The Safety of **Soft Contact Lenses** in Children

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REVIEW

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 Contact lens-related adverse events fall into two categories: children with contact lenses. This has been driven by patients, serious-notably microbial keratitis-and non-serious. The latter parents, practitioners, and the contact lens research commu- category typically indudes episodes of a painful red eye such as nity and is caused by the increased interest in myopia control1-6 contact lens-induced acute red eve (CLARE) with and without and the improved self-esteem and quality of life enjoyed by infiltrates, contact lens peripheral ulcer (CLPU), and infiltrative per 10,000 years.

*MCOptom, PhD, FAAO University of Houston College of Optometry (MAB), Houston, Texas This is an open-access article distributed under the terms of the Creative Commons Attribution-Non Commercial-No Derivatives License 4.0 (CCBY-NC-ND), where it is permissible to download and share the work provided it is properly cited. The work cannot be changed in any way or used commercially

children wearing contact lenses.⁷⁻⁹ Furthermore, the introduction keratitis. Of course, some events may be allergic in origin and may of daily disposable soft lenses obviates the need for deaning and not involve the cornea, so researchers often use the term corneal storage, making them an attractive option for children and *infiltrative events* to indicate corneal involvement beyond mere teenagers alike.^{10,11} Indeed, Chalmers et al.¹² recently reported staining or superficial punctate keratitis. Corneal infiltrative that, among patients of all ages in a prospective registry, only two events (CIEs) may be defined as a noninfectious infiltration of corneal infibrative events occurred in 960 patient years of daily white blood cells into the avascular corneal stroma, often with disposable soft lens wear (489 years silicone hydrogel and 471 accompanying hyperemia.¹² Microbial keratitis is a subset of this years hydrogel)-an incidence of corneal infiltrative events of 21 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?



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



Efron N, Nichols JJ, Woods CA, et al. Trends in US contact lens prescribing 2002 to 2014. Optom Vis Sci 2015;92:758-67.



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.

new survey of American Optometric Association (AOA) practicing member optometrists offers some insight into doctors' attitudes and practices when i mes 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

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 Infor-mation Center, in conjunction with the Sports Vision Section and Contact Lens and Comea 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 optome rist's decision to fit a child in contact lenses.1

"The growing body of researchin 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. Walline, O.D., Ph.D., Ohio State University College Optometry and leader of the Adolescent and Child Health initiative to Encourage Vision Empowerment (ACHIEVE) tudy, the largest randomized trial of its kind.23 "Findings from the Children & Contact Lenses survey show that, increasingly, optometrists understand that children who need refractive mor correction are capable of wearing and caring for soft contact lenses. The survey also shows that practitioners are

Infestine W. Sindt, O.D., is Associate Professor of Clinical Ophthalmology, repartment of Ophthalmology and Vision Sciences, University of Iowa, and hair of the Contact Lens and Comea Section of the AOA. Colleen Rile O.D., M.S., is Vice President, Professional Development and Medical Affairs, VISTAKON®, Division of Johnson & Johnson Vision Care, Inc. ons expressed are those of the authors and not necessarily those of

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omfortable 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 (63%) of respondents were men. Three of 10 respondents (29%) were solo practitioners, 28% were employed in a nonretail setting, 28% were narmers in aroun practitioners, 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 plasses as the primary method of vision correction and prescribe contact lenses as a secondary correction. However, a gradual shift in ontometrists' 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 begin 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 childen with contact lenses because of requests from the child or parent, and 10% said that "recent research or studies" on the subject, and children's participa tion 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



Availability of **daily** disposable lenses Improved contact lens materials

Requests from the child or parent

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



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opia progression	Results: Of the 971 respondents, concern was higher (median 9/10) in Asia than in 10, p. < 0.001) and they considered themselver more active in implementing men	any other contin
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	by inclusion time outdoor and praining cannot approxime, that and the	
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Youngest age for fitting SCLs







Minimum myopia for fitting SCLs







Reasons for not prescribing alternatives to single vision refractive corrections



40

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?



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



Gifford P. Gifford, K. The Future of Myopia Control Contact Lenses. Optometry and Vision Science. Vol. 93 April 2016

Some basic, easy to interpret, important statistics



"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%Cls





Reporting incidence of adverse events





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?



What can major epidemiological studies tell us?

Microbial

Lens Type	Any Presumed Microbial Keratitis (95% CI)	"Severe" Microbial Keratitis (95% CI)	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, BAppSc (Optom),^{2,3} Thomas Naduvilath, PhD,^{1,2,3} John K. G. Dart, DM,^{4,5} Garry Brian, FRANZCO,^{3,6} Brien 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 (Cl, 1.1–1.5); in daily wear soft CL wearers (0.0, 1.1–1.5); in daily wear soft CL wearers (0.0, 1.1–1.5); in daily wear soft CL wearers (0.0, 1.1–2.5); daily disposable CL wearers (0.0, 2.5); daily disposable CL wearers (0.0, 2.5); daily disposable CL wearers (0.0, 2.5); daily wear silicone hydrogel CL wearers (1.1–1.6); silicone hydrogel CL wearers (0.1, 1.7–2.4); daily disposable (CL, wearers (0.2, 2.5); daily disposable (CL, 4.6–2.5); daily disposable (CL, 4.6–2.5); daily disposable (CL, 4.6–2.5); and in overnight wear of silicone hydrogel 25.4 (Cl, 2.1–2.3); b. 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.



