MYOPIA CONTROL AND CONTACT LENSES: A CLINICAL REVIEW

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There is a growing body of evidence in the literature supporting a number of therapies for myopia control.[1-3] Among these therapies are multifocal soft contact lenses and overnight orthokeratology (ortho-k). In this article, I review the efficacy, safety, and benefits of these two contact lens modalities.

Before doing so, however, it is important to note that overnight ortho-k is approved by the U.S. Food and Drug Administration (FDA) for the "temporary reduction of myopia" and not for myopia control. Thus, prescribing these lenses as part of a program of reducing myopia progression could be considered an off-label use. Likewise, among multifocal soft contact lenses, including those discussed here, only CooperVision's MiSight has received FDA approval for myopia control. At least three designs are marketed elsewhere in the world and have received CE marking in the European Union.

REVIEW OF EFFICACY

Because of the change in transient corneal curvature and refractive error induced by ortho-k, nearly all studies present efficacy in terms of axial elongation. Axial elongation is the underlying cause of myopia progression, and the two are highly correlated. For reference, a 0.1mm difference is equivalent to approximately 0.25D. Thus, for consistency, efficacy for multifocal soft contact lenses and overnight ortho-k will be presented in terms of axial elongation and its reduction.

Ortho-K

Discussions of overnight ortho-k for myopia control began to appear in the literature fewer than 20 years ago. In the first peer-reviewed study, Cho et al reported on two years of follow-up on 35 children fitted by eight private practitioners and compared them to a matched, historical control group wearing single-vision spectacles.[4] The increase in axial length was 0.29mm ± 0.27mm and 0.54mm ± 0.27mm in the ortho-k and control groups, respectively (p = 0.01). The results were confirmed by Walline et al, who fitted 40 children, 8 to 11 years old, in overnight ortho-k, of whom 28 completed two years of wear.[5] The increase in axial length was 0.25mm ± 0.22mm compared with 0.57mm ± 0.51mm in a historical control group (p = 0.0004). Subsequent studies have shown similar results.[6-14]

In the ROMIO clinical trial, 102 children, 6 to 10 years old, were randomly assigned to ortho-k or spectacles.[7] For the 78 patients completing the two-year study, the mean axial elongation was 0.36mm ± 0.24mm and 0.63mm ± 0.26mm in the ortho-k and control groups, respectively (p <0.01). Meta-analysis of the efficacy of ortho-k on myopia progression suggests that the treatment effect in the randomized clinical trials (–0.28mm, 95% CI, –0.35mm to –0.20mm) was no different from that in cohort studies (–0.27mm, 95% CI, –0.32mm to –0.22 mm) and the two-year treatment effect across all studies corresponds to a 43% slowing of axial elongation.[15]

Hiraoka et al reported five-year data on 43 of 59 originally enrolled subjects (22 ortho-k and 21 control).[8] The increase in axial length was 0.99mm ± 0.47mm and 1.41mm ± 0.68mm for the ortho-k and control groups, respectively (p = 0.02). Santodomingo-Rubido et al examined 14 of the original 29 ortho-k patients at seven years, along with 16 of the 24 control subjects.[16] The seven-year change in axial length was 0.91mm and 1.36mm for the ortho-k and control groups, respectively (33%, p = 0.06). By this time, the subjects were all between 17 and 19 years old and myopia would have stabilized in the majority of subjects, regardless of treatment.[17] Interestingly, these differences of more than 0.4mm are the largest cumulative effect across the entire myopia control literature.

Soft Multifocal

There is broad consensus that soft contact lenses with a central distance zone and increased positive power in the periphery can significantly slow myopia. However, we should avoid the temptation to lump all studies and designs together. For example, lenses may manipulate power in the periphery by increased spherical aberration,[18] broad areas of positive power,[19,20] or multiple concentric treatment zones.[21-25] Likewise, some designs were never commercially available[18,19,22] while others have been discontinued.[23] A comprehensive table appears in a recent publication,[26] but discussion here will be limited to commercially available designs with at least two years of data on treated and controls.

