

# OrthoK

THE COMPLETE GUIDE TO ORTHOKERATOLOGY SUCCESS IN MYOPIA CONTROL



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<sup>^</sup> Myopia Control in 2019. Wallace, CLSpectrum. Mar 2019  
<sup>†</sup> Global Prevalence of Myopia and High Myopia and Temporal Trends from 2000-2050. Ophthalmology, May 2016.

# OrthoK

THE COMPLETE GUIDE TO ORTHOKERATOLOGY SUCCESS IN MYOPIA CONTROL

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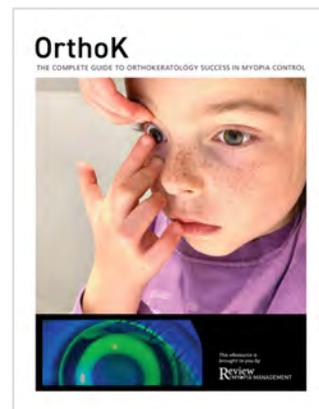
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# Introduction to the Complete Guide to Orthokeratology

By Michael J. Lipson, OD, FAAO, FSLs, and Jennifer Harthan, OD, FAAO, FSLs



**Myopic children undergoing OrthoK have 37-63% less axial elongation than those wearing spectacles or daytime contact lenses.**

**O**rthokeratology (OrthoK) has emerged as one of the leading treatments available for managing progressive myopia and axial elongation in children.<sup>1,2</sup> For eye care professionals (ECPs), staying on top of the latest lens designs, clinical research, and patient management standards is critical to providing the most comprehensive care to children with myopia. In this extensive eResource, we bring together leading experts in the field of OrthoK to provide ECPs with in-depth information on all aspects of the prescribing and management of OrthoK.

By all definitions, myopia is truly a

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**We bring together leading experts in the field of OrthoK to provide ECPs with in-depth information on all aspects of the prescribing and management of OrthoK.**

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pandemic and is filled with complexity. Numerous factors influence the risk of developing myopia, including the age of onset, degree of myopia, and rate of progression. Long-term vision-threatening complications of myopia, such as cataracts, primary open-angle glaucoma,

retinal detachments, myopic maculopathy, and choroidal neovascular membranes are associated with high axial length.<sup>3-6</sup> The higher the degree of myopia and axial length, the greater the risk of these conditions.

To reduce the risk of developing those complications, efforts to minimize axial elongation are necessary for our myopic pediatric patients. Currently, we are not able to prevent myopia or completely halt progression. However, numerous studies and clinical experience show that we can prescribe interventions that significantly slow the rate of myopia progression. OrthoK is certainly one intervention that has been shown to slow axial elongation.

Since receiving FDA indication for temporarily correcting refractive error in 2002, OrthoK has been prescribed for children and adults as an alternative to glasses, daytime contact lenses, and refractive surgery. Over time, clinicians observed that myopic children using OrthoK were not progressing in myopia like those wearing other types of correction.<sup>7,8</sup> Extensive study of this effect has shown myopic children undergoing OrthoK have 37-63% less axial elongation than those wearing spectacles or daytime contact lenses.<sup>9,10</sup> The mechanism by which this occurs is thought to be by introducing relative peripheral myopic defocus created by the optical changes induced by the mid-peripheral ring of steepening seen on corneal topography. Questions exist about whether this is the precise mechanism, and, in addition, if there may be other



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mechanisms involved. However, there is no question that OrthoK does slow axial elongation. Therefore, ECPs need to learn about OrthoK.

In this educational effort, topics addressed include: implementing OrthoK into practice, equipment and procedures,

determination of OrthoK candidacy, fitting and problem solving, and patient and practice management. The perspectives shared by this outstanding group of experts from their unique experiences will provide insight into how to begin prescribing and managing OrthoK or how

to enhance your existing OrthoK practice.

Practicing OrthoK can provide so many personal and professional rewards. We hope you enjoy this educational effort and find it a valuable reference source for information on the growing field of orthokeratology. ●



**DR. MICHAEL LIPSON** is recently retired from his position as an optometrist/associate professor at The University of Michigan, department of Ophthalmology and Visual Science. His clinical practice involves specialty contact lenses: OrthoK, keratoconus, post-corneal transplant, post-refractive surgery, and severe dry eye patients. He has published peer-reviewed clinical research studies on OrthoK, vision-related quality of life, myopia management and new lens designs. He lectures nationally and internationally on those same topics. Dr. Lipson developed a validated questionnaire to assess vision-related quality of life for all types of vision correction, including OrthoK. He has authored chapters in textbooks on OrthoK, scleral lenses, and general contact lens topics. Dr. Lipson is the author of the book *Contemporary Orthokeratology*. He also is a reviewer for a number of highly respected peer-reviewed journals in the ophthalmic community. He is a consultant to the specialty contact lens industry, emphasizing OrthoK education. He is on the GPLI Advisory Board, served as Vice-President of the Scleral Lens Education Society, and served on the Scleral Lens Education Society Board for many years.



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# The History of Orthokeratology: How Far Have We Come?

By Craig W. Norman, FCLSA, and Patrick J. Caroline, FAAO



SECTION PHOTOS CREDIT: PATRICK J. CAROLINE

**Orthokeratology has become a sophisticated fitting process that includes highly permeable lens materials, spherical and toric designs, and serial mapping of the corneal surface to note the amount and location of changes made to the cornea.**

It's 2022, and eye care practitioners worldwide are prescribing myopia management interventions to reduce myopia progression in children and teenagers.

In most professional circles, myopia is no longer viewed as simply a refractive error but as a precursor to changes in axial length that potentially may result in debilitating visual loss.

Myopia management has many paths, including orthokeratology (Or-

thoK), soft lens multifocals, pharmaceuticals, and innovative spectacle lenses.

OrthoK is the process of reshaping the cornea to temporarily reduce refractive error. There are scores of OrthoK lens designs marketed across the globe, including from three of the top four soft lens companies. Their use is taught in all academic institutions to optometrists (and many ophthalmologists) in training. It has become a sophisticated fitting process that includes highly permeable lens materials,

spherical and toric designs, and serial mapping of the corneal surface to note the amount and location of changes made to the cornea – all aiding to provide predictable outcomes with few complications.

The path that OrthoK has taken to come to its current state is an exciting journey with many twists and turns. There were early attempts to reduce corneal curvature, including the ancient Chinese use of sandbags on the eyes at night to flatten the cornea. A novel invention created by

Dr. J. Bell in 1850 was an eye cup with a spring-mounted plunger to pound the cornea flat through the closed eye. These early attempts to flatten the cornea had limited (if any) traction and have nothing in common with what we know today as OrthoK.

### Early Design Development

By the mid-20<sup>th</sup> century, the understanding of the physiology of the eye had been well established, particularly related to the need for oxygenating the cornea. This period was also the beginning of the transition from large diameter sclerals to corneal lenses. Coinciding with this, after World War II, polymethylmethacrylate (PMMA) became the material of choice for contact lenses. While PMMA provided excellent optics and machining capabilities, its non-permeable nature caused corneal edema, resulting in steepening of the corneal curvature. Additionally, if these lenses were inadvertently fitted too flat, the cornea was reshaped, and patients were noting that they were seeing better without their eyeglasses than ever before.

From these observations, interest in the discipline of the planned reshaping of the cornea began to generate more scientific interest. George Jessen (co-founder of Wesley-Jessen Corporation) described a process he called “orthofocus” at a watershed 1962 contact lens specialists conference in Chicago.<sup>1</sup> Part of his description was that the base curve (BOZR) of his design would be fitted flatter than

the flat keratometry (K) reading by an amount equal to the amount of myopia targeted for the temporary reduction, which went on to be known as the Jessen Factor. At the same conference, his business partner, Newton Wesley, proposed that much research needed to be done,

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**George Jessen (co-founder of Wesley-Jessen Corporation) described a process he called “orthofocus” at a watershed 1962 contact lens specialists conference in Chicago.**

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while also suggesting that “orthokeratology”<sup>2</sup> was better terminology to be used. Although there have been many attempts to use another branding for this category, the term remains in place today around the world. The lens designs used at this time, and for many years to come, were standard spherical lenses worn during daytime hours and fit by either using the Jessen method or by employing a series of progressively flatter lenses to alter the corneal shape.

The following two decades widened the interest as early adopters of OrthoK began to publish their works, i.e., May

and Grant,<sup>3,4</sup> Nolan,<sup>5</sup> Freeman,<sup>6,7</sup> Kerns,<sup>8,9</sup> Polse, et al.,<sup>10</sup> and Coon.<sup>11</sup> Although there was individual variability and poor predictability, these early adopters demonstrated a modest temporary reduction in myopia (approximately 1.00D to 1.50D). Additionally, unwanted induced astigmatism often was present due to poor lens centration. An example of lens designs from this time is in Figure 1. A patient with -1.50D correction would be fitted 1.50D flatter than the flat-test K. The fluorescein pattern shows this flat fit with central bearing and excessive edge lift, demonstrating an unstable fitting relationship and accompanying decentration. The tear profile demonstrates the fitting relationship as well.

### Beyond Keratometry

Until this time, contact lens fitting of all types, including OrthoK, was primarily based on manual keratometry and spectacle refraction. This began to change in the late 1970s when along with others, Sami El Hage, OD, PhD, described the use of “Photokeratoscopy and Controlled Keratoreformation” (CKR),<sup>12</sup> his term for OrthoK. Topography provided the ability to graphically document the curvature of the cornea both as a baseline and post-fit to compare the impact of the OrthoK fit. (Figure 2)

This technique provided graphical documentation of the impact of contact lens wear by comparing baseline and post-fit images and would go on to become standard of care in years to come.

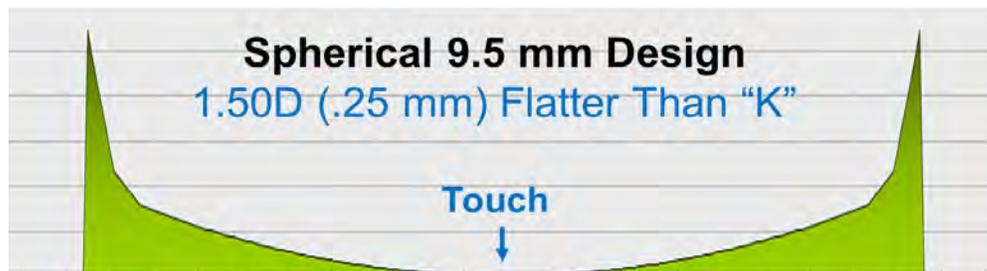
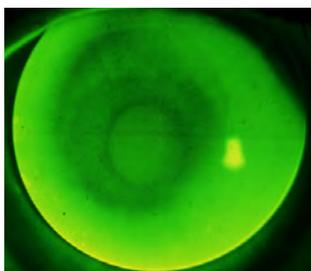


Figure 1: Fluorescein pattern and tear film profile of early spherical OrthoK design



**Figure 2: Pre-fit and post-fit topography of flat fitting spherical rigid lens with superior decentration**

### Reverse Geometry

Al Fontana described a “One-Piece Recessed Optic Design,” where the lens had a posterior optic zone of 6.00mm and fitted 1.00D flatter than the flattest K measurement, while the lens periphery was fit on K. (Figure 3) Although this appears to be a reverse

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**Stuart Grant proposed what he termed “night therapy and retention” as a means of correction for patients who desired freedom from spectacles and contact lenses during the day.**

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geometry lens by description, it isn’t. Sophisticated CNC lathing technology to produce this design was not yet commercially available.

In the late 1980s, Richard Wlodyga provided a more detailed description (Figure 4) by designing a lens with a flat base curve radius (BOZR), a reverse curve radius  $\geq 1.00D$  steeper than the base curve, and a 3.00D steeper secondary curve to control centration.

Wlodyga’s three-curve design was interesting, but he could not get it accurately fabricated like Fontana before him. He reached out to Nick Stoyan from Contex Labs. Their association resulted in a commercially viable product – a 9.6mm lens, 6.0mm OZ, with an aspheric peripheral curve 0.50mm wide, and the introduction of a “reverse curve” that tied these curves together. Ultimately, Stoyan patented this design technology.

The Contex lens-fitting philosophy was based on keratometry readings. The initial lens was fitted 1.50D flatter than the flattest K reading, then employing increasingly flatter lenses until the targeted endpoint was achieved. This system was termed “accelerated orthokeratology.”

El Hage also used his topography expertise to aid in the design and fitting of his three-zone CKR lens. Other inventors soon followed. Tom Reim improved upon the reverse zone, and John Mountford employed a tangent periphery rather than alignment curves. At the same time, Roger Tabb, Al Blackburn, John Reinhart, Jim Reeves, George Glady, and Jim Edwards also made additional improvements.

In the early 2000s, numerous design and manufacturing patents related

to Corneal Refractive Therapy (CRT) were filed by Jerry Legerton and Bill Meyers. They changed the reverse curve construction to that of a sigmoid curve to alter the sagittal height of the lens.

### The Last Three Decades

Daytime wear of OrthoK was recommended well into the 1990s. Stuart Grant proposed what he termed “night therapy and retention”<sup>13</sup> as a means of correction for patients who desired freedom from spectacles and contact lenses during the day. He further suggested that this would be convenient, requiring minimal adaptation, as the lens was worn only during sleep. The eyelid pressure from closed eyes would increase effectiveness while possibly retarding myopic progression.

Soft contact lens manufacturers long were enamored with the possibility of extended wear, which led GP material manufacturers to explore this as well. In 2002, the FDA approved Menicon Z gas permeable contact lenses for 30-day continuous wear. Polymer Technology received FDA premarket approval (PMA) for overnight wear of the Boston Equalens II in 2003. Paragon’s HDS materials (60 and 100) received FDA premarket approval for overnight wear in 2002.

