

REVIEW

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The Safety of Soft Contact Lenses in Children

Mark A. Bullimore*

ABSTRACT

Purpose. There is increasing interest in fitting children with soft contact lenses. This review collates data from a range of studies to estimate the incidence of complications, specifically corneal infiltrative events and microbial keratitis, in patients under the age of 18 years.

Methods. Peer-review papers were identified using PubMed and the Web of Science. A broad range of studies are summarized including large-scale epidemiological studies of contact lens-related complications, hospital-based case series, long- and short-term prospective studies, and multicenter retrospective studies.

Results. Nine prospective studies representing 1800 patient years of wear in 7- to 19-year-olds include safety outcomes. In three large prospective studies representing between 159 and 723 patient years of soft contact lens wear in patients 8 to 14 years, the incidence of corneal infiltrative events is up to 136 per 10,000 years. Data from a large retrospective study show similar rates of corneal infiltrative events: 97 per 10,000 years in 8- to 12-year-olds (based on 411 patient years of wear) and 335 per 10,000 years in 13- to 17-year-olds (based on 1372 patient years of wear). None of the prospective studies report any cases of microbial keratitis. Five clinical studies where safety data are not reported constitute a further 493 patient years. One retrospective study found no cases of microbial keratitis occurred in 8- to 12-year-olds (411 patient years) and an incidence of 15 per 10,000 patient years in 13- to 17-year-olds (1372 patient years)—no higher than the incidence of microbial keratitis in adults wearing soft contact lenses on an overnight basis.

Conclusions. The overall picture is that the incidence of corneal infiltrative events in children is no higher than in adults, and in the youngest age range of 8 to 11 years, it may be markedly lower.

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Key Words: cornea, soft contact lens, incidence, children, complications, infiltrate, microbial keratitis

In the past decade, there has been increasing interest in fitting children with contact lenses. This has been driven by patients, parents, practitioners, and the contact lens research community and is caused by the increased interest in myopia control^{1–6} and the improved self-esteem and quality of life enjoyed by children wearing contact lenses.^{7–9} Furthermore, the introduction of daily disposable soft lenses obviates the need for cleaning and storage, making them an attractive option for children and teenagers alike.^{10,11} Indeed, Chalmers et al.¹² recently reported that, among patients of all ages in a prospective registry, only two corneal infiltrative events occurred in 960 patient years of daily disposable soft lens wear (489 years silicone hydrogel and 471 years hydrogel)—an incidence of corneal infiltrative events of 21 per 10,000 years.

Contact lens-related adverse events fall into two categories: serious—notably microbial keratitis—and non-serious. The latter category typically includes episodes of a painful red eye such as contact lens-induced acute red eye (CLARE) with and without infiltrates, contact lens peripheral ulcer (CLPU), and infiltrative keratitis. Of course, some events may be allergic in origin and may not involve the cornea, so researchers often use the term *corneal infiltrative events* to indicate corneal involvement beyond mere staining or superficial punctate keratitis. Corneal infiltrative events (CIEs) may be defined as a noninfectious infiltration of white blood cells into the avascular corneal stroma, often with accompanying hyperemia.¹² Microbial keratitis is a subset of this category, but usually accounts for around 5% of all corneal infiltrative events.^{13,14} 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 culture,¹⁵ although variations are common.

All soft contact lenses approved by the United States Food and Drug Administration for daily and overnight wear carry no age restriction, implying that they are safe in both adults and children.

*MCOptom, PhD, FAAO

University of Houston College of Optometry (MAB), Houston, Texas.

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But what is the evidence for this assertion? Are soft contact lenses less safe, equally safe, or safer in children than in adults? This review of the peer-reviewed scientific literature presents data from a range of different types of clinical studies related to the usage and safety of contact lenses in children in an attempt to address this question.

Surveys of Practitioner Attitudes and Behavior

Sindt and Riley reported results of a survey mailed to 4004 American Optometric Association practicing member optometrists in July 2010.¹⁶ A total of 576 surveys were returned for a response rate of 14.4%—a rate that can clearly result in bias. Nearly all responding optometrists (97%) reported fitting contact lens patients under the age of 18, and these patients represent 41% of the total contact lens patient population in the practices of respondents. Fig. 1 shows the age at which practitioners feel it appropriate to introduce a child to soft contact lenses. Over 70% feel that children can be introduced to these lenses at 12 years of age or younger. Responding optometrists most often fit spectacles as the primary method of vision correction in children ages 8 to 9 (51%) and 10 to 12 (71%). A gradual shift in optometrists' approach to vision correction occurs as children get older, with 21% noting that they were more likely to fit 10- to 12-year-olds in contact lenses than they were a year before. Nearly half (49%) prescribe contact lenses first for 13- to 14-year-olds, and 66% recommend contact lenses as the main form of vision correction for 15- to 17-year-olds. Reasons for doctors who are now more likely to fit children in contact lenses include availability of daily disposable lenses (30%), improved contact lens materials (23%), requests from the child or parent (19%), recent research or studies (10%), and children's participation in activities and sports.