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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"

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,
 Keay L, Edwards K, Stapleton F. Signs, symptoms, and comorbidities in contact lens-related microbial keratitis. Optom Vis Sci 2009;86:803-9.
 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.





What can major epidemiological studies tell us?...

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



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:		
Lee et al. (2014)	67	≤16	34%	19%	47%	 Replacement schedule Material 		
Young et al. (2013)	18	≤18	44%	39%	17%	 Daily vs. overnight wear 		

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 Hong Kong. Am J Ophthalmol 2013;156:1040-4.



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



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



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.



"Age is a significant non-linear factor"



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.

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Incidence of MK and CIEs in CLAY study



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.

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• Effect of age: behaviour, not biology





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?





Fitting children with SCLs

ORIGINAL ARTICLE Sec. Al

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

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ARSTRACT

Purpose. Despite several studies that show 8- to 11-year-old children are capable of wearing a various contact lens modalities, parens 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 Lense in Rediatrics (CLIP) Study to compare contact lens fitting and follow up between 8 to 12 year-oid children and 13- to 17 year-oid leteragers.

Methods. At the baseline visit, all subjects underwent a contact lens fitting, including visual acuity, a manifest refraction, autorefraction, and biomicroscopy. 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 biomicroscopy 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. Biomicroscopy 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 (+ \$20) total chair time for children was 110.6 + 39.2 min, significantly more than 95.3 ± 25.2 min for teen (Studen's 14est, p = 0.003). Most of the difference was caused by insertion and removal training, which lasted 41.9 ± 32.0 min for children and 30.3 ± 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 biomicroscopy signs increased significantly over the 3-month period.

Destroctocopy 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 eve 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

Thilden require contact lenus for a variety of reasons. They may require contact lenus of a variety of reasons. They may require contact lenu wear because of a phulain.¹⁴ ocu-lar transm.¹⁵ and holpsin thengy.¹¹ of a refractive cort of phulain wear because lar transm.¹⁵ and holpsin thengy.¹¹ of a refractive cort of phulain the iming of a correction of moletum. There is no contract lenus of a refractive cort of phulain the iming of a cortection of moletum. Contact lenses for aphakia, trauma, and amblyopia therapy may be hyperopic or astigmatic refractive errors, and these errors may not be medically necessary, but contact lenses for refractive error are generally identified until children begin to perform concentrated near work dective; so eye care practitioners, parents, and children must decide activities, typically around the age of 6 or 7 years. Contact lenses may together whether a child should be fitted for contact lens wear. therefore be used to correct refractive error beginning early in life.