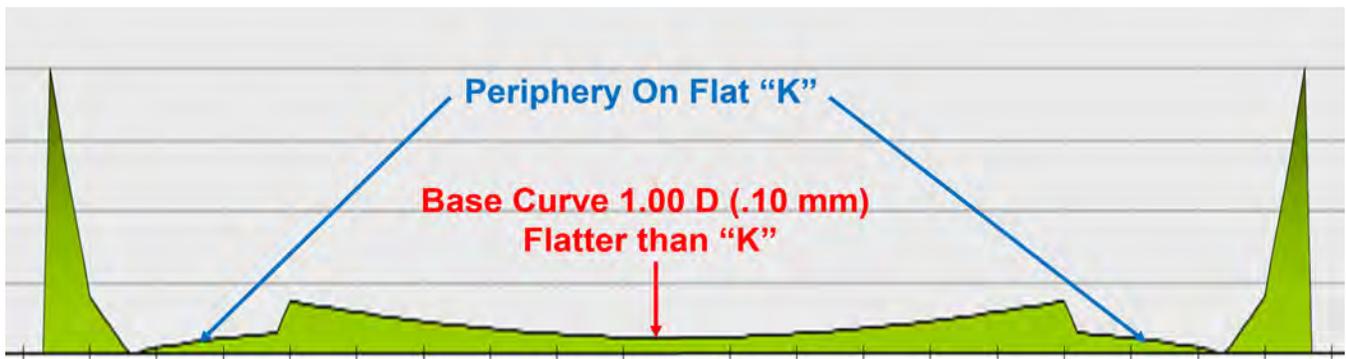


Figure 3: Fontana One-Piece Recessed Optic Design Tear Profile (Caroline)



Figure 4: Wlodyga three-curve design (Caroline)

OrthoK fitters embraced Grant's suggestion of overnight wear, and when combined with higher Dk lens materials, this ushered in the era of overnight OrthoK.

As interest increased in OrthoK, eye care practitioners needed a place to share their clinical findings with their peers. The National Eye Research Foundation (NERF) had attracted like-minded ECPs to periodic meetings for years. The Global Orthokeratology Symposium (GOS) held its inaugural meeting in the summer of 2002. Over 350 practitioners from 30 countries and approximately 20 exhibitors were in attendance. The meeting was held in Toronto, Ontario, Canada, because OrthoK was not an FDA-approved category in the U.S. at that time. Additionally, the meeting organizers were interested in gaining insight from Asian participants during a time when their travel to the U.S. was more restricted.

Among the many highlights of the conference was a session where the

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## The Global Orthokeratology Symposium held its inaugural meeting in the summer of 2002.

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different country attendees met among themselves to discuss the formation of their own OrthoK associations, which many did in the U.S. and internationally. The GOS conference was held annually over the next few years before morphing into what is now the Global Specialty Lens Symposium (GSLs). In an oddity reminiscent of today, the 2003 GOS was canceled due to the SARS outbreak, where citizens of countries outside of Canada were temporarily not allowed to travel into the country.

### Regulatory Approvals

In January 2002, Paragon Sciences received FDA panel approval for overnight corneal reshaping with the

Paragon CRT Lens for patients with myopia between -0.50D to -6.00D and astigmatism up to 1.75D. Ultimately, it had no age restrictions, which would become quite valuable in years to come. In June 2004, the panel approved the Bausch & Lomb Vision Shaping Treatment (VST) for overnight OrthoK using Boston Equalens II. Later that year, B&L received supplemental approval for OrthoK fitting using topography and software. The initial VST lens designs were the BE Retainer, Contex OK, DreamLens, and Euclid Emerald.

Interestingly, they were available only in red and yellow colors, which served a dual purpose. It allowed the patient to differentiate between the right and left lens easily. Additionally,

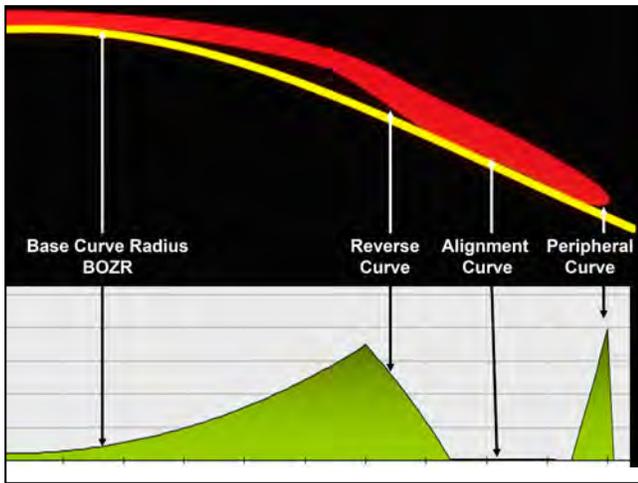


Figure 5: The construction of OrthoK designs continued to morph as innovators with four to five curves (or zones) attempted to improve fitting characteristics.

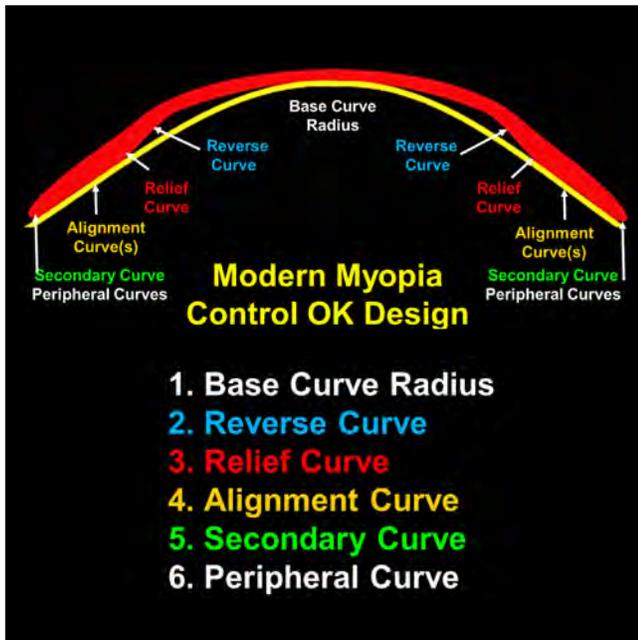


Figure 6a: Designs with five to six curves or zones and small optic zones may lead to even better overall fitting of OrthoK and expanded use in eye care practices around the globe.

it was a method of tracking the VST design use, as there was an agreement among the different patent holders to share royalties. Presently, there are a dozen different designs marketed under the VST approval.

The construction of OrthoK designs continued to morph as innovators with four to five curves (or zones) (Figure 5) attempted to improve fitting characteristics.

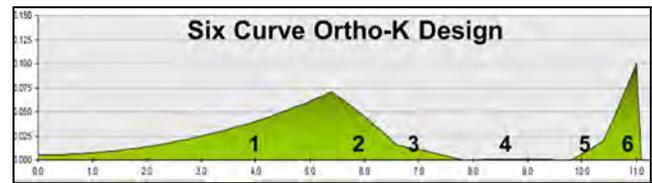
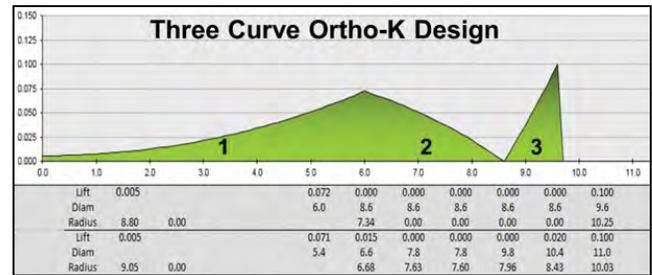


Figure 6b

### The Orthokeratology Handbook

Roger Kame and Todd Winkler published *The Orthokeratology Handbook*<sup>14</sup> in 1995, describing in detail the new accelerated OrthoK process and introduced the term “reverse geometry lenses.” This resource did an excellent job of providing real-life case histories, including corneal topographies.

John Mountford et al. penned *Orthokeratology Principles and Practice*,<sup>15</sup> in what remains today a valuable asset for the aspiring orthokeratologist, providing insight on fitting, lens design, baseline, and post-fit topography for the OrthoK candidate.

The science of OrthoK evolved as well. Swarbrick et al. described the corneal response to overnight OrthoK in numerous papers.<sup>16,17</sup> Cho and the Hong Kong Polytechnic team studied myopia progression reduction with OrthoK,<sup>18,19</sup> toric OrthoK designs,<sup>20</sup> the validity of the Jessen Factor,<sup>21</sup> and more. Nichols et al. looked at the patient response in overnight OrthoK.<sup>22</sup> Since the early 2000s, hundreds of peer-reviewed publications have been published on this topic, with scores of studies in progress. Most of the recent OrthoK publications emanate from Asia. These are often large-scale studies involving hundreds of wearers, as Asia, and China in particular, has seen the use of OrthoK for myopia control performed on millions of eyes.

New developments continue as empirical fitting has become refined, topography-based designs with software manipulation of parameters increase in popularity, and the use of asymmetrical back surfaces is more widely accepted. Designs with five to six curves or zones (Figures 6a and 6b) and small optic zones may lead to even better overall fitting of OrthoK and expanded use in eye care practices around the globe. •



**CRAIG W. NORMAN** is an adjunct faculty member at the Michigan College of Optometry's Vision Research Institute. He is co-curator of the Contact Lens Museum. He has received speaking honoraria or consulting fees from ABB Optical Group, Bausch Medical, Contamac, Euclid Systems, GPLI, Lentechs, Oculus USA, and Valley Contax.

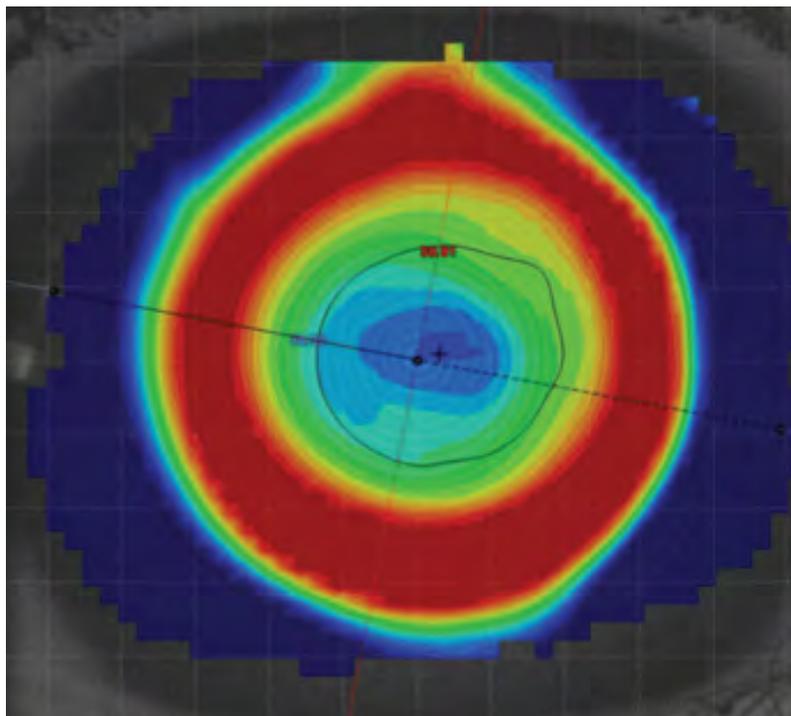


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# Indications for Orthokeratology Wear

By Leah Johnson, OD, FAAO, FSLs



**Figure 1: Topography image post-OrthoK treatment with non-uniform central flattening and paracentral steepening.**

**T**here are two aspects to consider when discussing the indication for orthokeratology (OrthoK): the regulatory aspect and the clinical aspect. In considering regulatory approval, OrthoK is approved in many countries worldwide for the temporary correction of myopia, in varying degrees of myopia and lower amounts of astigmatism. Currently, the maximum U.S. Food and Drug Administration (FDA) OrthoK approval is up to -6.00D of myopia and a maximum of 1.75D of astigmatism. Off-label refractive error correction includes hyperopia, presbyopia, and

higher amounts of myopia and astigmatism than approved. In considering the clinical aspect, OrthoK has increased in popularity for pediatric myopia.<sup>1</sup> More practitioners are prescribing overnight OrthoK as a treatment to reduce myopic progression and axial elongation in children instead of standard, single-vision correction.<sup>2,3</sup>

## Regulatory Approvals and Prescribing Trends

The FDA grants OrthoK contact lens approvals for the lens design and material together. The FDA gave the first daily wear 510(k) OrthoK approval in

1998 to Contex and the first overnight premarket approval (PMA) OrthoK approval in 2002 to Paragon Vision Sciences for the temporary reduction of myopia.<sup>4,5</sup> Following this, the FDA granted additional overnight PMA OrthoK approvals to Euclid Systems Corporation and Bausch + Lomb in 2004. Menicon received PMA approval in 2019 for overnight OrthoK. In addition, many OrthoK lens designs have been added to these PMA approvals for overnight OrthoK wear as contact lens finishing laboratories manufacture the medical device. Timeline 1 summarizes the OrthoK trade names along with approved refractive error correction.

While many ECPs, researchers, and parents look at OrthoK as an effective modality to slow childhood myopia progression, the U.S. FDA has not approved any OrthoK lens for myopia control as of April 2022. The U.S. FDA considers myopia control equal to the slowing of myopia progression. Therefore, adding “myopia control” to OrthoK’s current indication for use would be an indication change that would require safety and effectiveness data and a new FDA approval. To date, the only contact lens FDA approved for myopia control in the U.S. is a soft, daily disposable, dual-focus lens by CooperVision. CooperVision’s MiSight 1 day contact lenses have seven years of safety and efficacy data to earn the indication for myopia control.<sup>6,7</sup> At times in the eye care industry, the

PHOTO CREDIT: DR. MARIA LIU AT UC BERKELEY

# U.S. ORTHOKERATOLOGY FDA APPROVALS

Original PMA approval year with associated device trade names, materials available, and refractive error approval range.

