

American Academy of Optometry
Section on Cornea and Contact Lenses
Information for Eyecare Practitioners
Position Paper on Orthokeratology with Contact Lenses
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What are the Contact Lens Corneal Reshaping Procedures?

Orthokeratology (i.e., corneal reshaping, corneal refractive therapy, vision shaping treatment) is a process which uses specially designed rigid contact lenses to temporarily reshape the corneal contour. The purpose of corneal reshaping is to reduce or modify myopia or astigmatism by applying rigid gas permeable (GP) lenses which have a curve that is flatter than the cornea. As the curvature of the cornea changes in response, myopia is reduced and uncorrected vision improves. Once the desired effect is achieved, lenses are often worn as retainers at night to maintain the effect. The usefulness of orthokeratology for a given patient will depend on both the magnitude of change achieved and how lasting the effect is. In the past this procedure used a series of lenses to accomplish temporary improved vision.

In 2002, the U.S. Food and Drug Administration (FDA) approved a procedure called corneal refractive therapy. This procedure uses special design lenses worn only at night to temporarily reduce nearsightedness. The goal is to use one set of lenses from beginning to end, with maximum affect taking place after a couple of weeks. Sometimes one or two lens design changes may be needed. This has been accompanied by the FDA approval [for night-time wear](#) of several additional orthokeratology designs .

What is the Mechanism of Action?

Many theories exist to explain the mechanism of orthokeratology with the most widely accepted being that of corneal "sphericalization". (1-3) The non-contact lens wearing cornea is aspheric with the central corneal having the steepest curvature and becoming progressively flatter towards the periphery. GP contact lens wear is postulated to cause central corneal flattening accompanied by paracentral steepening, which results in a corneal shape factor that approaches zero (i.e., spherical). This process is accelerated by the use of reverse geometry lens designs which have a secondary curve that is steeper than the base curve to allow appropriate changes in the midperipheral cornea (i.e., "accelerated orthokeratology"). In other words, when a rigid contact lens applies pressure to the cornea in one area, the cornea yields to that force and pushes out in another area where there is less force. Therefore, flattening of the apex of the central cornea is accompanied by midperipheral steepening, essentially resulting in a redistribution of corneal tissue. (4) This is believed to be the basis for changes occurring in orthokeratology.

How Successful is Orthokeratology?

Orthokeratology appears to be quite successful for patients with less than two diopters of myopia. Early studies reported only about a one diopter decrease in myopia.

(1,5,6) More recent research with newer lens designs have reported approximately twice as much myopia reduction and has been found effective for reduction of myopia of as much as 4D. (7-9). In addition, with these designs, almost all of the refractive change occurred within the first 7 to 14 days (10-12) with a significant effect in both corneal flattening and improvement in visual acuity occurring within 10 minutes of lens wear. (13) In a three month study completed by 31 subjects, the mean reduction in the myopic spherical equivalent refraction was 2.08D in the right eye and 2.16D in the left eye.(7) Seventy-four percent of the subjects achieved 20/20 or better unaided visual acuity in their right and 61% had unaided visual acuity of 20/20 or better in their left eye.

Can the Amount of Myopia Reduction Be Predicted?

Predicting the amount of myopia reduction for a given orthokeratology candidate has been difficult. However, recently it has been found that the corneal eccentricity tends to decrease and approach zero (a sphere) due to the sphericalization effect of orthokeratology; thus the amount of myopia reduction can be predicted from the amount of baseline corneal eccentricity. (2) As the average corneal eccentricity is approximately 0.5, the potential reduction in refractive error to obtain a spherical cornea would be approximately 2.50D. For high corneal eccentricity, such as 0.6, the potential reduction would be 3.00D, and for lower eccentricity such as 0.4, it would be 2.00D. However, this theory is controversial as total corneal sphericalization has not been found to be a common finding and corneal eccentricity represents an oversimplification of corneal contour. (14)

Who are Good Candidates for Orthokeratology?