Optometry and Vision Science, Vol. 84, No. 9, September 2007

		FI SEVIED journal ho	mepage; www.alsavier.co
Purpose: Previous studies in the United States have evaluated the benefits	Key Words: Daily disposable contact lens wear-Children-Myopia.		
of soft contact lenses (CL3) in 8- to 12-year-old children and 13- to 17-year-old teem. This study was undertaken in Singapore and evaluated the safety, efficacy, and physiologic performance of daily disposable soft	(Eye & Contact Leter 2009)8: 188–195)	Contact lens fitting a	nd training in a ch
lenses in a population of children.	The use of daily mean and contact laness (CI a) is a common and	contact icho htting a	na training in a chi
Methods: In this open-label, bilateral, 3-month dispensing study, 59 children (8-11 years) were fit with etafficon A spherical or toric daily dimensible lenses (LDAY ACLIVIE) or LDAY ACLIVIE for	generally asfe and effective method for the correction of myopia and astigmatism. ¹⁻⁴ Daily disposable soft lenses circum-	Lindsay Paquette ¹ , Debora Craig A, Woods ¹	h A. Jones 44, Megan Se
ASTICMATEM, Vistakon, Jacknowville, FL). All subjects were non- phytes requiring visual correction in both eyes. The refractive inclusion	vent the need for cleaning and disinfection systems and ensure that patients wear only deposit-free lenses. As a result, there is some	* Centre for Contact Long Research, School of C * School of Methodae (Optometry); Dealers Uni	ptometry, University of Water Iso, 200 U ensity, 75 Physics Rd, Watern Possis, VK
criteria were plano to -0.00 diopter (D) with astignations of <2.000C in both eyes, or hyperopia of +0.50 to +6.00D with astignations of <0.73D or law. The subjects anotherware (of low on avoidations which included a	evidence that the rate of complications is reduced with daily disposable lenses. ^{1,0} Although CL are widely used by young adults, their use is less	ARTICLE INFO	ABSTRACT
questionaire for parents and subjects, at 1 week, 1 month, and 3 months. Results: Of the 59 subjects enrolled, 53 (99%) completed the study successfully. Six subjects were discontinued because of loss handling Selection (free) measurements have for (months) and reaches source (months).	common among teenagers and rare with children. Contact lens wear has some significant potential benefits for this group com- pared with the use of spectacles; in particular, they are likely to be	Article biotory: Received 23 january 2015 Received in revised form 10 May 2015 Accepted 13 May 2015	Purpose: To determine th experience were able to Methods: 1715 children a Lowerk and 'Loncoth fol
Advance seems seem reported in dhere midjecht, indikaling the ideoxiding state, and its medi-asses were due to in chalance. Correll vision quality, overall context, and and-of-all your space largerithms and the postability of the first postability of the state of the state set of the postability occurs of the study. The quartitements results indicated the new of the parents and unbiplece potential of the state set of the study of a queues induced association of the study. The queues and the study of the space in technical you have a state of the study of the study of appears induced association. The study of the study of the space in technical you have a state of the study	before states but plotte, and note active plottes for disadle myrose mitholity in the disadle plottes. The state of the state myrose mitholity is the disadle plottes of the disadle state of the state of the state of the state of the state of the state of the disadle state, and disadle be considered as a structure option for this age group? However, differences in the reak-benefit ratio in dul- dient warring (CL as also pratits in a postmichly higher ratio of when my have compliance issues with CL ware regimes. A study revaluating the use of duly ware, results, ulicone hydroged CL ain children (h-12 year) and tense was conclusion be lived biaster. Conclusal senses in budieries (CLI) pashyd ¹⁶	Kopwerk Canada the Dates Dates Canada the strange Kopya Monga	I minimettion and remove means: Nume children it thouse right, seven discon 50.55 (15/179) were so with lenses at the first far there were no statistica time by aggroup (po 0.1 with with four still analyhild either house it have been dong the board either house and carefi scills an a vision correction 5 CLs an a vision correction 6 2005
3 notifiest). A high properties of tingspresses thickness mapping trained constraints with a second hysis and high physicals in the C-12 over a 3-most hereod. Overall, sitk haups findings showed the providence of consult stating in the only to her 27-m 5 months, which is its lower than that previously reported is adults, but higher than that reported in the US Contact Leases in Pediatrics study (WG).	constant fait to both the groups bettimed from approxal improve- ments to their approximate and participation in neutrino and that does not been appointed and participation in neutrino and that does not been appointed and the second appointed and alightly lengar time. However, since trained, the youngar children were equidal parties 14.8.R and their versary working into (VP) and conflort was similar to that of the tores. Contact lenses also implicitant works are similar to the tores of the others as was implicitant.	 Introduction A study reviewing data from the Examination Servery suggested the children is increasing in the Units 12.17, the prevalence of myspix we so 31.28 kp 1969–2004 [1]. Children 10.1016 	 National Health and Nutrition at the prevalence of myopia in d States [1]. For children aged at 124 in 197 1. increasing ren who require vision correc-
Control levelse C. L., D.T.M.T., P.Y.M.J. Pacifiation and Thelineau Department (G.M.J., Bangpare National Spreams, Engineer, Clinical Research (G.M.J., Visikian, Jakowsville, P.; Singpare Tay, Research Battinis (D.T.M.Y.), Committee (C. Sphikanoshy) (D.T.M.J., Vong Loe Lin School of Moldonie, National University of Singpare Tay Research Battinks, Singpare Taylor, Committee (C.C.A., Singpare Taylor Research Battinks, Singpare, Takinal Dep Contro, 11 That Rospill Avenue, Advence Array School and Dep Contro, 11 That Rospill Avenue, Advence Array School, 20 7000	regressions, supervises are speciary 10 that the other handler at white speciarios and participation in activities. Singapore is an inheritation, a structure, brogenous dity state in foods listed xins, where there quetters of the resident X million performs are thereas with help and hand nero making approach of the speciarios and handling and handling approach of appropriate and the speciarios and the resident X million performs are thereas with help and handling much of appropriate and the speciarios and handling and the same 3/4 K speciarios and handling and help and the speciarios and help and allow the speciarios and the speciarios and the speciarios and about the speciarios and the speciarios help and the speciarios and about the speciarios and the speciarios help and the speciarios and about the speciarios and the speciarios helps in the holes in delibers of the speciarios and the speciarios helps in the holes in the speciarios and anotaed delibers with the speciarios helps in the holes in delibers of the speciarios and the speciarios helps in the holes in the speciarios and anotaed and physics with the speciarios helps in the holes in the speciarios and the speciarios and the speciarios and the speciarios and anotaed and physics with the speciarios helps in the holes in the speciarios and anotaed and physics helps and the speciarios helps and the speciarios and the speciarios helps and anotaed and physics with the speciarios helps in the holes in the speciarios and anotaed helps and the speciarios and the speciarios helps and the speciarios helps and the speciarios and the sp	tion at a young are may benefit i options for correction should be con- cussion process with the child and extracted field of views and the abuse distortion, all of which are benefici interaction, all of which are benefici to the should be able to a state of the should be and "Composiding asther at: Cherne to Com and Young States," and States the should be for all others and the should be able to a first should be able to a state of the should be for all others to a should be able to a should be for all others to a should be able to a should be able for all others to a should be able to a should be able for all others to a should be able to a should be ab	tom contact lens wear, and all sidered and be part of the dis- their parent(s). Contact lenses agnification for myopes, unob- ses of prismatic peripheral field al regardless of age [2]. Mart Lens Research, School of Optimientry Wini, Warfrin, OK, Canata ROS, SCI 88 4000.
not to torther characteristic	("history athenisity (\$0%) on 27%). Additionally, around one third of	anabie proveikum (and a james), nor	ganunary@www.ennon.ca (M. Sears),

