follow-up at each time point, not enrollment. CIEs, corneal infiltrative events; PRC, People republic of China; US, United States; 2W, 2-weekly replacement, daily wear; M, monthly replacement, daily wear, DD, daily disposable; H, hydrogel; SiHy, silicone hydrogel.

Children were aged 7–15 years at baseline, although all but one trial of 35 subjects enrolled children with a maximum age of 11 or 12 years (96%). Overall, 73% completed the trials. This included the previously reported randomized clinical trial comparing a soft contact lens with positive spherical aberration and a spherical control lens.⁴⁴ Details of the other trials are described in the later article.²⁷ Across 816 patient years of contact lens wear, there were no cases of microbial keratitis. Among the 86 nonsignificant ocular adverse events that occurred in 53 children, there were two asymptomatic CIEs, which is an incidence of 25 per 10,000 patient years (95% CI: 7–89). The incidence of symptomatic CIEs is thus zero (95% CI: 0–47).

Woods et al. report on children followed for 6 years in a clinical trial investigating the ability of a dual-focus contact lens (MiSight 1 day, CooperVision, Inc) to control myopia progression.²⁸ Children aged 8–12 years were fitted with daily disposable hydrogel lenses (omafilcon A, CooperVision, Inc). Of the 144 children, 92 completed the year six visit (64%). Four CIEs were observed, all at scheduled visits, giving an incidence of 61 per 10,000 patient years (95% CI: 24–157). Two of these occurred in a single patient who thereafter discontinued lens wear. No cases of microbial keratitis were reported (95% CI: 0–58).

The Bifocal Lenses in Nearsighted Kids Study enrolled 294 myopic children, aged 7–11 years who were fitted in silicone hydrogel monthly replacement lenses—single vision or one of two multifocal designs with add powers of +1.50 or +2.50 D—of whom 287 completed the three-year study (98%).¹³ A subsequent article reports the frequency of ocular adverse events.³¹ Adverse events were documented by unmasked examiners and finalized by the trial’s executive committee. There were 325 ocular adverse events, of which 197 were probably or definitely related to contact lens wear (61%). There were 16 cases of CIEs, of which 13 were described as infiltrative keratitis (11 mild and two moderate). The investigators defined “mild” as “easily tolerated signs” or considered asymptomatic, leaving five cases of

symptomatic CIEs and an incidence of 58 per 10,000 patient years (95% CI: 25–135). One CIE was classified as probable microbial keratitis giving an incidence of 12 per 10,000 patient years (95% CI: 2–65). Details of the case are described elsewhere³¹ but discussed below.

RETROSPECTIVE STUDIES OF THE SAFETY OF CONTACT LENSES IN CHILDREN

Within clinical trials, patients are provided with contact lenses and solutions free of charge, and there are multiple visits to reinforce proper wear and care. Thus, rates of complications may be lower than when used by the broader, real-world population. The Contact Lens Assessment in Youth study group conducted a multicenter, retrospective study of soft contact lens wear among children, teenagers, and young adults attending academic eye care clinics in North America.⁴⁵ Charts from 3,549 patients were reviewed, including 260 children between 8 and 13 years (7%) and 879 teenagers, 13–18 years (25%). Monthly and 1–2-week replacement each accounted for 39% of subjects. Daily replacement accounted for 9.9% across all age groups, although this mode was most common (15.8%) among the 8–12-year-olds. The authors reported on 4,663 patient years including 1,054 patients younger than 18 years.²³ Reviewers masked to subject identity, age, and soft contact lens parameters adjudicated event diagnoses, yielding 187 CIEs in 168 wearers: eight instances of microbial keratitis, 110 of infiltrative keratitis, 41 contact lens peripheral ulcers, 14 contact lens–induced acute red eye with infiltrates, 13 contact lens–induced acute red eye without infiltrates, and one iritis. The lowest rate of CIEs was in 8–12-year-olds (97 per 10,000 patient years, 95% CI: 31–235) compared with 335 per 10,000 patient years in patients aged 13–17 years (95% CI: 248–443). No cases of microbial keratitis occurred in the 8–12-year-olds (95% CI: 0–93) and two occurred in the 13–17-year-olds representing an incidence of microbial keratitis of 15 per 10,000 patient years (95% CI: 2–48) in the latter age group. Note that the

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upper 95% CI limit is lower in the older children than the younger children due to the markedly larger teenage sample size. In addition to patient age, years of contact lens wear, use of a multipurpose lens care system, overnight wear, and use of silicone hydrogel lenses were all significant risk factors.