Individuals with low myopia who are motivated for a reversible, non-surgical means of reducing nearsightedness are good candidates for orthokeratology. Many individuals are motivated by an occupational or recreational need or requirement. Airline employees, military personnel, police officers and firemen are among the individuals who may request orthokeratology as a means of meeting an unaided visual acuity requirement. It is important to determine whether orthokeratology is feasible with the patient's refractive error and unaided visual acuity requirements while also emphasizing the importance of retainer contact lens wear. Prospective candidates should be aware that orthokeratology is not permanent and that their resulting vision may be variable. Also, the importance of monitoring acuity and complying with lens care and wearing time instructions should be emphasized. The patient should consult with the (potential) employer regarding their vision requirements prior to undertaking orthokeratology. Prospective candidates must be given a realistic overview of the expectations in terms of how much myopia may be reduced, the cost, and the time-frame along with the patient's availability for visits. Although the cost and the number of visits are often reduced as a result of the more rapid changes occurring with reverse geometry lens designs, patients need to be advised of the fees and that as many as 10-12 visits may be necessary for monitoring and design changes over a six month or greater period. Likewise, the patient's goals should be taken into consideration. Whereas 20/20 unaided visual acuity is often desirable, it may not be the required endpoint of therapy for a highly myopic individual who desires an improvement in unaided vision.

Young patients are good candidates although as the axial length of the eye continues to grow, promises of emmetropia may not be realistic for individuals with higher amounts of myopia or astigmatism. In a recent study 23 of 29 subjects (79.3%), age 8 – 11, completed 6 months of overnight orthokeratology.(15) The initial spherical equivalent refractive error ranged from -0.75D to -5.00D but after 6 months was equal to an average of -0.16D.

Highly astigmatic individuals are not good candidates nor are against-the-rule astigmatic patients. (16) Finally, individuals who are current rigid lens wearers most likely have already experienced some sphericalization of the cornea; therefore, orthokeratology may have little further impact.

What about Retainer Lens Wear?

When no further refractive change has been elicited or the corneal topography shows a uniform, appropriate contour, the orthokeratology patient enters a retainer lens wear regimen. Typically, this consists of continuing overnight wear of the prescribed overnight orthokeratology lens design. This has the benefits of eliminating the effects of dust and wind occurring with daily wear, the patient experiences little to no discomfort, and the speed of refractive change can be enhanced via the closed lid effect at night. (17) Patients with a very low baseline myopic prescription (often less than 2D) may achieve successful unaided vision during the day after wearing their lenses every other night, every third night or sometimes even less. (18) The patient typically gradually reduces their wearing time until they first experience a decrease in unaided visual acuity. The lower the amount of presenting myopia, the less amount of time necessary for retainer wear. A well informed patient should be able to monitor and modify their schedule accordingly.

What are Possible Complications Resulting from Orthokeratology?

Common problems resulting from orthokeratology are variability and decreased quality of vision. As a result of corneal changes - particularly after lens removal - patients can report variable and/or decreased vision. (1,6) Likewise, as the amount of refractive change reduction is rather unpredictable, some patients may not obtain satisfactory unaided visual acuity. (5,18) The need for a retainer lens after completion of the orthokeratology process and the individual variation in the number of hours of lens wear necessary to maintain the refractive endpoint can contribute to these symptoms.

Several reports of an increase in with-the-rule corneal astigmatism have also been documented. (1,6) Often this is the result of a lens that exhibits superior decentration inducing adverse changes in corneal topography. In some cases because of the effect of a flat fitting lens on the cornea, peripheral corneal distortion can occur. (4,19) Often this can result from an excessively aggressive approach (i.e., base curve radius is too flat).

Corneal staining can be a problem over time, especially if the lens is either fitting too flat resulting in a mechanical abrasion of the central epithelium or as a result of a tight fitting lens resulting in adherence. (20) In addition, trapped debris and adherent deposits due to a tight-fitting lens can result in this problem over time. Some minor corneal pigmentation as been observed with overnight use of these designs. (21)

There have been recent reports of microbial keratitis among orthokeratology patients which have raised concerns worldwide about the safety of corneal reshaping, especially in children. (22,23) In one report, 50 cases of microbial keratitis have been reported worldwide in orthokeratology; 80% of these cases occurred in East Asia.(24). It is imperative that all

orthokeratology patients – but especially young wearers – are compliant with lens care instructions to minimize the risk of infection. Because of the fact that these lenses are worn overnight, the current FDA approved designs are manufactured in very oxygen permeable lens materials.