prospective cohort study conducted on 981 Singaporean children older than 3 years showed incidence rates of 32% 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

Eye & Contact Lou • Volume 35, Number 4, July 2009



ars*, Krithika Nandakumar* telvensky Avenuer Wini, Watersko, ON, Canada N21, 363 1274, Aastralia

Purpose: To determine the ease with which children and youths without previous soft contact lens (SCI experience were able to handle, care for, adapt and be fitted with SCIs.
Methods: 1713 children aged 8-16 were recruited. Study visits included: screening and training visit
1-week and 3-month follow-ups. During the training visit, the time taken to demonstrate proficiency in last investigation and removed and core was recorded. A second training with new scheduled I measure the
Results: None children did not complete the screening visit and eight discontinued during the study. C
those eight, seven discontinued during the first week and one before the 3-month visit. Of those recruites
30.5% (162/175) were successfully fitted and completed the study. A majority of children were dispense
with lenses at the first training visit (94.6%, 163/171). The mean training time for all children was 30 mil
time by age group (p> 0.05) or gender (p> 0.05). Nine participants (5.3%, 9/171) required a second trainin
visit with four still usable to hardle lenses (2.2%, 4/171). By the 1-week visit 13.2% (22/167) of participan
either lost or tore lesses, no subsequent lost or torn lesses occurred. No serious adverse events occurre during the study.
Conclusion: Children and youths with no previous contact lens experience were easily litted, able to sur
cessfully wear and care for lenses. The results of this study should encourage practitioners to recomment
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itioners appea

fuction	However; according to Sindt and Riley [3] practitioners appear reluctant to recommend contact lenses as a refractive correction
ly reviewing data from the National Health and Nutrition	option to parents for their young children, noting that preference
tion Survey suggested that the prevalence of myopia in	for spectacles compared to contact lenses was highest for younger
is increasing in the United States [1]. For children aged	children and hitting contact tenses as a preference occurred when the child marched 12. M years of one Efron et al. (4) reported data
by 1999-2004 [1], Children who require vision correc-	from their international fitting survey for children with contact
young age may benefit from contact lens wear, and all or correction should be considered and be part of the dis- recess with the child and their parent(s). Contact lenses dwantages of increased magnification for myopes, unob- field of view and the absence of primatic peripheral field all of which are beneficial regardless of age [2].	Immen, that minors (under 18 years) represented only 13% of the total fits reported and that a majoring were fitted to teenagers, pos- sibly indicating a relustance to fit hyounger in age. This relucance could be due to concerns that younger children may not be manue enough to handle and care for contact lenses, or that the fitting of contact lenses designed for adult eyes will either be ansuccessful
	Dractitioners may have the view that risks associated with con-
conding author at: Centre for Constant Less Severants School of Optimietry	tact lens wear are too great to consider this as a viable option
Science, 200 University Avenue West, Waterlas, OK, Canada N21, 301.	for children. With respect to safety concerns, a study reviewing
868 4567x35034: tax: +1 519 888 4303.	National US data indicated that contact lens wear may not be as
Several entropy (O.A., Jones), megan ana selevate rise (M. Seara), education devate rise (K. Nandakamar), (risig, wood-defination etc. as 1).	sale for choices as for anoth (5), this study reported that contact lenses accounted for 23% of medical device-associated emergency room visits in a paediatric population. However, most of the adverse





Daily Disposable Contact Lenses versus Spectacles in Teenagers

Andrew J. Plowright*, Carole Maklonado-Codina[†], Gillian F. Howarth[‡], Jami Kern^{\$}, and Philip B. Morgan[†]

ARSTRACT

Purpose. To compare clinical and subjective quality-of-life (QoL) data for teenagers wearing daily disposable contact lenses or spectacles.

to reflection. Methods. This open-label study randomized subjects (aged 13 to 19 years) with no previous contact lens wear experience to netificon A (DAILIES 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 question naires, was conducted at baseline and at week 4 and months 3 and 6, with an additional study visit at week 2 for subjects randomized to wear contact lenses.