Walline et al fitted 8- to 11-year-old children with CooperVision's Proclear D soft multifocal contact lenses with a +2.00D add in a two-year prospective study. Twenty-seven of the 40 children completed the study and were age- and gender-matched to subjects from a previous study wearing single-vision soft contact lenses. The adjusted mean axial elongation was 0.29mm ± 0.16mm and 0.41mm ± 0.16mm for the multifocal and single-vision wearers, respectively (p <0.002). The authors concluded that soft multifocal contact lens wear resulted in a 29% reduction in axial elongation during the two-year treatment period.

Walline et al are conducting the three-year Bifocal Lenses In Nearsighted Kids (BLINK) study to compare add powers and measure peripheral refractive error to provide important information about the potential mechanism of myopia control.[26]

In the study, 294 children have been randomly assigned to wear CooperVision's Biofinity single-vision, +1.50D, or +2.00D add Biofinity D multifocal soft contact lenses. Results of this important clinical trial should be available in late 2019 or early 2020.

Sankaridurg et al recently reported on a two-year, five-arm clinical trial wherein children were randomly assigned to single-vision soft contact lenses, two soft lens designs that imposed myopic defocus across the peripheral and central retina, or two extended-depth-of-focus (EDOF) soft lenses incorporating higher-order aberrations to modulate retinal image quality.[27] The single-vision group progressed by 0.58mm ± 0.27mm, while all other groups had reduced progression ranging from 0.41mm to 0.46mm, representing a reduction in axial elongation between 22% and 32%. One of the EDOF designs is now available in some markets from mark'ennovy.

Chamberlain et al recently published results of a three-year randomized clinical trial of CooperVision's MiSight 1-day soft contact lens.[25] Myopic children from 8 to 12 years old were randomly assigned to the MiSight lens or CooperVision's Proclear 1-day, with both worn on a daily disposable basis. Of the subjects enrolled, 75.5% (109/144) completed the clinical trial. Mean change in axial length was 0.32mm (52%) less in the test group than in the control group (0.30mm ± 0.27mm vs. 0.62mm ± 0.30mm, p <0.001). A similar two-year clinical trial of the MiSight lens reported on children from 8 to 12 years old, of whom 41 wore the MiSight lens and 33 wore single-vision spectacles.[24]

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The treatment effect was similar to, albeit slightly smaller than, in Chamberlain et al, with less axial elongation in the MiSight group compared with the single-vision group (0.28mm vs. 0.44mm, p <0.001). The MiSight lens is a derivative of a previously evaluated experimental dual-focus soft contact lens.[26] When worn monocularly by 40 children from 11 to 14 years old, axial elongation after 10 months was 0.11mm ± 0.09mm compared with 22mm ± 0.10mm in the contralateral eye wearing a single-vision soft lens.

SAFETY

Safety in contact lenses is a concern with any population, but concerns are heightened in children, as they represent a vulnerable population and have longer to live with any visual consequences of corneal scarring. Contact lens-related adverse events fall into two categories: serious (notably microbial keratitis) and non-serious. The latter includes episodes of a painful red eye, such as contact lens peripheral ulcer (CLPU),

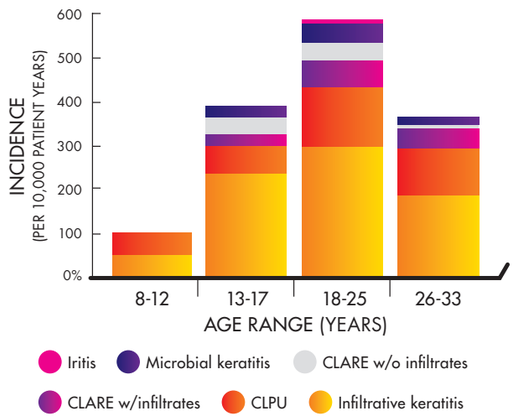

Figure 1. Incidence of corneal infiltrative events by age.

