

The Role of Orthokeratology in Myopia Control: A Review

Michael J. Lipson, O.D., F.A.A.O., F.S.L.S., Moya M. Brooks, M.D., and Bruce H. Koffler, M.D.

Abstract: The prevalence of myopia and high myopia has significantly increased worldwide and in the United States. The serious implications of these trends are being recognized. Myopia is not just a minor inconvenience requiring vision correction with glasses or contact lenses, but a disease process creating significant risk of serious vision-threatening eye disease. Various methods of treatment for myopia and myopic progression have been prescribed and studied in effort to find one that is effective, safe, and that patients will be compliant with. Numerous peer-reviewed studies have shown orthokeratology (OrthoK) is effective in slowing myopic progression. This review article covers the development of OrthoK, its mechanism of action, its evolution, and refinement from a refractive option to its use as a mean of slowing myopic progression. After detailing patterns of myopia progression, a description of theories and studies as to how OrthoK slows myopia progression in children is also explained. The review will focus on progression of myopia and the use of OrthoK to slow myopia progression after myopia has been diagnosed.

Key Words: Orthokeratology—Myopia progression—Myopia management—Myopia control.

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Prevalence of myopia is increasing dramatically in East Asia, in the United States, and worldwide.^{1,2} Myopia is being diagnosed at younger ages and is progressing to higher degrees. Implications of these trends for the future are serious.³ It is not just that more people will be dependent on glasses or contact lenses, but that more people will be faced with vision-threatening eye disease such as myopic macular degeneration, central and peripheral retinal pathology, and glaucoma and cataract, as a result of complications related to longer axial length and increasing myopia.⁴ But, numerous studies show that we can provide interventions with the ability to slow myopic progression.⁵ This review will cover the epidemiology of myopia; provide a description of modern orthokeratology (OrthoK, the use of specially designed rigid gas-permeable (GP) contact lenses worn while sleeping to reshape the cornea and thus the refractive error of the eye), and review

From the Department of Ophthalmology and Visual Science (M.J.L.), University of Michigan, Ann Arbor, MI; and Koffler Vision Group (B.H.K.), Lexington, KY.

M. Lipson is a consultant to Bausch and Lomb's Specialty Vision Products division. B. Koffler is on the speaker's bureau for Paragon Vision Sciences and Bausch and Lomb. The author has no funding or conflicts of interest to disclose.

Address correspondence to Michael J. Lipson, O.D., F.A.A.O., Department of Ophthalmology and Visual Science, University of Michigan, 39901 Traditions Drive, Suite 230, Northville, MI 48168; e-mail: mjlipson@umich.edu.

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the studies demonstrating that OrthoK is a safe and efficacious process not only to correct refractive error, but also to slow progression of myopia.

Various methods of treatment for myopia and myopic progression have been prescribed and studied in effort to find one that is effective, safe, and that patients will be compliant with. Currently, the three methods that have the greatest efficacy are OrthoK, atropine, and specially designed soft lenses.⁶ This review will focus only on OrthoK. In the United States, overnight OrthoK received Food and Drug Administration (FDA) clearance to correct myopia in 2002. At this time, prescribing OrthoK specifically to stop myopic progression is "off label." As will be described later, numerous peer-reviewed studies have shown OrthoK is effective in slowing myopic progression.^{7,8} Even without FDA clearance for an indication of myopia control, most patients report that myopia control is the main reason they became interested in OrthoK.⁹

EPIDEMIOLOGY OF MYOPIA/UNITED STATES AND WORLDWIDE

In the United States, myopia prevalence in adults has increased from 25% in 1979% to 41% in 2004.¹ More recent studies indicate that trend continues such that, as of 2016, the figure is near 50%.³ Globally, prevalence of myopia in East Asian countries has been reported as high as 90%.¹⁰

