AMERICAN ACADEMY OF OPHTHALMOLOGY
The Eye M.D. Association

Myopia Control during Orthokeratology Lens Wear in Children Using a Novel Study Design

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Purpose: To investigate the effect of overnight orthokeratology (OK) contact lens wear on axial length growth in East Asian children with progressive myopia.

Design: A prospective, randomized, contralateral-eye crossover study conducted over a 1-year period.

Participants: We enrolled 26 myopic children (age range, 10.8−17.0 years) of East Asian ethnicity.

Methods: Subjects were fitted with overnight OK in 1 eye, chosen at random, and conventional rigid gas-permeable (GP) lenses for daytime wear in the contralateral eye. Lenses were worn for 6 months. After a 2-week recovery period without lens wear, lens−eye combinations were reversed and lens wear was continued for a further 6 months, followed by another 2-week recovery period without lens wear. Axial eye length was monitored at baseline and every 3 months using an IOLMaster biometer. Corneal topography (Medmont E300) and objective refraction (Shin-Nippon NVision-K 5001 autorefractor) were also measured to confirm that OK lens wear was efficacious in correcting myopia.

Main Outcome Measurements: Axial length elongation and myopia progression with OK were compared with conventional daytime rigid contact lens wear.

Results: After 6 months of lens wear, axial length had increased by 0.04±0.06 mm (mean ± standard deviation) in the GP eye ($P = 0.011$) but showed no change (−0.02±0.05 mm) in the OK eye ($P = 0.888$). During the second 6-month phase of lens wear, in the OK eye there was no change from baseline in axial length at 12 months (−0.04±0.08 mm; $P = 0.218$). However, in the GP eye, the 12-month increase in axial length was significant (0.09±0.09 mm; $P < 0.001$). The GP lens-wearing eye showed progressive axial length growth throughout the study.

Conclusions: These results provide evidence that, at least in the initial months of lens wear, overnight OK inhibits axial eye growth and myopia progression compared with conventional GP lenses. Apparent shortening of axial length early in OK lens wear may reflect the contribution of OK-induced central corneal thinning, combined with choroidal thickening or recovery due to a reduction or neutralization of the myopiogenic stimulus to eye growth in these myopic children. *Ophthalmology 2014;■:1−11 © 2014 by the American Academy of Ophthalmology.*

Myopia is among the most common refractive errors that affect children. It is usually caused by excessive axial length of the eye, which causes light rays from distant objects to focus in front of the retina, giving rise to blurred distance vision. In children, myopia is typically progressive in early to middle childhood.[1] Early onset of myopia is frequently associated with the development of high myopia,[1] which can be associated with serious ocular complications, such as glaucoma, macular degeneration, and various pathologic retinal changes.[1,2] Thus, there are important benefits of interventions that might slow or arrest the development of myopia in children.

Myopia prevalence rates have been increasing worldwide. For example, in the United States the prevalence of myopia in the 12- to 54-year-old population increased from 25% in 1971 and 1972 to 41.6% in 1999 through 2004.[3] In Australia, increasing myopia prevalence has also been reported; the Sydney Adolescent Vascular and Eye Study (SAVES) followed a group of children over 5 to 6 years.[4] They reported an increase in myopia prevalence in 12-year-olds from 1.4% to 14.4%, and from 13% to 29.6% in 17-year-olds, over the study period.

However, the highest myopia prevalence rates have consistently been reported from East Asian countries. Epidemic levels of myopia prevalence have recently been reported from South Korea and China; 96.5% of 19-year-old South Korean males[5] and 95.5% of Chinese university students were found to have myopia.[6]

There has been growing clinical and research interest in developing strategies to control myopia progression, including both optical and pharmaceutical approaches.[7] To date, the most effective means for slowing myopia progression is the use of atropine drops.[7,8] Recent research using low concentrations of atropine (as low as 0.01%) seem to avoid many of the problems of 1% atropine, such as loss of accommodation and pupil dilation, without significant sacrifice of efficacy.[9]

Optical approaches have included the use of bifocal and progressive addition lenses. Although these approaches do

http://dx.doi.org/10.1016/j.ophtha.2014.09.028
ISSN 0161-6420/14

have a small, statistically significant effect, their clinical effect is minimal, even when subgroups that show enhanced efficacy are considered.[10] More recently, spectacle lenses and contact lenses designed to manipulate the peripheral retinal image have been investigated.[11–13] These approaches are based on the hypothesis developed by Smith et al[14] that manipulation of the peripheral retinal image to maintain myopic rather than hyperopic defocus may act to inhibit axial eye growth. Results from clinical studies using such optical manipulations have been encouraging.