contact lens-induced acute red eye (CLARE) with and without infiltrates, and infiltrative keratitis. The term corneal infiltrative event (CIE) refers to corneal involvement beyond staining. CIEs are defined as a noninfectious infiltration of white blood cells into the stroma with accompanying hyperemia.[28]

Microbial keratitis is a serious manifestation of this category, but usually accounts for approximately 5% of all CIEs in soft lens wearers.[29,30] Microbial keratitis is usually defined as one or more stromal infiltrates greater than 1mm, with meaningful pain and at least one of the following: anterior chamber reaction more than minimal, mucopurulent discharge, or positive corneal culture.[31]

No more than 15% of cases of microbial keratitis result in loss of two or more lines of visual acuity.[32,33] Because microbial keratitis is rare, the incidence is usually reported in terms of cases per 10,000 patient-years of wear, e.g., 3.3 per 10,000 patient-years, rather than 0.000033 per year.

Ortho-K

Beginning in 2001, there was a steady stream of case series and case reports of microbial keratitis associated with overnight ortho-k, particularly in children. Watt and Swarbrick summarized the first 50 published cases from 16 peer-reviewed papers.[34] In 2008, Van Meter et al published an Ophthalmic Technology Assessment for the American Academy of Ophthalmology on the Safety of Overnight Ortho-k for Myopia.[35]

The main source of reports of adverse events was 38 case reports or noncomparative case series, representing more than 100 cases of infectious keratitis. The report concluded that sufficiently large studies are needed to quantify the risks of treatment and risk factors for complications, and the efficacy of the modality for slowing the progression of myopia in children. The investigators were unable to identify the incidence of complications associated with overnight ortho-k, nor the risk factors for various complications.

In 2006, the FDA required Bausch + Lomb and Paragon Vision Sciences to conduct a post-market study of their respective overnight ortho-k/corneal reshaping lenses to address concerns about the use of these lenses in children. The two companies sponsored a large study using a retrospective cohort of children and adult patients fitted with overnight ortho-k lenses in 2005 and 2006.[36] Two hundred randomly selected practitioners, stratified by company and number of lens orders, were asked to participate and to provide information on fitting date, patient's age at fitting, and follow-up duration for up to 50 randomly selected lens orders.

The practitioners were asked to provide comprehensive information on any of these patients who experienced an episode of painful red eye that required a visit to a doctor's office. Data were submitted by 86 practitioners on 1,494 unique patients. Only patients with at least three months of lens wear from 2005 and later were analyzed, resulting in a sample of 1,317 patients (49% adults, 51% children) representing 2,599 patient-years of wear. Of the 50 episodes of painful red eye, eight presented with a corneal infiltrate; of these, six were in children. Of these cases, two were judged to be microbial keratitis by a five-person masked, expert-review panel and neither resulted in any long-term loss of visual acuity.

The overall estimated incidence of microbial keratitis was 7.7 per 10,000 patient-years (95% CI: 0.9, 27.8). Both cases occurred in children, giving an incidence of 13.9 per 10,000 patient-years (95% CI: 1.7, 50.4). This study remains the only estimate of the incidence of microbial keratitis in overnight ortho-k.[36]

It is important to acknowledge that overnight ortho-k is overrepresented in case series of Acanthamoeba (A.) keratitis. In a case-control study of 37 GP contact lens wearers with a diagnosis of A. keratitis identified during two multistate outbreaks, eight (22%) wore GP lenses for ortho-k.[37]

In contrast, none of the controls wore GP lenses for ortho-k. Risk factors across all cases included storing lenses in tap water (OR, 16.0; p = 0.001), so it is important for all practitioners to strongly encourage all patients to avoid having tap water and other nonsterile water come into contact with their eyes and contact lenses.

Soft Multifocal

Microbial keratitis associated with soft contact lenses has been well researched over the past few decades.