A notable group of world health experts estimates that, in 2010, there were almost 2 billion people in the world with myopia and project that, with current trends, half of the world population (approximately 5 billion) will be myopic by 2050.² (Fig. 1) In addition, myopia is being diagnosed at younger ages in many countries.¹¹ Extensive study has shown that children who develop myopia at a younger age tend to progress more quickly and ultimately progress to a higher level of myopia.^{4,12} Increasing degree of myopia is clinically apparent as the axial length of the eye increases during growth years. Although a thorough review of myopia demonstrated that any degree of myopia is a risk factor for future vision-threatening pathology, high myopia (more than 6.00D) is associated with very high risk of these conditions.⁴ The higher the degree of myopia, the greater the risk. For example, people with more than 6.00D of myopia have a 14.4 times greater chance of developing glaucoma and a 3.3 times greater chance of developing a posterior subcapsular cataract.^{4,13} Those with more than 8.00D of myopia have a 7.8 times greater risk of having a retinal detachment. Vision impairment, significantly reduced best-corrected vision, is 22 times more likely in myopia over 10.00D compared with those at 6.00D of myopia.¹³ With current trends, projections are that more than 900 million of the world's populations will be highly myopic (more than 5.00D) by 2050.²

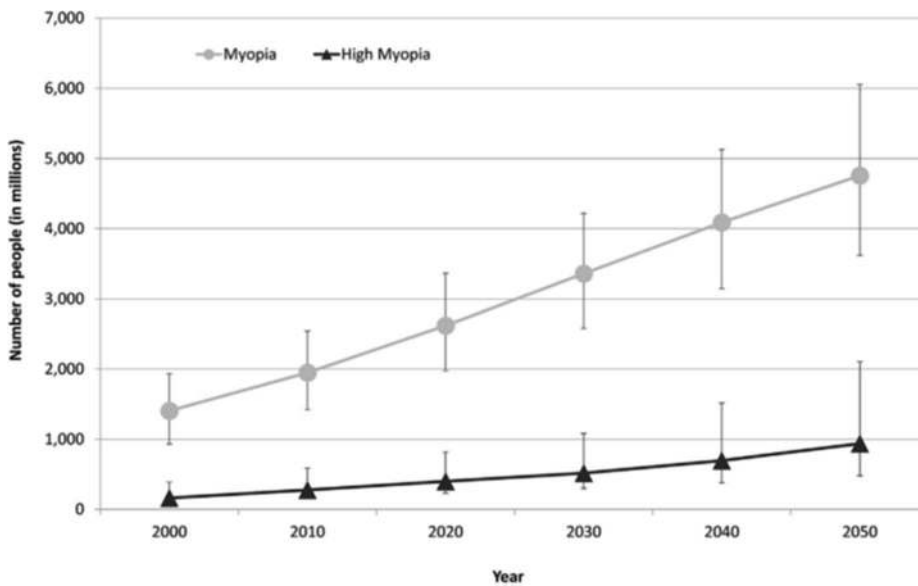


FIG. 1. Current and projected growth of myopia and high myopia. Graph showing the number of people estimated to have myopia and high myopia for each decade from 2000 through 2050. Error bars represent the 95% confidence intervals. From Holden, et al. 2015.

The serious implications of these trends are being recognized. Myopia is not just a minor inconvenience requiring vision correction with glasses or contact lenses, but a disease process creating significant risk of serious vision-threatening eye disease.^{4,13,14}

PROGRESSION OF MYOPIA

Myopia development and progression are complex and differ among individuals in genetics,¹⁵ influence of environmental causes,¹⁶ mode of correction,¹⁷ outdoor time,¹⁸ time spent on near tasks,¹⁹ ethnicity,²⁰ and progression patterns.²¹ Each of these characteristics has been extensively studied. Work on preventing the onset of myopia has been very limited, targeting time spent outdoors as a major contributing factor. This review will focus on progression of myopia, and the use of OrthoK to slow myopia progression after myopia has been diagnosed.

Onset of myopia can be found in newborns, but the majority is seen in school-age children. Jones et al.²² found 3 distinct patterns of myopia of development: first, those first becoming myopic around 6 to 7 years old, then a group developing myopia around 10 to 12, and finally those who first show myopia in their teens, each with their own unique pattern of progression. Studies show that the younger myopia develops, the faster it apparently progresses. Although older children and teens still show myopic progression, the rate of progression slows after 12 to 13 years of age.²² There is no minimum age for starting OrthoK. Cho's 2012 study²³ suggests that earlier age of intervention would have greater long-term benefit in limiting the ultimate level of myopia. In that study, 65% of the 7- to 8-year-old children in the spectacle-wearing control group were "fast progressors" versus 20% of the OrthoK group. Practical considerations in how early to prescribe OrthoK include the patient's maturity, motivation, responsibility for compliance in hygiene and lens care, and ability to report problems to eye care providers and parents. Candidacy should be carefully assessed on an individual case basis weighing relative risks versus

potential benefits and options for other myopia management modalities.

