PERSPECTIVE

Myopia Control in Children through Refractive Therapy Gas Permeable Contact Lenses: Is it for Real?

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• PURPOSE: **To compare the safety and efficacy of orthokeratology as a nonsurgical treatment for myopia in children with alternate methods, such as soft contact lenses, rigid gas permeable lenses, and spectacles, throughout multiple studies.**
• DESIGN: **Perspective with literature review.**
• METHODS: **Analysis of recent studies to determine the safety and effectiveness of orthokeratology versus soft contact lenses, rigid gas permeable lenses, and spectacles in children.**
• RESULTS: **In all of the studies reviewed, the use of orthokeratology lenses proved to reduce myopia, to improve visual acuity, and, with the exception of the SMART study, to reduce the rate of axial elongation. Orthokeratology has been shown to be as effective as other methods in treating myopia and to be more effective at treating axial elongation. There were no major adverse events in any of the studies comparing orthokeratology with other methods of myopia treatment.**
• CONCLUSIONS: **Studies show that the use of orthokeratology is a safe and efficacious nonsurgical treatment for myopia and that it is capable of slowing axial elongation, making it an effective myopic treatment for children. (Am J Ophthalmol 2013;156:1076–1081.**

UNCORRECTED REFRACTIVE ERRORS ARE THE world's leading cause of visual impairment, with myopia estimated to be the leading form of refractive error worldwide.[1,2] Nearly 30% of Americans and up to 85% of the East Asia population are affected by myopia. Instances of myopia in 19-year-old Korean males reached 96.54% in a recent study. The study also showed that myopia increased with education levels, indicating a positive correlation between myopia and educational achievement.[3] Many efforts have been made to try to suppress and even reverse myopic development, including pharmaceutical, surgical, and corrective lens solutions. The most successful of these treatments was the use of antimuscarinic medications, such as atropine, pirenzepine gel, and cyclopentolate. However, this approach led to adverse side effects of light sensitivity and blurred vision. The drugs required were not readily available to the patient, making the treatment costly and impractical.[4] Orthokeratology, or the more current technique of corneal reshaping or refractive therapy, is a more effective strategy for addressing myopia up to −5 diopters (D) and astigmatism up to 1.5 D. It alters how light is refracted by reshaping the cornea into a flatter surface while slowing axial length elongation in younger patients. It is reversible, so if the patient is unhappy with the treatment, they can simply discontinue wearing the lenses.

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DEVELOPMENT OF ORTHOKERATOLOGY

ORTHOKERATOLOGY WAS FIRST NOTED IN THE 1950S BY Wesley and Jessen when their patients were experiencing what they called spectacle blur caused by reshaping of the cornea after wearing hard contact lenses.[5] Although spectacle blur was seen as a nuisance at the time, it was the springboard for later studies. In the 1960s, Jessen created the first orthokeratology lenses out of polymethyl methacrylate, a hard plastic that was uncomfortable and did not allow oxygen to reach the cornea, preventing orthokeratology from expanding as a common practice.[6] Orthokeratology continued in the 1970s with the use of tight and 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 orthokeratology more of a novelty. The late 1970s ushered in a new era of contact lens materials. Rigid gas permeable lenses were designed from new plastic materials that allowed oxygen to reach the cornea, improving comfort and safety. However, the lenses still remained incapable of effectively correcting myopia, and the orthokeratology trend began to die down.[7] In 1989, the first reverse geometry lens was designed by Richard Wlodyga. The lens gave the secondary curve a steeper slope than the base curve, accelerating the time for the lens effect

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to occur, while improving correction from −1 D to −1.7 D of myopia and improved lens centration.[8] Using a higher Dk lens, which represents higher oxygen permeability, different reverse geometry rigid gas permeable lens designs, and advances in corneal topography, Contex was able to obtain approval for their orthokeratology design for daily wear from the Food and Drug Administration (FDA) in 1998. Many other investigators followed with their creative designs for better centration and astigmatism control. In 2002, the FDA approved an overnight wear contact by Paragon Vision Sciences, which revitalized this industry and was called corneal refractive therapy. Overnight wear, higher oxygen permeability, and accelerated results allowed corneal refractive therapy to become more popular to the eye care professional and the public.[9] Orthokeratology lenses represented more than 5% of the rigid gas permeable lens market in 2011, with double-digit growth in sales over the last few years.[10]

HOW ORTHOKERATOLOGY LENSES WORK

REVERSE GEOMETRY GAS PERMEABLE LENSES ARE USED TO reshape the cornea of a myopic eye. A normal cornea is steep centrally and gradually flattens to the periphery, causing light to be focused before it is able to reach the macula centrally and behind the retina in the periphery (peripheral hyperopia). These reverse geometry lenses differ from standard rigid gas permeable lenses because the central base curve is much flatter than the secondary curve. The reverse geometry lenses produce flattening of the central cornea, which allows light to be focused on the retina instead of in front of the retina. The lens creates a positive pushing pressure against the central cornea and a negative pulling pressure against the mid peripheral cornea, redistributing the epithelial cells to the mid periphery while flattening the central cornea via a thinning of the epithelial layer.[11] These 2 pressures give the cornea a more plateau shape.[12] The plateau shape allows for light to be refracted simultaneously onto the mid peripheral retina and macula, correcting myopia.

