

The Safety of Soft Contact Lenses in Children

REVIEW

OPEN

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.
(Optom Vis Sci 2017;94:00-00)

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 control¹⁻⁶ 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.¹³ 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.

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Summary: soft contact lenses in children



- ✓ Incidence of CIEs much **lower** in 8-12 year olds than in adults
- ✓ **No reported cases of MK** in over 2,000 prospective and 400 retrospective patient years of lens wear
- ✓ **Behaviour** increases incidence in older children
- ✓ **Daily disposable** SCLs may play a role in reducing corneal infiltrative events in all patients

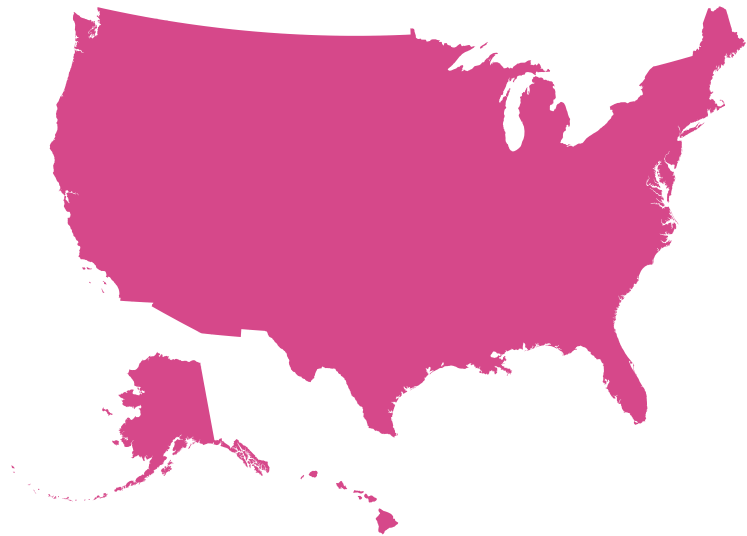


**Are we fitting children with
contact lenses?**



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What proportion of US contact lens wearers are children?



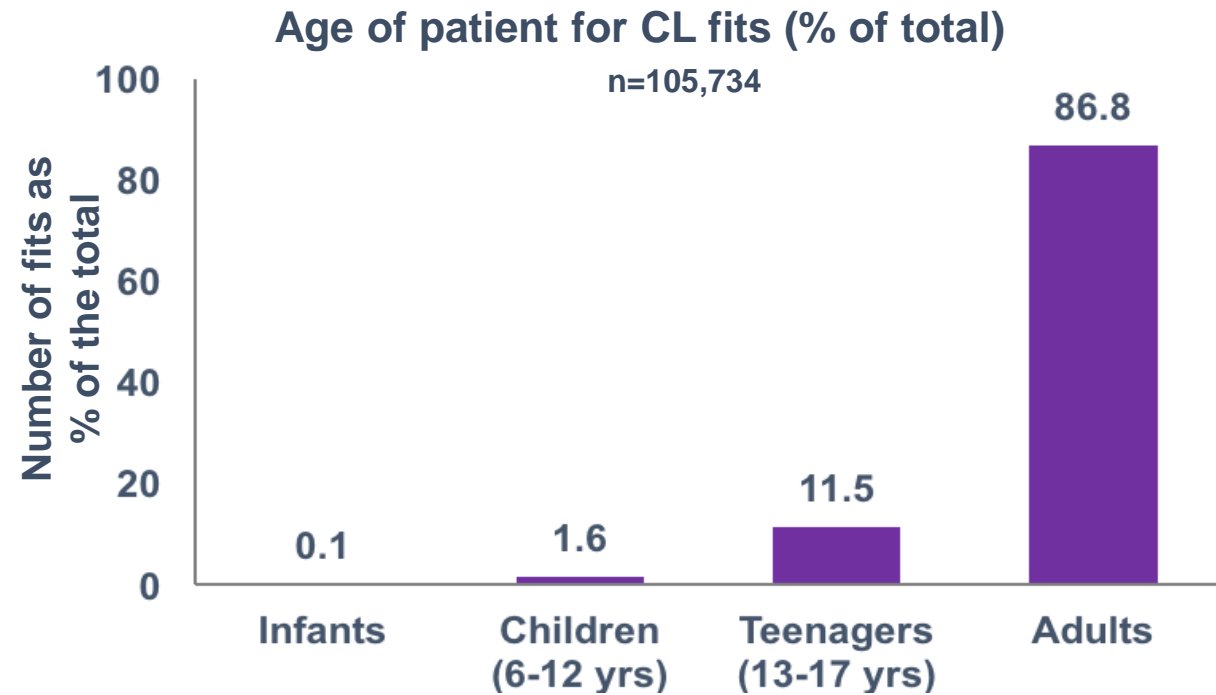
- **13 years** of survey data
- 1,650 responses from US practitioners
- Representing **7,702** contact lens fits

Patients ≤ 15 years account for **11%** of lens fits



What about other countries?

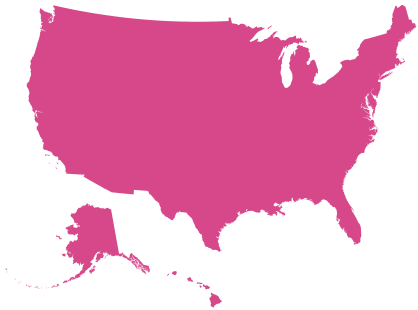
- 1000 survey forms to lens fitters in **38 countries**
- Every year, 2005 to 2009
- Practitioners reported next 10 fits or refits
- **105,734 fits**



What about other countries?



- Proportion of minors (<18 years) **varies considerably**
- **25%** in Iceland to **1%** in China



- US ranked fourth with **17%**:
 - 13% 13–17 year olds
 - 4% 6–12 year olds

Children fitted with highest proportion of **daily disposable** lenses



Age at which US optometrists introduce contact lenses



PRACTICE STRATEGIES

Practitioner attitudes on children and contact lenses

Christine W. Sindt, O.D., and Colleen M. Riley, O.D., M.S.

A new survey of American Optometric Association (AOA) practicing member optometrists offers some insight into doctors' attitudes and practices when it comes to fitting children with contact lenses. More than half of the AOA optometrists responding to the survey felt it was appropriate to introduce a child to soft contact lenses between the ages of 10 and 12, with daily disposable contact

A new survey finds many practitioners feel it may be appropriate to fit preteens with contact lenses.

lenses being the most frequently prescribed contacts for this age group, according to the new *Children & Contact Lenses* survey (see Figure 1).¹

The survey, conducted by the AOA Research and Information Center, in conjunction with the Sports Vision Section and Contact Lens and Contact Section of the AOA, with support from Vistakon®, Division of Johnson & Johnson Vision Care, Inc., was designed to gauge current trends in prescribing contact lenses in children ranging in age from 8 to 17 and to understand factors that influence an optometrist's decision to fit a child in contact lenses.¹

"The growing body of research in children's vision correction confirms that contacts provide collateral benefits to children beyond simply correcting their vision, including significantly improving how they feel about their physical appearance, acceptance among friends, and ability to play sports," said Jeffrey J. Wallace, O.D., Ph.D., Ohio State University College of Optometry and leader of the Adolescent and Child Health Initiative to Encourage Vision Empowerment (ACHIEVE) Study, the largest randomized trial of its kind.^{2,3} "Findings from the Children & Contact Lenses survey show that, increasingly, optometrists understand that children who need refractive error correction are capable of wearing and caring for soft contact lenses. The survey also shows that practitioners are

comfortable presenting the option of contact lens wear to children and parents when vision correction is required."

The methodology

A stratified, random sample of 4,004 AOA practicing member optometrists was mailed a survey on July 6, 2010. A total of 576 surveys were returned for a response rate of 14.4%. Virtually all the optometrists surveyed (97%) currently fit contact lens patients under the age of 18. The survey also found that patients younger than 18 account for about 41% of the total contact lens patient population in the practices of responding optometrists.

Nearly 8 of 10 (78%) respondents were practicing in major metropolitan areas, 14% were practicing in micropolitan areas (population more than 10,000 but less than 50,000), and 8% were practicing in rural areas. About two thirds (65%) of respondents were men. Three of 10 respondents (29%) were solo practitioners, 28% were employed in a nonretail setting, 28% were partners in group practices, 14% were employed in a retail setting, and 1% were in other practice settings. The majority of responses (39%) received were from optometrists who have been in practice for more than 25 years, 30% of responding optometrists have been in practice 11 to 24 years, 13% for 6 to 10 years, and 18% for 5 years or less.

The results

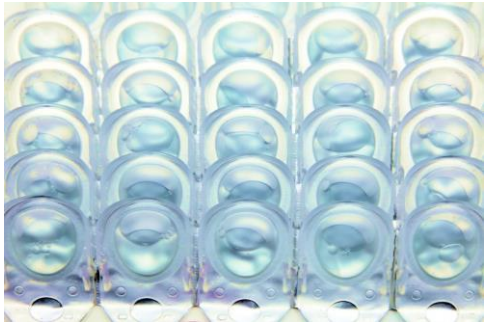
Responding optometrists most often fit children ages 8 to 9 (51%) and 10 to 12 (71%) in glasses as the primary method of vision correction and prescribe contact lenses as a secondary correction. However, a gradual shift in optometrists' approach to vision correction occurs as children get older, with 21% noting that they were more likely to fit 10- to 12-year-olds in contact lenses than they were a year prior. One of 5 respondents (20%) said they began prescribing contact lenses as the principal form of vision correction for children ages 10 to 12, nearly half (49%) prescribe contact lenses first for 13- to 14-year-olds, and two thirds (66%) recommend contact lenses as the main form of vision correction for 15- to 17-year-olds.

Of doctors who said they were now more likely to fit children in contact lenses, 30% attributed their change in fitting behavior to daily disposable lenses, 23% cited "improved contact lens materials," 19% said they were more likely to fit children with contact lenses because of requests from the child or parent, and 10% said that "recent research on contacts" on the subject, and children's participation in activities and sports, have influenced their decision.