Efron et al. summarized 13 years of survey data from 1650 responses from US practitioners representing 7702 contact lens fits.¹⁷ Each year, 1000 US-based practitioners were asked about the first 10 contact lens fits performed after receipt of the questionnaire. They report that patients 15 years and under account for 11% of lens fits, although no further data on children are provided. With respect to the global community, Efron et al. sent

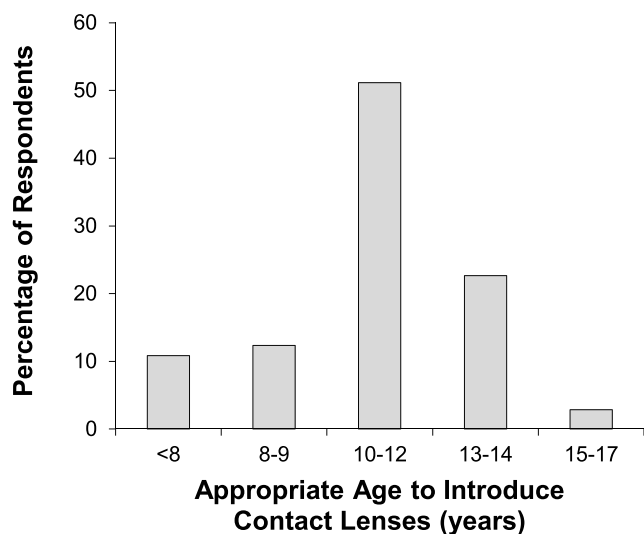


FIGURE 1.

The age at which practitioners (N = 576) feel it appropriate to introduce a child to soft contact lenses. Replotted from data reported by Sindt and Riley.¹⁶

up to 1000 survey forms to contact lens fitters in each of 38 countries between January and March every year from 2005 to 2009.¹⁰ Practitioners were asked to record data relating to the first 10 contact lens fits or refits performed after receiving the survey form. Data were received relating to 105,734 fits: 137 infants (0.1%), 1,672 children (6–12 years, 1.6%), 12,117 teenagers (13–17 years, 11.5%), and 91,808 adults (86.8%). The proportion of minors (<18 years old) fitted varied considerably between nations, ranging from 25% in Iceland to 1% in China, with the US ranked fourth with 17%: 13% 13- to 17-year-olds and 4% 6- to 12-year-olds. Children are fitted with the highest proportion of daily disposable lenses and have the highest rate of fits for part-time wear. Teenagers have a similar lens fitting profile to adults, with the main distinguishing characteristic being a higher proportion of new fits. Orthokeratology fits represented 28% of all rigid contact lenses prescribed to minors, including 47% of 6- to 12-year-olds, and the authors attribute this to growing popularity of myopia control. Children have the highest proportion (>25%) of newly prescribed daily disposable lenses—followed by teenagers and adults—consistent with the view of Walline et al. that this replacement frequency is especially suited to children and teenagers.¹¹ The authors assert that the simplicity of daily replacement, without the need for lens cleaning and maintenance, is likely to enhance compliance. It should be noted that the above data represent the proportions of contact lens fits—both new and refits. The proportion of children fit may thus overstate the proportion of children in the total population of wearers, although the mean age for new fits did increase from 27.6 years in 2002 to 31.8 years in 2014. Finally, only 1650 forms were returned over 13 years representing a response rate of 12.7% and leaving the potential for respondent bias.

Major Epidemiological Studies

Contact lens–related adverse events have been studied extensively and comprehensively for some 30 years. Researchers have quantified the incidence of serious events, notably microbial keratitis, associated with different modalities along with the patient-related factors associated with non-serious and serious events.^{18–22} Microbial keratitis was defined in these studies as either a positive corneal culture or a corneal infiltrate and overlying epithelial defect with at least one of the following: any part of the lesion being within the central 4 mm of the cornea, an anterior chamber response, or pain. Cases were usually classified as mild, moderate, or severe with the latter including loss of two or more lines of best-corrected visual acuity, surgical intervention, or both. Overnight wear is an unequivocal risk factor for microbial keratitis among soft contact lens wearers. Risk factors for microbial keratitis with daily wear include poor storage case hygiene, infrequent storage case replacement, solution type, male gender, high socio-economic status, smoking, and occasional overnight lens use.^{20,22} Children are rarely represented in these studies.

Dart et al.,¹⁸ Stapleton et al.,²¹ and Keay et al.¹⁹ all only report cases in patients 15 years and older, although it is unclear in some cases whether this represents the absence of pediatric cases or a study design decision. Collectively, these papers represent some 900 cases of presumed or confirmed microbial keratitis, but we cannot assume that cases of microbial keratitis did not occur in younger children. Stapleton et al. state that daily disposable contact lens wear “seems to be associated with the lowest risk of severe microbial keratitis.”²¹

When age is considered as a potential risk factor for contact lens-related microbial keratitis, data on young children are absent and the results on the youngest age group—usually 15 to 24 years—are equivocal. In a prospective, 12-month, population-based, case-control study, Stapleton et al. identified 90 moderate and severe cases related to daily wear of contact lenses and recruited 1090 community controls using daily wear contact lenses.²⁰ Data on frequency of case replacement were collected, but not frequency of lens replacement or material. They found that wearer age (15–24 vs. 25–54 vs. 55–64 years) was not associated with moderate and severe disease. In a similar study, Lim et al. report 58 cases of contact lens wearers presenting with microbial keratitis between 2008 and 2010 and recruited 152 contemporaneous controls.²³ Eligible contact lens wearers were individuals aged 14 to 67 years who had worn their lenses in the 4 weeks before the event. They found that patients aged between 25 and 44 years were at three times increased risk compared with younger wearers (14–24 years; 95% CI: 1.1–9.6, $P = .04$). Occasional overnight contact lens wear (less often than one night per week) was associated with a four times higher risk (95% CI: 1.2–15.4, $P = .03$) compared with daily use. Lim et al. emphasize that daily disposable lens wear was associated with a significantly reduced risk of microbial keratitis, compared to weekly, fortnightly, and monthly replacement ($P < .001$). Daily disposable lenses accounted for only 10% of the cases, but 28% of the controls.