Finally, regression of the myopic change toward the pre-fit level can occur once retainer lens wear has been initiated and even more so if contact lens wear is discontinued. Altogether, the refractive error tends to regress toward the baseline values. (5,6)

What is the Fitting and Management Process for Orthokeratology and Corneal Refractive Therapy?

To ensure the absence of corneal edema, the selection of a highly oxygen permeable lens material is recommended. This is especially important due to the minimal lens movement recommended and if overnight orthokeratology is being considered.

Reverse geometry or return zone (as they are called with corneal refractive therapy) lens designs are in common use today. These lenses have demonstrated faster and more regular topographic changes than conventional lens designs. These lens designs often utilize a large overall diameter (e.g., 10.0 – 11.0mm) with a small optical zone (e.g., often approximately 6.0mm). The reverse or return curvature is typically anywhere from two to eight diopters steeper than the base curve or a sigmoidal curve that returns the lens to the cornea for proper sagittal depth. The base curve is fitted flatter than “K” in an effort to achieve an area of central bearing surrounded by a band of mid-peripheral tear pooling and approximately 1mm of lens movement with the blink. (3)

The patient is typically evaluated the morning after initiating overnight lens wear. If the treatment does not appear to be complete, the patient can be evaluated after three nights of lens wear; otherwise, evaluations at one week, 2 – 4 weeks and three months followed by every six months is recommended. During the treatment phase, it is common procedure today to provide disposable soft lenses of gradually reducing power, to be worn until refractive stabilization is complete.

With current lens designs, the fluorescein pattern (touch centrally, midperipheral tear pooling, corneal alignment, and slight edge lift, with good lens centration) is achieved with only one pair of lenses. Some design changes may be needed for undercorrection or lens decentration.

The use of videokeratography for corneal topography evaluation is quite valuable in managing these patients and is highly recommended. These instruments may provide corneal eccentricity values which can assist in predicting the amount of change as well as how much change is occurring from visit to visit. The color map itself can both rule out poor candidates (i.e., corneal distortion, preclinical keratoconus) and provide beneficial information on the corneal topography in general. In addition, the use of difference maps can show how much change has occurred from visit to visit.

What is the Future for Orthokeratology?

Orthokeratology lens designs are being investigated for treatment of hyperopic and presbyopic refractive errors.(25) In addition, there appears to be the possibility that these designs can retard, halt or reverse eye growth through a precise and predetermined optical system at or near the corneal plane. This optical system would be designed to manipulate the peripheral optics such that the peripheral field image is positioned in front of the

peripheral retina while the central field image is positioned at the fovea.(26,27) In other words, myopia control could occur via an optimum orthokeratology lens design.

Another potential management option which would add to the permanency of orthokeratology, corneoplasty, is currently under investigation. Corneal intrastromal injection of an enzyme combined with orthokeratology lenses could enable longer maintenance of the modified corneal contour after orthokeratology, minimizing the need for retainer lens wear.

[The American Academy of Optometry's Position on Orthokeratology](#)

Orthokeratology [is recommended](#) as an alternative to refractive surgery for motivated individuals with low myopic refractive error. The introduction of highly oxygen permeable rigid lenses, in combination with reverse geometry lens designs and sophisticated corneal topography systems, has allowed practitioners to accelerate the myopia reduction process while being able to carefully monitor corneal changes. However, caution must be used when promoting orthokeratology, especially as it pertains to the amount of myopia reduction possible for a given patient. The risks, as well as benefits, of these corneal reshaping procedures should be explained to the prospective patient and these individuals should be carefully monitored, both through the initial wear phase as well as the retainer wear phase. In addition, patients need to be counseled to be compliant with lens care and wearing schedule instructions. These procedures have promise but further research is necessary to evaluate such factors as the predictability of refractive error reduction, refractive error stability over time, and overnight lens wear.