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Reasons that eye care professionals are now more likely to fit children in contact lenses



30%

Availability of **daily disposable** lenses

23%

Improved contact lens **materials**

19%

Requests from the child or parent

10%

Recent **research** studies

10%

Participation in activities or **sports**

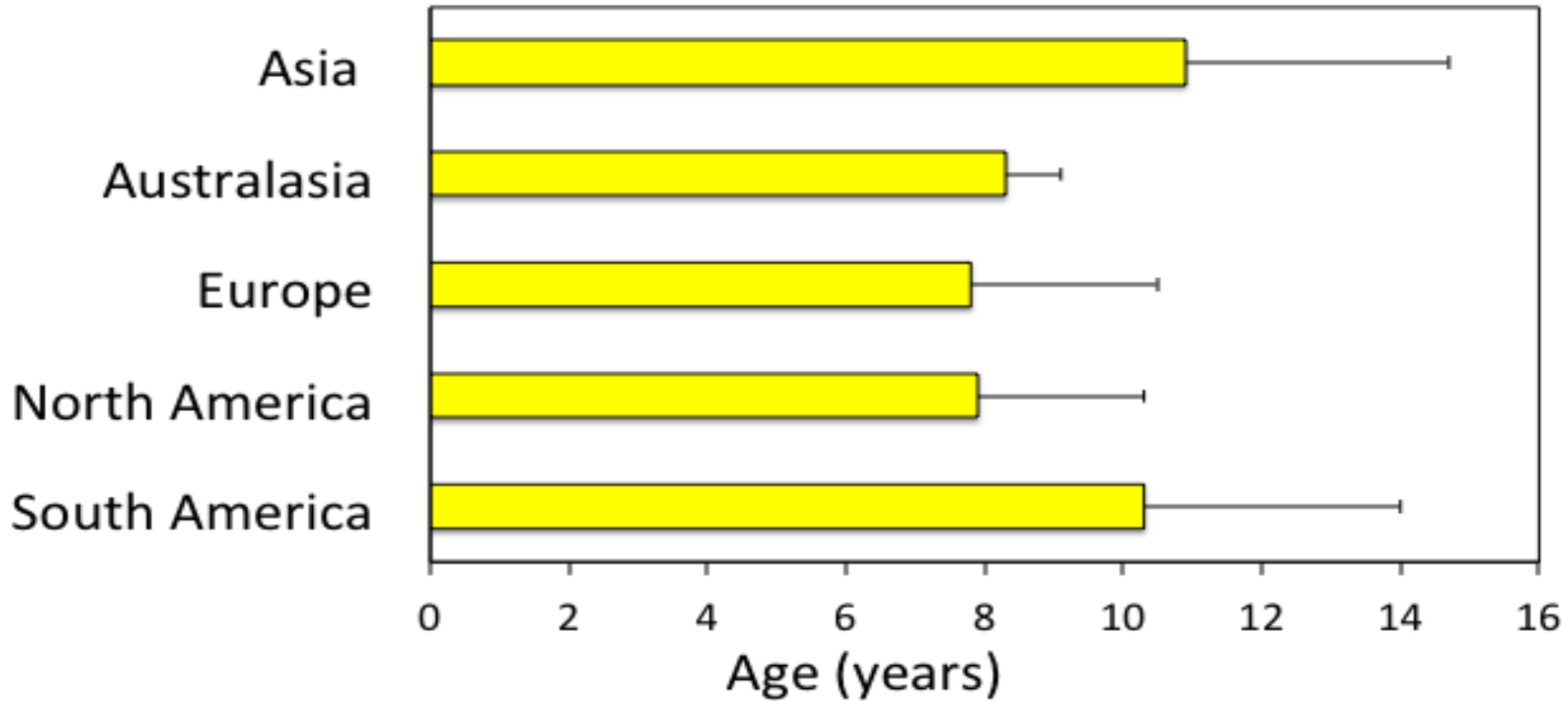


Attitudes to myopia correction and myopia control

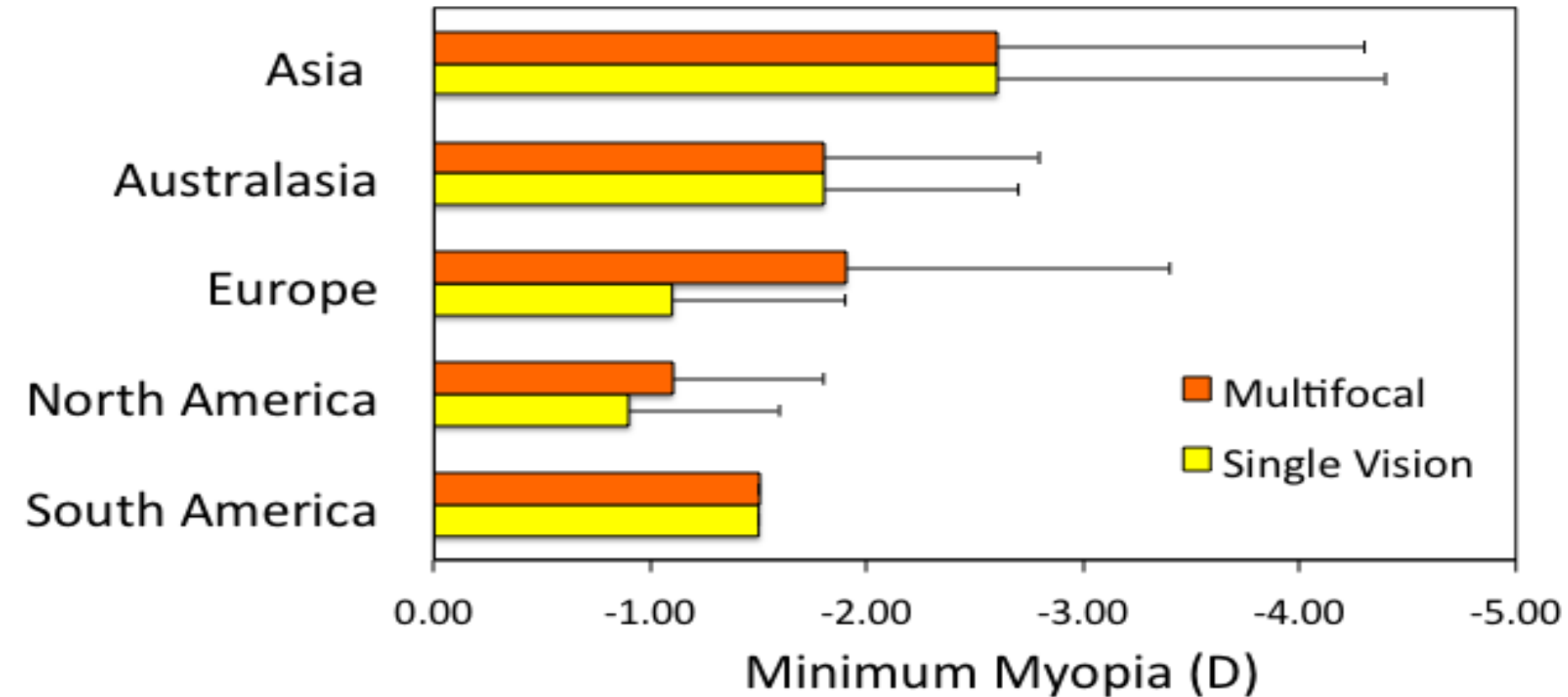
- Internet-based questionnaire distributed to eye care practitioners globally:
 - **Awareness** of increasing myopia prevalence,
 - Perceived **efficacy & adoption** of available strategies
 - And reasons for not adopting specific strategies.
- **971 respondents:**
 - Asia 291
 - Australasia 119
 - Europe 339
 - North America 133
 - South America 82



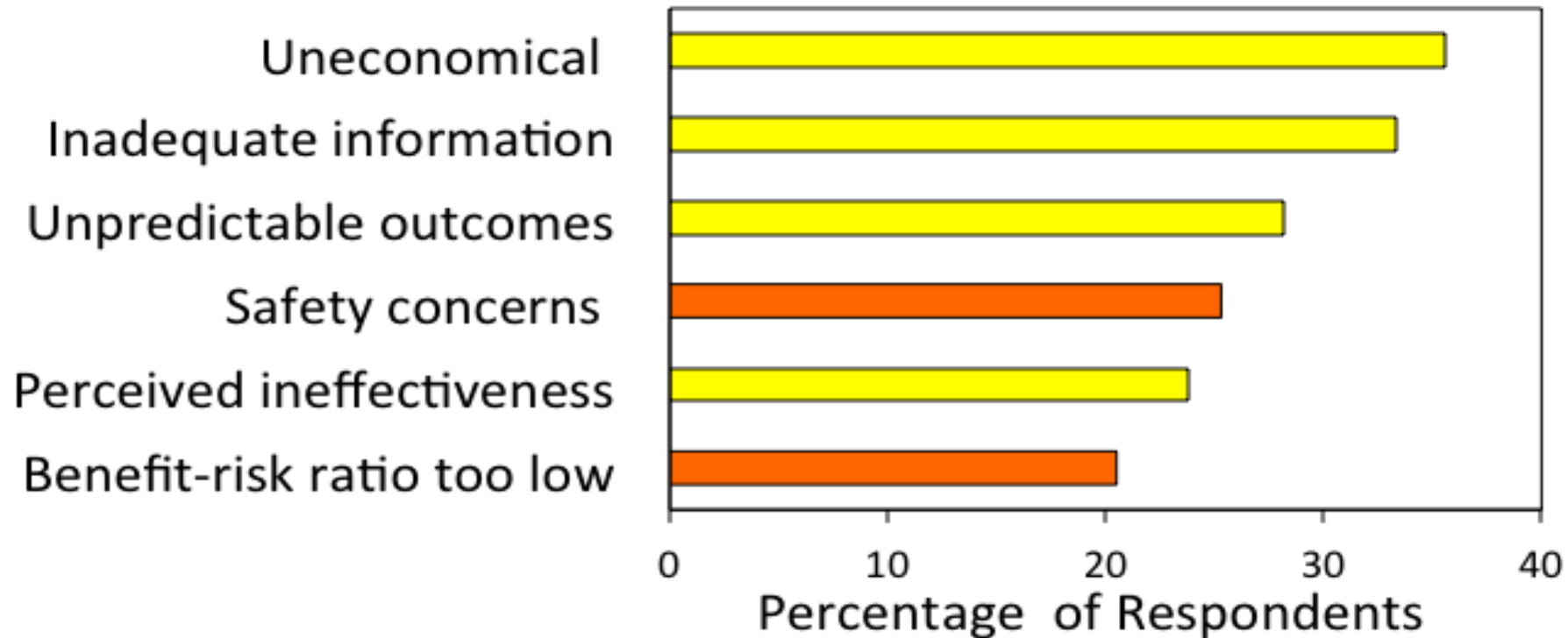
Youngest age for fitting SCLs



Minimum myopia for fitting SCLs



Reasons for not prescribing alternatives to single vision refractive corrections



If myopia control SCLs were available, would we fit more kids?