## 2002, PARAGON VISION SCIENCES<sup>2</sup>

Device Trade Name: Paragon CRT  
Approved Label Trade Names for Corneal Refractive Therapy:

- Paragon CRT, Paragon CRT 100, Paragon CRT Dual Axis, Paragon Z CRT, Paragon Z CRT Dual Axis
- RG-4
- Fargo
- iSee

Materials: Paflofocon D (Dk 101), Tisilfocon A (Dk 163)  
Approval: 6.00D myopia, 1.75D astigmatism  
Modality: Overnight Wear

## 1998, CONTEX INC<sup>1</sup>

Device Trade Name: Contex OK

Material: Siflufocon A (dk 33)  
Approval: 3.00D myopia  
Modality: Daily Wear



## 2004, EUCLID SYSTEMS CORPORATION<sup>3</sup>

Device Trade Name: Euclid Systems Orthokeratology Contact Lenses for Overnight Wear

Material: Oprifocon A (Dk 85), Tisilfocon A (Dk = 180)  
Approval: 5.00D myopia, 1.50D astigmatism  
Modality: Overnight wear

## 2004, BAUSCH + LOMB<sup>4,5</sup>

Bausch + Lomb Vision Shaping Treatment (VST)

Approved Private Label Trade Names:

- BE Retainer
- Contex OK E System
- DreamLens
- Forge Ortho K
- iSee2
- MesaGrande
- MiracLens
- MoonLens
- Orthofocus
- REMlens
- Vipiok
- WAVE NightLens

Materials: Oprifocon A (Dk 86)  
Approval: 5.00D myopia, 1.50D astigmatism  
Modality: Overnight wear

## 2019, MENICON CO. LTD<sup>6,7</sup>

Device Trade Name: Menicon Z Night

Approved Private Label Trade Name:

- ACUVUE Abiliti Overnight
- ACUVUE Abiliti Overnight Therapeutic Lenses for Myopia Management

Material: Tisilfocon A (Dk 163)  
Approval: 4.00D myopia, 1.50D astigmatism  
Modality: Overnight wear



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2. Premarket Approval (PMA) Paragon CRT. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P9700245043>
3. Premarket Approval (PMA) Euclid Systems Orthokeratology. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P010062>
4. Premarket Approval (PMA) Boston Orthokeratology Shaping Lenses. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P0100625001>
5. Bausch + Lomb. <https://www.bausch.com/ecp/our-products/orthokeratology/vision-shaping-treatment/designs>
6. Premarket Approval (PMA) Menicon Z. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P9900185005>
7. Premarket Approval (PMA) Acuvue Abiliti. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P9900185006>

Timeline 1 summarizes the OrthoK trade names along with approved refractive error correction.

**Myopia management is a general, holistic meaning and not equivalent to myopia control.**

term myopia management has been used interchangeably with myopia control, but it is not the same thing according to the FDA. Myopia management is a general, holistic meaning and not equivalent to myopia control. With much evidence-based literature published on effective treatment modalities to slow myopia progression, perhaps treatment options will develop into the standard of care for children with myopia.<sup>8</sup> Europe has granted marketing authorization approval (CE Mark) for several overnight OrthoK materials and designs with an indication of myopia control. See Timeline 2 for a summary of approvals.

As regulatory approval for overnight wear of OrthoK lenses approaches 20 years, researchers have studied the mechanism and efficacy of OrthoK for myopia correction and the effects in slowing the progression of myopia and axial length elongation in children. OrthoK's mechanism in correcting myopic refractive error works through hydraulic forces flattening the central corneal epithelium and steepening the paracentral cornea.<sup>9-11</sup> OrthoK's mechanism in slowing myopia progression is not as completely understood, but it has been hypothesized that the paracentral steepening, along with central, non-uniform flattening (Figure 1), induces a relative peripheral refractive shift

and higher-order aberrations, which may be related to slowing axial length elongation.<sup>12,13</sup>

### OrthoK for Special Cases

Compared to OrthoK correction for myopia, there are significantly fewer research publications for using OrthoK for hyperopia and presbyopia. For myopic presbyopes, OrthoK creates a transition of an aspheric treatment zone on the cornea (Figure 1), creating a similar effect to a soft multifocal contact lens with a center-distance and gradual peripheral plus. While there are no indications specifically for presbyopia, many myopic presbyopes benefit from OrthoK's myopia correction with the aspheric treatment zone, creating a multifocal effect. OrthoK can also be customized to achieve monovision correction for those who require additional plus for near vision. Contrasting the mechanism of OrthoK for myopia, OrthoK for hyperopia acts oppositely, steepening the central cornea and increasing central thickness, surrounded by an annulus of paracentral flattening.<sup>14</sup>

There are no regulatory approvals for the hyperope and hyperopic presbyope, yet custom OrthoK lenses can be designed to reshape the cornea to correct hyperopia. Through case reports, hyperopia and hyperopic presbyopia

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**OrthoK provides a unique option to be spectacle and contact lens free during the day.**

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**Timeline 2 summarizes CE Mark marketing authorization approvals for myopia control for overnight OrthoK materials and designs.**

have been stated to be correctable through +2.00D.<sup>15</sup> Custom OrthoK lenses have also been designed for post-laser refractive surgery patients who have experienced treatment regression.

### Long-Term Benefits of OrthoK

There are other excellent reasons to prescribe OrthoK as an alternative to glasses, daytime contact lens wear, or refractive surgery. Outside of refractive surgery and extended wear for soft contact lenses, OrthoK offers patients the option for continuous corrected vision. While OrthoK is intended to be worn overnight, if a patient awakens in the middle of the night or when they wake up in the morning, they will

have continuous clear vision, with and without lenses. From active lifestyles with sports involving dust and chalk to swimming and other water sports, OrthoK provides a unique option to be spectacle and contact lens free during the day.

Studies note that children wearing OrthoK lenses have a higher quality of life, are more self-confident, willing to try new things, and are more active in sports, with an increased total time spent outdoors.<sup>16, 17</sup> Additionally, corneal changes induced by refractive surgery are permanent, making its option contraindicated for progressive myopes. In contrast, the treatment offered by OrthoK is generally reversible, and the parameters can be adjusted to compensate for the changes in refractive error.<sup>18</sup> ●



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# Getting Started with Pediatric Orthokeratology

By Maria Liu, OD, PhD, MPH, MBA, FAAO



PHOTO CREDIT: GETTY IMAGES/ MRS

OrthoK is an excellent option for younger children who may not be able to handle contact lenses for daytime wear.

**F**itting orthokeratology (OrthoK) in pediatric patients can be both challenging and highly rewarding. Due to its unique overnight wear modality, all the lens wear and care can happen at home under the parents' supervision. OrthoK is an excellent option for younger children who may not be able to handle contact lenses for daytime wear. Here is what you will need to get started treating your pediatric myopes with OrthoK, from the diagnostic instruments required to the talking points when consulting with patients and their parents.

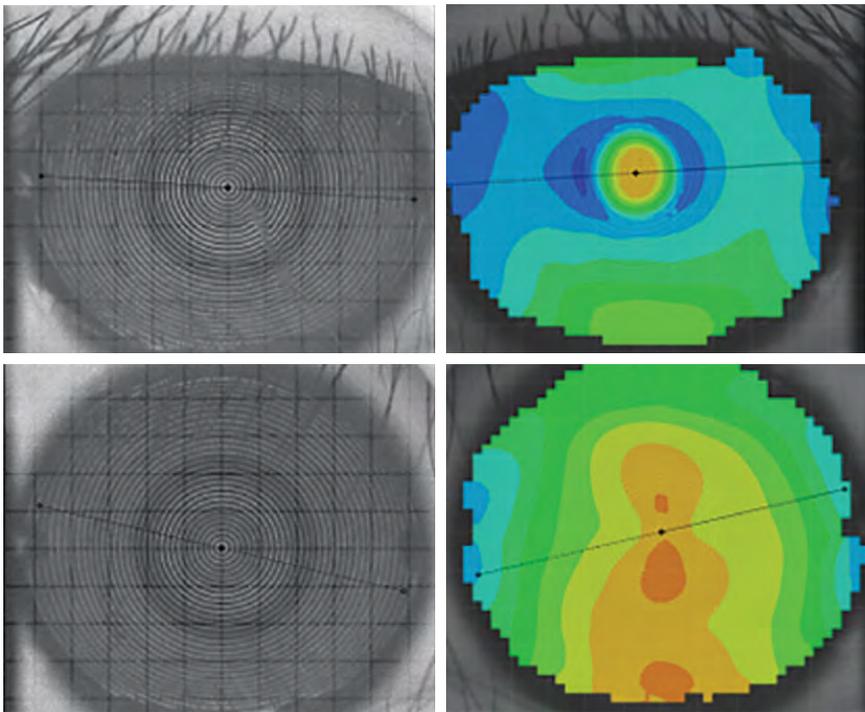
## Instruments Required for OrthoK Workups

In addition to an up-to-date comprehensive exam, several additional workups are critical in aiding the candidate selection, predicting the difficulty of the OrthoK fitting, and the anticipation of the likelihood of good visual outcomes.

## Autorefractometry vs. Subjective Refraction

Autorefractometry is an essential procedure for OrthoK patients, both at the baseline and at each follow-up visit. As a result of the non-uniform central flattening and the

higher-order aberration (HOA) induced by OrthoK,<sup>1,2</sup> there is a significant lack of agreeability between the refractive results acquired by subjective refraction and autorefractometry. While subjective refraction is heavily biased toward the input along the visual axis and is more influenced by ambient lighting and pupil size, autorefractometry measures the eye's optics through a fixed sampling area and is relatively independent of pupil size.<sup>3,4</sup> Consequently, autorefractometry provides a more reliable and objective way of monitoring the residual refractive error during OrthoK treatment.



**Figure 1.** An eyelash distorting the tear film and the reflected Placido rings (top left), causing erroneous reading and topographical map (top right). The image of the Placido rings after the eyelash was pulled out of the way (bottom left) and the corrected color-coded map (bottom right).

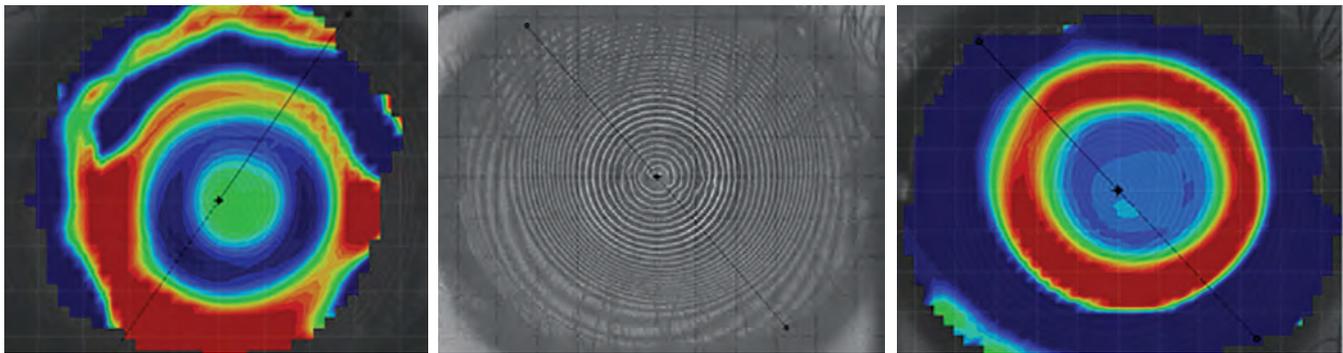
### Corneal Topography

Another critical auxiliary test for OrthoK fitting is corneal topography, which provides comprehensive information about the cornea, such as central curvature, magnitude, extent of toricity, and the asphericity at various chord lengths. Although there are different technology platforms available such as Placido-based topography, Scheimpflug-image based tomography, and OCT-based imaging systems, the Placido-based topography remains the most popular choice among OrthoK practitioners due to its lower cost, more CL-focused software features, and built-in OrthoK fitting algorithms. Note that the Placido-based topography has several limitations that may significantly impact the interpretation of OrthoK fitting.