In a 1-year prospective study of 6245 overnight silicone hydrogel (lotrafilcon A) lens wearers,¹⁵ Chalmers et al. found 159 symptomatic corneal infiltrative events that were judged to be lens related (2.5%) of which 10 were classified as microbial keratitis.¹³ The age distribution is not described in detail but included subjects as young as 5 years. None of the 10 cases of presumed microbial keratitis occurred in patients under 18 years.¹⁵ Wearers who were at the younger and older ends of the age distribution had a significantly higher risk of developing infiltrates. Age <25 years and >50 years was significantly associated with the development of corneal infiltrates (<25 years OR = 1.75, 95% CI: 1.24–2.48 and >50 years OR = 2.04, 95% CI: 1.40–2.98).

Chalmers et al. used similar methodology in a 1-year prospective study of daily disposable soft lenses.¹² Of the 977 patients completing the 12-month survey, 13% were 15 years or younger. Increasing patient age was significantly related to development of a contact lens-related adverse event for the 11 cases with office visits (odds ratio 1.05, 95% CI: 1.01–1.10, $P = .03$). In other words, for every year older, there was a 5% increase in the risk of a contact lens-related adverse event requiring an office visit. The only adverse event among the patients younger than 18 years was an allergic conjunctivitis. Note that only two corneal infiltrative events occurred in 960 patient years of daily disposable soft lens wear (489 years silicone hydrogel and 471 years hydrogel)—an incidence of corneal infiltrative events of 21 per 10,000 years. Although not stated in the published paper, 202 children between 8 and 17 years were enrolled, accounting for 171 patient years of wear and no infiltrates (Robin Chalmers, personal communication).

These conflicting results may be attributable to variations in event severity, definitions, material, wearing schedule, and study setting, but there is no clear evidence of increased risk among 15- to 24-year-olds. The dogma in the literature is that the risk is higher in younger patients,²² but the data from the above studies conducted in the past decade do not support this narrative. Regardless, most

studies use a broad range encompassing teenagers and college students while ignoring younger children.

Hospital-Based Case Series of Microbial Keratitis in Children

Serious corneal infections can occur in children wearing contact lenses, even if not being particularly prominent in the above well-conducted, large-scale, prospective epidemiological studies. Although reports for Europe and the US are scarce, there are a number of hospital-based case series, all from Taiwan and Hong Kong, describing the characteristics of children presenting with microbial keratitis over a 4- to 10-year period. Fong et al. conducted a retrospective 10-year study of microbial keratitis at National Taiwan University Hospital, reporting 453 patients of whom only 22 were 15 years or younger (4.9%).²⁴ Contact lens use accounted for 44% of cases with pseudomonal keratitis, the most common pathogen. The authors attribute this high proportion to the high prevalence of myopia and the popularity of contact lens wear in Taiwan. No details are provided regarding the ages of the pediatric cases, their severity, nor the types of lenses worn.

Hsiao et al. reviewed the medical records of 78 children (≤ 16 years) with microbial keratitis over a 4.5-year period at Chang Gung Memorial Hospital, Taiwan.²⁵ Contact lens wear was a factor in 33 of cases (41%), of which 8 (10%) were rigid gas permeable lenses that were worn overnight for orthokeratology and 25 (31%) were soft lenses. No data are provided on soft lens replacement schedule. The mean visual acuity at resolution in the 25 soft lens wearers was 0.24 logMAR (20/35), but the proportion undergoing surgical intervention is not given (15% of all 81 eyes) nor the number with poorer than 20/40 visual acuity. Most of the 33 contact lens wearers claimed they did not use correct disinfectant with their lenses or wore the lenses overnight. Only one soft contact lens-related case of microbial keratitis was under 12 years old, and the authors remark that most Taiwanese children who start to wear soft contact lenses are aged approximately 13 years.

In a follow-up study at the same hospital, Lee et al. reviewed the medical records of 67 children aged 16 years or younger who were diagnosed with and treated for microbial keratitis.²⁶ Around half the cases occurred in patients 11 years and under. The leading risk factor was again contact lens use, accounting for a significantly higher proportion of cases (53%) compared to the previous study. This was entirely because of an increase in the number of cases attributed to orthokeratology, which increased from 10 to 19% ($P = .011$) likely reflecting higher numbers of orthokeratology wearers rather than any increase in the underlying risk. Soft contact lens wear still accounted for a little over 30% of cases of microbial keratitis (34%), but no data are given on soft lens replacement or wear schedule. The patients with orthokeratology were significantly younger than those with soft contact lens (11.9 years vs. 14.8 years, $P < .001$), but visual acuity outcomes are not provided for either group. *Pseudomonas aeruginosa* remained the most commonly isolated organism (31%).

Finally, Young et al. reported 18 patients <18 years of age with microbial keratitis who presented over a 10-year period in Hong Kong (mean age 12.4 years, range 3–17 years).²⁷ Contact lens wear was the associated risk factor in 15 cases (83%), with 7 (39%) associated with orthokeratology lenses and 8 (44%) associated with soft lens wear including 1 user of colored contact lenses. *Pseudomonas*

was the most commonly isolated organism (10 cases, 63%). The authors provide details of all cases in a comprehensive table demonstrating that among the eight cases in soft contact lens wearers, five were biweekly or monthly replacement, and one each were extended wear, daily wear, and cosmetic. Two soft lens wearers had final best-corrected visual acuity worse than 20/40.

Although the above studies document that microbial keratitis can occur in children wearing contact lenses in Asia, it is not possible to estimate the frequency or incidence of these serious events. Likewise, few data are given on age distribution lens material or replacement schedule in these studies. Only Young et al.²⁷ make any reference to replacement schedule and none of their cases were in daily disposable lenses.