HISTORY OF ORTHOKERATOLOGY

The first attempt at corneal manipulation to reduce refractive error can be traced back to the early Chinese who applied small bags of sand to the eyelids thereby reducing corneal curvature and myopia.²⁴ Orthokeratology may be defined as a technique of programmed application of contact lenses to compress or manipulate corneal curvature.²⁵ It was first noted in the 1950s by Wesley and Jessen²⁶ that their patients were experiencing what they called "spectacle blur" caused by reshaping of the cornea after wearing hard contact lenses. Other practitioners, at this time, noted that many myopic contact lens wearers had improvement in visual acuity and/or a reduction in myopic correction after removal of rigid contact lenses.^{27,28} Although spectacle blur was seen as a nuisance, it was the springboard for later studies. In the 1960s, Jessen²⁹ created the first OrthoK lenses out of polymethylmethacrylate, a hard plastic that did not allow oxygen to pass through the lens, preventing OrthoK from expanding as a common practice. Orthokeratology continued in the 1970s with the use of flat-fitting rigid contact lenses. These lenses were able to reduce myopia only by approximately 1 D and were ineffective at allowing oxygen to pass through the lens, making OrthoK more of a novelty. The late 1970s ushered in a new era of contact lens materials. Rigid GP lenses were designed from new plastic materials that allowed more oxygen to reach the cornea, improving comfort and safety. However, the lenses still remained incapable of effectively correcting myopia, and the OrthoK trend faded.^{30,31}

In 1989, the first reverse geometry lens was designed by Nick Stoyan and Wlodyga.³² The lens was created with the secondary curve of steeper slope than the base curve, accelerating the time for the lens effect to occur, while increasing the ability to correct higher degrees of myopia and improving lens centration.³³ Soon after, technological advances included use of higher Dk lens materials (higher oxygen permeability), innovative reverse geometry lens

designs, and improved corneal topography. With this additional capability, it became apparent that mapping the entire corneal surface before and after OrthoK treatment was critical to achieving optimal results. Contex Inc. (Sherman Oaks, CA) was able to obtain approval for a daily-wear OrthoK design from the FDA in 1998. Subsequently, other investigators followed with creative designs for better centration and astigmatism control. El-Hage³⁴ is credited with being the first to use corneal topography to fit OrthoK lenses and monitor the resulting corneal changes. Corneal topographer manufacturers developed software allowing captured maps to be analyzed in more and detailed ways for precise design and to monitor corneal changes during OrthoK follow-up. This includes various types of topographical analysis including axial, tangential, elevation, and difference maps. Technology advances currently allow for the use of corneal topography for OrthoK to obtain accurate baseline measurements, determine initial lens selection, design initial lenses, monitor topographic changes after OrthoK lens wear, and accurately monitor lens treatment/position over many years of lens wear. In 2002, the FDA approved an overnight OrthoK design by Paragon Vision Sciences to include all age groups and corrections up to -6 D. Marketed as corneal refractive therapy,³⁵ this approval revitalized the industry. Since then, numerous companies have entered the OrthoK market with creative designs and materials. This has allowed for more customization to enhance lens centration and correct more complex prescriptions. Overnight wear, higher oxygen permeability, computerized lens designs, and accelerated results have created more popularity for OrthoK with eye care professionals and the public.³⁶ Orthokeratology lenses represented more than 5% of the U.S. GP lens market in 2011 and have grown to about 19% in 2016.³⁶ Currently, numerous OrthoK designs have attained FDA clearance in the United States (Table 1) with many others available worldwide.