First, unlike the Scheimpflug-image based tomography, which measures

Tools	Benefits
Autorefractor	<ul style="list-style-type: none"> <li>• reliable &amp; objective measurements</li> <li>• useful for measuring residual refractive error</li> </ul>
Corneal Topography - Placido-Based Systems	<ul style="list-style-type: none"> <li>• comprehensive information about the cornea</li> <li>• CL-focused software features</li> <li>• built-in OrthoK fitting algorithms</li> </ul>
Ocular Biometry	<ul style="list-style-type: none"> <li>• detailed information (including keratometry, corneal pachymetry, white-to-white [WTW], pupil size, barycenter, and the axial components of the ocular structure)</li> <li>• challenging to have a reliable quantification of the amount of myopia progression or axial elongation without a biometer</li> <li>• axial length measurement on quarterly or semiannual basis is essential if myopia control is the primary indication of the treatment</li> </ul>
OrthoK Fitting Sets	<ul style="list-style-type: none"> <li>• follow recommended fitting guide</li> <li>• can provide early feedback regarding vision and lens modifications</li> <li>• provides “wow” factor for treatment</li> </ul>

**Table 1: What’s Needed for Getting Started with OrthoK**



**Figure 2. An apparent pseudo-central island post-OrthoK (left) and the corresponding distorted Placido image (middle), due to tear film disruption caused by a mild central epithelial defect. The image was retaken after a drop of artificial tear showing ideal fitting (right).**

the true corneal contour, Placido-based topographers measure the first reflective surface of the eye, which is the tear film. As a result, any factors that distort the tear film, such as trichiasis, epithelial defect, debris in the tear film, or tight-fitting facial mask, will induce errors in calculating the corneal curvature. (Figures 1-2)

Secondly, when the topography is measured with central fixation, the Placido rings are projected in reference to the visual axis rather than the pupillary axis, which, if not corrected in patients with significant angle kappa, can overestimate nasal-temporal asymmetry and the level of temporal decentration in post-OrthoK maps. (Figure 3)

Finally, although most corneal topographers are calibrated with simplified model eyes, the agreeability for important indices such as asphericity and peripheral elevation has not been thoroughly tested among various models of Placido-based topographers or across different platforms. Consequently, although corneal topography offers a powerful understanding of the overall corneal shape with great resolution before or during OrthoK treatment, practitioners need to take great caution in all steps, including image acquisition, data interpretation,

and the utilization of topographical results in OrthoK management.

### Ocular Biometry

As OrthoK is gaining significant popularity due to its dual benefit of myopia correction and axial growth inhibition, ocular biometry – which provides detailed information, including keratometry, corneal pachymetry, white-to-white (WTW), pupil size, barycenter, and the axial components

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## Ocular biometry is becoming an integral part of pediatric OrthoK management.

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of the ocular structure – is becoming an integral part of pediatric OrthoK management. As the direct measurement of refractive change is not always available in OrthoK patients, the reliable measure of the change of axial length over time is crucial in quantifying the anti-myopia efficacy of the treatment. Note that axial elongation in children is a combined product of the physiological growth and

the accelerated elongation that is visually driven.<sup>5</sup> Due to the age-dependency of physiological growth and its significant individual variability, the axial inhibiting efficacy reported in clinical studies may not be readily applicable to every patient, especially in a population younger than those in the studies.

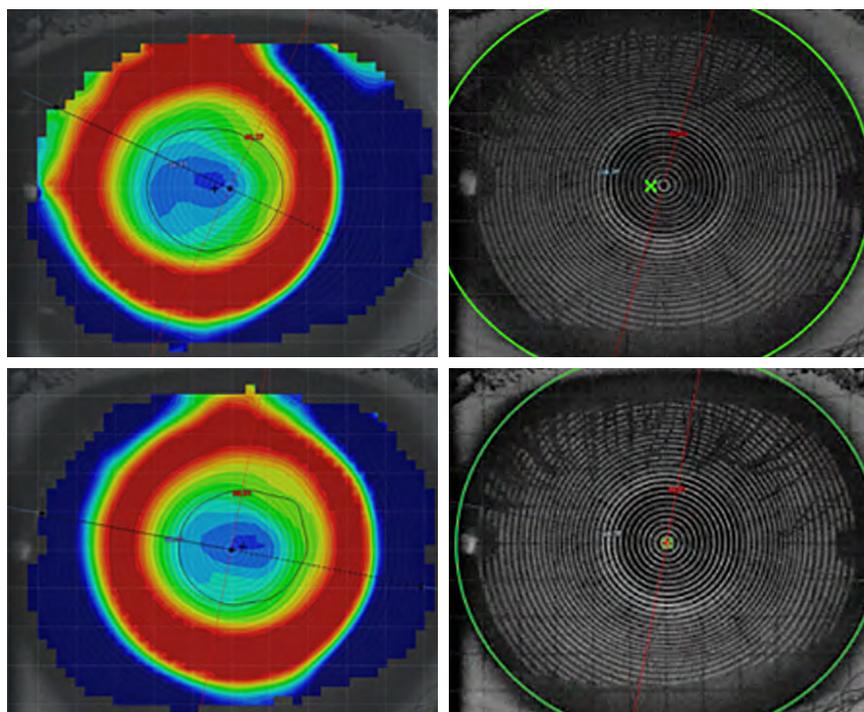
Additionally, although the precision of the measurement is much higher in interferometry-based biometers compared to that offered by high frequency A-scan ultrasonography, the axial length measured with an optical biometer is subject to potential confounding from the transient changes in choroidal thickness, such as diurnal variation<sup>6-8</sup> or treatment-induced choroidal thickening,<sup>9,10</sup> as the signal is reflected from the front surface of the RPE layer, not the sclera. As a result, the axial length should be measured around the same time of the day. Any axial shortening immediately after the initiation of OrthoK should be noted as a temporary change that may not be sustainable in the long run.

Another useful feature offered by optical biometers that tends to be overlooked is the WTW, which is a more reliable and repeatable technique in measuring the horizontal corneal diameter,<sup>11</sup> a critical variable determining the overall

diameter of the OrthoK lens. As WTW measures corneal diameter to the sclera rather than the corneal junction of the limbus, it is usually slightly larger than the traditional HVID, which measures to the corneal junction of the limbus.<sup>11</sup> Depending on the manufacturers' techniques used in generating the fitting guidelines of their OrthoK lenses, an adjustment may be necessary to account for the difference between corneal diameter measured by HVID or WTW. In addition to the WTW feature, pupil size and pupil barycenter, a surrogate marker of angle kappa, are also available in most optical biometers and are considered critical predictive variables in the visual performance of any refractive treatment.<sup>12-14</sup> Potential visual side effects such as glare, halo, and reduced contrast sensitivity should be discussed during the pre-fitting consultation for children with larger pupil size and significant angle kappa.

### Fitting Sets

Although most of the OrthoK designs can be fitted empirically, having fitting sets available can significantly improve the fitting efficiency, allow immediate dispensability, and reduce frequency of visits, which can be highly valuable for practices with high patient volume and busy schedules. Not all companies provide fitting sets for their designs. For those that do, they can provide an initial assessment of the fitting relationship between the OrthoK design and cornea and be utilized as a “wow” factor for patients and parents. Additionally, the direct side-by-side comparison of the subtle differences in fluorescein patterns induced by small parameter changes allows the most effective understanding of the lens design and its clinical implication, which



**Figure 3. A post-treatment tangential map showing an apparent temporal decentration of the right lens due to uncorrected angle kappa (top left) and the corresponding Placido image showing the significant misalignment between the center of the Placido rings and the geometric center of the cornea (green X, top right). The tangential map showing ideal centration with corrected angle kappa (bottom left) and the corresponding Placido image showing good alignment between the center of the Placido rings and corneal center (bottom right).**

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**Having fitting sets available can significantly improve the fitting efficiency, allow immediate dispensability, and reduce frequency of visits.**

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is usually not possible with an empirical fitting approach.

For patients and parents who have reservations about proceeding with this management option, a lens from the diagnostic fitting set can be appropriately selected and placed on the patient's cornea. After 20-30 minutes of in-office wear time, the lenses are removed, generally demonstrating a significant improvement in vision, creating the “wow” factor. This can

solidify the decision to proceed with OrthoK treatment.

### Discussion Points of the Pre-Fitting Consultation

A thorough and objective consultation is essential in setting up a realistic expectation in the long-term anti-myopia efficacy, the visual outcome of OrthoK treatment in children, and minimizing unnecessary dropout. Among all of the pertinent objective factors, including baseline level

of myopia, age of myopia onset, rate of progression, amount of astigmatism and corneal toricity, pupil size, and any pre-existing ocular conditions, such as allergic conjunctivitis, trichiasis and/or epiblepharon, and lagophthalmos, the level of myopia and the age of onset are the most important indicators of the long-term success of OrthoK treatment.<sup>15,16</sup>

It has been well documented that the higher the level of myopia, the higher the risk of epithelial defects, the lower the probability of full correction, the faster the daytime regression of vision and more visual fluctuation, and the higher the dropout rate.<sup>17</sup> As a result, practitioners need to be more proactive in early patient and parent education so that treatment can be initiated at lower levels of myopia to maximize the visual performance and the long-term safety of OrthoK.

Despite some recent hypotheses that the anti-myopia efficacy of OrthoK is less significant in lower myopes,<sup>18</sup> the results have not been proven in any prospective studies with more rigorous designs that take into account the selection bias commonly seen in retrospective studies and the potential confounding factor of the age of the patients. As myopia tends to worsen with age, there is a positive association between the age of the patient and the severity of myopia in any random patient sample. In other words, patients with lower myopia are likely younger than those with higher myopia. However, note that comparing the relative axial elongation between a 6-year-old patient with -1.00D and a 10-year-old with -4.00D is statistically and clinically meaningless. The physiological axial elongation of the 6-year-old is much more significant than that of the 10-year-old, resulting in an apparently faster axial growth

and less myopia-controlling effect in the lower myope, which was primarily attributable to the confounding from the younger age of that subject. As the primary origin of most myopia-related retinal complications is excessive scleral stretching, it is plausible to expect a better accumulative outcome in preserving the histological and physiological characteristics of posterior sclera with early intervention to lower the risk of subsequent complications as a result of excessive scleral thinning and expansion.

### **Average Efficacy and Individual Variability**

Concerning parent communication on the axial inhibiting efficacy of OrthoK treatment, it is important to discuss the average efficacy reported in the clinical studies and the significant individual variability responding to the treatment. Although the exact mechanisms explaining the treatment variability are not fully understood, the age of myopia onset is likely a significant contributing factor. The earlier the onset of myopia, the faster the progression, and likely the less efficacy of any intervention.<sup>19</sup> Consequently, an objective discussion on the expected long-term outcome of OrthoK wear is crucial in guiding the patients' and their parents' long-term planning in this modality.

### **Long-Term Safety**

In addition to the visual performance and the expected anti-myopia efficacy, another critical topic to discuss before the fitting is the long-term safety of OrthoK treatment and its relative advantages and limitations compared to other anti-myopia options, especially multifocal soft contact lenses (MFSC).

In general, the risk of serious complications, such as microbial keratitis or non-infectious infiltrative keratitis, related to OrthoK wear is very low and not significantly higher than that of daytime soft contact lens (SCL) wear.<sup>17,20</sup> It is especially important to emphasize to parents that proper lens wear and care and good compliance to routine follow-ups are the most significant factors on the patients' side to ensure the long-term safety of OrthoK wear. Although there is currently no direct comparison between overnight OrthoK and daytime MFSC in the same clinical trial, the average axial inhibiting efficacy of OrthoK is comparable to that of MFSC in various designs.<sup>14</sup> Consequently, the decision for either option as a myopia control treatment for children with low to moderate myopia would be more dependent on the parents' perception of the treatment, the child's preference, their lifestyle, and the independence in lens wear and care, etc. Note that most anti-myopia clinical trials with either OrthoK or MFSC have targeted low to moderate myopes between 8 to 12 years old. Anti-myopia efficacy results may not be perfectly applicable to younger patients or higher myopia. It is vital to ensure that parents interpret the evidence from the trials with a grain of salt rather than rigidly apply it to their child's outcome.

With careful patient selection, comprehensive workup, and thorough pre-fitting consultation, OrthoK in the pediatric population offers a unique combination of advantages, including effective control of excessive axial elongation and clear daytime vision without any correction. Parents' complete oversight of lens wear and care serves as an irreplaceable option in myopia management. ●



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# Orthokeratology Designs for Myopia Management

By Andrew D. Pucker, OD, PhD, FAAO, FSLs, FBCLA

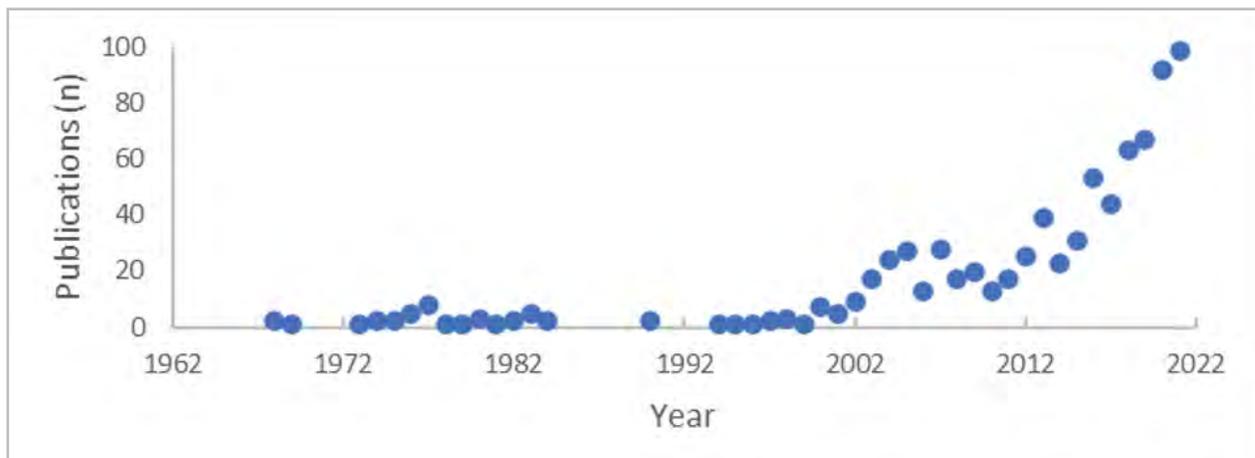


Figure 1: Number of OrthoK PubMed.gov publications by year

The art of orthokeratology (OrthoK) management has grown by leaps and bounds over the past decade. This increased appreciation in OrthoK likely stems from the synergy between OrthoK's ability to slow myopia progression and the explosion of OrthoK peer-reviewed literature (Figure 1),<sup>1,2</sup> which helps guide our treatment strategies.