Chalmers et al.²⁹ recently estimated the incidence of CIEs and microbial keratitis with a combination of prospective and retrospective data in the Retrospective Cohort Study of Safety (ReCSS) study. The prospective data are from the MiSight 1 day trial of daily disposable hydrogel lenses described above.²⁸ The retrospective study reviewed clinical charts from 782 children in seven US eye care clinics. Subjects had been fitted with various soft contact lenses between the ages of 8 and 12 years and observed up to the age of 16 years, as available. The mean follow-up was 2.7 ± 1.6 years giving 2,134 patient years. Records of potential adverse events were reviewed to consensus by an adjudication panel. Around half of the patients were fitted with daily disposable lenses, with the remainder mostly split evenly between monthly and two-weekly replacement. The authors report 20 CIEs, but four were from the prospective study and described above.²⁸ The remaining 16 CIEs give an incidence of 75 per 10,000 patient years (95% CI: 46–121). Adjudication resulted in two cases of presumed or probable microbial keratitis, an incidence among the retrospective cohort of 9.4 per 10,000 patient years (95% CI: 3–34). Both were in teenage boys and resolved with no loss of visual acuity. Further details are provided below.

SUMMARY OF STUDIES AND COMPARISON WITH ADULTS

Table 1 summarizes the seven prospective studies described above. The number of CIEs, symptomatic CIEs, and cases of microbial keratitis are shown, along with the incidence and 95% CIs calculated for symptomatic CIEs and microbial keratitis. Collectively, these seven studies document 3,752 patient years of wear. Two of the seven prospective studies reported no CIEs. Perhaps not surprisingly, these were the two smallest studies. Two other studies report that all CIEs were asymptomatic. The remaining three studies collectively report 16 symptomatic CIEs, giving an overall incidence of 42 per 10,000 patient years (95% CI: 26–69). Of course, the seven studies represent different countries, varying replacement schedules, and different materials. When considering only daily disposable hydrogel lenses, there were six symptomatic CIEs in 2,363 patient years giving an incidence rate of 25 per 10,000 patient years (95% CI: 11–55). For reusable silicone hydrogel lenses, there were 10 symptomatic CIEs in 1,230 wearer years. Although this incidence rate of 81 per 10,000 patient years (95% CI: 44–149) is larger, the confidence intervals are broad and overlapping. From adult studies, we know that the rates of CIEs are lowest with daily disposable lens wear^{21,46} and that, although silicone hydrogel lenses are associated with higher rates of CIEs, they are also associated with less severe outcomes.^{25,47} Nonetheless, daily disposable soft lenses feature in cases of microbial keratitis in the subsequent section.

Asymptomatic CIEs along with other noninfiltrative presentations were usually observed at the many scheduled study visits in these prospective studies. The clinical significance of these may be unclear, but they cannot be captured easily with retrospective study

designs.²² Overall, symptomatic CIEs represent around 30% of all CIEs (Table 1) and the incidence of all CIEs is 141 (95% CI: 108–184).