EVOLUTION OF ORTHOKERATOLOGY FOR MYOPIA CONTROL

As overnight OrthoK became more popular, patients and clinicians observed an apparent reduction or cessation of their myopic progression. The first randomly controlled trial compar-

ing axial length changes in subjects fitted with OrthoK lenses to single-vision spectacle wearers was reported by Cho and Cheung.²³ Over a 2-year period, the OrthoK wearers showed a mean axial length increase of 0.29 (SD 0.27) mm vs. 0.54 (0.27) mm ($P=0.01$) for the spectacle wearers. One study showed a significantly smaller change in the cycloplegic retinoscopy in wearers of OrthoK lenses versus those wearing soft lenses.³⁷ Subsequent studies and meta-analysis studies have confirmed these findings.^{7,8,17,37-41}

ANATOMICAL/MORPHOLOGICAL CHANGES WITH ORTHOKERATOLOGY

Studies have shown that myopic OrthoK lenses elicit a flattening of the central cornea and a steepening of the mid-peripheral cornea, accompanied by changes to both the epithelial and stromal corneal layers.⁴²⁻⁴⁴ This pattern is reversed in hyperopic OrthoK, with steepening centrally and flattening in the mid periphery.⁴⁵

Far less is known about the mechanisms that elicit these corneal morphological changes. Choo et al. have enumerated many possible mechanisms by which OrthoK lenses may reshape the cornea.⁴⁶⁻⁴⁸

Corneal bending was one of the first proposed mechanisms in which some believed that the entire central cornea, including anterior and posterior curvatures, was altered by reverse geometry lenses. This theory now seems less likely, and new technologies such as optical coherence tomography, Orbscan videokeratography, and the Pentacam Scheimpflug photography system capable of calculating the posterior corneal curvature may be used to better assess the veracity of this postulated mechanism.⁴⁹⁻⁵¹

Epithelial cell redistribution and pressure differentials beneath the contact lens may result in forces that push against the central cornea and cause the redistribution or migration of epithelial cells to the mid periphery.⁴⁶ This theory suggests that epithelial cells are mobile but is complicated by what we know about cellular attachments and connections between epithelial cells.^{52,53}

Remodeling or compression of epithelial cells in their local environment because of changing pressures/forces that do not require these cells to migrate from their original site is another theory.⁴⁷ (Fig. 2).

TABLE 1. Orthokeratology Lens Designs With FDA Clearance in the United States

OrthoK Designs	Fitting Method	FDA License
BE Retainer	Topography/diagnostic evaluation	B&L/VST
CKR	Topography/design software	B&L/VST
Contex-OK E-System	Empirical/topography	B&L/VST
CRT, CRT Dual Axis	Nomogram/empirical/design software	Paragon CRT
DreimLens	Empirical	B&L/VST
Emerald, Sapphire	Empirical	B&L/VST
Fargo	Empirical	B&L/VST
Forge-Eyespace	Topography/design software	B&L/VST
GOV	Empirical/diagnostic lens evaluation	B&L/VST
iSEE	Fitting calculator	B&L/VST
MiraLens	Empirical	B&L/VST
Night Move	Empirical	B&L/VST
OrthoFocus	Empirical/topography	B&L/VST
RG4	Nomogram/empirical/diagnostic evaluation	Paragon CRT
Super Bridge/E-Lens Overnight Orthokeratology Lens	Fitting nomogram	B&L/VST
Vipok	Fitting nomogram	B&L/VST
Wave Contact Lens System	Topography/design software	B&L/VST

FDA, Food and Drug Administration.

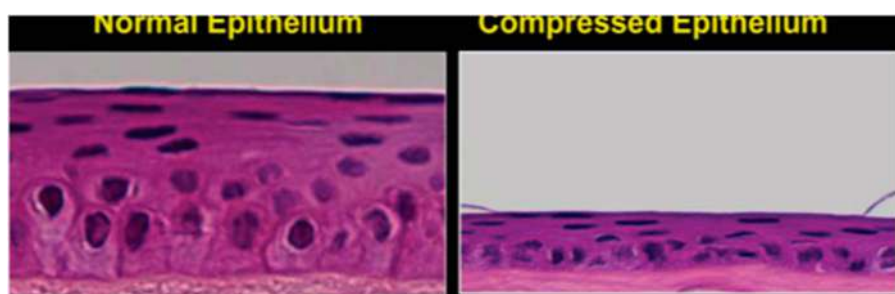


FIG. 2. Central corneal epithelial thinning after OrthoK. Choo et al. *Eye Contact Lens* 2004. full color online