With these points in mind, this section will describe the anatomy of typical OrthoK lenses and how the literature has shaped our current understanding of modifying OrthoK lens parameters for myopia management. The conclusion will discuss common troubleshooting issues in OrthoK myopia management.

## Standard Lens Parameters

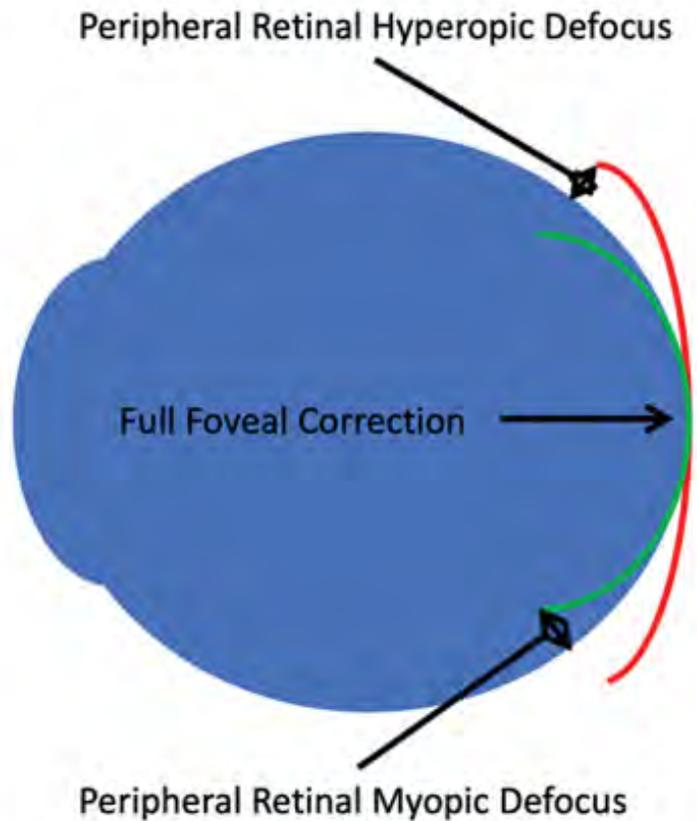
Understanding the anatomy of the gas-permeable, rigid contact lenses used

for OrthoK is essential to maximizing visual benefits and slowing the progression of myopia. The core of an OrthoK design is the base curve, which corresponds to the optic zone region of the lens (Figure 2).<sup>3</sup> With OrthoK, lenses are fit flatter than the patient's central keratometry values by an amount that roughly equals the patient's refractive error plus an additional amount called the Jessen factor (~+0.75 D).<sup>3</sup> This extra amount of refractive error correction is essential because there is not a strict one-to-one relationship between base curve flattening and refractive error correction, and because the patient's refractive error regresses throughout the day.<sup>3</sup> Thus, if a patient is overcorrected by a small amount, they will be roughly emmetropic by the end of the day. While investigators have evaluated different Jessen factors, there have been limited clinically meaningful differences found

between them.<sup>4,5</sup>

The curve peripheral to the base curve is the reverse curve, which is the region of the lens that is steeper than the base curve.<sup>3</sup> This is the lens region where the fluid from the cells within the optic zone is pushed via lens-induced hydrodynamic forces. This fluid redistribution causes mid-peripheral corneal steepening, which subsequently causes induced relative peripheral retinal myopic defocus (myopic growth-stop signal).<sup>6</sup>

Regarding myopia control, the theory suggests that with higher myopic prescriptions there will be greater induced relative peripheral retinal myopic defocus induced by OrthoK because there will be greater mid-peripheral cornea steepening induced compared to refractive errors closer to emmetropia. This, in theory, should generate more significant stimulus for slowing myopic progression. Never-



**Diagram of image shell of myopic eye fully corrected with single vision spectacles or coated lenses (red) vs. orthokeratology or multifocal soft contact lenses (green).**

theless, Yu et al. found that anisometric patients did not have a greater slowing of myopic progression in the more myopic eye, casting doubt on this theory.<sup>7</sup> This lack of additional effect in more myopic eyes could be due to a potential ceiling effect as demonstrated by soft multifocal contact lenses providing roughly equal treatment effects with +2.00D and +2.50D add lenses.<sup>8,9</sup>

The curves peripheral to the reverse curve are the alignment curve and the peripheral curve.<sup>3</sup> Each of these curves is integral for lens centration and stabilization. Some lenses may have an additional landing zone curve to promote lens alignment.<sup>10</sup> The landing zone also creates the semi-seal needed to encourage the hydrodynamic forces that promote fluid redistribution from the central corneal re-

gion to the mid-peripheral corneal region. When studies have compared different standard OrthoK designs, no clinically meaningful differences in myopia control have been detected.<sup>11, 12</sup>

Many modern OrthoK designs may also incorporate a toric alignment curve and/or peripheral curve, which are indicated to help with centration when more than about 30  $\mu\text{m}$  of corneal elevation difference is present between the two principal corneal regions as determined with topography.<sup>13</sup> Toric OrthoK designs have been shown to improve lens fit, and Zhang et al. found that toric OrthoK designs provide significantly better myopia control than spherical OrthoK designs after one year of treatment. However, the additional treatment effect was small ( $0.04 \pm 0.13$  mm vs.  $0.09 \pm 0.13$  mm).<sup>14</sup> Toric OrthoK

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**When studies have compared different standard OrthoK designs, no clinically meaningful differences in myopia control have been detected.**

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designs may promote better myopia control via optimizing lens alignment or inducing a more even treatment zone.

### Optimizing Lens Parameters

Outside of toric designs, decreasing the optic zone diameter from the standard  $\sim 6$  mm to  $\sim 5$  mm or adding a concentric ring multifocal to the OrthoK design are the primary parameters that have been tested to determine if they provide better myopia control. In theory, reducing the optic zone diameter and having a smaller corneal treatment diameter would allow more of the retina to be exposed to peripheral hyperopic defocus, because more of the optics induced by the reverse curve would be within the pupil region. This modification is supported by Gifford et al., who found that prescribing lenses with smaller optic zones results in smaller corneal treatment zones that transition into a steeper mid-peripheral cornea at smaller distances from the corneal center.<sup>15</sup>

Guo et al. have since determined in a one-year trial that fitting a patient with lenses with a 5 mm treatment zone resulted in significantly slower myopia progression than fitting lenses with a 6 mm treatment zone.<sup>16</sup> This same study determined that when comparing the slowing of a 5 mm optic zone lens to a

historical spectacle control group, the 5 mm optic zone group had 89% less myopia progression than the spectacle control group.<sup>16</sup> With regards to multifocal OrthoK designs, Loertscher et al. found that their experimental multifocal OrthoK lens provided significantly greater axial length growth slowing than standard OrthoK lenses at 18 months (-0.044 mm vs. 0.129 mm).<sup>17</sup> To the best of the author's knowledge, there are no commercially available multifocal OrthoK designs in the United States, though they are likely on the horizon.

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**Three of the most commonly encountered issues in fitting OrthoK for myopia management purposes are inadequate refractive error correction, lens decentration, and lens binding.**

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#### **Common Troubleshooting Issues**

Three of the most commonly encountered issues in fitting OrthoK for myopia management purposes are inadequate refractive error correction, lens decentration, and lens binding (Figure 3).<sup>3, 18</sup> Inadequate refractive error correction and lens decentration can often be alleviated by following the manufacturer's troubleshooting guide or switching to a toric OrthoK design.<sup>13</sup> However, one added layer to prescribing OrthoK to young children is that some of the patients have small eyes (mean adult horizontal corneal diameter =  $12.0 \pm 0.5$  mm).<sup>19</sup> With OrthoK lenses being intra-limbal lenses covering most of the cornea, standard OrthoK diameters/designs may not always be an option for

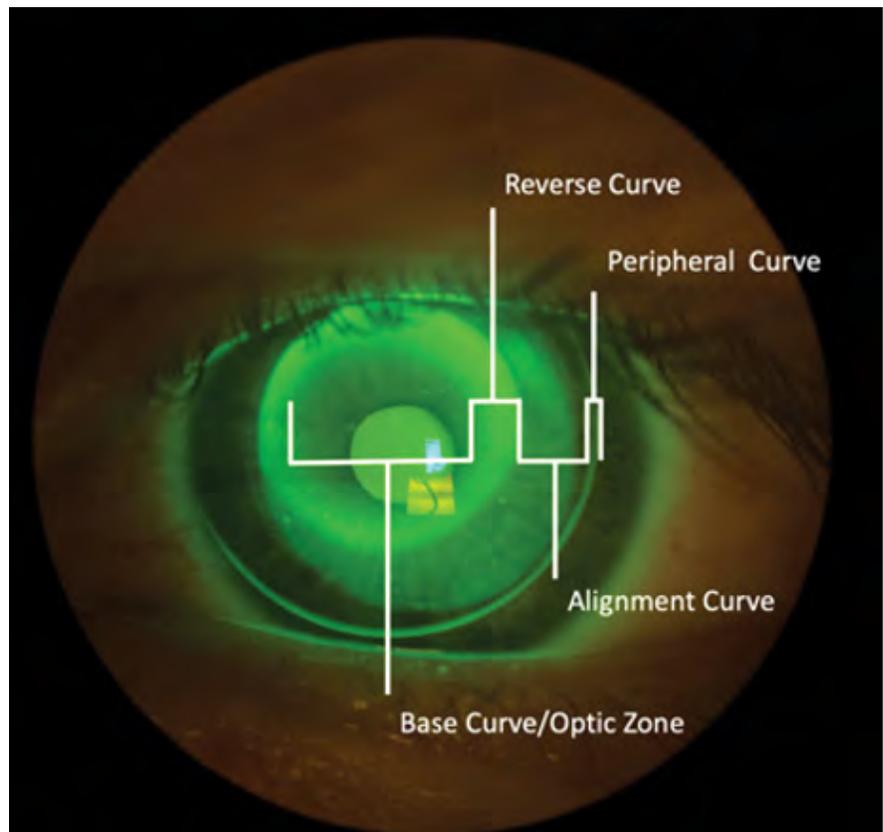


Figure 2: Slit lamp biomicroscopy image of OrthoK with lens regions noted

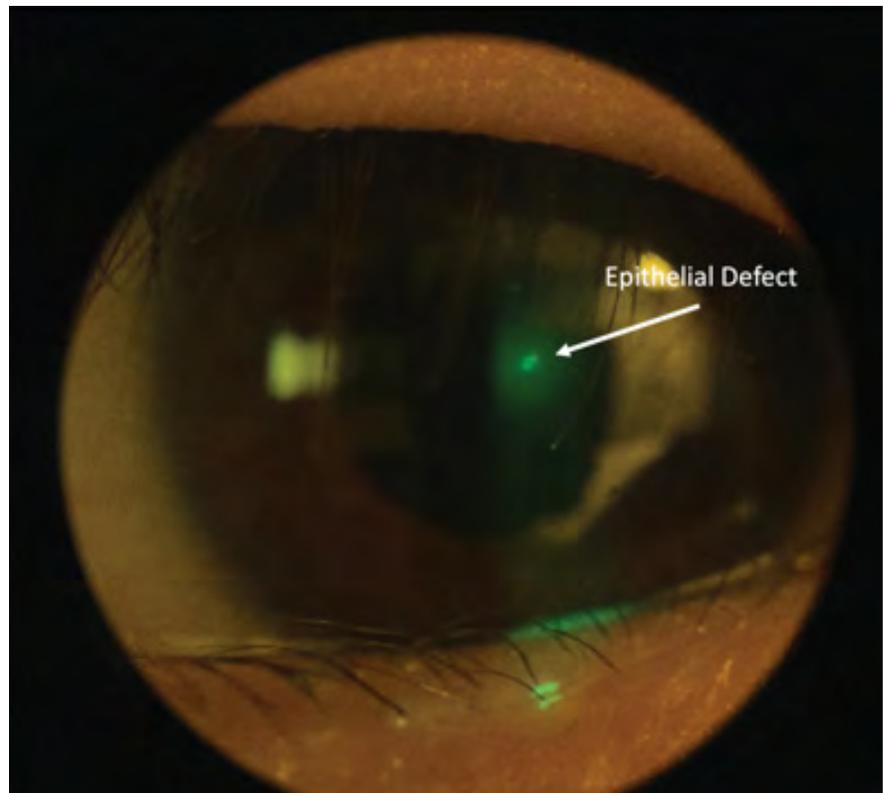


Figure 3: Example image of corneal damage secondary to OrthoK lens binding

children with small eyes. Therefore, a more customized OrthoK lens design may be needed to achieve acceptable vision.