TABLE 1

RATES OF MICROBIAL KERATITIS AND CORNEAL INFILTRATIVE EVENTS FROM LARGE STUDIES OF CHILDREN WEARING SOFT CONTACT LENSES

AUTHORS	LENSES AND REPLACEMENT SCHEDULE	AGE (YEARS)	PATIENT YEARS	MICROBIAL KERATITIS		CIEs	
				INCIDENCE	95% CI	INCIDENCE	95% CI
Walline et al (2004)	1-week replacement hydrogel	8–11	159	0	0, 233	0	0, 233
Walline et al (2008)	Daily disposable hydrogel (93%)	8–11	723	0	0, 81	83	34, 173
Sankaridurg et al (2013)	Monthly replacement silicone hydrogel	7–14	369	0	0, 100	136	50, 300
Chalmers et al (2015)	Daily disposable silicone hydrogel/ hydrogel	8–17	171	0	0, 216	0	0, 216
Cheng et al (2016)	Daily disposable silicone hydrogel/ hydrogel	8–11	262	0	0, 141	0	0, 141
Chamberlain et al (2019)	Daily disposable hydrogel	8–12	344	0	0, 107	0	0, 108

The incidence is 20 to 25 per 10,000 patient-years in patients wearing contact lenses on an overnight basis, but 2 to 4 per 10,000 patient-years for daily-wear patients.[32,33,38-42] For adults in daily wear soft contact lenses, the incidence of CIEs has been estimated as 300 to 400 per 10,000 patient-years.[29,30,43] These large epidemiological studies tell us little about children wearing contact lenses, as even the largest studies report cases in patients 15 years old and older.[33,44,45]

The Contact Lens Assessment in Youth (CLAY) study sought to address this gap.[46] This meticulous multicenter, retrospective, observational study's goal was to assess the safety profile of soft contact lens wear in pediatric patients observed at academic eyecare clinics for routine and problem-oriented eye care.

The investigators reviewed charts from 3,549 patients, representing 14,276 office visits.[30] Across all patients, there were 187 CIEs over 4,663 soft contact lens patient-years. Importantly, the incidence varied dramatically with age, as illustrated in Figure 1 (redrawn from Chalmers et al[30]). The 8- to 12-year-old children had dramatically lower rates of adverse events than teenagers. In contrast, young adults had markedly higher rates. The incidence of CIEs for 8- to 12-year-old children was 97 per 10,000 patient-years (95% CI: 31, 235) compared with 335 per 10,000 patient-years (95% CI: 248, 443) in 13- to 17-year old children. For adolescents, the incidence was higher.

There is a growing list of publications on myopia control using multifocal soft contact lenses in children; however, nearly all fail to report safety outcomes, even though the children were examined regularly over one or two years. Six studies with at least 150 patient-years of contact lens wear have reported the incidence of CIEs, microbial keratitis, along with other information (Table 1).[18,25,28,47-49]

The table demonstrates that it is possible to make a valid assessment of the safety of soft contact lenses for children based on retrospective and prospective studies. These are explored in detail in an open-access peer-reviewed publication.[50] None of the six studies reported any cases of microbial keratitis and only two observed CIEs. Note that the upper limit never exceeds 300 per 10,000 patient-years.

The overall picture is that the incidence of CIEs in children is markedly lower than in adults. The prospective studies of children represent more than 2,000 patient-years of soft contact lens wear. Combining the six prospective studies, the estimated incidence of CIEs in children is 54 per 10,000 patient-years, and the upper 95% limit is 86 per 10,000 patient-years. Even in the absence of any cases, the upper 95%

limit for microbial keratitis can still be estimated as 18 per 10,000 patient-years.