Orthokeratology lenses also are linked to slowing axial length elongation, a major cause of myopia, by treating peripheral hyperopia. A study by Smith and associates showed the relationship of peripheral vision and axial length elongation. In the study, the authors ablated the fovea and macula of monkeys with a laser, leaving the peripheral retina intact, and compared this group with another group in which they ablated the mid periphery of the retina, leaving the fovea and macula intact. Elongation occurred only in the monkeys that had damage to the mid periphery of the retina. The group that had macular damage showed no increase in axial length.[13]

These results were confirmed in a study that gave chicks a 2-zone lens that mimicked central hyperopia, central myopia, peripheral hyperopia, and peripheral myopia. The lenses that altered vision in the periphery had the most effect in stimulating eye growth. The lenses that affected only the central vision did not show a significant change in eye growth.[14] Because emmetropization is now thought to be linked to peripheral vision, focusing light on to the central retina will temporarily fix the myopia only and will not slow its progression.[15] The orthokeratology lens design reduces peripheral hyperopia by aligning the image shell on to the mid-peripheral retina, allowing eyes to move toward the ideal optical state. Myopic eyes treated with spectacles or conventional contact lenses do not correct peripheral hyperopia, causing elongation to continue.

EFFICACY OF ORTHOKERATOLOGY

THE EFFICACY OF ORTHOKERATOLOGY TREATMENT HAS been long debated because of early studies showing only slow improvement in patients with low degrees of myopia and increased rates of infection.[16] However, development of reverse geometry lenses, materials that improve oxygen permeability, and better training in orthokeratology fitting and patient compliance have led to increased benefits and safety of this procedure.

The Contact Lens and Myopia Progression study by Walline and associates was conducted to determine how conventional rigid gas permeable lenses affected myopia progression in children versus soft contact lens wearers. The initial mean cycloplegic retinoscopy of both groups was −2.09 D. After 3 years of wear, the cycloplegic retinoscopy of rigid gas permeable wearers was −1.56 D, whereas the soft contact lens cycloplegic retinoscopy was −2.19 D. The study showed a 29% slower progression of myopia in the rigid gas permeable group when compared with the soft contact lens group. The results were significant with a P value of 0.002 This study also showed that there was no significant difference in axial length ($P = 0.72$) between the two groups, but the soft contact lens group demonstrated greater corneal steepening than the rigid gas permeable group, which likely was the cause of the worsened myopia.[17] The Contact Lens and Myopia Progression study revealed that wearing spherical rigid gas permeable lenses was an ineffective treatment for slowing the progression of myopia and that it required something beyond spherical rigid gas permeable lenses.

The Longitudinal Orthokeratology Research in Children (LORIC) study, conducted by Cho and associates, was a 2-year pilot study in Hong Kong to determine if orthokeratology can treat and prevent myopia. The orthokeratology treatment was conducted by the same examiner to improve accuracy, and the spectacle control data were

provided by a previous study conducted by Edwards.[18] The children all had a spherical equivalent refraction between −0.25 D and −4.50 D, with astigmatism of less than 2.00 D. After the 2-year study had been completed, the spherical equivalent refraction error for the orthokeratology group showed a mean myopic reduction of 2.09 ± 1.34 D, whereas the spectacle group showed a mean myopic increase of 1.20 ± 0.61 D. The axial length change was 0.29 ± 0.27 mm, with a vitreous chamber depth change of 0.23 ± 0.25 mm for the orthokeratology group and 0.54 ± 0.27 mm for axial length, with a vitreous chamber depth change of 0.48 ± 0.26 mm for the spectacle group. The axial length and vitreous chamber depth change in the orthokeratology group were half of that of the spectacle group, which was statistically significant with a *P* value of 0.005. This study showed that orthokeratology not only was an effective treatment of myopia up to −4.00 D, but also that it can prevent myopia by slowing axial length and vitreous chamber growth.[19]