Regarding lens binding, the landing zone curve can be flattened, which subsequently decreases suction, thereby loosening the lens. Cho et al. have also compared the frequency of lens binding in fenestrated and non-fenestrated OrthoK

lenses. The authors found that fenestrations did not decrease the frequency of lens binding compared to non-fenestrated OrthoK lenses.<sup>18</sup>

### Conclusion

OrthoK is currently an exciting option for slowing the progression of myopia. This versatile treatment regimen likely slows

the progression of myopia by inducing peripheral retinal myopic defocus, though other factors such as decreased contrast sensitivity may play a role. While data suggest that manipulating elements such as lens optic zone diameter may improve myopia control efficacy, the explosion of research in this field may provide additional innovative options soon. ●



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# Orthokeratology: Scheduling Patients for Success

By Nick Despotidis, OD, FAAO, FCOVD, FAAOMC

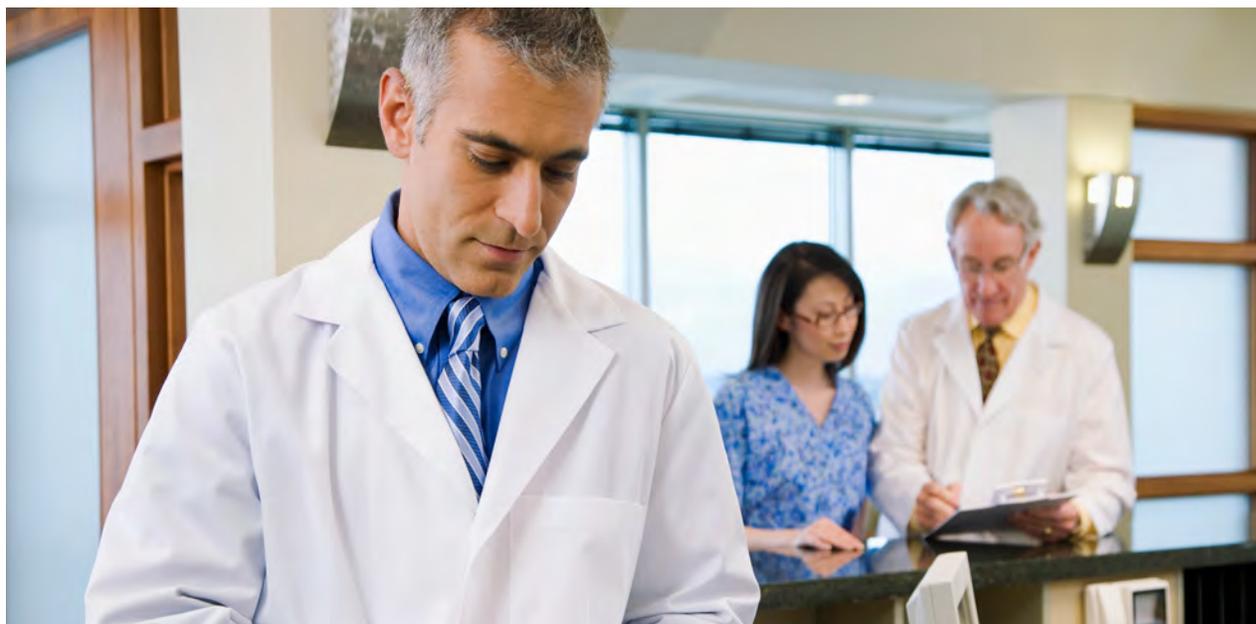


PHOTO CREDIT: GETTY IMAGES/DON MASON

Improvements in scheduling and patient management can streamline the process and minimize the stress of introducing myopia management into your office.

**E**xamining an orthokeratology (OrthoK) patient after their first night of wear is often accompanied by feelings of anticipation.

A doctor may wonder, *how good will the vision be?* Patients and parents may also have questions racing through their minds. It's not unusual for an anxious parent to share some of those questions at the first follow-up visit. A typical conversation might start like this:

*"It took half an hour to put the lenses on last night. It was much harder than during the in-office lesson. There was a lot of discomfort – is that normal? My child's eyeglasses did not work this morning, but their vision is blurry without them, so how will they see at school? I'm really concerned!"*

This type of interaction creates stress for the parent, patient, and doctor alike. Improvements in scheduling and patient management can streamline the process and minimize the stress of introducing myopia management into your office. What follows are systems developed from years of focusing on this exciting subspecialty, resulting in a more enjoyable environment to practice within. In addition, a well-designed OrthoK schedule helps cultivate patient referrals and eliminates the need for external marketing for practice growth. Some key insights are presented below.

## Thinking of Parents' Needs When Creating a Schedule

As a practice integrates OrthoK, its appointment schedule may be occupied

## TIMING ALLOTTED FOR EACH VISIT

Virtual parent conference*	20 minutes
Consultation	90 minutes
Application and removal class* (A&R)	90 minutes
Follow-up visits	20 minutes

\*Notice the terms used throughout the OrthoK process, such as parent conference, homework, pass, quiz. These terms mirror what most families are familiar with and aid scheduling compliance.

by traditional eye exams, medical evaluations, or soft contact lens check-ups; frequently, OrthoK visits are “squeezed in.” In turn, a lack of order radiates throughout the office. This may create a busy practice but not necessarily a happy one. Why is being busy so bad? It can inhibit patient referrals and make staff and doctors miserable. When an office fails to control its schedule, practitioners may end up working harder and longer, all while feeling less fulfilled (not to mention, often less successful too).

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**OrthoK is much more than a contact lens fit. These visits require more time than is necessary to strictly fit lenses.**

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OrthoK is much more than a contact lens fit. These visits require more time than is necessary to strictly fit lenses. Sufficient time throughout the appointments is crucial to answer parents’ questions and to fulfill their conscious and subconscious needs. An example of a conscious need is confirming their child is seeing clearly during the day, while another is assuring their eyesight is not rapidly deteriorating.

However, a subconscious concern may be the guilt associated with their child’s myopia progression. Most parents recognize the role of genetics in myopia development, and they aren’t surprised to learn that the environment may also contribute to their child’s nearsightedness. On follow-up visits, practitioners can advocate for parents by speaking to

## TASKS PERFORMED AT EACH VISIT

<b>Virtual parent conference</b>	<b>Parent and child history, online habits, main concerns</b>
<b>Consultation preliminary testing</b>	<b>Retinal photos, autorefraction, keratometry, topography, biometry</b>
<b>Consultation testing</b>	<b>Refraction, biomicroscopy, binocularity, diagnostic lenses</b>
<b>Application and removal (A&amp;R)</b>	<b>Apply and remove lenses three times, review compliance forms</b>
<b>Follow-up visits</b>	<b>Topography, refraction with and without lenses, biomicroscopy</b>

children about, for example, moving their smartphones outside their rooms when they’re studying or sleeping. Coming from a health professional, this advice carries weight and reaffirms what parents often preach to their kids. Never underestimate the value parents place on this discussion.

A structured OrthoK schedule can provide success to the practice while offering elite care to patients. It’s also sustainable over the long term, without exhausting doctors or staff. Here is a summary of the types of visits that are included in a well-structured OrthoK practice.

### Virtual Parent Conference

Myopia management typically begins with an in-person consultation, but before that, consider assigning a doctor to call the parent beforehand. This technique has been particularly useful during the pandemic when safety protocols have become paramount, though it can detract from

family engagement on the day of the visit. This short, virtual parent conference helps solidify the relationship between the doctor, parent, and child, too. It also serves a vital role in obtaining a patient’s detailed medical history so that on the day of the in-office consultation visit, more time can be focused on making the child feel safe as they undergo testing. This added step shows that you care as a doctor, making the practice worthy of discussion.

### Initial Consultation

Consider allotting 90 minutes for the initial consultation, which typically includes preliminary testing and a financial discussion.

Some practices require parents to reserve their child’s appointment with a deposit to discourage no-shows. A deposit also ensures that parents who commit to the consultation are serious and eager about finding the best solution for their child’s vision problem.

The consultation begins with preliminary testing: autorefraction, topography or tomography, keratometry, optical biometry, and retinal photographs. Consider having a prize ready for the child (as predetermined during the virtual parent conference); this can range from a bag filled with snacks to a small toy. The gift deflects the child’s attention from testing stress to something much more pleasant. A parent’s interest in controlling their child’s myopia with OrthoK does not mean their child will share in their enthusiasm. A little leverage by way of a small prize often assures the child’s cooperation.

The doctor’s objective during the consultation is threefold: gain the child’s trust, establish confidence with the parents, and fit the child properly. Consider starting every visit by speaking directly with the child, reinforcing that they are not at the office to get contact lenses, but instead, they are trying to find the best option for correcting their vision. Assure them that recommendations will be discussed with their parents in their presence so that they can participate in the discussion. This helps the child feel empowered, no matter their age. Beginning the examination after gaining the child’s trust is worthwhile, whether it takes mere minutes or much longer.

Once the initial evaluation has been completed, make a confident recommendation based on the examination findings. Continue to make time to answer all of the parents’ questions. Never rush. Questions may include the side effects of overnight OrthoK wear, the child’s ability to care for OrthoK lenses, or the child’s obsession with online games or social media.

After patiently addressing all of the questions, many offices move on to the fee discussion for the program. Many practices may have a technician or office

## APPLICATION AND REMOVAL (A&R) TASK LIST

TIMING	TASK
Upon enrollment	Eye drop homework*
Before training	Homework reminder
During training	Proficiency is demonstrated three times
During training	Compliance forms read and signed
After training	Call to answer remaining questions
After training	Five-question oral quiz*

*\*Notice the terms used throughout the OrthoK process, such as parent conference, homework, pass, quiz. These terms mirror what most families are familiar with and aid scheduling compliance.*

manager discuss the fees of the OrthoK program, while in other offices, the doctors do this. Some have found it beneficial to bring the family to a separate room to review the program’s cost and answer any further questions.

Then, consider scheduling the first few appointments at the end of the consultation. Proactively scheduling appointments may seem like a minor step, but it has enormous benefits because it avoids squeezing patients into a busy schedule after the application and removal class.

### Application and Removal (A&R) Instruction

This appointment, which usually takes place two weeks after the initial consul-

tation, can make or break most programs. It’s a pivotal time for both the child and the parents. For example, a parent may experience buyer’s remorse if the child struggles during the lesson. To make things go smoothly, be proactive at the outset of enrollment. At the initial consultation, have a technician teach the child how to instill eye drops and ask them to practice daily up to their A&R class. Other beneficial tools include handouts and eye drop instillation videos to assist the child if further support is needed.

Correspond with parents a week before their child’s class to confirm their child is practicing, and offer support if needed. While this step is not mandatory, without it, a child may show up to the lesson without

having practiced, making the training longer and more arduous for the technician, their parents, and themselves. Refer to eye drop instillation practice as homework, which is a crucial play on words since students are certainly used to completing homework, if not necessarily practicing.

On the day of the in-office A&R training, have the care kit and compliance forms prepared with the OrthoK lenses. Consider asking the parents to wait in the reception room until the child can independently apply and remove the lenses two times, after which the parents are brought in to witness the third attempt. Some parents may want to video record their child's technique to use as reference later.

Once the child displays proficiency, the technician should review the compliance forms with the parent and child. Have the child initial the compliance form themselves so they understand it's their responsibility, not their parents'. Parents should also sign consent forms at this visit.

Some practices inform the child that a short "quiz" will be given on their follow-up visit, assuring they understand the nuances of the procedure. Sample questions might include: *What solution do you use to rinse the OrthoK lenses? How often do you dispose of the case?*

To avoid the bottleneck and stress encountered at the first follow-up, consider proactively calling and emailing parents to answer the plethora of questions that often

accompany the first few nights of wear. This frees up the staff and doctors, solidifying the office's relationship with parents during a very stressful time in the program. It cannot be overstated: consistent communication with parents and patients yields healthy growth and stability for the practice.

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## Consistent communication with parents and patients yields healthy growth and stability for the practice.

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### Follow-up Visits

Traditionally, patients are seen the day after their A&R class, one week, one month, and every three months thereafter. These visits are opportunities to do more than merely check how a lens fits. During each visit, discuss the benefits of limiting screen time and increasing time outdoors and in-person activities. Consider emailing every parent after their child's appointments to assure all questions were answered to their satisfaction. Articles embedded in the email that reinforce recommendations are an excellent source of additional education. The concern doctors show for the patient at each follow-up

helps create the "wow" factor, and it also helps differentiate practices. Here is where the opportunity lies (or is lost): making the time to make every family feel special and well-cared for.

### Conclusion

Encourage referrals with consistent communication with parents and individualized discussions with their children about factors that affect their vision and their health. Making the time through intentional scheduling is paramount. Squeezing OrthoK patients in between other types of visits undermines hard work.

Thinning the patient schedule to allow more time for each OrthoK visit – whether with a virtual parent conference, an initial consultation, an A&R class, or a follow-up visit – takes a leap of faith, but it is precisely this that wows parents into becoming supporters and referrers of your care.

This sounds simple, but making time to speak with families to convert them to raving fans takes courage. For the same reason, it's precisely why many practitioners will never make this commitment. In turn, they may never realize the practice they desire: one that provides them with respect from patients and their staff while maintaining freedom outside their offices.

Dare to be different: have the courage to make the tough decision to design your schedule in a way that lays the groundwork for consistent practice growth. ●



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# The Orthokeratology Process from Start to Finish

By Michael J. Lipson, OD, FAAO, FSLs, and Jennifer Harthan, OD, FAAO, FSLs



PHOTO CREDIT: GETTY IMAGES/ANDRESR

**Before initiating treatment, ECPs should have important conversations on all aspects of OrthoK wearing, lens care, follow-up, and expectations to ensure successful outcomes.**

**M**any factors influence the rate of myopia progression, including the patient's degree of myopia at baseline, ethnicity, age, number of myopic parents, amount of near work performed, time spent outdoors, and urban or rural location.<sup>1-4</sup> When deciding to initiate orthokeratology (OrthoK) treatment, these risk factors, and several others, should be considered. It has been reported that the risk of sight-threatening complications increases with increasing myopia (greater than  $-6.00D$ ) and axial length elongation (greater than  $26.00\text{ mm}$ ).<sup>5</sup> Thus, myopia management intervention should be initiated even at low levels of myopia to prevent potential complications, including cataracts, glaucoma, retinal detachments, and

myopic maculopathy. Intervention should be considered for children who are considered pre-myopes (between  $+0.75D$  and  $<-0.50D$ ) and have a combination of other risk factors present, and treatment should be initiated for those children who exhibit progressing myopia,  $<-0.50D$  in the relaxed accommodative state.<sup>6</sup>

OrthoK treatment should provide control of myopia progression of approximately 30-60%.<sup>7</sup> However, if a patient is not achieving sufficient myopia management, alternative therapies or additive therapies should be considered. Adverse events or non-compliance with treatment warrants discontinuation of OrthoK wear.<sup>8,9</sup> Children  $<14$  years of age wearing OrthoK for two years who

stopped wear had increased axial length growth, most likely due to thinning of the choroid during the post-treatment period. However, upon reinstatement of OrthoK treatment, axial length elongation slowed, suggesting OrthoK should be worn throughout the critical age periods when myopia is most likely to progress.<sup>10</sup>

## How to Monitor Myopia Progression

Myopia progression is monitored by refractive error and/or axial length changes.<sup>4,11</sup> Both measures should be monitored during OrthoK treatment. It is difficult to assess the true progression of myopia based on refractive error alone, as the patient's refractive error may vary both

throughout the day and from day to day. Pupil diameter, OrthoK treatment zone size, induced higher-order aberrations, lens warpage from handling, and the age of the lens may all contribute to variations in the patient's refractive error. For patients wearing OrthoK to manage myopia progression, refractive error should be assessed, but more importantly, the axial length should be measured before and during treatment.<sup>12,13</sup>

### Essential Factors to Consider for Success with Myopia Management

Myopia management can be rewarding for everyone involved – the practitioner, staff, patient, and family members. Before initiating treatment, ECPs should have important conversations on all aspects of OrthoK wearing, lens care, follow-up, and expectations to ensure successful outcomes. Training should be performed with providers and staff to ensure everyone in the office is fully equipped and educated to manage patients enrolled in myopia management programs.