Long-Term Prospective Studies of Contact Lenses in Children

A number of prospective, large-scale clinical trials have followed children wearing contact lenses over a study period of 2 to 3 years. A pair of studies was conducted 20 years ago at Indiana University. Terry et al. reported a 3-year study of changes in 10- to 13-year-old children's self-concepts after the replacement of their spectacles with contact lenses.²⁸ From a sample of 125 children who wore spectacles, 69 children were randomly designated to receive reusable (CIBASoft; CIBA Vision, now Alcon, Fort Worth, TX) soft contact lenses. Horner et al. reported a 3-year, randomized clinical trial of myopia progression in 175 11- to 14-year-olds wearing reusable (CIBASoft) soft contact lenses versus spectacles.²⁹ Of those randomized to contact lenses, 68 completed the 3-year trial. Unfortunately, no data on safety or adverse events are reported in either of the above publications.

Walline et al. randomly assigned 116 subjects aged 8 to 11 years to wear rigid gas permeable or 2-week replacement soft contact lenses (CIBA Focus 2; CIBA Vision, now Alcon, Fort Worth, TX) in a 3-year clinical trial.³⁰ Of the 57 randomized to soft lenses, 53 completed the trial wearing soft lenses. No subjects in either treatment group experienced a sight-threatening adverse event. No infections were reported, but four soft lens wearers experienced an adverse event—three caused by “tight-fitting soft lenses” that resolved completely after refitting with other brands. The other adverse event was a result of a “contact lens solution allergy, which resolved after changing the brand of solution.” Assuming these not to be corneal infiltrative events, the 95% CI are 0 to 233 per 10,000 patient years. No adverse events were reported among the rigid gas permeable lens wearers.

Sankaridurg et al. reported comprehensive data on 240 children aged 7 to 14 years enrolled in a prospective randomized clinical trial of daily wear of monthly replacement, silicone hydrogel lenses.³¹ Children were randomized to one commercial single-vision design and three experimental lens designs aimed at reducing myopia progression—a central zone to correct for the distance refractive error and a peripheral optical zone that was relatively positive in power. All were manufactured in lotrafilcon B silicone hydrogel (CIBA Vision, now Alcon, Fort Worth, TX) and worn bilaterally on a daily wear, monthly replacement schedule. A total of 189 children completed 1 year of contact lens wear, and 170 children completed 2 years. There were no events of microbial keratitis, although 55 non-serious adverse events (annual incidence, 14.2%) were seen: contact lens papillary

conjunctivitis (16 events, 4.1%), superior epithelial arcuate lesions (6 events, 1.5%), corneal erosions (8 events, 2.1%), infiltrative keratitis (5 events, 1.3%), asymptomatic infiltrative keratitis (7 events, 1.8%), and asymptomatic infiltrates (13 events, 3.4%). The authors conclude that adverse events with daily wear of silicone hydrogels in children were mainly mechanical in nature, and significant infiltrative events were few. Only the five cases of symptomatic infiltrative keratitis would meet the definition of symptomatic corneal infiltrative events used in other studies,^{13,14,22} representing an incidence of corneal infiltrative events of 136 per 10,000 patient years (95% CI = 50–300).

In the largest clinical trial to date of contact lenses in children, Walline et al. randomized 8- to 11-year-old myopic children at five clinical centers in the United States.^{9,32} Of the 584 subjects, 237 were randomly assigned to wear spectacles and 247 to wear daily disposable (1-Day Acuvue; Johnson & Johnson Vision Care, Jacksonville, FL) or biweekly replacement (Acuvue 2; Johnson & Johnson Vision Care) soft contact lenses. Daily disposable lenses were fitted in 93% of children. At the end of the 3-year trial, 241 subjects were examined 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 two cases of conjunctivitis (one bacterial and one viral), recurrent phlyctenulosis, corneal dystrophy not noted at baseline, recurrent anterior uveitis, six cases of keratitis—four attributed by the authors to “poor compliance,” one to a “tight-fitting contact lens,” and one of “unknown etiology.” All adverse events completely resolved without permanent decrease in best-corrected visual acuity. Although not explicit, the implication is that the reported keratitis was not microbial or serious in nature and confirmed by personal communication from the lead author. Regardless of the underlying assumptions and assertions regarding “tight-fitting lenses” and “poor compliance,” the six cases of keratitis are assumed to be corneal infiltrative events and represent an incidence of corneal infiltrative events of 83 per 10,000 patient years (95% CI = 34–173).

Clinical Trials Where One or More Groups Wear Soft Contact Lenses

In addition to the above studies, there have been a number of reports of smaller samples wearing soft contact lenses in clinical studies of myopia control. Unfortunately, only one of the six studies reports safety data.

Anstice and Phillips fitted 40 children, 11 to 14 years old, with a Dual-Focus soft contact lens in one eye and a single vision soft contact lens in the other.² The lenses were made of hioxifilcon A, worn on a daily wear basis and replaced every 2 months. Subjects were followed for 20 months. Six children dropped out because of difficulties with handling contact lenses ($n = 3$), adverse publicity regarding contact lens solutions ($n = 1$), dislike of cycloplegia ($n = 1$), or contact lens-related discomfort ($n = 1$). Adverse events were not reported.

Sankaridurg et al. fitted 45 Chinese children, aged 7 to 14 years, with novel myopia-control, monthly replacement, silicone hydrogel contact lenses and followed them for 12 months. They were compared with a matched group ($n = 40$) wearing spectacles. No safety data were reported.⁴

Walline et al. fitted soft multifocal (Proclear Multifocal; CooperVision, Victor, NY) contact lenses to forty 8- to 11-year-old children, of whom 32 were examined after 1 year and 27 after 2 years.⁵ Lenses were replaced on a monthly basis and safety data were not reported.