sages stouchings is wear consider energies. Results, A total of 10 benages were encolled in the study; 13 discontinued before study completion, 10 (17.5%) from the contact leng group and 35,7%) from the spectacle group (b = 0.04). Visual acuity was good for both groups at all study visits. Biomicroscopy assessments were similar at baseline for both groups; Significant differences in Pediatric Relactive 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 month of wear, including appearance, satisfaction, activities, and peer per-ceptions, without negatively impacting vision or eye health. Teenagers were able to handle contact lenses with the same amount of confidence as spectacles (Ootom Vis Sci 2015/92/44-52)

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

a visible advanterie compared within correction, constact interes are a visible advanterie compared within specards. ⁴¹ ¹¹ Previous modes have demonstrated data contexts lines was can have a politicar impact for temperature advantage and an advantage persons and acceptance by pers. ⁴⁴ Those effects universally data on the water having generar uniform within his or the vision correction method. ⁴⁴ Tenenges, who was an per work compared with how a langer and vision correction intere are used compared with hor how a langer and vision correction intere are used compared with hor sets. ⁴⁵ Interesting the set of the set of the set of the set of the set of langer and the set of the set of the set of the set of the set of langer and set of the set of the set of the set of the set of langer and set of the set of t	those who corrected a vision with operative alows? Novembeles, non-rey care provides one may be indicatent to presente entrance lenses for semigers. This, is par, may be because of one semigrading the should only one provide the obscure program tem- restrikence may also have general ancourse specific safety and overall compliance in this age grouns. Recent studies, however, have shown that daily disposable contain lessons: en arbite pro- limation correction in tenzages ("A" becomes, children prostage vision correction in tenzages ("A" becomes, children prostage to the correction in tenzages ("A" becomes, children prostages).
⁹ BioHenel, Mie ¹ Phio, Mic Queen, YAAD ¹ Bio, Jones, R. KC Queen ¹ MM, PhD ¹ Mark, PhD ¹	that is year applied in the at lower that is during events that interrupt onnatcle lens wear compared with older temagers or young addits. ⁷⁴ Daily disposable correct lenses are designed to be worn once and then replaced with a sew pair of lenses the following day, with the advantage that there is no law care system or overnight storage

Optimizery and Vision Science, Vol. 92, No. 1, January 201



1. Walline JJ, Jones LA, Rah MJ, et al. Contact Lenses in Pediatrics (CLIP) Study: chair time and ocular health. Optom Vis Sci 2007;84:896-902.

2. Li L, Moody K, Tan DT, et al. Contact lenses in pediatrics study in Singapore. Eve Contact Lens 2009;35:188-95.

DOI: 10.1097/ICL.0b013e3181abb5bb

3. Paquette L, Jones DA, Sears M, et al. Contact lens fitting and training in a child and youth population. Cont Lens Anterior Eye 2015;38:419-23.

Contact Lenses in Pediatrics Study in Singapore

Lim Li, FRCS, Kurt Moody, O.D., Donald T.H. Tan, FRCS, Khoo Chong Yew, FRCS,

Por Yong Ming, FRCS, and Quah Boon Long, FRCS.

4. 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







1. Walline JJ, Jones LA, Rah MJ, et al. Contact Lenses in Pediatrics (CLIP) Study: chair time and ocular health. Optom Vis Sci 2007;84:896-902.

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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





Six studies report safety outcomes with >150 patient years



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





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



CLINICAL TRIALS

A Randomized Trial of the Effect of Soft Contact Lenses on Myopia Progression in Children

Jeffrey J. Walline,¹ Lisa A. Jones,¹ Loraine Sinnott,¹ Ruth E. Manny,² Amber Gaume, Marjorie J. Rab,³ Monica Chithara,¹ and Stacy Lyons,³ on behalf of the ACHIEVE Study Group

Putross. Soft contact lenses have been reported to increase the of wearing gas-permeable,^{6,7} corneal reshaping,^{8,9} or soft con-tact lenses,^{6,10,11} However, treatment options believed to acprogression of myopia. The purpose of this study was to determine whether soft contact lenses affect the progression of myopia in children. fermons. Children between the ages of 8 and 11 years with

-1.00 to -6.00 D myopia and less than 1.00 D astigmatism were randomly assigned to wear soft contact lenses (n = 247) or spectacles (n = 237) for 3 years. Refractive error and spectacles (n = 25/) for 5 years. Refractive error and meal curvatures were measured annually by cycloplegic torefraction, and axial length was measured annually by scan ultrasound. Multilevel modeling was used to compare e rate of change of refractive error, corneal curvature, and ial length between spectacle and contact lens wearers

urrs. There was a statistically significant interaction be cen time and treatment for myopia progression (P = 0.002); e average rate of change was 0.06 D per year greater for itact lens wearers than spectacle wearers. After 3 years, the asted difference between contact lens wearers and spectaearers was not statistically significant (95% confidence le weaters was not statistically significant (95% contidence letrval [CI] = -0.46 to 0.02). There was no difference be-ween the two treatment groups with respect to change in sial length (ANCOVA, P = 0.37) or change in the steepest omeal curvature (ANCOVA, P = 0.72).