- Are we missing out on a practice **growth** opportunity?
- **Ethical** considerations?
- How **safe** is soft contact lens wear in children?



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Balancing the risks

Am I placing child at risk of
SCL-related infection?

**Lifetime risk of microbial
keratitis: daily wear (DD)**

1 in 64

Am I placing child at risk of
myopia associated pathology if
I do nothing different?

**Lifetime risk of retinal
detachment (> -5.00D)**

1 in 15



**Some basic, easy to interpret,
important statistics**



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“Statistics is never having to say you’re certain”



- Any estimate carries uncertainty
- For mean, it is expressed as **standard deviation**
- For incidence, convention is to report **95% confidence intervals** (95% CI)
- In opinion polls, they call it the “margin of error”

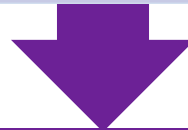


“Statistics is never having to say you’re certain”

For example:

If six cases observed during 723 patient years

Incidence is 83 per 10,000 patient years (95% CI: 34, 173)



In other words, over 10,000 patient years of wear

83 cases should be expected (as low as 34, as high as 173)

Upper limit is the more important number

Small samples lead to **broad** 95% CIs



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Reporting incidence of adverse events

Incidence of MK with loss of visual acuity in daily wear of SiHy SCLs:

0.00011, 95% CI: 0.00009, 0.00014



Easier to report and interpret as:

1.1 per 10,000 patient years, 95% CI: 0.9, 1.4



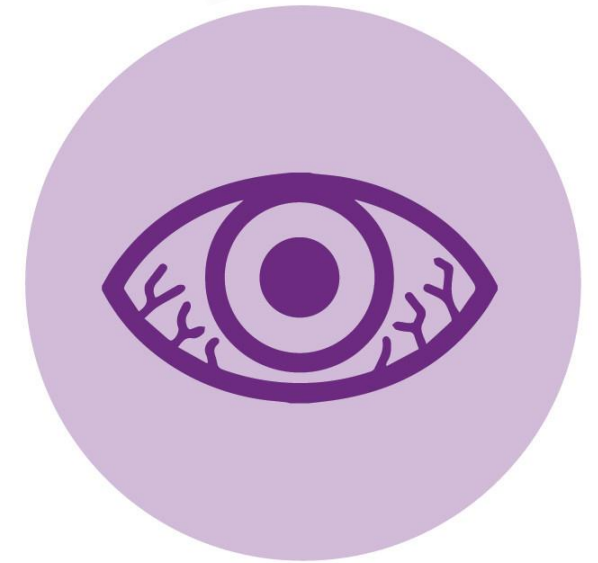
Serious adverse events

Microbial keratitis (MK)

- *pseudomonas, acanthamoeba*

Definition:

- “one or more **corneal stromal infiltrates** >1mm,
- **pain more than mild**, and
- one or more of following:
 - **anterior chamber reaction** more than minimal,
 - **mucopurulent discharge**, or
 - **positive corneal culture**”



Non-serious adverse events

Include:

- Contact lens-induced acute red eye (**CLARE**)
- Contact lens peripheral ulcer (**CLPU**)
- **Allergic conjunctivitis**
- Researchers often use '**corneal infiltrative events**' (**CIEs**) to indicate corneal involvement beyond mere staining or superficial punctate keratitis

Symptomatic CIEs:

defined as non-infectious infiltrate, hyperaemia, and discomfort



What can major epidemiological studies tell us about incidence of events in children wearing soft lenses?



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What can major epidemiological studies tell us?

Lens Type	Any Presumed Microbial Keratitis (95% CI)	“Severe” Microbial Keratitis (95% CI)	Microbial Keratitis With >2 Lines Vision Loss (95% CI)
Daily wear RGP	1.2 (1.1–1.5)	1.2 (1.1–1.5)	0 (0.0–0.0)
Pure DW soft	1.9 (1.8–2.0)	1.1 (1.1–1.2)	0.4 (0.4–0.4)
Pure DW DD soft	2.0 (1.7–2.4)	0.5 (0.5–0.6)	0 (0.0–0.0)
Pure DW SH	11.9 (10.0–14.6)	8.0 (6.7–9.8)	1.1 (0.9–1.4)
Occ O/N soft	2.2 (2.0–2.5)	1.8 (1.6–2.0)	0.2 (0.2–0.2)
Occ O/N DD soft	4.2 (3.1–6.6)	2.4 (1.7–3.7)	0 (0.0–0.0)
Occ O/N SH	5.5 (4.5–7.2)	5.3 (4.3–6.9)	1.6 (1.2–2.1)
Overnight wear soft*	19.5 (14.6–29.5)	13.3 (10.0–20.1)	4.0 (2.9–6.6)
Overnight wear SH	25.4 (21.2–31.5)	16.9 (14.1–20.9)	2.8 (2.3–3.5)
Any lens type	4.2 (3.4–5.5)	2.7 (2.2–3.5)	0.6 (0.5–0.7)

The Incidence of Contact Lens–Related Microbial Keratitis in Australia

Fiona Stapleton, PhD,^{1,2,3} Lisa Keay, PhD,^{2,3} Katie Edwards, BAAppSc (Optom),^{2,3}
Thomas Nadavilath, PhD,^{1,2,3} John K. G. Dart, DM,^{4,5} Garry Brian, FRANZCO,^{3,6} Brian A. Holden, DSc^{1,2,3,6}

Objective: To establish the absolute risk of contact lens (CL)-related microbial keratitis, the incidence of vision loss and risk factors for disease.

Design: A prospective, 12-month, population-based surveillance study.

Participants: New cases of CL-related microbial keratitis presenting in Australia over a 12-month period were identified through surveillance of all ophthalmic practitioners (numerator). Case detection was augmented by records’ audits at major ophthalmic centers. The denominator (number of wearers of different CL types in the community) was established using a national telephone survey of 35 914 individuals.

Testing: Cases and controls were interviewed by telephone to determine subject demographics and CL wear history. Visual outcomes were determined 6 months after the initial event. Annualized incidence and confidence intervals (CI) were estimated for different severities of disease and multivariable analysis was used in risk factor analysis.

Main Outcome Measures: Annualized incidence (with CI) of disease and vision loss by CL type and wear modality and identification of independent risk factors.

Results: We identified 285 eligible cases of CL-related microbial keratitis and 1798 controls. In daily wear rigid gas-permeable CL wearers, the annualized incidence per 10 000 wearers was 1.2 (CI, 1.1–1.5); in daily wear soft CL wearers 1.9 (CI, 1.8–2.0); soft CL wearers (occasional overnight use) 2.2 (CI, 2.0–2.5); daily disposable CL wearers 2.0 (CI, 1.7–2.4); daily disposable CL wearers (occasional overnight use) 4.2 (CI, 3.1–6.6); daily wear silicone hydrogel CL wearers 11.9 (CI, 10.0–14.6); silicone hydrogel CL wearers (occasional overnight use) 5.5 (CI, 4.5–7.2); overnight wear soft CL wearers 19.5 (CI, 14.6–29.5) and in overnight wear of silicone hydrogel 25.4 (CI, 21.2–31.5). Loss of vision occurred in 0.6 per 10 000 wearers. Risk factors included overnight use, poor storage case hygiene, smoking, Internet purchase of CLs, <6 months wear experience, and higher socioeconomic class.

Conclusions: Incidence estimates for soft CL use were similar to those previously reported. New lens types have not reduced the incidence of disease. Overnight use of any CL is associated with a higher risk than daily use.

Financial Disclosure(s): Proprietary or commercial disclosure may be found after the references. *Ophthalmology* 2008;115:1655–1662 © 2008 by the American Academy of Ophthalmology.



What can major epidemiological studies tell us?

- Three major papers collectively represent some **900 cases** of presumed or confirmed microbial keratitis¹⁻³
- *Only* report cases in patients **15 years and older**
- **Unclear** whether this represents **absence** of pediatric cases or a study design decision
- **Cannot assume** that cases of microbial keratitis **do not occur** in younger children

Stapleton et al. state that daily disposable CL wear “seems to be associated with the lowest risk of severe microbial keratitis”

1. Dart JK, Radford CF, Minassian D, et al. Risk factors for microbial keratitis with contemporary contact lenses: a case-control study. *Ophthalmology* 2008;115:1647-54,
2. Keay L, Edwards K, Stapleton F. Signs, symptoms, and comorbidities in contact lens-related microbial keratitis. *Optom Vis Sci* 2009;86:803-9.
3. Stapleton F, Keay L, Edwards K, et al. The incidence of contact lens-related microbial keratitis in Australia. *Ophthalmology* 2008;115:1655-62.



Incidence of corneal infiltrative events in adults



Authors	Lens Wear	Incidence (per 10,000 yrs)	95% CI
Chalmers et al. (2007)	30-night continuous wear of silicone hydrogel	329	284, 379
Chalmers et al. (2011)	Retrospective, mostly daily wear	432	361, 513
Szczotka-Flynn et al. (2014)	Daily wear of silicone hydrogel lenses, monthly replacement	316	116, 700
Carnt et al. (2009)	Multiple 3-month trials of various silicone hydrogel and solution combinations	2,061	1,455, 2,667

Chalmers RL, McNally JJ, Schein OD, et al. Risk factors for corneal infiltrates with continuous wear of contact lenses. *Optom Vis Sci* 2007;84:573-9.

Chalmers RL, Wagner H, Mitchell GL, et al. Age and other risk factors for corneal infiltrative and inflammatory events in young soft contact lens wearers from the Contact Lens Assessment in Youth (CLAY) study. *Invest Ophthalmol Vis Sci* 2011;52:6690-6.

Szczotka-Flynn L, Jiang Y, Raghupathy S, et al. Corneal inflammatory events with daily silicone hydrogel lens wear. *Optom Vis Sci* 2014;91:3-12.

Carnt NA, Evans VE, Naduvilath TJ, et al. Contact lens-related adverse events and the silicone hydrogel lenses and daily wear care system used. *Arch Ophthalmol* 2009;127:1616-23.



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What can major epidemiological studies tell us?...

...that children are rarely represented in large epidemiological studies of contact lenses



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Microbial keratitis in children...it happens!