BENEFITS

Bullimore and Brennan recently listed three broad benefits of lowering a patient's ultimate level of myopia.[51] First, patients with lower myopia will have better uncorrected visual acuity, less difficulty performing everyday tasks, and report fewer challenges related to their vision.[52] Furthermore, patients with lower myopia have better corrected visual acuity than those with higher myopia.[53]

Second, the myopic child of today is the refractive surgery candidate of tomorrow. The lower the level of myopia, the easier it is to achieve minimal residual refractive error after corneal refractive surgery, resulting in better postoperative uncorrected visual acuity and fewer secondary surgical enhancements. Lower myopia is also associated with better postoperative visual quality.[53] Higher myopia requires greater amounts of corneal stroma to be removed in LASIK, SMILE, and other ablative procedures, making them poor surgical candidates and increasing the risk of postoperative corneal ectasia.[54] Hence, they may need to seek alternative procedures, such as phakic intraocular lenses, with their associated increased risks.

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Third, greater myopia increases the risk of a range of eye diseases, including cataract, glaucoma, and retinal detachment, but the strongest association is for myopic maculopathy, also referred to as myopic retinopathy or myopic macular degeneration.[55-57] More importantly, there is no treatment for myopic maculopathy, making it the leading cause of irreversible vision loss.

Bullimore and Brennan[51] analyzed five large population-based studies of the prevalence of myopic maculopathy in older patients, collectively representing some 21,000 patients.[58-62] When plotting the prevalence of myopic maculopathy on a logarithmic scale as a function of degree of myopia, all five studies show a remarkably similar slope with a range of 1.56x to 1.87x and a mean of 1.67x per diopter (Figure 2, redrawn from Bullimore and Brennan [51]). Thus, each 1-diopter increase in myopia is associated with a 67% (= 1.67 – 1) increase in the frequency of myopic maculopathy. Restated, slowing an individual's myopia by 1.00D should reduce the likelihood of that patient developing myopic maculopathy by 40% (= 1 – 1/1.67).

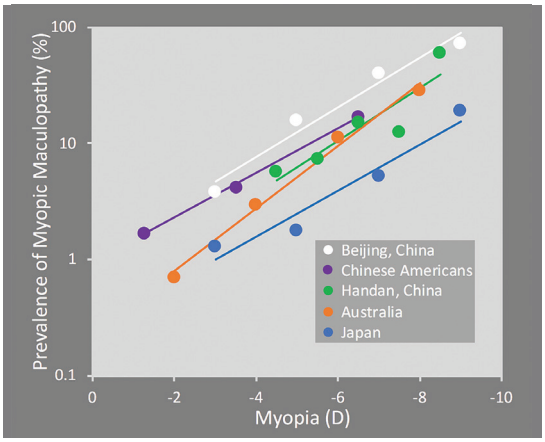

Figure 2. Prevalence of myopic maculopathy by level of myopia.

Furthermore, given the constant slope of the data, this benefit accrues regardless of the level of myopia. Thus, while the overall risk of myopic maculopathy is higher in a –7.00D myope than in a –4.00D myope, slowing progression by 1.00D during childhood will lower the risk by 40% in both. This supports Flitcroft's statement that "there is no safe level of myopia."[63] Indeed, myopes with less than 5.00D of refractive error contribute approximately 50% of the cases of myopic maculopathy in the studies in Australia and Singapore, because of the greater prevalence of lower levels of myopia.[58,64]

SUMMARY

Myopia can be slowed in children with overnight ortho-k and specially designed soft contact lenses. Both modalities carry some risk of minor complications and more serious events. Soft contact lens wear in children from 8 to 12 years old—when we are most likely to initiate myopia control—is likely to be safer than in adults. Selecting a daily disposable option will further lower the risks,[28,33] making microbial keratitis rare.

Practitioners must be cognizant, however, that the frequency of adverse events will increase as those interesting teenage years are encountered,[31] likely due to behavioral changes.[65] Overnight ortho-k is associated with a higher incidence of microbial keratitis,[36] with rates similar to other overnight modalities.[33] The benefits of slowing myopia are at least threefold: better

uncorrected vision, better refractive surgery outcomes, and, most importantly, reduced likelihood of vision loss in later life.[51] **CLS**

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