The incidence of CIEs in children must be placed in the context of studies of adult soft contact lens wearers. A multicenter, retrospective chart review of 3,549 soft lens wearers aged 8–33 years, mostly daily wear, yielded 4,663 patient years and an incidence of CIEs of 401 per 10,000 patient years (95% CI: 348–461).²³ If the analysis is limited to adults, the incidence increases to 463 per 10,000 patient years (95% CI: 392–546). A one-year prospective study of 218 daily wearers (158.4 patient years) of daily wear monthly replacement silicone hydrogel lenses estimated the incidence to be 822 (95% CI: 488–1,357) and 190 (95% CI: 65–543) per 10,000 patient years, for all and symptomatic CIEs, respectively.⁴⁸ Finally, an incidence of symptomatic CIEs of 2,061 per 10,000 patient years (95% CI: 1,548–2,696) was reported for multiple three-month trials of various silicone hydrogel contact lens and lens solution combinations (189 patient years total).⁴⁹ The incidence of all CIEs was 3,704 per 10,000 patient years (95% CI: 3,047–4,412). The incidence of CIEs in this last study⁴⁹ is markedly higher than the others. This is likely due to the more frequent and rigorous examination schedule and that 62% of the CIEs (almost all classified as infiltrative keratitis) were associated with one of four contact lens solutions studied. No studies have examined the risks and acceptance of different lens care solutions in children, and further research is warranted in this area.

The above results are largely consistent with a meta-analysis of 23 studies before 2007 on a total of 9,336 subjects, that found the incidence of any CIE for hydrogels and silicone hydrogel reusable lenses was 770 (95% CI: 220–2,670) and 1,440 (95% CI: 430–4,820) per 10,000 patient years, respectively.⁵⁰ Most of the studies of silicone hydrogel lenses were for extended wear. This is substantially higher than the incidence in children, although this work predates the availability of daily disposable lenses. A one-year prospective study of monthly replacement daily wear silicone hydrogel by the same group estimated the incidence to be 822 (95% CI: 488–1,357) and 190 (95% CI: 65–543) per 10,000 patient years, for all and symptomatic CIEs, respectively.⁴⁸ Other studies reviewed above estimate the incidence to be 463 per 10,000 patient years²³ or higher.^{48,49} The exception is a recent study of daily disposable wear.²¹

The rates of symptomatic CIEs observed in retrospective studies of children fit between 8 and 12 years seem to be higher than prospective studies, although still less than 100 per 10,000 patient years.^{23,29} The lower rate observed among children participating in clinical trials may be due to higher levels of subject education, recruitment bias, or due to the fact that materials are provided free of charge.

The incidence increases in teenagers then peaks in young adulthood, before reducing to the rates seen in older adults (age 26+). This increase may be due to poor wear and care behaviors adopted by teenagers and college-age wearers⁵¹ or due to changes in systemic inflammatory responses which increase during this time.⁵²

PUBLISHED CASES OF MICROBIAL KERATITIS IN CHILDREN

Microbial keratitis in daily soft contact lens wearers is rare regardless of the age of the population. Among the seven

prospective pediatric studies representing 3,752 patient years of wear, there was only one case of microbial keratitis (Table 1). Thus, the crude overall incidence is 2.7 per 10,000 patient years (95% CI: 0.5–15). This is similar to the rate observed in adults.¹⁸ Bullimore et al.¹⁸ summarized the incidence of microbial keratitis in daily and overnight soft contact lens wearers from six large studies representing nearly 600 cases.^{47,53–57} The incidence of microbial keratitis for daily wear soft contact lenses ranges from 1.9 to 6.4 per 10,000 patient years with a mean weighted by the number of cases of 3.1 per 10,000 patient years.

Two other cases are from the ReCSS study.²⁹ All three cases of microbial keratitis among teenagers listed in Table 1 are described in detail in the published articles. The cases indicate the challenges of classifying microbial keratitis.

The ReCSS study²⁹ used a definition of microbial keratitis that is broadly consistent with other studies of contact lens–related microbial keratitis,^{24,26,47,58} whereas other studies have used a numerical scoring system,⁵⁷ relied on the judgment of the treating clinician,^{53,55} or required a positive corneal culture.⁵⁴ Cases were independently reviewed by three Adjudication Panel members who later convened by telephone to discuss the cases until they agreed to a diagnosis through a consensus process. Not all of the criteria for presumed microbial keratitis were met for either of the two cases. First, the size of the infiltrates was not specified. For the first case, there was no anterior-chamber reaction, and the case is silent on discharge and corneal culture, but there was a subsequent corneal scar. Two of the three adjudicators classified the case as presumed or probable microbial keratitis but may have been influenced by the patient sleeping in lenses, the emergency department visit, and the aggressive treatment. The second case may not have met the requirement for pain greater than mild. The anterior-chamber reaction was mild, and the case was silent on discharge and culture. Finally, there was no corneal scar—a requirement for classification as presumed microbial keratitis. Given the presentation, the treatment might again be considered aggressive, particularly the addition of homatropine. Initially, two of the three adjudicators regarded this not to be microbial keratitis.