- Several retrospective studies of **hospital populations** that include children
- Fong et al. (2004) **10-year study** of microbial keratitis at National Taiwan University Hospital
 - 453 patients of whom **only 22 were 15 years or younger** (4.9%)
 - Contact lens use accounted for **44%** of cases
 - ***pseudomonas*** is most common pathogen
 - **No details** are provided regarding ages of pediatric cases, severity, nor types of lenses worn
- Three other studies on children only....



Microbial keratitis in children...it happens!



Authors	Cases	Age	SCLs	Ortho-k	Other	Limitations
Hsiao et al. (2004)	78	≤16	31%	10%	59%	No data on: <ul style="list-style-type: none"> • Replacement schedule • Material • Daily vs. overnight wear
Lee et al. (2014)	67	≤16	34%	19%	47%	
Young et al. (2013)	18	≤18	44%	39%	17%	

Hsiao CH, Yeung L, Ma DH, et al. Pediatric microbial keratitis in Taiwanese children: a review of hospital cases. Arch Ophthalmol 2007;125:603-9.
 Lee YS, Tan HY, Yeh LK, et al. Pediatric microbial keratitis in Taiwan: clinical and microbiological profiles, 1998-2002 versus 2008-2012. Am J Ophthalmol 2014;157:1090-6.
 Young AL, Leung KS, Tsim N, et al. Risk factors, microbiological profile, and treatment outcomes of pediatric microbial keratitis in a tertiary care hospital in Hong Kong. Am J Ophthalmol 2013;156:1040-4.



**But surely there are studies of
safety of soft lenses in children?**



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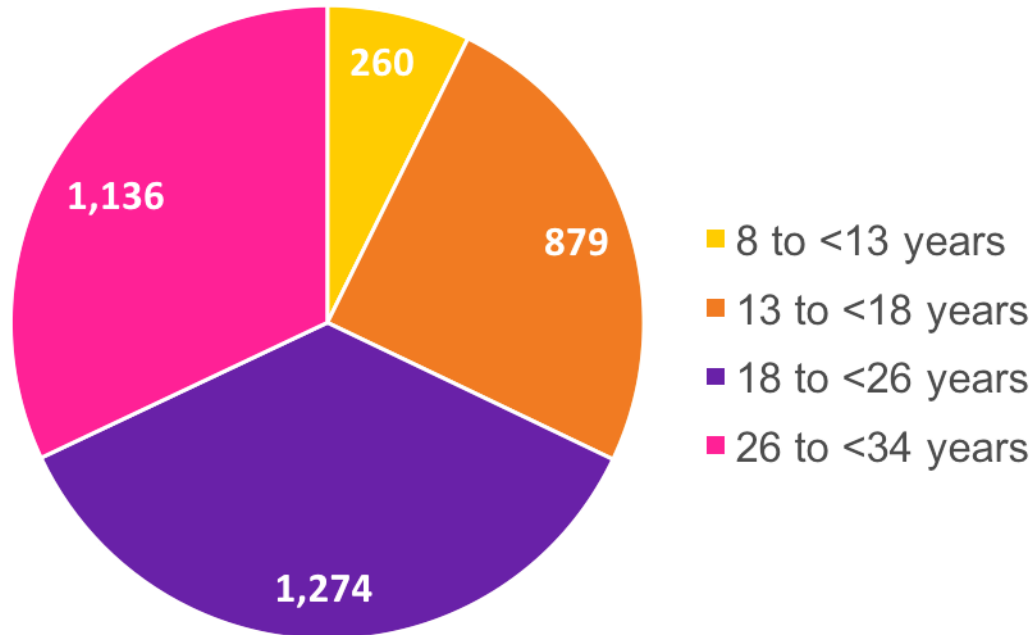
The Contact Lens Assessment in Youth (CLAY) study

- Multicenter, retrospective, **observational** study
- Evaluated **risk factors** that interrupt SCL wear among children, teenagers, and young adults in North America
- Assessed **safety profile** of SCL wear in pediatric population **outside** confines of prospective clinical studies
- Cohort represents patients presenting to **academic eye care clinics** for routine and problem-oriented eye care
- Includes both **habitual** and **newly prescribed** SCL wearers



The Contact Lens Assessment in Youth (CLAY) study

Reviewed charts from 3,549 patients (14,276 visits)



79% of existing SCL wearers had documented replacement schedule:

- 79% existing SCL wearers
- 21% new fits

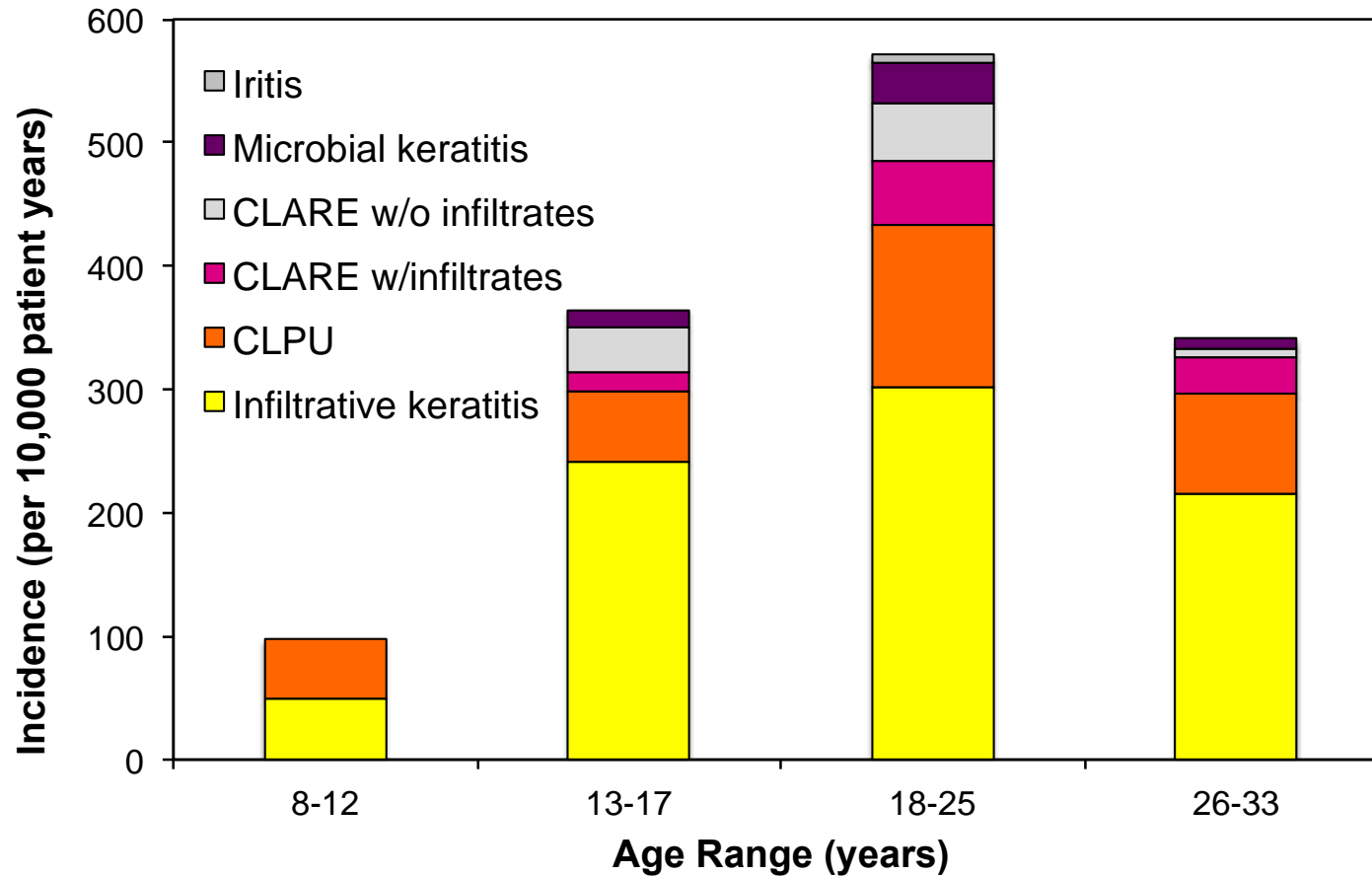
Frequency of adverse events in CLAY study

- **14,305** visits
- **4,663** SCL patient years
- Average of 20 months of SCL wear
- **187** corneal infiltrative events in 168 wearers

Reviewers masked to wearer age and CL parameters adjudicated events



“Age is a significant non-linear factor”



Cornea

Age and Other Risk Factors for Corneal Infiltrative and Inflammatory Events in Young Soft Contact Lens Wearers from the Contact Lens Assessment in Youth (CLAY) Study

Robb L. Chalmers,¹ Heidi Wagner,² G. Lynn Mitchell,³ Dawn Y. Lam,⁴ Beth T. Ktnoshita,⁵ Meredith E. Jansen,⁶ Kathryn Ritchdale,⁷ Luigina Sorbara,⁸ and Timothy T. McMahon⁹

Purpose. To describe age and other risk factors for corneal infiltrative and inflammatory events (CIEs) in young, soft contact lens (SCL) wearers and to model the age-related risk.

Methods. A multicenter, retrospective chart review of 3549 SCL wearers (8–33 years at first observed visit, +8.00 to −12.00D, oversampling <18 years) captured CIEs from January 2006 to September 2009. The review noted age, sex, SCL worn, use of lens care products, and SCL wearing history. Event diagnoses were adjudicated to consensus by reviewers masked to wearer identity, age, and SCL parameters. Significant univariate risk factors for CIEs were subsequently tested in multivariate generalized estimating equations.

Results. Charts from 14,305 visits observing 1,663 SCL years yielded 187 CIEs in 168 wearers. Age was a significant nonlinear risk factor, peaking between 15 and 25 years ($P < 0.008$). Less than 1 year of SCL use was protective versus longer years of wear ($P < 0.0005$). Use of multipurpose care products (2.86×), silicone hydrogels (1.85×), and extended wear (2.57×) were significantly associated with CIEs in the multivariate model ($P < 0.0001$ each).