References

1. Kerns RL. Research in orthokeratology, Part VIII: Results, conclusions and discussion of techniques. *J Am Optom Assoc* 1978;48:308-314.
2. Mountford J. An analysis of the changes in corneal shape and refractive error induced by accelerated orthokeratology. *Int Contact Lens Clin* 1997;24:128-143.
3. Marsden HJ, Kame RT. Orthokeratology: Advanced fitting techniques. In Bennett ES, Weissman BA (eds): *Clinical Contact Lens Practice* Philadelphia, JB Lippincott, 1997:49A-1 to 49A-9.
4. Swarbrick HA, Wong G, O'Leary DJ. Corneal response to orthokeratology *Optom Vis Sci* 1998;75(11):791-799.
5. Polse KA, Brand RJ, Schwalbe JS et al. The Berkeley orthokeratology study, Part II: efficacy and duration. *Am J Optom Physiol Opt* 1983;60:187-198.
6. Binder PS, May CH, Grant SC. An evaluation of orthokeratology. *Ophthalmol* 1980;87:729-744.
7. Rah MJ, Jackson JM, Jones LA, Marsden HJ, Bailey MD, Barr JT. Overnight orthokeratology: Preliminary results of the Lenses and Overnight Orthokeratology (LOOK) study. *Optom Vis Sci* 2002;79(9): 598-605.
8. Cho P, Cheung SW, Edwards M. The Longitudinal Research in Children (LORIC) in Hong Kong: A pilot study on refractive changes and myopic control. *Curr Eye Res* 2005;30:71-80.
9. Nichols JJ, Marsich MM, Nguyen M, Barr JT, Bullimore MA. Overnight Orthokeratology. *Optom Vis Sci* 2000;77:252-259.
10. Tahhan N, Du Toit R, Papas E, Chung H, La Hood D, Holden B. Comparison of reverse geometry lens designs for overnight orthokeratology. *Optom Vis Sci* 2003;80(12):796-804.
11. Soni PS, Nguyen TT, Bonanno JA. Overnight orthokeratology. *Eye Contact Lens* 2003;29:137-145.
12. Alharbi A, Swarbrick HA. The effect of overnight orthokeratology on corneal thickness. *Invest Ophthalmol Vis Sci* 2003;44:2518-2523.
13. Sridharan R, Swarbrick HA. Corneal response to short-term orthokeratology lens wear. *Optom Vis Sci* 2003;80(3):200-206.
14. Marsden HJ, Joe JJ, Edrington TB. Changes in corneal eccentricity with orthokeratology. *Optom Vis Sci* 1994;71(12s):94.

15. Walline JJ, Rah M, Jones LA. The Children's Overnight Orthokeratology Investigation (COOKI) pilot study. *Optom Vis Sci* 2004;81(6):407-413.
16. Mountford J. Advanced orthokeratology Part 2: Patient selection and trial fitting. *Optician* 2002;224(5867):26-37.
17. Winkler T, Kame RT. Night therapy. In Winkler T, Kame RT: *Orthokeratology Handbook*. Boston, Butterworth-Heinemann 1994;69-76.
18. Rinehart JM, Bennett ES. Orthokeratology. In Bennett ES, Hom MM. *Manual of Gas Permeable Contact Lenses* (2nd ed.) Elsevier Science, St. Louis, 2004:424-483.
19. Kerns RL. Research in orthokeratology, Part IV: Results and observations. *J Am Optom Assoc* 1977;48:227-238.
20. Mountford J. Orthokeratology. In Phillips AJ, Speedwell L: *Contact Lenses* Oxford, Butterworth-Heinemann, 1997:653-692.
24. Rah MJ, Barr JT, Bailey MD. Corneal pigmentation in overnight orthokeratology: a case series. *Optometry* 2002;73(7):425-434.
22. Hutchinson K, Apel A. Infectious keratitis in orthokeratology. *Clin Exp Ophthalmol* 2002;30(1):49-51.
23. Young AL, Leung AT, Cheng LL, et al. Orthokeratology lens-related corneal ulcers in children: a case series. *Ophthalmol* 2004; 111(3):590-595.
24. Swarbrick H, Watt K. Microbial keratitis in orthokeratology: The worldwide perspective. Presented at the annual Global Orthokeratology Symposium, Chicago, IL, July, 2005.
25. Legerton J. Corneal Refractive Therapy for hyperopia and presbyopia. Presented at the Global Orthokeratology Symposium, Toronto, Canada, July, 2004.
26. Smith EL. Mechanisms of myopia. Presented at the annual Global Orthokeratology Symposium, Chicago, IL, July, 2005.
27. Caroline PJ. The myopia control data: What does it all mean? Presented at the annual Global Orthokeratology Symposium, Chicago, IL, July, 2005.

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