Some have proposed that epithelial cells containing various cytoplasmic components and organelles may actually transfer intercellular components to adjacent cells through intracellular connections such as gap junctions, in response to the presence of OrthoK lenses. “Compressive forces in the central epithelium may induce a movement of intercellular fluid toward the limbus, resulting in smaller cells in the center and enlarged cells in the mid periphery” writes Choo et al.⁴⁷

Zhong et al.⁵⁴ found a reduced density of keratocytes in the corneal stroma and a modification of their shape. Another proposed mechanism involves an OrthoK lens–induced alteration of the rate of cellular mitosis, such that there is an increase in cellular proliferation in the mid periphery. Limbal stem cells and/or the basal epithelial layer may play a role in this mitotic theory.⁵⁴

In addition, OrthoK may induce alterations in cellular sloughing because of changes in apoptosis resulting in an increase in cells in the corneal mid periphery.⁴⁹ Stromal remodeling may also play a role in long-term OrthoK use and induced corneal changes.^{47,48} Verifying such changes on a cellular level will be challenging. One or more of these proposed mechanisms may be involved and more research is needed.⁵⁴

HOW DOES ORTHOKERATOLOGY SLOW MYOPIC PROGRESSION?

The most accepted theory of myopia progression centers on refractive changes peripheral to the macula. Pioneering work on myopia progression and peripheral refraction was performed with monkeys by Smith et al.⁵⁵ Studies in humans demonstrate that myopic eyes show relative hyperopia in the periphery that hyperopic and emmetropic eyes do not,⁵⁶ and children who develop myopia have more relative hyperopic peripheral defocus than emmetropic children two years before the onset of myopia.¹¹ Children with peripheral hyperopic defocus are more likely to develop myopia.⁵⁶ In addition, myopic children corrected with spectacles show significant hyperopic defocus.⁵⁷ Therefore, peripheral hyperopia is likely the signal for increased eye growth. Light focusing posterior to the peripheral retina may act as a signal for increasing axial length and higher degree of myopia. With OrthoK, the creation of an oblate shape of the cornea and the junction where the oblate portion of the cornea returns to its original curvature causes the image to focus centrally at the fovea, while peripheral light focuses anterior to the peripheral retina (myopic defocus).⁵⁸ This results in an image profile focusing centrally at the fovea, while peripheral to the macula, thereby myopic defocus is created. This myopic defocus, shown in Figure 3, is believed to be the mechanism that slows myopia progression during OrthoK wear.^{55,56,59} Although these

studies are quite convincing, there are studies showing no effect of peripheral defocus on axial length increase while other studies show a strong effect.^{21,60–63} Although clinical research has demonstrated that peripheral myopic defocus created with OrthoK is the significant mechanism by which myopia progression is slowed, other mechanisms may also influence slowing of progression during OrthoK. Another factor may be the change in lag of accommodation.^{64–67} This change occurs because of the increase in positive spherical aberration created after OrthoK and may be protective against progression of myopia.

In addition, researchers have studied changes in choroidal thickness in progressive myopes and during OrthoK wear.^{68,69} Progressive myopes show thinner choroidal thickness than emmetropes or myopes who are not progressing.^{70,71} Myopic OrthoK wearers have shown greater choroidal thickness than myopic controls wearing spectacles.⁷¹ The mechanism of the effect on choroidal thickness has not been established but shows great potential for future study.

Individual studies and meta-analyses on myopia control with OrthoK have shown a 40% to 60% mean reduction in rate of refractive change compared with controls using spectacles to correct myopia.^{6–9,36,72–75} It should be noted that studies reporting “mean reduction in rate of myopic progression” are describing the average for all subjects in the study. (Table 2). Within a study showing 50% mean reduction in myopia progression, some individuals may show 100% reduction in refractive change (no progression), whereas others may show 0% reduction (progression equal to that of the spectacle-wearing controls). Two studies reported results slightly different. These studies grouped the results in terms of the percentage of subjects who had little or no progression, moderate rate of progression, and fast progression. Both