The third case is from the prospective Bifocal Lenses in Nearsighted Kids Study; the age of the subject is not provided.^{13,31} There was no operational definition of microbial keratitis in the published Manual of Procedures, which describes the grading of slitlamp observations by severity, but does not mention microbial keratitis.¹³ No mention of the infiltrate size was provided, although the resulting 0.3-mm scar may suggest it was less than 1 mm. There was no discharge reported and no culture taken. The anterior-chamber reaction was mild, but there was a small peripheral corneal scar.

All three of the above cases had excellent outcomes with only two resulting in small peripheral corneal scars. There was no permanent loss of vision reported, although the first case is silent on the issue. Both the patients where age is given are teenagers. This is consistent with a previous retrospective study of contact lens–related adverse events where no cases of microbial keratitis were observed in children aged 8–12 years but two were documented in teenagers aged 13–17 years.²³

Fortunately, few cases of microbial keratitis result in long-term loss of visual acuity as demonstrated in the comprehensive literature on adult contact lens wearers. In the largest published study of the incidence of contact lens–related microbial keratitis,

39 of 285 cases (15%) resulted in more than two lines of permanent vision loss. Similarly, a large prospective study of overnight silicone hydrogel wear reported 10 instances of presumed microbial keratitis of which two resulted in loss of vision (20%).²⁴ In a case–control study of 349 cases of contact lens–related microbial keratitis, only 15 had a visual acuity of 20/40 or worse at resolution (4%), although an additional 13 were lost to follow-up or discharged before resolution (4%).⁵⁸

Many case series of children presenting or referred to tertiary eye care centers with microbial keratitis have been published.^{59–74} In developed countries, contact lens wear is responsible for 40% or more of cases^{64,66,67,71,72,74} but few present visual outcomes. One report reviewed all 107 pediatric cases of microbial keratitis over 24 years at Bascom Palmer Eye Institute—an average of 4.5 cases per year. The mean age was 13±4.6 years, and contact lens wear was associated with 78% of cases. Around half of all cases were treated with combined fortified antibiotics and over 80% had a final visual acuity of 20/60 or better. One of the contact lens wearers required a penetrating keratoplasty due to a residual corneal scar. This case series gives a picture of the frequency and severity of cases that might be observed by clinicians in these settings.

The first and only known population-based study of keratitis in children was recently published.⁷⁵ All cases of keratitis in a well-defined pediatric population in Olmsted County, Minnesota, from 2000 through 2009 were reviewed. There were 134 cases of “keratitis due to contact lens wear” during the 10-year period, giving an annual incidence of 0.37 per 10,000. The mean age at diagnosis was 16.5 (range: 11.0–18.9) years. This includes all cases regardless of severity, and thus, most might be expected to be CIEs and not microbial keratitis. Of interest is that nine cases resulted in a final visual acuity of 20/40 or worse in the affected eye, giving an annual incidence of 0.025 per 10,000. Of course, the number of children wearing soft contact lenses in this population is unknown, but were it 10%, the incidence of microbial keratitis with vision loss would be 0.25 per 10,000 patient years of wear.

The increased use of daily disposable soft contact lenses has the potential to reduce the incidence of CIEs and microbial keratitis compared with reusable lenses in all patients, including children, assuming they maintain compliant behavior.

LIMITATIONS

This review includes both prospective studies with well-characterized cohorts and retrospective reports. Complication rates for subjects enrolled in a clinical trial may not reflect the rate in clinical practice and thus rates in retrospective studies are higher. Lost to follow-up is a potential source of bias, although the prospective studies listed in Table 1 generally have good to excellent retention of subjects (range 67%–98%). Similarly, there always exists the potential for serious adverse events to be treated by practitioners other than the trial investigators⁷⁶ and thus not be captured in the data, despite excellent follow-up in the trial.