Conclusions. Patient age, years of lens wear, use of multipurpose care products, silicone hydrogels, and extended wear were all significantly associated with CIEs with SCL wear. Use of SCLs in young patients aged 8 to 15 years was associated with a lower risk of infiltrative events compared with teens and young adults. In terms of safety outcomes, SCLs appear to be an acceptable method of delivering optics designed to manage myopia progression in children and young teens in the future. *Invest Ophthalmol Vis Sci.* 2011;52:6690–6696. DOI: 10.1167/iov.10.7018

Cornea Contact lens wearers younger than 25 years are at increased risk of corneal infiltrative events (CIEs) during continuous wear of silicone hydrogel SCLs, as shown in controlled, randomized, prospective clinical trials and observational studies.^{1,2} In addition to age under 25 years, overnight wear and smoking have also been confirmed as risk factors for CIEs with various types of SCLs and wearing schedules.^{3–7} Unlike microbial keratitis (MK), CIEs are not sight threatening, but they warrant careful study because they can be painful and difficult to differentiate from MK. These inflammatory and infiltrative events also require medical resources in the form of extra eye care visits and pharmaceutical management and may jeopardize the patient's ability or willingness to continue SCL wear. Although it is widely accepted that SCL wearers younger than 25 years are at higher risk for CIEs, SCL wearers younger than 18 have not been studied in sufficient numbers to establish the risk among children and teens or the lower age at which the risk abates. Because young patients are often excluded from registration trials for devices that are not specifically intended for pediatric use, there is a paucity of information on children and teenage SCL wearers, except in controlled clinical trials.^{1,8}

Current studies of human myopia suggest that progression of myopia is linked to peripheral hyperopic defocus.^{9,10} Early reports from animal and human trials suggested that the rate of myopia progression may be slowed by correcting peripheral refractive error, either biconically or monovisually.^{11–14} Treatments to prevent myopia progression will most likely require the application of adaptive optics directly on the corneal surface via SCLs, to maintain proper relationship with the defocus of the peripheral retina and to maximize the child's ability to wear lenses for more waking hours.¹⁵ With several SCL designs in development for the management of myopia progression in children and teens,¹⁶ there could be a sizeable increase in SCL prescriptions for myopic children and teens in the near future.¹⁷

In preparation for this potential increase in young SCL wearers who must wear SCLs for years, it is essential to establish the safety profiles for SCLs in children and teens outside of controlled clinical trials.^{18,19} In a recently published retrospective clinical chart review, the risk profile by age for all complications capable of interrupting lens wear was found to peak at younger than age 25, although that estimate did not control for

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⁷Supported by an unrestricted grant from CIBA Vision and ongoing logistical support from the American Optometric Association and the American Academy of Optometry Council on Research. The CLAY study team formed at the 2008 Summer Research Institute sponsored by the American Optometric Association and American Academy of Optometry Council on Research.

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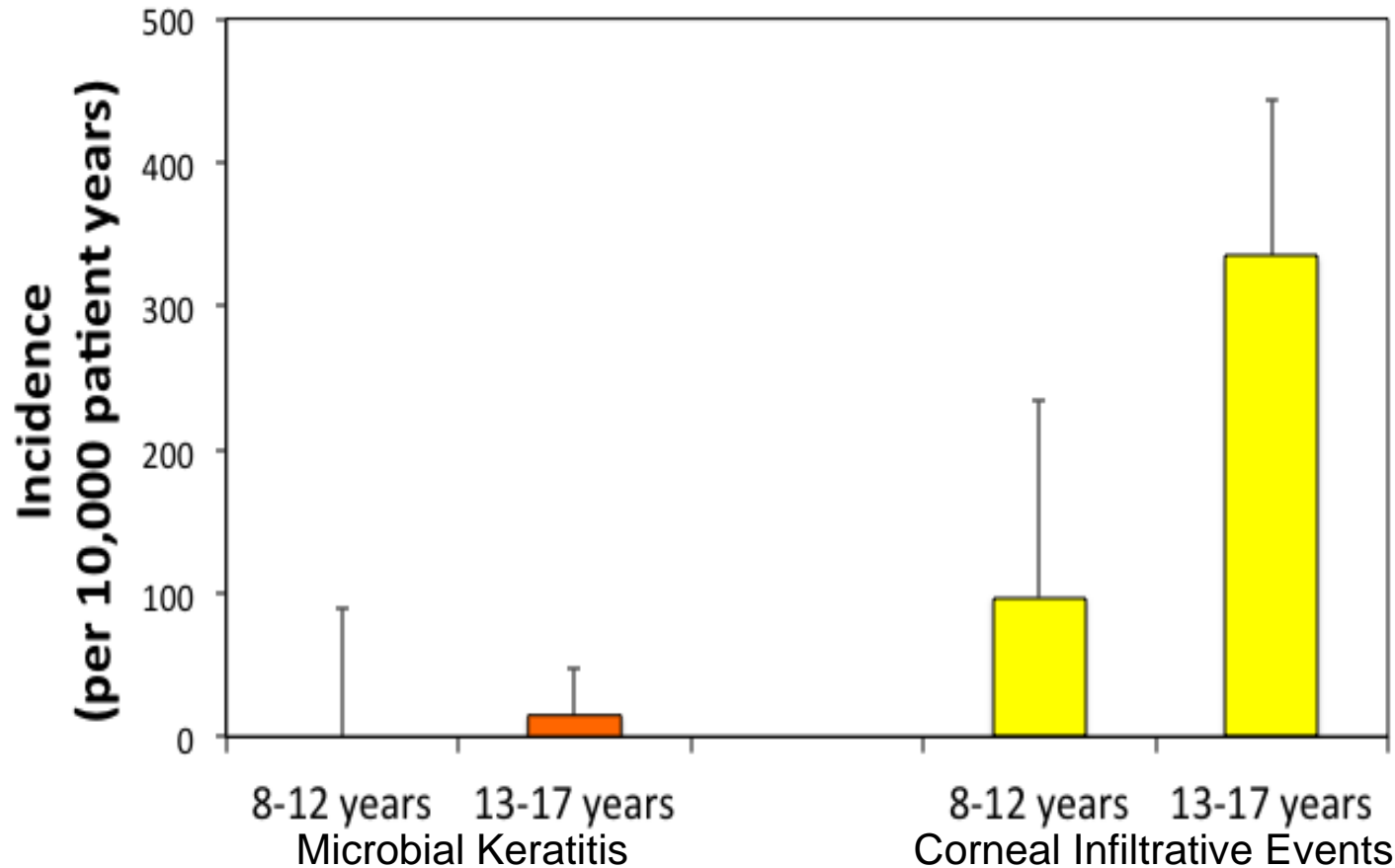
Disclosure: R.L. Chalmers, Ciba Vision (F, C, R), Alcon Research, Ltd. (C), Bausch & Lomb (C, R), Johnson & Johnson Vision Care (C, R); H. Wagner, Ciba Vision (F, C, R), Alcon Research, Ltd. (C), Bausch & Lomb (C, R); G.L. Mitchell, Ciba Vision (F, D, Y, Lam, Ciba Vision (F); B.T. Ktnoshita, Ciba Vision (F); M.E. Jansen, Ciba Vision (F); K. Ritchdale, Ciba Vision (F); L. Sorbara, Ciba Vision (F); T.T. McMahon, Ciba Vision (F).

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Chalmers RL, Wagner H, Mitchell GL, et al. Age and other risk factors for corneal infiltrative and inflammatory events in young soft contact lens wearers from the Contact Lens Assessment in Youth (CLAY) study. *Invest Ophthalmol Vis Sci* 2011;52:6690-6.

Incidence of MK and CIEs in CLAY study



Cornea

Age and Other Risk Factors for Corneal Infiltrative and Inflammatory Events in Young Soft Contact Lens Wearers from the Contact Lens Assessment in Youth (CLAY) Study

Robin L. Chalmers,¹ Heidi Wagner,² Lynn Mitchell,³ Dawn Y. Lam,⁴ Beth T. Ktnoshita,⁵ Meredith E. Jansen,⁶ Kathryn Ritchdale,⁷ Luigina Sorbara,⁸ and Timothy Y. McMahon⁹

PURPOSE. To describe age and other risk factors for corneal infiltrative and inflammatory events (CIEs) in young, soft contact lens (SCL) wearers and to model the age-related risk.

METHODS. A multicenter, retrospective chart review of 3549 SCL wearers (8–33 years at first observed visit, +8.00 to −12.00D, oversampling <18 years) captured CIEs from January 2006 to September 2009. The review noted age, sex, SCL worn, use of lens care products, and SCL wearing history. Event diagnoses were adjudicated to consensus by reviewers masked to wearer identity, age, and SCL parameters. Significant univariate risk factors for CIEs were subsequently tested in multivariate generalized estimating equations.

RESULTS. Charts from 14,305 visits observing 1,663 SCL years yielded 187 CIEs in 168 wearers. Age was a significant nonlinear risk factor, peaking between 15 and 25 years ($P < 0.008$). Less than 1 year of SCL use was protective versus longer years of wear ($P < 0.0005$). Use of multipurpose care products (2.86×), silicone hydrogels (1.85×), and extended wear (2.57×) were significantly associated with CIEs in the multivariate model ($P < 0.0001$ each).