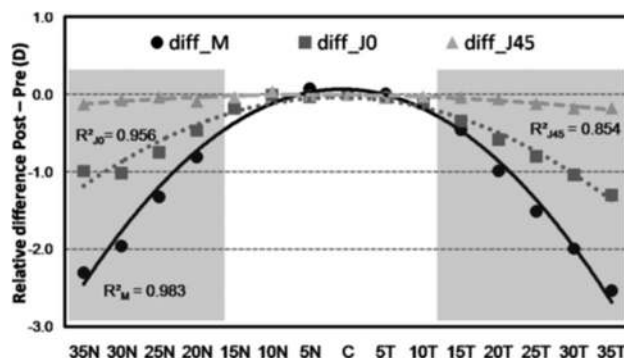


FIG. 3. Difference in peripheral refraction before and after OrthoK in 5° increments nasally and temporally. Queiros, Gonzalez-Mejome, et al. *Optom Vis Sci* 2010.

TABLE 2. Myopia Control Studies Showing Percent Reduction in Myopia Progression With OrthoK vs. a Control Group. Compiled by: M. Lipson

Study	Year	Control Group	Percent Reduction in Myopia Progression	Years of Follow-up
Cho (LORIC) ⁷²	2005	Spectacles	50	2
Walline et al. ⁷³	2009	Soft contact lenses	54	2
Kakita et al. ³⁹	2011	Spectacle	39	2
Santodomingo-Rubido et al. ⁷⁴	2011	Spectacle	39	2
Cho and Cheung (ROMIO) ²³	2012	Spectacle	43	2
Hiraoka et al. ⁴¹	2012	Spectacle	36	5
Charm and cho ⁷⁵	2013	Spectacle	60	2

studies reported similar results with 60% of OrthoK wearers categorized as “slow progressors,” 25% having “average” rate of myopia progression, and 15% “fast progressors.”^{36,76} This compares to spectacle wearers who showed rates of progression of 20, 60, and 20%, respectively.

Currently, OrthoK lenses are designed and prescribed to correct myopic refractive error and provide good unaided visual acuity. As refractive error is corrected with OrthoK, the demonstrated myopia control effect has been a beneficial side effect.⁷⁷ Although OrthoK has a significant effect in slowing myopic progression, as described above, the results vary with individuals. Although some OrthoK patients show little or no myopic progression, some do continue to progress. Factors that may contribute to this variable effect include age of myopia onset, age at start of OrthoK, increasing age, degree of baseline myopia, degree of baseline astigmatism, rate of progression before initiating OrthoK, pupil size, peripheral refractive profile (before and after OrthoK), retinal topography (shape), lens design, size of resulting treatment zone, and position of the treatment zone.^{5,39,78–81} These studies show that better myopia control (less myopic progression) is positively associated with older age of myopia onset, older age at start of OrthoK, higher degree of baseline myopia, larger pupil size, and smaller resulting central treatment zone (more peripheral myopia induced by ring of steepening outside treatment zone). Even with these data, relative to peripheral refraction, the exact location or amount of peripheral myopic defocus that will result in the best control of myopia progression has not been determined. Future developments in peripheral refraction testing in combination with customized lens design may show even better myopia control with OrthoK.

There are studies on the effect of OrthoK on myopia progression of long duration, 7 years, and 12 years.^{37,81} But, most studies on myopia progression with OrthoK have been 2 to 3 years in duration. During each of these studies, refractive and axial length data have been gathered at baseline, end of the study, and at 1-year or 6-month intervals. The data in both shorter- and longer-term studies have not shown definitive trends in the slowing of myopia progression relative to the time point in the process or the duration of the process.^{23,37,39,41} This is due in large part to the variability factors previously mentioned.

As with other myopia control modalities, the issue of a “rebound effect” after discontinuation has been questioned. There is minimal study on this subject. One study and one case report demonstrated a return to the previous rate of myopic progression in those discontinuing OrthoK.^{82,83} In other words, during OrthoK, rate of

myopic progression was reduced, but after discontinuation of OrthoK, the rate of myopia progression increased to its previous rate but not faster than its previous rate. One case report detailed a patient who discontinued OrthoK and stabilized at a degree of myopia less than their baseline myopia 3 years earlier.⁸⁴