The purpose of the Children's Overnight Orthokeratology Investigation (COOKI) study, conducted by Walline and associates, was to determine the spherical equivalence refraction change and safety of orthokeratology treatment over a period of 6 months. The COOKI study showed that the mean spherical equivalence refraction error changed from −2.44 ± 1.38 D at baseline to −0.16 ± 0.66 D at 6 months in the orthokeratology wearers. Of the eyes tested, 47.4% had 20/20 visual acuity or better and 100% achieved 20/40 visual acuity or better. Ideal visual acuity levels were obtained after 1 week of wear, with the effect lasting throughout the day at two weeks.[20] This time was reduced from previous studies that required up to 300 days of wear for spherical lenses and 40 days for early reverse geometry designs.[21] The COOKI study showed that use of orthokeratology lenses was more effective than spherical rigid gas permeable lenses at treating myopia in children and that it was safe for overnight use.

Walline and associates also conducted the Corneal Reshaping and Yearly Observation of Nearsightedness (CRAYON) study to determine the efficacy of the LORIC study, which indicated that orthokeratology lenses can treat myopia and slow axial length elongation. The CRAYON study compared orthokeratology lenses with soft contact lens. The study showed a mean change in axial length of 0.16 mm less in the orthokeratology group, which was statistically significant with a *P* value of 0.0004. The mean change in vitreous chamber depth was 0.10 mm less in the orthokeratology group, a statistically significant difference with a *P* value of 0.006.[22] The CRAYON study confirmed the results of the LORIC study by Cho and associates that showed that orthokeratology lenses can reduce axial length elongation by half and are an effective preventative treatment for myopia progression.

The Stabilizing Myopia by Accelerated Reshaping Technique (SMART) study was the first large-scale study to determine if wearing reverse geometry overnight orthokeratology lenses would slow the progression of myopia in children. The SMART study enlisted 162 children to test the efficacy of orthokeratology. The orthokeratology lenses were compared with soft contact lens that were changed every month. The SMART study was conducted in 10 clinics throughout the United States. After the 3-year study, 85% of orthokeratology patients achieved an uncorrected visual acuity of 20/20 or better and 99% achieved an uncorrected visual acuity of 20/40 or better. The 3-year test results of the SMART study showed that the orthokeratology group was less myopic than the soft contact lens group, with a mean change spherical equivalence refraction for the orthokeratology group being −0.19 D in the right eye and −0.15 D in the left eye at the end of the third year. These readings were obtained after the orthokeratology lenses were removed from the patients and their refraction and topography were allowed to stabilize at two separate time points. The mean change in spherical equivalence refraction for the soft contact lens groups was −1.00 D in the right eye and −1.02 D in the left eye at the end of the third year. The SMART study did show a statistically significant difference in spherical equivalent refraction, but did not show any significant change in axial length between the orthokeratology and soft contact lens group. Lack of change of the axial length between the two groups is considered to be the result of the study being conducted by different practices with different techniques and machines for determining axial length (Gerowitz RS. Contact Lens and Anterior Eye 2012(35):E-Abstract 40).

Another study that validates the efficacy of orthokeratology treatment on myopic children titled "Influence of Overnight Orthokeratology on Axial Elongation in Childhood Myopia" was conducted in Japan to compare axial length in orthokeratology patients versus in those with spectacles. The baseline data for the orthokeratology group included a mean spherical equivalence refraction of −2.55 ± 1.82 D, a mean uncorrected visual acuity of 0.80 ± 0.32 D, and a mean axial length of 24.66 ± 1.11 mm. The baseline data for the spectacle group included a mean spherical equivalence refraction of −2.59 ± 1.66 D, a mean uncorrected visual acuity of 0.83 ± 0.31 D, and a mean axial length of 24.79 ± 0.80 mm. After two years, the spherical equivalence refraction for the orthokeratology group improved to a mean of −0.68 ± 1.02 D and had a mean axial length change of 0.39 ± 0.27 mm. The spectacle group spherical equivalence refraction dropped to −3.83 ± 1.76 D and had an axial length change of 0.61 ± 0.24 mm. The difference was statistically significant, with a *P* value of less than 0.0001.[23] Axial length measurements were tightly controlled using the IOL Master by Carl Zeiss Meditec and one technician to perform all the measurements. The results from the "Influence of Overnight Orthokeratology on Axial Length Elongation in Childhood Myopia" study confirm the results of the LORIC and CRAYON