Lam et al. performed a 2-year double-masked randomized clinical trial of soft contact lenses 221 children aged 8 to 13 years.³ Subjects were randomly assigned to a Defocus Incorporated Soft Contact (DISC) lens ($n = 111$) or single-vision contact lenses ($n = 110$). The DISC lenses incorporated concentric rings that provided +2.50D of addition power, alternating with the normal distance correction. The lenses were replaced every 6 months. Only 128 children (58%) completed the 2-year study (DISC, $n = 65$; single vision, $n = 63$). No safety data were reported, although the authors state that “adverse reactions were low” and that “17 excluded due to ocular health problems.”

Cheng et al. randomized 127 subjects (8–11 years) to either soft contact lenses with positive spherical aberration or a spherical control lens, both made of the same material (etafilcon A with Lacreon technology).³³ During this treatment phase, subjects were followed for up to 2 years, with 109 completing at least 1 year of follow-up. Thereafter, 82 subjects participated in a withdrawal phase wherein all wore 1-Day Acuvue Moist soft contact lenses with 77 completing 18 months of follow-up. No cases of microbial keratitis or corneal infiltrative events were reported, although there were two instances of contact dermatitis and four of allergic conjunctivitis.

Aller et al. randomized 79 myopic subjects (8–18 years) to either single-vision (Vistakon Acuvue 2) soft contact lenses or bifocal (Acuvue Bifocal; Johnson & Johnson Vision Care) soft contact lenses worn on a daily wear basis for 12 months, with a 2-week replacement schedule.¹ Of these, 78 completed the 1-year clinical trial. No safety data were reported.

Prospective Studies of Fitting Children and Teenagers

There have also been a handful of short-term studies published, demonstrating the feasibility of fitting children as young as 8 years with soft contact lenses. Although limited in duration, they all report data on adverse events.

The Contact Lenses in Pediatrics (CLIP) Study compared contact lens fitting and follow-up between 8- to 12-year-old children and 13- to 17-year-old teenagers.³⁴ The study enrolled 84 children and 85 teens and fit them with soft contact lenses (Acuvue Advance with Hydraclear or Acuvue Advance for Astigmatism; Johnson & Johnson Vision Care), presumably on a 2-week replacement schedule. All but 12 completed the 3-month study (86%) and no serious adverse events were observed, but “three cases of viral keratitis and two cases of suspected contact lens overwear” were reported. The authors’ Table 4 indicates one episode of a corneal infiltrate, although the severity is unclear.

In a similar study in Singapore, Li et al. recruited and fitted 59 children (8–11 years) with spherical or toric daily disposable soft lenses.³⁵ Of the 59 subjects enrolled, 53 (90%) completed the study successfully. Six subjects discontinued due to lens handling difficulties ($n = 4$), unacceptable lens fit ($n = 1$), and an adverse event ($n = 1$). Adverse events were reported in three subjects, including the discontinuation, all because of a chalazion.

Plowright et al. randomized subjects (aged 13–19 years) with no previous contact lens wear experience to daily disposable soft contact lenses or spectacles for 6 months.⁸ A total of 110 teenagers were enrolled; 13 discontinued before study completion, 10 from the contact lens group and 3 from the spectacle group ($P = .04$). No serious adverse events occurred during the study, although a 19-year-old discontinued the study at month 3 because of a contact lens–induced peripheral ulcer (CLPU) and subsequent topical medication (chloramphenicol). The CLPU was resolved at a follow-up visit 21 days later leaving a small peripheral scar.

Paquette et al. recruited 179 children aged 8 to 16 years without previous soft contact lens experience and fitted them with soft contact lenses.³⁶ Of those recruited, 90.5% (162/179) were successfully fitted and completed the 3-month study. No serious adverse events occurred, although five subjects presented with non-clinically relevant corneal staining, one participant presented with a corneal infiltrate, and one participant presented with a lens care reaction. The corneal infiltrate self-resolved within 1 week with the participant later resuming lens wear.

Although not a prospective study, Turnbull et al. reported a case series of 110 patients of whom 32 were prescribed dual focus soft contact lenses for myopia control (mean age: 11.4 ± 2.4 years).³⁷ Over a mean follow-up of 1.33 ± 0.80 years for these soft lens wearers, no adverse events were observed.

Large-Scale Retrospective Studies of Safety—The CLAY Study

The Contact Lens Assessment in Youth (CLAY) Study was a multicenter, retrospective, observational study to evaluate the risk factors that interrupt soft contact lens wear among children, teenagers, and young adults in North America. The goal was to assess the safety profile of soft contact lens wear in a pediatric population outside the confines of prospective clinical studies. The cohort represented patients presenting to academic eye care clinics for routine and problem-oriented eye care and included both habitual and newly prescribed soft contact lens wearers.

Lam et al. described the methodology, including the important over-sampling of youngest age to make statistical comparisons, the demographics, and clinical characteristics of this cohort at the first observed visit.³⁸ Charts from 3,549 patients (14,276 visits) were reviewed; 79% were existing soft contact lens wearers and 21% were new fits. The age distribution was 8 to ≤ 13 years ($n = 260$, 7%), 13 to ≤ 18 years ($n = 879$, 25%), 18 to ≤ 26 years ($n = 1274$, 36%), and 26 to ≤ 34 years ($n = 1136$, 32%). Seventy-seven percent of current soft contact lens wearers had a documented replacement schedule. Based on patient-reported replacement schedules, daily replacement composed the smallest percentage (9.9%) across all age groups, although this mode was most common (15.8%) among the youngest soft contact lens wearers (8–12 years). Monthly and 1- to 2-week replacement each accounted for 39% in the overall population. Microbial keratitis and other adverse events are not reported in this first publication.