CONCLUSIONS. Patient age, years of lens wear, use of multipurpose care products, silicone hydrogels, and extended wear were all significantly associated with CIEs with SCL wear. Use of SCLs in young patients aged 8 to 15 years was associated with a lower risk of infiltrative events compared with teens and young adults. In terms of safety outcomes, SCLs appear to be an acceptable method of delivering optics designed to manage myopia progression in children and young teens in the future. *Invest Ophthalmol Vis Sci.* 2011;52:6690–6696. DOI: 10.1167/iov.10.7018

Contact lens wearers younger than 25 years are at increased risk of corneal infiltrative events (CIEs) during continuous wear of silicone hydrogel SCLs, as shown in controlled, randomized, prospective clinical trials and observational studies.^{1–4} In addition to age under 25 years, overnight wear and smoking have also been confirmed as risk factors for CIEs with various types of SCLs and wearing schedules.^{1–4} Unlike microbial keratitis (MK), CIEs are not sight threatening, but they warrant careful study because they can be painful and difficult to differentiate from MK. These infiltrative and inflammatory events also require medical resources in the form of extra eye care visits and pharmaceutical management and may jeopardize the patient's ability or willingness to continue SCL wear. Although it is widely accepted that SCL wearers younger than 25 years are at higher risk for CIEs, SCL wearers younger than 18 have not been studied in sufficient numbers to establish the risk among children and teens or the lower age at which the risk abates. Because young patients are often excluded from registration trials for devices that are not specifically intended for pediatric use, there is a paucity of information on children and teenage SCL wearers, except in controlled clinical trials.^{1–4}

Current studies of human myopia suggest that progression of myopia is linked to peripheral hyperopic defocus.^{5,6} Early reports from animal and human trials suggested that the rate of myopia progression may be slowed by correcting peripheral refractive error, either biconically or monovisually.^{7–14} Treatments to prevent myopia progression will most likely require the application of adaptive optics directly on the corneal surface via SCLs, to maintain proper relationship with the defocus of the peripheral retina and to maximize the child's ability to wear lenses for more waking hours.¹⁵ With several SCL designs in development for the management of myopia progression in children and teens,¹⁶ there could be a sizeable increase in SCL prescriptions for myopic children and teens in the near future.¹⁷

In preparation for this potential increase in young SCL wearers who must wear SCLs for years, it is essential to establish the safety profiles for SCLs in children and teens outside of controlled clinical trials.^{18,19} In a recently published retrospective clinical chart review, the risk profile by age for all complications capable of interrupting lens wear was found to peak at younger than age 25, although that estimate did not control for

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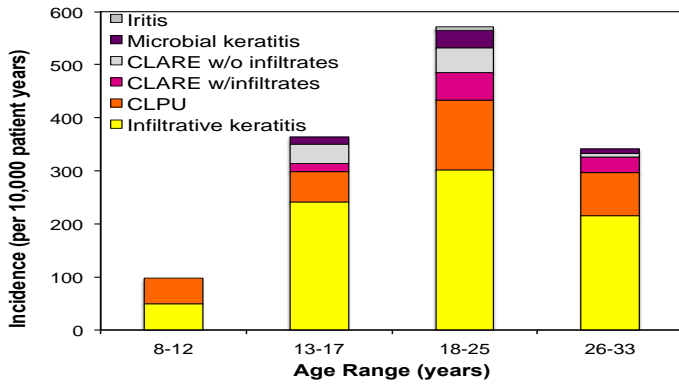
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➔ **Effect of age: behaviour, *not* biology**

Shower in CLs



#Times cold/flu



Nap in CLs



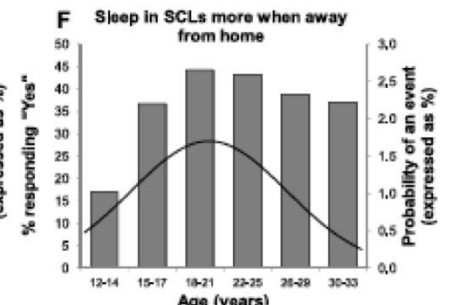
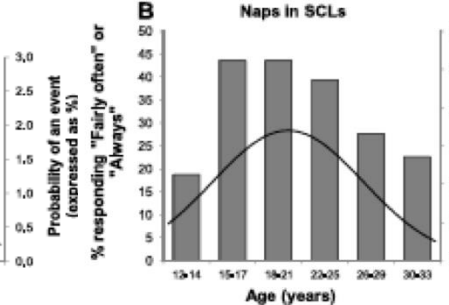
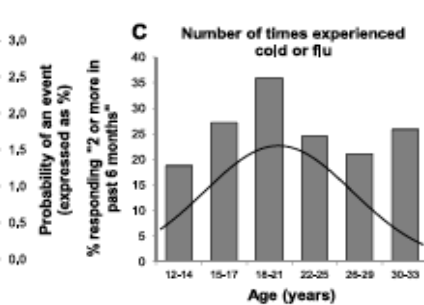
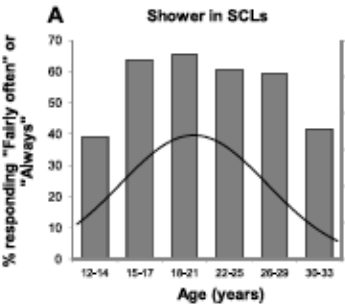
#Nights sleep <6hrs



Sleep in CLs: after alcohol



Sleep in CLs: away from home



Chalmers RL, Wagner H, Mitchell GL, et al. Age and other risk factors for corneal infiltrative and inflammatory events in young soft contact lens wearers from the Contact Lens Assessment in Youth (CLAY) study. Invest Ophthalmol Vis Sci 2011;52:6690-6.



What about *prospective* studies of safety of soft lenses in children?



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ORIGINAL ARTICLE

Contact Lenses in Pediatrics (CLIP) Study: Chair Time and Ocular Health

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The Ohio State University College of Optometry, Columbus, Ohio (JW, LAJ, DAB, MCJ, New England College of Optometry, Boston, Massachusetts (MJR, NQ), and University of Houston College of Optometry, Houston, Texas (REM, AG, AK)

ABSTRACT
Purpose: Despite several studies that show 8- to 11-year-old children are capable of wearing a various contact lens modalities, parents often report that their eye care practitioner would not fit their child with contact lenses until the child was about 13 years old. We conducted the Contact Lenses in Pediatrics (CLIP) Study to compare contact lens fitting and follow-up between 8- to 12-year-old children and 13- to 17-year-old teenagers.
Method: At the baseline visit, all subjects underwent a contact lens fitting, including visual acuity, a manifest refraction, autorefraction, and biometry. Subjects then underwent contact lens insertion and removal training, which consisted of talking about contact lens care as well as inserting and removing a contact lens three times. Subjects returned for follow-up visits at 1 week, 1 month, and 3 months, and visual acuity, contact lens fit assessment, and biometry were performed. The time of the fitting, the insertion and removal training, and each follow-up visit were measured individually and added for a total chair time. Biometry examinations were conducted according to a standardized protocol.
Results: We enrolled 84 children and 85 teens in the study. Of the 169 subjects, 93 (55.0%) were female, 78 (46.2%) were white, 44 (23.3%) were Hispanic, and 28 (17.6%) were black. The mean (\pm SD) total chair time for children was 110.6 \pm 39.2 min, significantly more than 65.3 \pm 25.2 min for teens (Student's *t* test, $p = 0.003$). Most of the difference was caused by insertion and removal training, which lasted 41.9 \pm 32.0 min for children and 30.3 \pm 20.2 min for teens (Student's *t* test, $p = 0.01$). The presence of conjunctival staining increased from 7.1% of the subjects at baseline to 19.9% of the subjects at 3 months (χ^2 , $p = 0.0006$), but the changes were similar between children and teens. No other biometry signs increased significantly over the 3-month period.
Conclusions: The total chair time for children is approximately 15 min longer than teens, but most of that difference is explained by longer time spent teaching children insertion and removal. Because insertion and removal is generally taught by staff members, the eye care practitioner's time with the patient is similar between children and teens. Furthermore, neither children nor teens experienced problems related to contact lens wear during the study. Eye care practitioners should consider routinely offering contact lenses as a treatment option, even for children 8 years old.
Optom Vis Sci 2007;84:896-902

Key Words: contact lenses, pediatrics, silicone hydrogel, chair time, children, teenagers

Children require contact lenses for a variety of reasons. They may require contact lens wear because of aphakia,^{1,2} ocular trauma,^{3,4} anisometropia therapy,^{5,6} or refractive error. Contact lenses for aphakia, trauma, and anisometropia therapy may be medically necessary, but contact lenses for refractive error are generally elective: as eye care practitioners, parents, and children must decide together whether a child should be fitted for contact lenses and, if so, when.

Many children require vision correction as an early age because myopic refractive error typically develops at about 8 years of age.^{15,16} There is less consensus about the timing of a correction of moderate, hyperopic or astigmatic refractive errors, and these errors may not be identified until children begin to perform concentrated near work activities, typically around the age of 6 to 7 years. Contact lenses may therefore be used to correct refractive error beginning early in life.

Contact Lenses in Pediatrics Study in Singapore

Lim Li, F.R.C.S., Kurt Moody, D.O., Donald T.H. Tan, F.R.C.S., Khoo Chong Yew, F.R.C.S., Por Yung Ming, F.R.C.S., and Quah Boon Long, F.R.C.S.

Purpose: Previous studies in the United States have evaluated the benefits of soft contact lenses (CLs) in 8- to 12-year-old children and 13- to 17-year-old teens. This study was undertaken in Singapore and evaluated the safety, efficacy, and physiologic performance of daily disposable soft lenses in a population of children.
Methods: In this open-label, bilateral, 3-month dispensing study, 59 children (8-11 years) were fit with standard A spherical or toric daily disposable lenses (1-DAY ACUVUE or 1-DAY ACUVUE for ASTIGMATISM, Visioline, Jacksonville, FL). All subjects were non-physics requiring visual correction in both eyes. The refractive inclusion criteria was plano to -9.00 diopter (D) with astigmatism of ≤ 2.00 DC in both eyes, or hyperopia of +0.50 to +6.00 D with astigmatism of ≤ 1.75 D or less. The subjects underwent follow-up evaluations, which included a questionnaire for parents and subjects, at 1 week, 1 month, and 3 months.
Results: Of the 59 subjects enrolled, 52 (88%) completed the study successfully. Six subjects were discontinued because of lens handling difficulties (four) and unacceptable lens fit (one), and an adverse event (one). Adverse events were reported in three subjects, including the discontinuation, and in each case due to a challenge. Overall vision quality, overall comfort, and end-of-day comfort were graded significantly better at each of the follow-up visits compared with baseline with spectacle correction. All subjects had no adverse events or complications. All subjects were able to independently wear and care for their lenses successfully and hence, should be considered as a treatment option for this age group.
Conclusions: A study evaluating the use of daily wear, reusable, silicone hydrogel CLs in children (8-11 years) and teens was conducted in the United States. The Contact Lenses in Pediatrics (CLIP) study¹⁵ concluded that both the groups benefited from significant improvements to their quality of life with CL wear and improved how they felt about their appearance and participation in activities. The chair-time involved in fitting children was similar to that required for teens, although insertion and removal (I&R) training took slightly longer time. However, once trained, the younger children were equally adept at I&R and their average wearing time (WT) and comfort was similar to that of the teens. Contact lenses also significantly improved the quality of life of the subjects as was seen in how both children and teenagers believed about their appearance and participation in activities.
Singapore: is an industrialized, urban, prosperous city-state in South East Asia, where three quarters of the resident 4.5 million population are Chinese, with Malay and Indian making up much of the remainder. Both the incidence and progression rates of myopia are higher in Singaporean children than in the west.¹⁶ A prospective cohort study conducted on 981 Singaporean children older than 3 years showed incidence rates of 21% to 48% for 7- to 9-year-old children, with the rates being higher in children of Chinese ethnicity (50% vs. 27%). Additionally, around one third of

children were fit with standard A spherical or toric daily disposable lenses (1-DAY ACUVUE or 1-DAY ACUVUE for ASTIGMATISM, Visioline, Jacksonville, FL). All subjects were non-physics requiring visual correction in both eyes. The refractive inclusion criteria was plano to -9.00 diopter (D) with astigmatism of ≤ 2.00 DC in both eyes, or hyperopia of +0.50 to +6.00 D with astigmatism of ≤ 1.75 D or less. The subjects underwent follow-up evaluations, which included a questionnaire for parents and subjects, at 1 week, 1 month, and 3 months.
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Contact Lens Anterior Eye 18 (2015) 419-423



Contact lens fitting and training in a child and youth population

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1. Introduction

A study reviewing data from the National Health and Nutrition Examination Survey suggested that the prevalence of myopia in children is increasing in the United States [1]. For children aged 12-17, the prevalence of myopia was 12% in 1971, increasing to 21.2% by 1999-2004 [1]. Children who require vision correction at a young age may benefit from contact lens wear, and all options for correction should be considered and be part of the discussion process with the child and their parent(s). Contact lenses provide advantages of increased magnification for myopes, unobstructed field of view and the absence of prismatic peripheral field distortion, all of which are beneficial regardless of age [2].