When patients are being considered for a myopia management program, particularly OrthoK, practitioners should thoroughly evaluate their risk factors, ocular and medical history, axial length measurements, cycloplegic refraction, corneal shape, binocular vision status, and ocular health.<sup>14</sup> Extensive education should be done to review the risks and benefits of OrthoK with the patient and/or parents. The most important safety and overall success factors with OrthoK are compliance with lens wear, lens care (handling, cleaning, and disinfection), and adherence to the recommended follow-up schedule.<sup>15</sup>

### Long-Term Effect on Axial Length

OrthoK has been shown to slow axial elongation in myopic children. Because

the rate of axial elongation is fastest for children under 10 years of age,<sup>16</sup> the younger a patient starts OrthoK, the more significant the impact on limiting the ultimate axial length of the patient as an adult. Recent studies have assessed the long-term risks involved with OrthoK and risks associated with myopia due to longer axial length.<sup>15,17,18</sup> Results of these studies show that the risks of vision loss associated with OrthoK are less than the risk of vision loss from complications associated

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**Refractive error should be assessed, but more importantly, the axial length should be measured before and during treatment.**

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with myopia over a person's life. Initiating treatment, such as OrthoK, to slow axial elongation can provide long-term benefits for patients to reduce the risk of vision loss throughout patients' lifetimes.

### Does Treatment Zone Size Matter?

Efforts to optimize the effect of OrthoK slowing axial elongation with lens design changes are ongoing. One factor gaining significant attention is the back-optic zone diameter (BOZD). The working theory is that reducing the BOZD will result in a smaller treatment zone (TZ) diameter on the cornea. With that, a greater area of myopic defocus is created on the retina from the ring of plus power. Results of studies show trends that suggest this may be true but are not conclusive. For example, one study found that reducing the TZ did not

change the peripheral refraction.<sup>19</sup> In the first randomized clinical trial investigating BOZD,<sup>20</sup> the one-year results showed a trend toward less axial elongation with smaller BOZD. Retrospective studies show trends toward this effect but do not draw completely unanimous conclusions.<sup>21,22</sup> Assessing myopia progression rates, slow progressors after OrthoK have statistically smaller BOZD than fast progressors. However, no correlation was found between TZ diameter size and axial elongation.<sup>22</sup> Although smaller BOZD shows a trend toward creating slower axial elongation, other factors may come into play.

### Is the Effectiveness Sustained After Treatment is Discontinued?

The answer to whether effectiveness is sustained after OrthoK treatment is discontinued is not simple. There are multiple factors to consider, such as baseline degree of myopia, ethnicity, age at initiation, age at discontinuation, length of OrthoK treatment, and individual differences. While axial elongation is slowed during OrthoK treatment, discontinuation may result in variable responses. One study demonstrated that those who discontinued at 14 years of age or younger would show progression at a rate similar to what they had before OrthoK treatment.<sup>10</sup> Articles have discussed the potential for a rebound effect, where the rate of myopia progression is faster after treatment discontinuation compared to before treatment. No studies have shown a rebound effect with OrthoK. From reported clinical experiences, some axial length growth may occur if OrthoK treatment is discontinued after age 18, but it is likely to be minimal. Overall, close monitoring of refraction and axial length after discontinuation of OrthoK (every three to six months) is recommended.<sup>14</sup> ●



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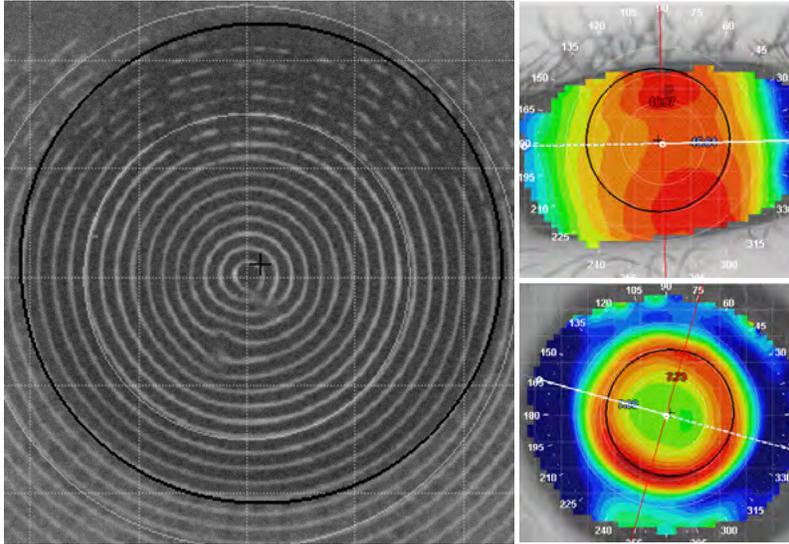
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# Effective Communication for Laboratory Consultation

Bruce Morgan, OD, FAAO, and Bethany Peebles, FAAO, ABOC, NCLE-AC



**Figure 1: Distorted central mires; Figure 2 (top right): Narrow aperture (vertical chord length is only 5.6mm); Figure 3: Treatment ring is well centered and complete.**

**P**rofessional golfers often rely on their caddies to enhance their chances of success. This is particularly true when the caddy is local and knows the golf course design like the back of their hand. Likewise, contact lens labs and their consultants are there to enhance the success of practitioners when fitting orthokeratology (OrthoK) lenses (along with other specialty fits). The lab consultant cannot fit the lens for you, but their deep understanding of their lens designs and troubleshooting can certainly enhance a practitioner’s success and efficiency as they navigate through the process. Therefore, even the most proficient and experienced fitters see the value of having that lab consultant with them as support to serve the patient in the best possible manner.

Effective communication is essential to success in any team environment, particularly when the team is not in the same room, as is the case with lab consultants. The practitioner’s responsibility is to provide the most accurate and detailed information possible when working with the consultant on a fit. This could include past patient history with contact lenses, overall goals of the patient, thorough description of the lens fit, imaging such as corneal topography (particularly vital with OrthoK), photography, videos, and horizontal or diagonal visible iris diameter along with, of course, keratometry, refraction, and best corrected visual acuity (BCVA) data. For OrthoK fits, topography and photos or videos of the fluorescein pattern provided to the consultant are particularly

helpful since the consultant is essentially “flying blind” without them.

## Topography

With topography vital to the success of OrthoK, obtaining accurate pre-fit and post-fit images should be front and center for the practitioner. Taking multiple captures is perhaps the best way to ensure quality and valuable information for both practitioners and consultants. It is recommended that at least four images of each eye be taken at baseline to prove repeatability and accuracy. For children, it is common to need more than four images per eye.

When taking topographies, it is vital to obtain the widest possible capture, which may require manual separation of the lids. The tear film quality must be optimized, and instilling artificial tears may be necessary. For Placido disc topographers, reviewing the actual ring reflections versus the color map can help detect irregularities in the tear film that may degrade the image significantly. Incomplete rings or rings that are blending into one another (ring jamb) are a sign that the tear film was irregular or that the capture was impeded by a lid or even the eyelashes. (Figures 1 and 2)

Sending a topography image that is not accurate, out of focus, or is cut off superiorly or inferiorly will be of little use to you or the consultant. When sending the topography image, make sure you use the proper scale (most likely normalized power) and display (i.e., tangential power and/or axial power, etc.) that the particular lab requests. Some labs may have topography

FIGURE 3 PHOTO CREDIT: CHAD ROSEN, OD

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## It is important to center the lens before assessing the fluorescein pattern manually.

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software that coincides with the practitioner's brand of topographer. In that case, it is ideal to send the entire patient file to the consultant. This allows the consultant to manipulate the scale and displays as needed and is particularly helpful when looking at post-fit comparison data to determine centration and overall proper lens alignment. If, for some reason, a topography image cannot be sent to the lab, describing the centration and completeness of the treatment ring (typically red in color) in a tangential power display is the most useful for the consultant. (Figure 3)

### Lens Fit Analysis

Although it is not always perfectly correlated to how the OrthoK lens centers and performs in the closed eye situation, it is essential to assess the lens on the eye with the slit lamp. It can provide the consultant with very valuable information, particularly if design changes are needed at some point in the process. It is common for the OrthoK lens to be decentered slightly with the patient vertical and eyes open. Therefore, it is important to center the lens before assessing the fluorescein pattern manually. Again, a quality photo or video image is worth a thousand words. Suppose you do not have a camera attached to the slit lamp. In that case, there are many adapters available that will allow photography with a standard cell phone, and at times, just taking a photo with the cell phone in your hand through the oculars can

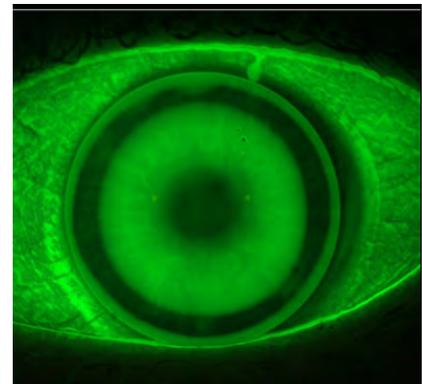
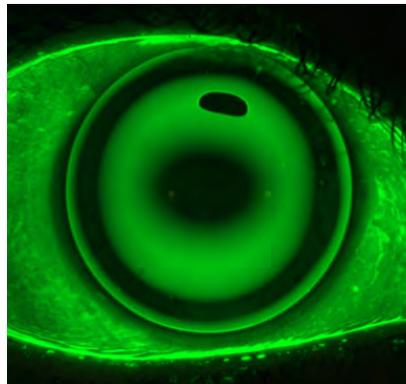
be successful. If photography or video is not possible, describe each zone of the fluorescein pattern in detail, including quality and quantity.

For example, describe the treatment zone/central applanation as well defined or poorly defined and provide the width in millimeters. It is also helpful to indicate if the treatment zone is round or oval. (Figure 4) For the alignment curve/zone, describe whether that ring shape alignment is distinct and a full 360° or note indistinct areas of alignment. (Figure 5) Depending on the specific design, the edge can be described as tight, acceptable, or excessive. While the fluorescein description alone does not always warrant a change, these details

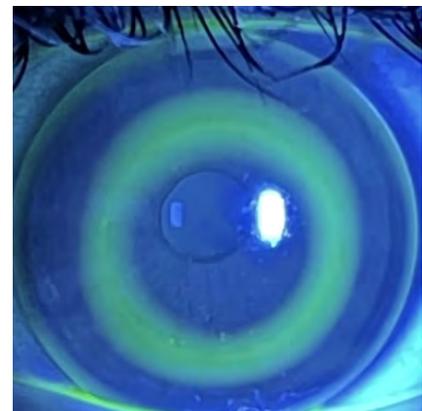
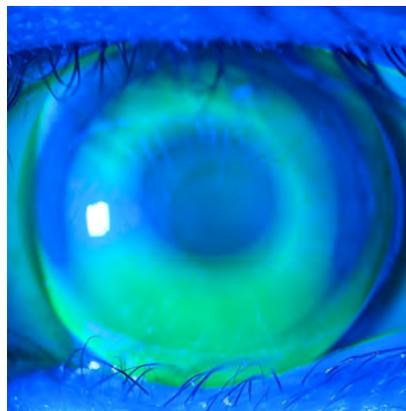
become vital to the consultant's ability to suggest changes in particular zones of the design to improve overall centration and effectiveness when combined with post-treatment topography and acuities.

### Refraction and BCVA Data

Along with the obvious baseline refraction and BCVA, it is important to track the refraction throughout the process of OrthoK carefully and have that data on hand when conferring with the consultant. OrthoK patients are somewhat unique in that their post-fit refraction may not produce the expected visual acuity, particularly during the transition period in the first week or two. The cornea may



**Figure 4:** The fluorescein pattern on the left shows a lens with an oval central applanation, and the fluorescein pattern on the right shows a lens with a circular or round applanation.



**Figure 5:** The fluorescein pattern on the left shows an incomplete or indistinct alignment zone with fluorescein bleeding through inferior, while the fluorescein pattern on the right shows 360° of alignment.