In a subsequent report, Chalmers et al. reported the frequency of corneal infiltrative events (microbial keratitis, CLARE with and without infiltrates, CLPU, and infiltrative keratitis) in the aforementioned sample from 14,305 visits observing 4,663 soft contact lens years including an average of 20 months of soft contact lens wear

in 1,054 patients under the age of 18 years.¹⁴ Reviewers masked to wearer identity, age, and soft contact lens parameters adjudicated event diagnoses. The chart review yielded 187 corneal infiltrative events in 168 wearers: 8 instances of microbial keratitis, 110 of infiltrative keratitis, 41 CLPUs, 14 CLARE with infiltrates, 13 CLARE without infiltrates, and 1 iritis. Age was a significant nonlinear risk factor, peaking between 15 and 25 years ($P = .008$). The risk of a corneal infiltrative event increased in a nonlinear fashion up to age 21 and then decreased similarly, with the peak years at risk from age 15 to 25 years. Fig. 2 replots the published data in terms of incidence (cases per 10,000 patient years of wear) based on the number of cases and duration of follow-up reported by the authors. Note that all incidence rates have confidence intervals and those for all corneal infiltrative events are given below. The figure demonstrates the marked lower rate of corneal infiltrative events in patients 8 to 12 years old (97 per 10,000 patient years, 95% CI = 31–235) than in patients 13 to 17 years old (335 per 10,000 patient years, 95% CI = 248–443). No cases of microbial keratitis occurred in the 8- to 12-year-olds and two occurred in the 13- to 17-year-olds representing an incidence of microbial keratitis events of 15 per 10,000 patient years (95% CI = 2–48) in the latter age group, substantially lower than the incidence for all corneal infiltrative events. 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 (in decreasing order) were all significant risk factors.

Wagner et al. subsequently reported that the risk of interruption to soft contact lens wear followed the same pattern as corneal infiltrative events, increasing from ages 8 to 18 years, showing modest increases between ages 19 and 25 years, and then declining

after age 25 years.³⁹ New lens wearers (≤ 1 year) were less likely to experience interrupting events ($P < .001$).

The CLAY Study Group has subsequently begun to investigate the underlying behavioral, biological, or environmental factors that may potentially drive the above age-related complications. They developed a Contact Lens Risk Survey to assess known or presumed risk factors for soft contact lens complications and administered the survey to a nonclinical population of 542 soft contact lens wearers aged 12 to 33 years.³⁹ Wearers aged 18 to 21 years reported more recent nights with less than 6 hours of sleep ($P < .001$), more colds/flu ($P = .049$), and higher stress levels ($P < .001$). Wearers 18 to 21 and 22 to 25 years were more likely to wear soft contact lenses when showering ($P < .001$) and also reported more frequent naps with soft contact lenses ($P < .001$). The 18- to 25-year age group were more likely to report sleeping in SCLs after alcohol use ($P = .031$), when traveling ($P = .001$), and when away from home ($P = .024$).

Finally, the researchers investigated whether the surveyed risk factors were correlated with their previously established age-related risk profile for corneal infiltrative events (Fig. 2).⁴⁰ To match the known age-related risk profile, a distribution should show a rise in behaviors from 12- to 17-year-olds, peaking among 18- to 25-year-olds, and declining in 26- to 33-year-olds. Visual inspection showed good agreement between the age-related risk curve (Fig. 2) and age-binned survey responses for various behaviors, e.g., showering and napping in soft contact lenses. The rate of all-risky behaviors was around twice as high in 18- to 21-year-olds compared to the 12- to 14-year-olds. Although the presence of risky soft contact lens wearing behaviors does not imply a causal

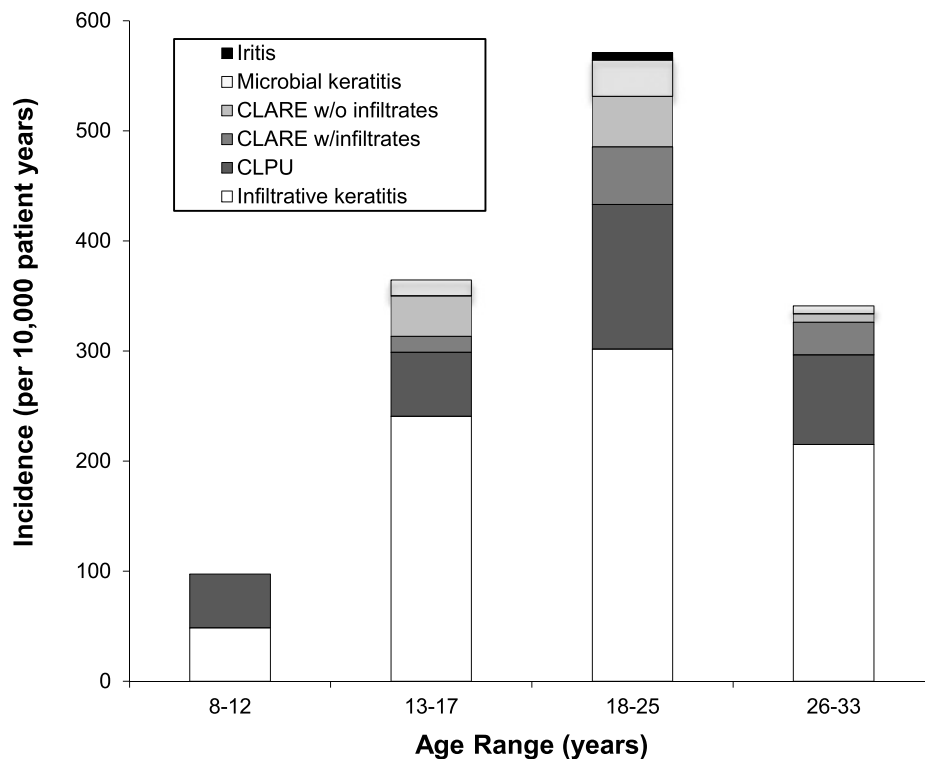


FIGURE 2.