The data on rates of CIEs in children fitted with different contact lens wear modalities and materials and using different contact lens solutions are not as robust as in adults. It is likely that the relative differences in rates by modality, material, and solution may be similar in adults versus children, but further research is needed to confirm this. It is clear that rates of CIEs may be influenced by materials and solutions.⁴⁹ From the data we do have, we conclude

that the rates of CIEs in children are low, potentially due to a combination of parental influence, behaviors, and lens fitting practices. As described above, practitioners seem more likely to fit children with daily disposable soft lenses.^{29,32} In a multivariate analysis, the aforementioned Contact Lens Assessment in Youth study demonstrated that age was an independent nonlinear risk factor for CIEs, with the rate lowest in children aged 8–12 years.²⁹ In the same multivariate analysis, a replacement schedule was not retained from the univariate model, but lens material, care system, extended wear, and years of wear remained significant risk factors.

The combined estimate of incidence is crude, and all estimates make a number of assumptions including that risk is constant over time. Some studies report that events occur more often in the first few months of wear, whereas others find the first year of wear to be protective.^{26,77} Authors have used different definitions of CIEs and microbial keratitis, some detailed, some superficial, which further complicate the ability to accurately define rates and may explain some of the differences among studies.

A further limitation is that some studies of myopia control^{11,12} fail to report safety outcomes leading to the possibility of underreporting of adverse events. Future clinical trials that fit contact lenses in children should rigorously document, adjudicate, and report adverse events using a predetermined classification system and procedure. Failure to do so reduces confidence in the final classification. Cases of microbial keratitis make up only a small percentage of all CIEs. In a multicenter, retrospective study of soft contact lens wear in children, teenagers, and adults, 187 CIEs were identified, of which eight were microbial keratitis (4%).²³ Similarly, a large prospective study of overnight silicone hydrogel wear reported 183 unique CIEs, of which 10 were classified as microbial keratitis (5%).²⁴ A recent case-control study of university students identified 164 CIEs, but no cases of microbial keratitis.⁷⁸ Collectively, these low proportions emphasize the importance of rigorous classification and the potential effect of misclassification on estimates of incidence.

CONCLUSION

It is possible to make a valid assessment of the safety of soft contact lenses in children by assembling data from a number of studies. The prospective studies collectively represent 3,752 patient years of wear in children who were fit with soft contact lenses. The overall picture is that the incidence of CIEs in children is lower than in adults. For microbial keratitis, the overall incidence in children wearing soft contact lenses is 2.7 per 10,000 patient years (95% CI: 0.5–15)—similar to that reported for adults.¹⁸ This non-zero incidence is the result of a single case whose classification as microbial keratitis is discussed above. Similarly, a recent retrospective study of 782 children representing 2,134 patient years found two cases of presumed or probable microbial keratitis, an incidence of 9.4 per 10,000 patient years (95% CI: 3–34). The classification of these two cases as microbial keratitis is also discussed above. Pooling the 6,297 patient years from prospective and retrospective studies gives an incidence of microbial keratitis of 4.8 per 10,000 patient years (95% CI: 1.6–16), but with no cases of vision loss.

No contact lens wearer, including children, is immune to CIEs, but continued education regarding proper wear and care and appropriate and early response to adverse symptoms can further reduce the risk of any long-term consequences. ECPs should ensure they educate all patients about modifiable risk factors

including not swimming or sleeping in soft contact lenses, not reusing or “topping off” cleaning solutions, and not extending the use of contact lenses beyond the prescribed replacement schedule.⁷⁹ Prescribing and promoting healthy contact lens wear in children will allow them to achieve the added benefits of improved quality of life⁴³ and help the slowing of myopia progression with certain lens designs^{1,10} to mitigate risks of associated visual impairment, while minimizing the incidence of adverse events. The opportunity to help slow progressing myopia using proven soft contact lenses needs to be proactively considered by all those involved in providing eye care to young myopic children.

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