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ABSTRACT

Purpose: To determine the ease with which children and youths without previous soft contact lens (SCL) experience were able to handle care for, adapt and be fitted with SCLs.
Methods: 179 children aged 8-16 were recruited. Study visits included: screening and training visits, 1 week and 3 months follow-up. During the training visit, the three tasks to demonstrate proficiency in lens insertion and removal and care was recorded. A second training visit was scheduled if necessary.
Results: Nine children did not complete the screening visit and eight discontinued during the study of three visits, seven discontinued during the first visit and one before the 3-month visit. Of those recruited, 161 (90.5%) were successfully fitted and completed the study. A majority of children were dispensed with lenses at the first training visit (104/161, 64.6%). The mean training time for all children was 30 min. There were no statistically significant differences in the number of lenses required to fit or instruction time by age group ($p > 0.05$) or gender ($p > 0.05$). Contact lens users (CLUs, 9/17) required a second training visit with four still unable to handle lenses (2/5, 4/17) by the 1 week visit (2/25, 2/27) or participants either lost or wore lenses, no subsequent lost or torn lenses occurred. No serious adverse events occurred during the study.
Conclusions: Children and youths with no previous contact lens experience were easily fitted, able to successfully wear and care for lenses. The results of this study should encourage practitioners to recommend SCLs as a vision correction option.
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2. Methods

However, according to Smith and Ribey [3] practitioners appear reluctant to recommend contact lenses as a refractive correction option to parents for their young children, noting that preference for spectacles compared to contact lenses was highest for younger children and fitting contact lenses as a preference occurred when the child reached 13-14 years of age. Effen et al. [4] reported data from their international fitting survey for children with contact lenses, that minors (under 18 years) represented only 13% of the total fit reported and that a majority were fitted to teenagers, possibly indicating a reluctance to fit younger in age. This reluctance could be due to concerns that younger children may not be mature enough to handle and care for contact lenses, or that the fitting of contact lenses designed for adult eyes will either be unsuccessful or take more chair time.
 Practitioners may have the view that risks associated with contact lens wear are too great to consider this as a viable option for children. With respect to safety concerns, a study reviewing National ID data indicated that contact lens wear may not be as safe for children as for adults [5]. This study reported that contact lenses accounted for 22% of medical device associated serious adverse events in paediatric populations. However, most of the adverse

ORIGINAL ARTICLE

Daily Disposable Contact Lenses versus Spectacles in Teenagers

Andrew J. Plowright^a, Carole Maldonado-Codina^a, Gillian F. Howarth^a, Jami Kerr^b, and Philip B. Morgan^a

ABSTRACT

Purpose: To compare clinical and subjective quality-of-life (QoL) data for teenagers wearing daily disposable contact lenses or spectacles.
Methods: This open-label study randomized subjects (aged 13 to 19 years) with no previous contact lens wear experience to wear Hikon A (BAEES AquaComfort Plus) contact lenses or spectacles for 6 months. A full clinical workup, as well as subjective QoL measures using the Pediatric Refractive Error Profile and Quality of Life Impact of Refractive Correction questionnaires, was conducted at baseline and at week 4 and month 3 and 6, with an additional study visit at week 2 for subjects randomized to wear contact lenses.
Results: A total of 110 teenagers were enrolled in the study; 13 discontinued before study completion, 10 (12.5%) from the contact lens group and 3 (5.7%) from the spectacle group ($p = 0.04$). Visual acuity was good for both groups at all study visits. Biometry assessments were similar at baseline for both groups. Significant differences in Pediatric Refractive Error Profile responses were noted between vision correction groups across visits for appearance ($p < 0.001$), satisfaction ($p < 0.001$), activities ($p < 0.001$), peer perception ($p < 0.003$), and overall score ($p < 0.001$). For Quality of Life Impact of Refractive Correction, the contact lens group gave more favorable responses than the spectacle group ($p < 0.02$). After 6 months of wearing contact lenses, teenagers had a more positive attitude toward comfort, vision, and safety with contact lenses. No serious adverse events were reported during the study.
Conclusions: The daily disposable lenses used in this study are suitable for vision correction for teenagers, offering improvements in QoL measures during the first months of wear, including appearance, satisfaction, activities, and peer perceptions, without negatively impacting vision or eye health. Teenagers were able to handle contact lenses with the same amount of confidence as spectacles.
Optom Vis Sci 2015;92:44-52

Key Words: daily disposable, contact lens, teenagers, quality of life, randomized controlled study

For teenagers who require vision correction, contact lenses are a viable alternative compared with spectacles.¹⁻⁴ Previous studies have demonstrated that contact lens wear can have a positive impact on teenagers, particularly those who participate in sports, and for those who wish to improve self-perception of appearance and acceptance by peers.⁴⁻⁶ These effects ultimately lead to the wearer having greater satisfaction with his or her vision correction method.^{4,5} Teenagers who wear contact lenses tend to have a longer total vision correction time per week compared with those who correct their vision with spectacles alone.⁴ Nevertheless, some eye care practitioners may be reluctant to prescribe contact lenses for teenagers. This, in part, may be because of concerns regarding the anticipated time required to educate young wearers about the safe use and correct use of contact lenses. Eye care practitioners may also have general concerns regarding safety and overall compliance in this age group. Recent studies, however, have shown that daily disposable contact lenses are suitable for vision correction in teenagers.⁷⁻⁹ Moreover, children younger than 14 years appear to be at lower risk of ocular events that interrupt contact lens wear compared with older teenagers or young adults.^{7,8}
 Daily disposable contact lenses are designed to be worn once and then replaced with a new pair of lenses the following day, with the advantage that there is no lens care system or overnight storage

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- Plowright AJ, Maldonado-Codina C, Howarth GF, et al. Daily disposable contact lenses versus spectacles in teenagers. *Optom Vis Sci* 2015;92:44-52.



Fitting children with SCLs

- Four studies¹⁻⁴
- 55 to 179 children and teenagers
- Most document only three months of wear
- **Three CIEs in 116 patient years of wear**



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SCL myopia control

- Growing list of publications of myopia control using multifocal SCLs in children
- **Only 1 of 9 report any safety outcomes**



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Six studies report safety outcomes with >150 patient years



- Let's look at the three largest.....



CooperVision®

Walline et al. (2009) - ACHIEVE study

- Assessed influence of SCLs on myopia progression and self-esteem
- **584 myopic children** (8 to 11 yrs), 5 US clinical centres
- 237 randomised to wear spectacles
- 247 randomised to:
1-Day ACUVUE® daily disposable (93%) or ACUVUE® 2 biweekly replacement SCLs (7%)
- **9 contact lens wearers (3.7%) experienced 13 adverse events**

1-Day ACUVUE® and ACUVUE® 2 are trademarks of Johnson and Johnson Medical Limited

Walline JJ, Jones LA, Sinnott L, et al. Randomized trial of the effect of contact lens wear on self-perception in children. *Optom Vis Sci* 2009;86:222-32.



Walline et al. (2009) - ACHIEVE study

- 6 cases of “keratitis”
 - **Not MK** - confirmed by communication from Jeff Walline
- Classifying as **corneal infiltrative events**:
 - **Incidence:**
83 per 10,000 patient years (95% CI: 34, 173)



Sankaridurg et al. (2013) - BHVI

- **240 children** aged 7 to 14 years in randomized clinical trial
- Lotrafilcon B silicone hydrogel worn on daily wear, monthly replacement schedule
- 189 children completed 1 year of contact lens wear
- 170 children completed 2 years
- **No events of microbial keratitis although 55 non-serious adverse events**



Sankaridurg et al. (2013) - BHVI

Adverse event	Number of cases (%)
Microbial keratitis	0 (0)
Contact lens papillary conjunctivitis	16 (4.1)
Superior epithelial arcuate lesions	6 (1.5)
Corneal erosions	8 (2.1)
Infiltrative keratitis	5 (1.3)
Asymptomatic infiltrative keratitis	7 (1.8)
Asymptomatic infiltrates	13 (3.4)

**Incidence of symptomatic CIE:
136 per 10,000 patient years (95% CI: 50, 300)**

ORIGINAL ARTICLE

Adverse Events during 2 Years of Daily Wear of Silicone Hydrogels in Children

Padmaja Sankaridurg^{*}, Xiang Chen[†], Thomas Naduvilath[‡], Percy Lazon de la Jara[§], Zhi Lin[¶], Li Li[¶], Earl L. Smith, III[¶], Jian Ge^{**}, and Brian A. Holden[†]

ABSTRACT
Purpose. Type and incidence of adverse events and rate of discontinuations for 2 years of daily wear with silicone hydrogel contact lenses in Chinese children with myopia.
Methods. Two hundred forty children aged 7 to 14 years were enrolled in a prospective randomized clinical trial from November 2008 to April 2009. Children with myopia of up to -3.50 diopters (D) spherical equivalent with astigmatism less than or equal to -0.75 D were randomized to one commercial and three experimental lens designs of Lotrafilcon B silicone hydrogel lenses (four groups) used bilaterally on a daily wear, monthly replacement schedule. The main outcome measures were incidence per 100 patient-years (incidence, in percentage) of adverse events and rate of discontinuations.
Results. There were no events of microbial keratitis. Fifty-five adverse events (incidence, 14.2%) were seen. There were also 12 recurrent events. The type and incidence percentage were contact lens papillary conjunctivitis (16 events, 4.1%), superior epithelial arcuate lesions (SEALs, six events, 1.5%), corneal erosions (eight events, 2.1%), infiltrative keratitis (five events, 1.3%), asymptomatic infiltrative keratitis (seven events, 1.8%), and asymptomatic infiltrates (13 events, 3.4%). There were differences in the incidence of SEALs between groups ($p = 0.023$), with the incidence of SEALs being greater with one of the experimental designs. No event resulted in any vision loss. Seventy participants (29.2%) discontinued, with one-third (26 participants, 10.8%) occurring in the first month of lens wear. Discomfort and non-lens-related reasons such as safety concern and discomfort were frequently cited reasons for discontinuations.
Conclusions. Adverse events with daily wear of silicone hydrogels in children were mainly mechanical in nature, and significant infiltrative events were few. The large number of dropouts in the early days of lens wear and their reasons for discontinuation suggest that adaptation and patient motivation are critical for survival in lens wear.
Optom Vis Sci 2013;90:961-9.