The incidence of various corneal infiltrative events as a function of patient age. Incidence was calculated per 10,000 patient years. Calculated from data reported by Chalmers et al.¹⁴

relationship, the prevalence of specific behaviors by age mirrors the age-related risk of having an inflammatory event from the authors' previous study. This suggests that the age-related variation in adverse events is a result of patient behavior rather than biological factors.

SUMMARY

The publications reviewed above encompass a wide range of study goals. Studies were designed to evaluate the influence of a lens design on myopia progression, the effects of contact lenses on self-esteem, the ease of fitting and adaptation to wear, the safety of contact lens wear, or some combination.

Table 1 summarizes most of the prospective studies cited above. In those representing at least 100 patient years of lens wear, the incidence of corneal infiltrative events and the 95% confidence intervals can be estimated based on the number of events reported, the number of patients completing the study, and the duration of follow-up. For the three large clinical trials, the incidence of corneal infiltrative events for children wearing contact lenses is up to 136 per 10,000 years with upper 95% confidence intervals of up to 300 per 10,000 years.^{30–32} Where specified by the authors,³¹ only symptomatic infiltrates are included in Table 1. There are additional asymptomatic events and non-infiltrative presentations observed at the many scheduled visits in prospective studies. The clinical significance of these may be unclear, but they cannot be captured easily with retrospective study designs.⁴¹

The largest of these numbers reflects the wearing of reusable silicone hydrogel lenses and includes subjects as old as 14 years.³¹

The estimate of corneal infiltrative events of 83 per 10,000 years for Walline et al.³² is probably high because it assumes their six cases of lens-related keratitis to be corneal infiltrative events, although the authors make no mention of the presence or absence of corneal infiltrates. Thus, the incidence may be much lower. The incidence for the CLAY study is also calculated for two age groups based on their published data.¹⁴ The incidence of corneal infiltrative events for the three studies enrolling 8- to 11-year-olds^{30,32} or 7- to 14-year-olds³¹ agree well with the estimate for 8- to 12-year-olds from the CLAY study (0, 83, and 136 per 10,000 years vs. 97 per 10,000 years).¹⁴ Their incidence of corneal infiltrative events falls within the range for the three prospective studies and the upper 95% confidence intervals all fall between 173 and 300 per 10,000 years.

The summary of the incidence of corneal infiltrative events in Table 1 can be placed in the context of epidemiological studies of adult contact lens wearers (some described above, some not because they did not include patients under 18 years of age). In the last decade, the annualized incidence of *symptomatic* corneal infiltrative events in adults has been reported as follows:

- 318 per 10,000 patient years in patients attempting 30-night continuous wear of silicone hydrogel lenses¹³;
- 340 per 10,000 patient years for extended wear low Dk hydrogel lenses and 720 per 10,000 patient years for extended wear silicone hydrogel lenses based on a meta-analysis⁴²;
- 432 per 10,000 patient years in a retrospective chart review of mostly daily wear¹⁴; and

TABLE 1.
Summary of studies of contact lenses in children

Authors	Country	Age Range (yr)	Duration (yr)	N	Patient years	Incidence of CIE		
						CIEs	(per 10,000 patient years)	95% CI
Prospective studies								
Terry et al. (1997) ²⁸	US	10–13	3	69		*		
Horner et al. (1999) ²⁹	US	11–14	3	68		*		
Walline et al. (2004) ³⁰	US	8–11	3	57	159	0	0	0, 233
Sankaridurg et al. (2013) ³¹	PRC	7–14	2	240	369	5	136	50, 300
Walline et al. (2008) ³²	US	8–11	3	247	723	6	83	34, 173
Chalmers et al. (2015) ¹²	US	8–17	1	202	171	0	0	0, 216
Anstice and Phillips (2011) ²	NZ	11–14	1.7	40	57	*		
Sankaridurg et al. (2011) ⁴	PRC	7–14	1	45	43	*		
Walline et al. (2013) ⁵	US	8–11	2	40	59	*		
Lam et al. (2014) ³	HK	8–13	2	221	256	*		
Cheng et al. (2016) ³³	US	8–11	1 + 1.5	127	262	0	0	0, 141
Aller et al. (2016) ¹	US	8–18	1	79	78	*		
Walline et al. (2007) ³⁴	US	8–17	0.25	169	39	1		
Li et al. (2009) ³⁵	SG	8–11	0.25	59	13	0		
Plowright et al. (2015) ⁸	UK	13–19	0.5	55	23	1		
Paquette et al. (2015) ³⁶	CND	8–16	0.25	179	41	1		
Retrospective studies								
Turnbull et al. (2016) ³⁷	NZ	6–17		32	43	0		
Chalmers et al. (2011) ¹⁴	US	8–12		243	411	4	97	31, 235
Chalmers et al. (2011) ¹⁴	US	13–17		811	1,372	46	335	248, 443

Where possible, the incidence of symptomatic corneal infiltrative events (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.

*Data not reported.