non. These data provide remainings to our care practicerned with the phenomenon of "myopic creep." Soft s wear by children does not cause a clinically relevant ase in axial length, corneal curvature, or myopia relative to ctacle lens wear. (ClinicalTrials.gov, NCT00522288.) (Invest htbalmol Vis Sci. 2008;49:4702–4706) DOI:10.1167/iovs.08-

Myopia typically develops around the age of 8 to 10 years¹⁻⁴ and progresses through the teen years.³ Several we shown that children in this age group are capabl

the ¹Ohio State University College of Optometry, Columbus ²University of Houston College of Optometry, Houston d the ⁵New England College of Optometry, Boston, Mass

: J.J. Walline, Johnson & Johnson Vision Care (F, 5

are (E): S I works costs of this article were defrayed in part by pag accordance with 18 U.S.C. §1734 solely to indicate this fact esponding author: Jeffrey J. Walline, 338 West Tenth Avenue

celerate myopia's progression may be met with resistance, whereas those perceived to slow the progression in children care practitioners to prescribe soft contact lenses as a viable ent option for young myopic individuals

The reluctance may stem in part from investigations of changes in myopic refractive error after soft contact lens wear that began to annear in the mid-1970s These initial reports indicated that adult patients adapting to soft contact lens wear may experience an increase in myopia associated with a steepening of the corneal curvature. In investigations of the hypothesis that the increase in myopia was due to relatively hypoxic conditions causing corneal swelling, later studies com-pared high- and low-Dk (oxygen permeable) contact lens wear-ers and found that low-Dk contact lenses increase the progresers and round that tow JK contact tenses increase the progres-sion of myopia over short periods more than do high JK contact kenses.^{35,16} The results of these studies gave further credence to the hypoxia theory of progression. The studies noted were conducted on adults, but in two inclusion the difference to buscness the increase.

Creatence to the hypoxia theory or progression. The studies noted were conducted on adults, but in two studies, the effect of contact lens wear on myopia's progres-sion in children was examined. In a chart review by Andreo,¹⁷ myopic changes in 14- to 19-year-old patients who wore contact lenses were compared to those of control subjects who wore spectacles. All subjects were examined 11 to 13 months after the baseline examination, and there was not a significant difference in the progression of myopia between co

and spectacle wearers.¹⁷ In a separate study, Horner et al.¹³ randomly assigned sub-jects between the ages of 11 and 14 years to wear low-Dk soft contact lenses or spectacles for 3 years. Cycloplegic autorefrac-tion was performed every 6 months, and the change in spherical equivalent refractive error was, on average, 0.15 D greater for the soft contact lens wearers; this difference was not statistically significant. There were no data reported on cornea

statistically significant. I nere were no data reported on cornear curvature or axial growth during the investigation. The purpose of this study was to compare the changes in ocular components and refractive error of soft contact lens wearers and spectacle wearers over 3 years, to determine whether soft contact lenses affect the progression of myopia in

Mercury

The subjects of this report participated in the Adolescent and Child The subjects of this report participated in the Adolescent and Child Health Initiative to fincourage Vision Impowement (ACHIRV) Study, a randomized clinical trial designed to investigate the effects of contact lens wear on children's self-perception. The protocols were approved by each clinical stic's institutional leview loard and adhered to the tends of the Declaration of Heddinki Eligibility criteria and methods are reported in detail elsewhere,¹⁸ but they are briefly presented

Oblabalturieur & Voual Scietur, November 2008, Vol. 49, No. 11 Copyright @ Association for Research in Vision and Ophtha



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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.

CooperVision

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)



CLINICAL TRIALS

A Randomized Trial of the Effect of Soft Contact Lenses on Myopia Progression in Children

Jeffrey J. Walline,¹ Lisa A. Jones,¹ Loraine Sinnott,¹ Ruth E. Manny,² Amber Gaume,⁷ Marjorie J. Rab,³ Monica Chithara,¹ and Stacy Lyons,³ on behalf of the ACHIEVE Study Group

Parons. Soft contact lanes how been reported to increase the dwarfing gapermenkle, $^{-1}$ contrad evaluating W^{-1} or do not evaluate the progression of myol. The parpose of this study was tast lenses. Simil However, remained option believed to associate myopia's progression my be net with resistance myopia in children. Memoos. Children between the ages of 8 and 11 years with