SAFETY OF ORTHOKERATOLOGY

Because most OrthoK wearers are children, safety of OrthoK is a prime concern. Many years ago, there were reports of serious complications in OrthoK users in southeast Asia.^{83,85} Detailed analysis of these case reports showed a lack of compliance with care, limited or no regulation of fitting practices, and inappropriate lens materials or designs used. Recent studies and meta-analyses in the United States and worldwide have shown OrthoK to be very safe with very rare reports of complications.^{86–88} One of the largest of these investigations⁸⁶ involved 58 studies in English and 112 in Chinese and summarized their findings with the following statement—“There is sufficient evidence to suggest that OrthoK is a safe option for myopia correction and retardation. Long-term success of OrthoK treatment requires a combination of proper lens fitting, rigorous compliance to lens care regimen, good adherence to routine follow-ups, and timely treatment of complications.” They also reported no long-term effect of OrthoK on corneal endothelium. In a large retrospective study of OrthoK wearers in the United States involving 1,316 patients, representing about 2,600 patient-years of wear, there were only two events of microbial keratitis (MK).⁸⁷ This results in an estimated incidence of MK with OrthoK of 7.7 per 10,000 years of wear. In comparison, the incidence of MK for overnight wear of soft contact lenses was 19.5 per 10,000 wearers for conventional hydrogels and 25.4 per 10,000 wearers for silicone hydrogels. Another retrospective study on OrthoK wearers in the United States involved 296 patients during a 4.5-year period and reported three adverse events (keratitis greater than grade 2).⁸⁸ Each of these events resolved without loss of best-corrected visual acuity. This study showed that OrthoK was effective in providing good vision correction with few isolated minor complications.

PRACTICAL CONSIDERATIONS

As described earlier, controlling myopia progression has become an important public health issue. For eye care practitioners, current trends indicate that myopia control will become expected and standard of care. Orthokeratology is a safe and effective method to slow myopic progression in children. But, OrthoK is a specialized process requiring practitioners to seek specialized training, certification, and practical experience to become skilled in fitting and management of OrthoK patients. Caring for OrthoK patients is different than for traditional contact lenses. As such, office routines for OrthoK fitting, office visits, follow-ups, and lens care training must be modified to address the uniqueness of the process. In addition, to monitor myopia progression, additional testing and equipment may be required. Most importantly, corneal topography is required to fit and manage OrthoK patients. Relative to myopia progression, status may be monitored through refraction (with and without lenses on), corneal topography, and/or axial length. Studies have suggested axial length as the ultimate measure of myopic progression, but cycloplegic refraction (subjective and objective) has also been found to be effective.⁵

Because OrthoK lenses are worn overnight, careful, regular follow-up is critical to ensure ongoing corneal health and maintenance of clean lenses. Lens care and cleaning is not difficult, but compliance with prescribed lens care products and routines is critical to maintain a clear cornea and to minimize the potential for complications.^{86,88,89}

ORTHOKERATOLOGY AROUND THE WORLD

In the United States, it is estimated that there are between 500,000 and one million users of OrthoK (Personal Communication 2017—David Bland, Cary Herzberg, Rich Jeffries and Joann Simonson), whereas there may be as many as 1.5-million OrthoK wearers in China.⁹⁰ Surveys show some countries with as many as 25% of GP fittings for OrthoK lenses.⁹¹ That same study also found that although most doctors believed that OrthoK was an effective method of controlling myopic progression, only a small percentage of doctors are actually prescribing OrthoK in their practice.

SUMMARY

OrthoK allows patients to enjoy good vision without need for vision correction during their waking hours. Orthokeratology, as it is currently practiced, provides excellent vision, improves vision-related quality of life,^{92–95} is very safe, and is able to slow the rate of myopic progression in children. Because OrthoK gained FDA clearance (in the United States) as an option to correct refractive error, it has become more popular with eye care practitioners and with patients. As described earlier, even without specific FDA clearance to control myopic progression, most patients state that the reason they choose OrthoK is to slow increasing degree of myopia. Controlling myopic progression is of interest to eye care practitioners for reasons described earlier, and OrthoK shows a significant myopia control effect that patients readily accept and adapt to.

OrthoK is a unique field of specialty in contact lens eye care requiring practitioners to attain certification and specialty training. The process provides patients and practitioners an option to correct refractive error while slowing the rate of myopic progression. Future study may help further improve the effectiveness of OrthoK designs in slowing myopic progression.

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