CIEs indicates corneal infiltrative events; CND, Canada; PRC, China; HK, Hong Kong; NZ, New Zealand; SG, Singapore; UK, United Kingdom; US, United States.

- 316 per 10,000 patient years in a prospective study for daily wear of silicone hydrogel lenses with monthly replacement.⁴³
- 2,061 per 10,000 patient years in multiple 3-month trials of various daily wear silicone hydrogel contact lens and lens solution combinations.⁴⁴

Note that these estimates are for symptomatic corneal infiltrative events and *not* microbial keratitis, and values have been recalculated from the data presented in each paper except the meta-analysis.⁴² The incidence of corneal infiltrative events in the last of the above studies⁴⁴ is almost three times that of any others. This is likely caused by the more frequent and rigorous examination schedule and that 62% of the corneal infiltrative events (almost exclusively classified as infiltrative keratitis) were associated with one of four contact lens solutions studied. In the remaining studies, the incidence of corneal infiltrative events varies depending on wearing schedule, replacement schedule, study design, and setting, but the range covers only a factor of two—from 318 to 720 per 10,000 patient years, even though the list includes both daily wear and extended wear. By comparison, Table 1 demonstrates that for the three prospective studies in children, the incidence of corneal infiltrative events is substantially lower (up to 136 per 10,000 patient years).^{30–32} The 95% confidence intervals are broad because of the size of the cohorts, but the upper limits are no higher than 300 per 10,000 patient years. Thus, it seems reasonable to conclude that the risk of corneal infiltrative events in children wearing soft contact lenses is no higher than in adults and if anything may be markedly lower. Furthermore, the incidence of corneal infiltrative events is particularly low when the population is limited to children 12 years and younger.^{14,30,32} Indeed, the 95% confidence intervals for the two age groups in the CLAY study do not overlap (Table 1).¹⁴

Microbial keratitis in soft contact lens wearers is rare regardless of the age of the population, with sleeping in lenses a significant risk factor.²¹ None of the nine prospective studies documenting soft contact lens wear in children that include safety outcomes described in detail above and summarized in Table 1 encountered a single case of microbial keratitis. Collectively, these studies represent 1800 patient years of wear in 7- to 19-year-olds. The five clinical studies where safety data are not reported constitute a further 493 patient years. The only study that allows an estimate of the incidence of microbial keratitis in children wearing contact lenses found no cases of microbial keratitis occurred in 8- to 12-year-olds and an incidence of 15 per 10,000 patient years (95% CI = 2–48) in 13- to 17-year-olds.¹⁴ Despite there being no cases in the younger age group, the upper 95% confidence interval may be estimated as 90 per 10,000 patient years, higher than that for the 13- to 17-year-olds. The majority of the reported cases are attributed to sleeping in lenses, and the incidence is no higher than the incidence of microbial keratitis in adults wearing contact lenses on an overnight basis.^{13,21}

In 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 different studies. The retrospective data from the CLAY study documents 1783 patient years of wear in 8- to 17-year-olds. The prospective studies where safety outcomes are reported collectively represent a further 1800 patient years of wear in 7- to 19-year-olds. **The overall picture is that the incidence of corneal infiltrative events in children is no higher than in adults, and in the youngest age range of 8 to 11 years, it may be markedly**

lower. The lower rate of adverse events in this youngest group is a result of patient behavior rather than biological factors, and greater parental supervision may also help to mitigate risks.⁴⁰

Finally, **the introduction of daily disposable soft contact lenses may play a role in reducing corneal infiltrative events in all patients, including children.** Walline et al. fitted 93% of their 247 patients in daily disposable soft lenses and reported no cases of microbial keratitis and an incidence of corneal infiltrative events that is 83 per 10,000 patient years at most, and probably much lower.³² Similarly, Chalmers et al. reported no cases of microbial keratitis and only two corneal infiltrative events occurred in 960 years of daily disposable soft lens wear in patients aged between 8 and 76 years, representing an incidence of 21 per 10,000 years.¹²

LIMITATIONS

This review includes a wide range of studies with a variety of specific aims, although most of the larger studies are prospective with well-characterized cohorts. Nonetheless, the complication rate for subjects enrolled in a scientific endeavor may not reflect the rate in clinical practice, although the available retrospective data do show very similar rates. Selection bias may occur, with children perceived to be at higher risk not being recruited or fit with contact lenses as enthusiastically by cautious clinical investigators and practitioners alike. The estimates of incidence are crude and make a number of assumptions including that risk is constant over time. This may not be the case given reports that events occur more often after the first year of contact lens wear.^{39,45} A further limitation is that studies of myopia control focus on the effectiveness of the study treatment and only one of the six summarized above reports safety outcomes leading to the possibility of underreporting. For future clinical trials of myopia control in children, authors should rigorously classify and report adverse events and avoid editorial comments about patient compliance and lens fit. If an event happens, it should be reported without attribution. Among the studies summarized here, loss to follow-up is as high as 42%,³ representing a further source of bias. In contrast, Walline et al. limited loss to follow-up to less than 4% in their 3-year clinical trial.⁹ As studies of all types of contact lenses in children proliferate, it would be useful for authors to summarize all and any adverse events, preferably using a standardized set of diagnoses such as those used by Chalmers et al.¹⁴ or Sankaridurg et al.³¹ Additional robust safety data are needed for children wearing contact lenses. Industry, academia, and the broader contact lens community can engage in this endeavor as new myopia control modalities are evaluated. Likewise, efforts should be undertaken to include children in future epidemiologic research.

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Mark A. Bullimore
 356 Ridgeview Lane
 Boulder, CO 80302
 e-mail: bullers2020@gmail.com