-1.00 to -6.00 D myopia and less than 1.00 D astigmatism were randomly assigned to wear soft contact lenses (n = 247) or spectacles (n = 237) for 3 years. Refractive error and or spectacles (n = 25/) for 5 years. Refractive error and corneal curvatures were measured annually by cycloplegic autorefraction, and axial length was measured annually by Ascan ultrasound. Multilevel modeling was used to compare the rate of change of refractive error, corneal curvature, and xial length between spectacle and contact lens wearers Resurs. There was a statistically significant interaction be-

may be embraced. Concern over "myopic in myopia associated with the initiation wear reported in adults, may contribute to care practitioners to prescribe soft contact lenses as a viable treatment option for young myopic individuals. The reluctance may stem in part from investigations of

changes in myopic refractive error after soft contact lens wear that began to appear in the mid-1970s.¹²⁻¹⁴ These initial rethat began to appear in the mid-19/08.⁻⁻⁻ These initial re-ports indicated that adult patients adapting to soft contact lens wear may experience an increase in myopia associated with a steepening of the corneal curvature. In investigations of the hypothesis that the increase in myopia was due to relatively tween time and treatment for myopia progression (P = 0.002); the average rate of change was 0.06 D per year greater for hypoxic conditions causing corneal swelling, later studies com-pared high- and low-Dk (oxygen permeable) contact lens wear-ers and found that low-Dk contact lenses increase the progrescontact lens wearers than spectacle wearers. After 3 years, the adjusted difference between contact lens wearers and spectaadjusted difference between contact lens wearers and specta-cle wearers was not statistically significant (9% confidence interval [CI] = -0.46 to 0.02). There was no difference be-tween the two treatment groups with respect to change in axial length (ANCOVA, P = 0.37) or change in the steepest corneal curvature (ANCOVA, P = 0.72).

ers and count that non-JAC contact senses increases the progres-sion of myopin over short periods more than do high J& contact lenses.¹¹ The results of these studies gave further credence to the hypoxia theory of progressions. The studies, the effect of contact lens wear on myopia's progres-sion in children was examined. In a chart review by Andreo, myopic changes in 14 to 19-year odd patients who were con-Conclusions. These data provide reassurance to eve care practi-NCLINONS. I HESE GUIL PROVIDE PERSUITANCE TO EYE CATE PRACE-ners concerned with the phenomenon of "myopic creep." Soft natce tens wear by children does not cause a clinically relevant crease in axial length, corneal curvature, or myopia relative to tact lenses were compared to those of control subjects who wore spectacles. All subjects were examined 11 to 13 months spectacle lens wear. (ClinicalTrials.gov, NCT00522288.) (Invest Ophthalmol Vis Sci. 2008;49:4702–4706) DOI:10.1167/iovs.08after the baseline examination, and there was not a significant difference in the progression of myopia between contact lens and spectacle wearers.¹⁷ and spectacle weares.¹⁷ In a separate study, Horner et al.¹¹ randomly assigned sub-jects between the ages of 11 and 14 years to wear low-Dk soft contact lenses or spectacles for 3 years. Cycloplegic autorefrac-tion was performed every 6 months, and the change in spher-

Myopia typically develops around the age of 8 to 10 years¹⁻⁴ and progresses through the teen years.⁵ Several rts have shown that children in this age group are capable

From the ³Ohio State University College of Optometry, Columbus ; the ³University of Houston College of Optometry, Houston ; and the ³New England College of Optometry, Boston, Massa Study Group members are listed in the App

hnson & Johnson Vision Care and the Vision Care . d for publication March 24, 2008; revised May 13, and accepted August 27, 2008

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M. Statikara, Johnson & Johnson Vision Care (F, R); Vision Care (F); S. Lyons, Johnson & Joh son Vision Care (I The publication costs of this article were defrayed in part by page charge payment. This article must therefore be marked "advertise-ment" in accordance with 18 U.S.C. §1734 solely to indicate this fact. Corresponding author: Jeffrey J. Walline, 338 West Tenth Avenue, Columbus, OH 43210-1240; walline.100su.edu.

ical equivalent refractive error was, on average, 0.15 D greater for the soft contact lens wearers; this difference was not statistically significant. There were no data reported on corneal statistically significant. Incre were no atta reported on correca curvature or axial growth during the investigation. The purpose of this study was to compare the changes in ocular components and refractive error of soft contact lens wearers and spectacle wearers over 3 years, to determine whether soft contact lenses affect the progression of myopia in whether soft contact lenses affect the progression of myopia in

Mercuron

The subjects of this report participated in the Adolescent and Child The subjects of this report participated in the Adolescent and Child Health Initiative to Encourage Vision Impowement (ACHIIV) Study, a randomized clinical trial designed to investigate the effects of contact lens wear on children's self-perception. The protocols were approved by each clinical site's institutional Review Noard and athered to the tends of the Declaration of Heddinki. Sliphibility criteria and methods are reported in detail elsewhere,¹⁸ but they are briefly presented

Investigative Ophthaltnology & Youal Science, November 2008, Vol. 49, No. 11 Copyright © Association for Research in Vision and Ophthaltnology



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Sankaridurg et al. (2013) - BHVI