TABLE. Orthokeratology Lenses Compared against Various Control Groups

Study	Age of Patients (y)	Change in Axial Length in Orthokeratology Patients (mm)	Change in Axial Length in Control Group (mm)	Method of Control	Length of Study (y)	Difference between Orthokeratology and Control Groups (%)	P Value
LORIC	7 to 12	0.29	0.54	Glasses	2	46.30	0.005
CRAYON	8 to 11	0.25	0.57	Soft contact lens	2	56.14	0.0004
IOOALECM	8 to 16	0.39	0.61	Glasses	2	36.00	0.0001
MCOS	6 to 12	0.47	0.69	Glasses	2	31.88	0.001
IOOALECM 5-y follow-up	8 to 16	0.99	1.41	Glasses	5	29.79	0.863
ROMIO	6 to 10	0.36	0.63	Glasses	2	57.14	0.001

CRAYON = Corneal Reshaping and Yearly Observation of Nearsightedness; IOOAECM = Influence of Overnight Orthokeratology on Axial Elongation in Childhood Myopia; LORIC = Longitudinal Orthokeratology Research in Children; MCOS = Myopia Control with Orthokeratology Contact Lenses in Spain; ROMIO = Retardation of Myopia in Orthokeratology. Each study showed that the group with orthokeratology treatment showed a reduction in axial length.

studies showing that that orthokeratology treatment reduces the rate of elongation of axial length and helps to treat myopia. There was published a 5-year follow-up of the "Influence of Overnight Orthokeratology on Axial Length Elongation in Childhood Myopia" study showing that orthokeratology was effective in long-term treatment. After 5 years, the mean change in axial length for the orthokeratology group was 0.99 ± 0.47 mm and that for the spectacle group was 1.41 ± 0.68 mm. The changes in axial length over each year were significantly different at the third year, with a *P* value of 0.0385. However, at year 5, the changes in axial length were no longer significantly different, with a *P* value of 0.8633.[24]

A recent study called "Myopia Control with Orthokeratology Contact Lenses in Spain," by J Santodomingo-Rubido and associates, was conducted to determine the effect of orthokeratology lenses on axial growth when compared with single-vision spectacles. The study found that the mean change in axial length over a 2-year period for the orthokeratology group was 0.47 mm and that for the spectacle group was 0.69 mm, which was statistically significant with a *P* value of less than 0.001.[25] These results show that orthokeratology has a slowing effect on axial length elongation when compared with the control group.

Finally, a randomized 2012 study conducted by Cho and Cheung assessed the effectiveness of orthokeratology and at what age orthokeratology most benefitted the patient. The study included 102 subjects 6 to 10 years of age. The study concluded that axial length elongation was slowed by 43% in children who wore orthokeratology lenses, a statistically significant difference with a *P* value of less than 0.001. At the end of the 2-year study, the average increase in axial length elongation of orthokeratology patients was 0.36 ± 0.24 mm and the average increase in the spectacle control group was 0.63 ± 0.26 mm. The study also concluded that children 7 to 8 years of age had a faster rate of axial length elongation than older children. This finding determined that younger children at approximately age 7 years benefitted to a greater degree from orthokeratology treatment.[26]

Each of these studies shows that orthokeratology has a sizable advantage in correcting and treating myopia when compared with single-vision spectacles, soft contacts, and standard rigid gas permeable lenses (Table).

SAFETY OF ORTHOKERATOLOGY LENSES

ADVANCEMENT IN LENS MATERIAL NOT ONLY HAS increased the rate at which orthokeratology can reach its maximum effect, but also it has increased safety. The original lens material used in orthokeratology, polymethyl methacrylate, had a negligible oxygen transmission (Dk = 0), causing them to be unsafe for extended wear. The material used in today's overnight extended wear gas permeable lenses have a Dk value ranging from 49 to 163, indicating high oxygen permeability and reduced risk of infection. There have been a total of 123 instances of microbial keratitis in orthokeratology patients reported between 1997 and 2007. Most of the reported cases were found in East Asian children ranging in age from 9 to 15 years of age. Common organisms found were *Pseudomonas aeruginosa* and *Acanthamoeba*. Risk factors determined in this study were inappropriate lens care, patient not following practitioner's instructions, and continuation of lens wear despite discomfort.[27] There is rising support for the safety of orthokeratology as a safe overnight treatment as patient compliance continues to improve. Orthokeratology does not seem to have an increased role in developing microbial keratitis as long as there is proper care for the lenses.[28]

The safety of orthokeratology also was evaluated in the SMART study, the COOKI study, a study at the Ohio State