Key Words: contact lenses, children, adverse events, dropouts, silicone hydrogel contact lenses

A range of childhood disorders of the eye such as keratoconus, amblyopia, pediatric aphakia, and common refractive errors such as myopia can be effectively managed with contact lenses.¹⁻³ Also, importantly, evidence suggests that contact lenses may play a significant role in controlling the progression of myopia.⁴⁻¹⁰ Despite the utility of contact lenses in children, there exists a general perception that contact lenses are not suitable for use in children. This concern stems from two areas (1) handling and care of contact lenses by children and (2) safety of contact lens wear, that is, the risk of developing contact lens-related complications. With regard to handling and managing contact lens wear, there now exists evidence that children aged 8 years and older can independently manage lens insertion and removal and also successfully wear contact lenses.¹¹ There have been reports of microbial keratitis with contact lens wear in children and were mainly case reports or case series attending emergency departments and involving overnight lens wear or other predisposing risk factors. Although this information is useful in identifying the issue, there is little evidence from large well-designed clinical trials on the rate of complications with long-term use of contact lens wear in children.

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CooperVision® MiSight® 1 day: data from 3-year clinical trial

- 8–12 year olds randomized to **MiSight® 1 day** or **Proclear® 1 day**
- 132 subjects received allocated intervention
- 344 documented patient years of lens wear
- **No cases of microbial keratitis over 3 year trial**
- 4 corneal infiltrative events
 - Incidence:
116 per 10,000 patient years (95% CI: 37, 280)
 - All observed at scheduled visits, so *asymptomatic*
- **Incidence of symptomatic CIE:
0 per 10,000 patient years (95% CI: 0, 108)**



CooperVision®

Summary:

Incidence of CIEs in children (per 10,000 yrs)

Authors	Lenses and Replacement Schedule	Age	Patient Yrs	Incidence	95% CI
Walline et al. (2004)	1-week replacement hydrogel	8–11	159	0	0, 233
Sankaridurg et al. (2011)	Monthly replacement silicone hydrogel	7–14	369	136	50, 300
Walline et al. (2011)	Daily disposable hydrogel (93%)	8–11	723	83	34, 173
Chalmers et al. (2015)	Daily disposable silicone hydrogel (50%) and hydrogel (50%)	8–17	171	0	0, 216
Cheng et al. (2016)	Daily disposable silicone hydrogel	8–11	262	0	0, 141
MiSight® 1 day study	Daily disposable hydrogel	8–12	344	0	0, 108
CLAY Study	Various materials and modalities	8–12	411	97	31, 235

Summary:

Incidence of CIEs in adults (per 10,000 yrs)

Authors	Lens Wear	Incidence	95% CI
Chalmers et al. (2007)	30-night continuous wear of silicone hydrogel	329	284, 379
Chalmers et al. (2011)	Retrospective, mostly daily wear	432	361, 513
Szczotka-Flynn et al. (2014)	Daily wear of silicone hydrogel lenses, monthly replacement	316	116, 700

Chalmers RL, McNally JJ, Schein OD, et al. Risk factors for corneal infiltrates with continuous wear of contact lenses. *Optom Vis Sci* 2007;84:573-9.

Chalmers RL, Wagner H, Mitchell GL, et al. Age and other risk factors for corneal infiltrative and inflammatory events in young soft contact lens wearers from the Contact Lens Assessment in Youth (CLAY) study. *Invest Ophthalmol Vis Sci* 2011;52:6690-6.

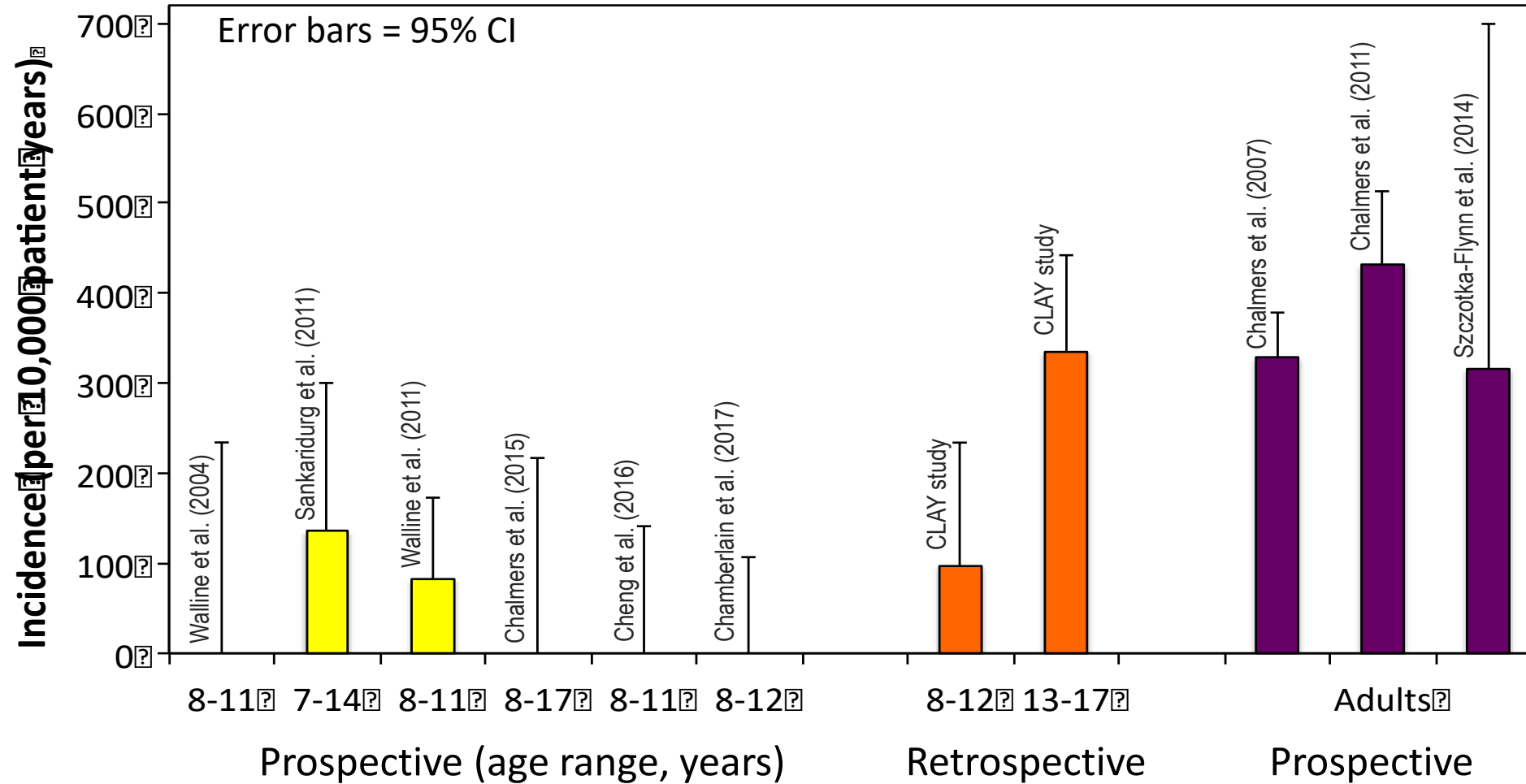
Szczotka-Flynn L, Jiang Y, Raghupathy S, et al. Corneal inflammatory events with daily silicone hydrogel lens wear. *Optom Vis Sci* 2014;91:3-12.



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Summary:

Incidence of CIEs from children to adults



Summary:

Incidence of microbial keratitis in children



Authors	Lenses and Replacement Schedule	Age	Patient Yrs	Incidence	95% CI
Walline et al. (2004)	1-week replacement hydrogel	8–11	159	0	0, 233
Sankaridurg et al. (2011)	Monthly replacement silicone hydrogel	7–14	369	0	0, 100
Walline et al. (2011)	Daily disposable hydrogel (93%)	8–11	723	0	0, 81
Chalmers et al. (2015)	Daily disposable silicone hydrogel/hydrogel	8–17	171	0	0, 216
Cheng et al. (2016)	Daily disposable silicone hydrogel	8–11	262	0	0, 141
MiSight® 1 day Trial	Daily disposable hydrogel	8–12	344	0	0, 107

**Combining all 2,028 patient years:
Upper 95% limit is 18 per 10,000 patient years**



CooperVision®

How does this compare with overnight orthokeratology?

In children (<18 years):

- **Incidence of MK is 14** per 10,000 patient years
(95% CI: **2, 50**)
- **Incidence of CIEs is 42** per 10,000 patient years
(95% CI: **15, 91**)



Summary

REVIEW

OPEN

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.
(Optom Vis Sci 2017;94:00-00)

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 control¹⁻⁶ 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.¹³ 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.

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Summary: soft contact lenses in children



- ✓ Incidence of CIEs much **lower** in 8-12 year olds than in adults
- ✓ **No reported cases of MK** in over 2,000 prospective and 400 retrospective patient years of lens wear
- ✓ **Behaviour** increases incidence in older children
- ✓ **Daily disposable** SCLs may play a role in reducing corneal infiltrative events in all patients