- **240 children** aged 7 to 14 years in randomized clinical trial
- Iotrafilcon 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 Brien 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, 3,42%), 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 onethird (26 participants, 10.8%) occurring in the first month of lens wear. Discomfort and non-lens-related reasons such as safety concern and disinterest 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 continuation suggest that adaptation and patient motivation are critical for survival in lens wear. (Optom Vis Sci 2013;90:00-00) Key Words: contact lenses, children, adverse events, dropouts, silicone hydrogel contact lense Annal ambi lenses.¹⁻⁹ Ala *BOpt, PhD *BOpt, PhD ¹MS: ¹MS: PhD ²BOpt ¹PhD, FAAC **MD Brien Holder PLdIJ, BAHJ; Su Astanlia (PS, X Science, Univer (PS, BAHJ; Stau Center, Gaungi venity of Houn

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of childhood disorders of the eye such as keratoconus, yopia, peedarric aphabia, and common refractive er- uch as myopia can be effectively managed with contact , importantly, evidence suggests that contact lenses	may play a significant role in controlling the progression of myopia. ¹⁰⁻¹⁰ 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 bechildren and (2) using of contact lenses

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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)







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.



Summary: Incidence of CIEs from children to adults





Summary: Incidence of microbial keratitis in children



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



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**)



ORIGINAL ARTICLE The Risk of Microbial Keratitis With Overnight **Corneal Reshaping Lenses** Mark A. Bullimore*, Loraine T. Sinnott[†], and Lisa A. Jones-Jordan[‡] ABSTRACT Purpose. To estimate the incidence of microbial keratitis (MK) associated with overnight corneal reshaping contact lenses and to compare rates in children and adults. Methods. A retrospective study of randomly selected practitioners, stratified by order volume and lens company, was

conducted. Practitioners were invited to participate and those agreeing were asked to provide deidentified patient information for up to 50 lens orders and to complete a comprehensive event form for any of these patients who have attended an nscheduled visit for a painful red eye. Duration of contact lens wear was calculated from the original fitting date or January 2005 (whichever was later) to when the patient was last seen by the practitioner wearing the lenses on a regular basis. Cases of MK were classified by majority decision of a 5-member expert panel. Results. For the 191 practitioners who could be contacted, 119 (62%) agreed to participate. Subsequently, 11 withdrew, 22

did not respond, and 86 (43%) returned completed forms corresponding to 2202 lens orders and 1494 platients. Limiting the sample to those patients with at least 3 months of documented contact lens wear since 2005 resulted in a sample of 1317 patients; 640 adults (49%) and 677 children (51%) representing 2599 patient-years of wear (adults = 1164; children = 1435). Eight events of corneal infiltrates associated with a painful red eye were reported (six in children and two in adults). Two were classified as MK. Both occurred in children but neither resulted in a loss of visual acuity. The overall estimated incidence of MK is 7.7 per 10,000 years of wear (95% confidence interval [CI] = 0.9 to 27.8). For children, the estimated incidence of MK is 13.9 per 10,000 patient-years (95% CI = 1.7 to 50.4). For adults, the estimated incidence of MK is 0 per 10,000 patient-years (95% CI = 0 to 31.7).

Conclusions. The risk of MK with overnight comeal reshaning contact lenses is similar to that with other overnight moalities. The fact that the CIs for the rates estimated overlap should not be interpreted as evidence of no difference. True differences fewer than 50 cases per 10.000 patient-years were beyond the study's power of detection. (Optom Vis Sci 2013:90:937-944

Words: microbial keratitis, overnight orthokeratology, contact lenses, extended wear, adverse effects



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Summary

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REVIEW

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 comeal 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

n the past decade, there has been increasing interest in fitting Contact lens-related adverse events fall into two categories: children with contact lenses. This has been driven by patients, serious—notably microbial keratitis—and non-serious. The latter parents, practitioners, and the contact lens research commu- category typically includes episodes of a painful red eye such as nity and is caused by the increased interest in myopia control¹⁻⁶ contact lens-induced acute red eye (CLARE) with and without and the improved self-esteem and quality of life enjoyed by infiltrates, contact lens peripheral ulcer (CLPU), and infiltrative children wearing contact lenses.⁷⁻⁹ Furthermore, the introduction keratitis. Of course, some events may be allergic in origin and may of daily disposable soft lenses obviates the need for deaning and not involve the cornea, so researchers often use the term corneal per 10,000 years.

storage, making them an attractive option for children and *infiltrative events* to indicate corneal involvement beyond mere teenagers alike.^{10,11} Indeed, Chalmers et al.¹² recently reported staining or superficial punctate keratitis. Corneal infiltrative that, among patients of all ages in a prospective registry, only two events (CIEs) may be defined as a noninfectious infiltration of corneal infiltrative events occurred in 960 patient years of daily white blood cells into the avascular corneal stroma, often with disposable soft lens wear (489 years silicone hydrogel and 471 accompanying hyperemia.12 Microbial keratitis is a subset of this years hydrogel)-an incidence of corneal infiltrative events of 21 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