University School of Optometry, and the Paragon Vision Sciences FDA postmarket surveillance. The SMART study found that there were 13 instances of grade 2 or higher biomicroscopic events in the orthokeratology group and 12 instances in the soft contact lens group. The soft contact lens group was the only group to show signs of corneal infiltrative keratitis (Gerowitz RS. Contact Lens and Anterior Eye 2012(35):E-Abstract 40). The COOKI study showed that 3 of 5 of the patients had fluorescein staining in the morning and 1 of 3 had staining in the afternoon. The mean staining rating was a 1.60 on a scale from 1 to 4, and none of the incidences was serious enough to stop use of the lenses. Walline and associates report low severity of staining in orthokeratology wearers and no reason to associate a high risk with overnight orthokeratology.[17] The FDA report for the Paragon Corneal Reshaping Therapy lens showed no slit-lamp instances that were worse than grade 2, and all instances could be corrected with no other complications.[9] It also showed that the orthokeratology lenses had no effect on intraocular pressure. Santodomingo-Rubido and associates evaluated the number of adverse events in orthokeratology patients versus a spectacle group. The study found that 9 of 61 patients experienced an adverse event and that 3 of those patients experienced adverse events not attributable to orthokeratology lens wear.[29]

The instances of microbial keratitis initiated a postmarket study conducted by the FDA and the Ohio State University. The results showed 7.7 instances of microbial keratitis per 10 000 person-years of wear, making orthokeratology wearers only slightly more susceptible to infection than daily soft contact lens wearers at 4.1 per 10 000 (Bullimore MA. Optom Vis Sci 2009;86:E-Abstract 90583). The original study by Schein and associates estimated the rate of microbial keratitis in 30-day extended wear silicone hydrogel lens wearers to be 14.4 per 10 000 person-years of wear.[30] The low instances and severity of adverse events in orthokeratology indicate that the method is safe for treating myopia in children. The lenses are worn for 6 to 8 hours per night and are made of a high Dk material, providing the eye with proper oxygenation. The lenses are also 10 mm in diameter and do not cover the limbus, preventing damage to stem cells. The lenses only change the shape of the epithelium and do not alter or damage the endothelium.

Training and certifications in fitting orthokeratology lenses, as required by the FDA, also has improved safety. Previously, orthokeratology lenses were able to be fit by anyone trained in rigid gas permeable lenses, but now certification is required by the companies to fit their orthokeratology lens design. Requiring a separate certification reduces the chance of a poor lens fit, another risk factor for microbial keratitis. Patient compliance is improving because of an effort by practitioners in promoting proper lens care, reducing the number of infections seen recently in orthokeratology wearers.

DEVELOPING APPLICATIONS OF ORTHOKERATOLOGY

ORTHOKERATOLOGY PROMISES TO IMPROVE ON ITS current standard by accelerating the time for the lenses to affect the cornea, better lens centration, greater safety with higher Dk valued lenses, and improved solutions for proper lens care. Lenses that are able to correct higher degrees of astigmatism also are being developed to allow more patients to wear orthokeratology lenses. There are also studies being conducted to make orthokeratology a treatment for keratoconus using the technique to reshape the cornea and then applying riboflavin and ultraviolet A light to stabilize the new shape of the cornea and to prevent further development of keratoconus.[31] Despite early trials being unsuccessful at stabilizing the cornea's shape, the orthokeratology lenses did flatten the cornea, reducing keratoconus in the patient. Advancements in collagen cross-linking materials would improve the success rate of the treatment. Recently, El Hage and Seiler presented 5 patients of who successfully underwent cross-linking with riboflavin and ultraviolet A light, combined with orthokeratology to treat myopia.[32] Koffler and associates showed in 1999 that a plateau-shaped gas permeable contact lens could be used to modify the shape and resultant refraction of undercorrected radial keratotomy eyes. The use of this orthokeratology method in postsurgical patients combined with cross-linking needs to be investigated further.[33] Another treatment being investigated is using orthokeratology to treat hyperopia by steepening the cornea. A study was conducted that showed that the use of hyperopia orthokeratology does steepen the cornea and produces the desired shape change in cats.[34]

CONCLUSIONS

THE INITIAL PRACTICE OF ORTHOKERATOLOGY PROVED TO be ineffective, but with new development of lens material and designs especially for overnight wear, orthokeratology has developed into a viable and effective treatment for myopia. Studies suggest that current techniques are highly effective at treating myopia of up to −6.00 D and astigmatism of up to −1.75 D. Orthokeratology is an effective option in slowing the progression of myopia by redirecting the image shell onto both the central and mid-peripheral retina, thereby producing emmetropization. Improved training, better lens hygiene, and patient compliance have promoted the safety of orthokeratology to make it as safe as other overnight methods. The future will bring further applications of orthokeratology to treat other refractive errors. Orthokeratology is a very useful tool in combating refractive errors in myopic children and, with further studies, should prove to be useful in a wide range of other refractive disorders.

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Biosketch

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