Orthokeratology (OK) is a well-established clinical technique that involves wearing specialized rigid contact lenses with a reverse geometry lens design overnight. For myopia correction, OK lenses flatten the central cornea to correct mild to moderate degrees of central or on-axis myopia after lens removal in the morning.[15] Over the last few years, a number of clinical studies have clearly demonstrated that overnight OK lens use in myopic children is effective in reducing the rate of myopia progression.[16–23] It is hypothesized that this effect results from the induction of myopic defocus on to the peripheral retina as a result of the effects of the OK lenses on mid peripheral and peripheral corneal topography.[24]

Previous studies of myopia control in OK have relied on conventional study designs that have typically involved separate study and control groups of children wearing lenses over 2-year study periods. Such clinical studies are cumbersome and expensive to conduct, require large sample sizes and carefully matched subject groups, and suffer from difficulties with maintaining subject matching over the lengthy study period. Significant dropouts have been noted in some of these studies, ranging from 13% to 46% overall and up to 54% in the OK treatment group,[16–23] confounding the conclusions that can safely be drawn, particularly when reasons for dropout differ between control and treatment groups.[25]

In the study reported herein, we used a novel contralateral eye crossover study design to avoid many of the problems associated with previous conventional clinical trials. Using this efficient strategy, a relatively short-term study with minimal subject numbers was used to test the hypothesis that overnight OK lens wear inhibits axial elongation and myopia progression compared with conventional daytime rigid contact lens wear. The contralateral eye study design allowed paired analysis to minimize subject numbers without sacrificing statistical power, and it limited the risks of attrition bias from study dropouts. The crossover study design provided efficient confirmation of study outcomes over 2 consecutive 6-month lens-wearing periods.

Methods

This 12-month study used a prospective, randomized, contralateral eye crossover study design. The research conducted in this study conformed to the tenets of the Declaration of Helsinki (2008), and the research protocol and documentation received approval from the University of New South Wales Human Research Ethics Committee before study commencement. All subjects and their parents or guardians gave written consent to study participation after the nature of the study and risks and benefits of participation in the research had been fully explained. Separate consent forms using appropriate language were prepared for subjects <10 years of age, >10 years of age, and for parents or guardians.

Subjects

A total of 32 subjects who met the study entry criteria were recruited for participation in this research. Inclusion criteria specified age between 8 and 16 years at initial study enrollment and East Asian ethnicity (Chinese, Singaporean, Taiwanese, Malaysian-Chinese, and Vietnamese) based on parental reports of ethnic background. Refractive criteria included myopia between −1.00 and −4.00 diopters (D) spherical equivalent, evidence of progression of myopia in the previous 12 months (based on a reported increase in spectacle prescription), <1.50 D of corneal toricity, and <1.00 D difference in spherical equivalent refraction between the 2 eyes. For study entry, subjects also were required to demonstrate good binocular coordination (based on a range of standard optometric tests of binocularity, including measurement of stereoacuity using the Titmus Fly Stereotest), good ocular health, and no contraindications for rigid contact lens wear.

Contact Lenses

The rigid lenses used for overnight OK were of a reverse geometry design (BE or A-BE; Capricornia Contact Lens Pty Ltd, Brisbane, Qld, Australia) that is available commercially for use as an overnight OK lens. Overall diameter of these lenses was either 11.00 mm (BE) or 10.60 mm (A-BE), depending on the subject's horizontal visible iris diameter and palpebral aperture dimensions. Both BE and A-BE lenses have an optic zone diameter of 6.00 mm, and specifications of the optic zone, first reverse curve, and peripheral alignment curve are identical between designs. The difference in lens diameter is achieved by using a slightly steeper and narrower second reverse curve in the A-BE lens to maintain sagittal height equivalence between the 2 designs.

The conventional rigid gas-permeable (GP) lenses used were a standard alignment fitting design (J-Contour, Capricornia), a 4-curve lens with an overall diameter of 10.00 or 10.50 mm, and a spherical back optic zone with a diameter of 8.50 or 9.00 mm, respectively. To achieve an acceptable lens fit, the Modcon lens design (Capricornia) with an overall diameter of 10.00 mm, a spherical back optic zone of 7.90 mm in diameter, and a tangent periphery, was used for 5 subjects during study phase 1 (2 of whom discontinued) and 4 subjects during study phase 2 (1 of whom was refitted from a J-Contour to a Modcon lens). The choice of lens design to use for the GP lens-wearing eye was based on conventional rigid contact lens fitting considerations to encourage comfortable and safe daily GP lens wear.

Both lenses (OK and GP) were fabricated from the hyper-Dk Boston XO_2 material (hexafocon B, Dk 141 ISO/Fatt units; Bausch & Lomb Boston, Wilmington, MA). Nominal center thickness for the OK lenses was 0.23 mm, and 0.17 mm for the GP lenses, giving nominal central Dk/t of 61 and 83 Dk/t units, respectively. The OK lens was supplied with a purple handling tint, and the GP lens had a light blue handling tint.

Before the commencement of the study, OK lenses were fitted to both eyes according to the manufacturer's recommended procedure. Initial lens selection was based on corneal topographic variables including apical corneal radius and corneal sagittal height at a 9.35-mm chord (or 8.95 mm for A-BE lenses), as measured by the Medmont E-300 corneal topographer (Medmont Ltd, Melbourne, Victoria, Australia), horizontal visible iris diameter, and desired refractive change. An overnight lens-wearing trial using lenses indicated by the proprietary BE lens-fitting software algorithm was conducted, and outcomes from this overnight trial were