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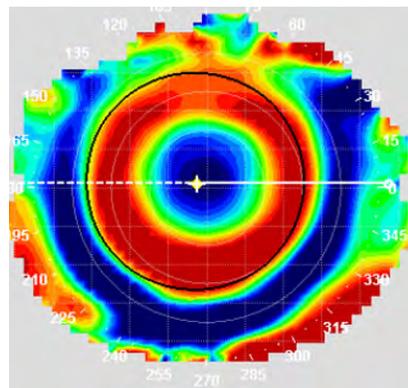
**It is important to report how many nights the patient has been wearing the current lens and the time of day the refractive data was obtained.**

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not undergo a perfectly smooth and even flattening within the transition period. Therefore, it is common that the refraction may show more or less myopia than the acuity reflects. In addition, if a small treatment zone is the goal or the patient has a large pupil, some patients may have interference from the peripheral plus power entering their pupil and confounding the refraction. (Figure 6)

The refraction taken in context with the uncorrected visual acuity (UCVA) and

topography image helps the consultant determine if an adjustment is needed to increase or decrease the treatment effect. Refraction over the lens is also helpful in determining if the base/treatment curve is appropriate, so be sure to have patients bring their lenses to all appointments, and if there is a question related to undercorrection or overcorrection, the refraction



**Figure 6: Small treatment zone bringing peripheral plus power well within pupil margin**

over the lens can be obtained and shared with the consultant. Lastly, it is important to report how many nights the patient has been wearing the current lens and the time of day the refractive data was obtained.

**Summary**

Working with a lab consultant to optimize OrthoK can be among the most rewarding experiences for a practitioner or can be quite frustrating. Proper communication is the key to ensuring it is the former. The practitioner must provide in detail what the consultant cannot see and be open to sharing the overall plan and goals for the patient. Teaming up with a consultant provides the opportunity to hone assessment skills, increase design knowledge, and ultimately increase efficiency and success. Let the lab consultant “caddy” be your guide and partner in providing the best outcome possible for your OrthoK patients – you won’t regret it! ●



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# Orthokeratology Patient Management and Follow-Up

By Stephanie Ramdass, OD, MS, MBA, FAAO, FSLC

SECTION PHOTOS CREDIT: STEPHANIE RAMDASS



**Figure 1.** A new OrthoK wearer demonstrates application of her lens onto the center of her cornea.



**Figure 2.** For some OrthoK wearers, it is easier to remove a lens using a small lens-removal tool after the patient looks in a mirror to confirm the position of the lens on the eye.

**T**here is tremendous skill and clinical time invested when carrying out an orthokeratology (OrthoK) fit. The ensuing processes are of equal importance to the fitting procedure, including the follow-up schedule and instructional review of care and handling steps associated with a newly established OrthoK wearer. Patient management and follow-up can differ depending on the wearer's age and if OrthoK use is prescribed for myopia management or myopia correction.

## OrthoK Dispense Day

The fitting and dispensing visits may coincide for a diagnostic

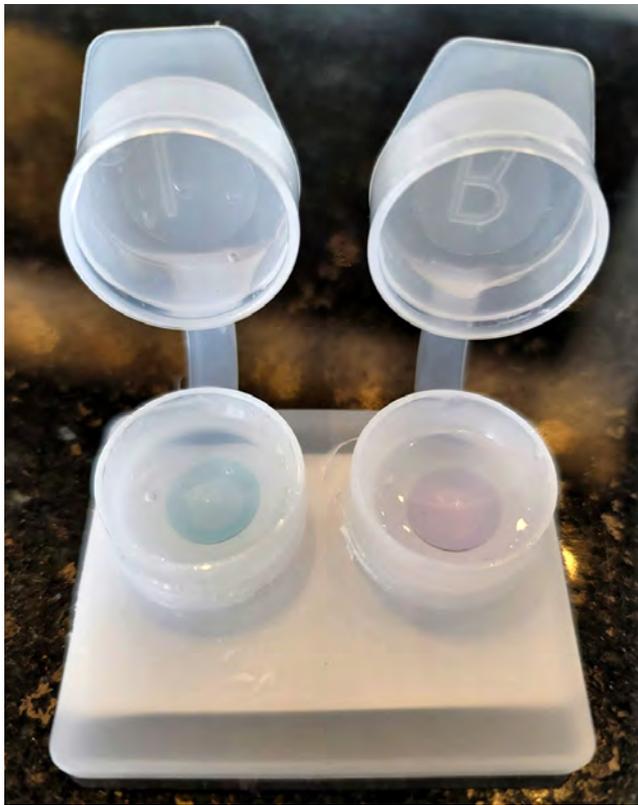
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**Patients and/or caregivers should be taught OrthoK lens removal with and without the aid of the lens-removal tool.**

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OrthoK fit. OrthoK lenses taken directly from your fitting set are clean and ready for dispensing; however, they should be evaluated as if they are new each time.

When new OrthoK lenses are dispensed, they should be inspected for smooth edges, cleaned, and conditioned before



**Figure 3. OrthoK lenses are typically manufactured in two different colors to easily identify right vs. left.**

application on the eye to optimize the first dispense experience. OrthoK lenses are typically plasma treated in the manufacturing process and will arrive from the lab soaking in solution. The purpose of this solution is to pre-condition the new lenses. Package inserts remind fitters that the lens is non-sterile upon arrival and to clean and condition the lens prior to use. Imperfect surface wetting will decrease the quality of vision for the patient when the lens is worn. If a drop of topical anesthetic was used during the OrthoK fitting visit, try to avoid anesthetic during the dispensing visit to set the patient's expectations for applying the lenses by themselves at home. Also, remind patients that OrthoK lenses are typically manufactured in two different colors (i.e., purple for the Right eye and blue for the Left eye) to avoid confusion during the application process. (Figure 3)

For the youngest OrthoK wearers who may need a caregiver to assist with the application at home, it is imperative to teach this individual how to apply the lenses in the office. Demonstrate that a drop of preservative-free lubricant artificial tears or saline can be used to rinse the lenses prior to application, or a drop of this solution can be placed into the bowl of the lenses prior to application. OrthoK lenses should be placed directly on the "center of the colored

part of the eye." (Figure 1) If it becomes dislodged and ends up on the sclera, instruct the patient and/or caregiver that the eye should look in the direction of the lens in order to recenter it. Alternatively, a drop of solution on the tip of a small lens-removal tool can be used to safely remove the OrthoK lenses. (Figure 2) Patients and/or caregivers should be taught OrthoK lens removal with and without the aid of the lens-removal tool. Care and handling of the lenses should be carefully reviewed at each visit to ensure safety when wearing lenses.

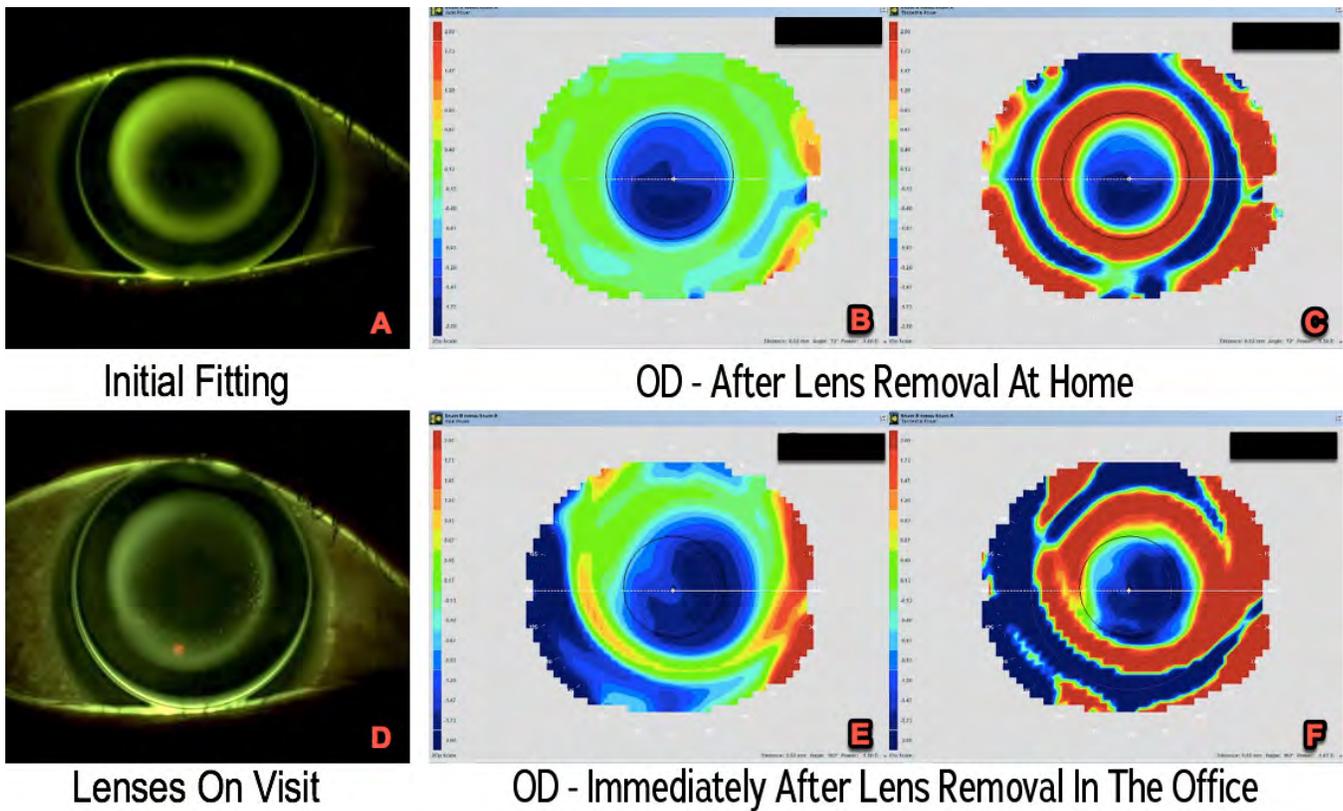
The follow-up visit schedule is determined, whether empirically or diagnostically fit, after the first night of OrthoK overnight wear. This may fall on the night of dispense day or may be at a suitable future date that will allow the patient to return early the following day for the one-day follow-up visit. Depending on the flexibility of both the caregiver's and the eye care practitioner's schedules, an early morning appointment may have to be booked outside of regular business hours, either earlier than usual or on the weekend, to minimize the time when lenses are worn in an open-eye state.

### **OrthoK One-Day Follow-up**

For any patient, child, or adult, the first overnight wear can be the most challenging part of OrthoK wear. Initial lens awareness is expected. Lenses should be applied just prior to bed, preferably in the bathroom immediately after handwashing. During OrthoK treatment, the patient should get a full night's rest, or at least six to eight hours of sleep, for optimal overnight results.

Ideally, a follow-up examination should occur early the next morning, where the caregiver drives the patient or the patient drives themselves to your office. If patients are wearing the OrthoK lenses to the office for their first follow-up visit, an early morning visit minimizes the time when lenses are worn in an open-eye state.

Practitioners often debate the significance of OrthoK treatment zone difference analysis on whether patients wear their OrthoK lenses to their office visit the day after their first night of overnight wear or if they don't. One study assessed the clinical impact of day-one removal of OrthoK.<sup>1</sup> A total of 11 subjects (22 eyes) participated in a randomized, crossover study where they were fit with OrthoK lenses according to the manufacturer's recommendations. During Phase 1, participants wore their OrthoK lenses overnight and removed them at home before their day-one follow-up. These same participants were then washed out of OrthoK wear over a one-to-two week period or until topography maps returned to baseline. Participants resumed treatment again overnight but wore their lenses to the office for the doctor to remove them in-office. When OrthoK lenses were worn to the



**Figure 4. Imaging shows the contrasting clinical outcome if a patient comes in wearing the OrthoK lens versus removing the lens at home prior to the one-day follow-up visit. The baseline image of the lens on-eye on dispense day (A). Axial (B), and tangential (C) difference maps post removal of the lens at home. Lens on-eye prior to in-office removal at the one-day follow-up visit (D). Axial (E), and tangential (F) difference maps immediately post removal of the lens in office.**

office, there was a trend for the corresponding tangential difference maps to appear more oval than circular and show a slight double ring effect. (Figure 4A-F) The treatment zone size typically appeared similar in width irrespective of the treatment phase. However, it was of a greater intensity when lenses were worn to the office.

From this pilot study, it appears that one-day treatment in patients undergoing OrthoK can be assessed the morning after overnight wear shortly after awakening, whether they present to the office wearing their lenses or not. As a clinician, it is essential to remember that assessing the ocular health of patients undergoing OrthoK is of the utmost importance. If a patient is dispensed OrthoK lenses and does not present wearing them once throughout their

treatment, you may never see them on the eye again. Patients should be encouraged to bring their OrthoK lenses to every visit.

For older patients who require sharp distance acuity to function throughout the day, it may be beneficial to prescribe daily disposable contact lenses in a descending power sequence to correct their vision until the one-week follow-up where the total treatment effect is nearly complete.<sup>2</sup> Patients may need additional instruction on the care and handling of the daily disposable lenses as well. Instruct patients to continue with nightly wear of the OrthoK lenses if the dispense day is successful, and schedule them back in one week.

#### OrthoK Follow-up Schedule

There is no standard protocol for the number of OrthoK follow-ups that must

be carried out. Table 1 provides a suggested sequence of appointments centered around maintaining corneal health and reinforcing best practices for patient care and handling, as these steps should be reviewed at each visit. The various tests at each visit can vary, with axial length measurements included for OrthoK patients undergoing myopia management.

#### OrthoK Evaluation and Lens-Induced Complications

During scheduled follow-up evaluations, ask patients to bring their OrthoK lenses with them. Always inspect for any lens irregularities that might impact the treatment effect or lead to ocular surface complications. Topography maps compared to baseline results, entering visual acuity, residual refraction, best corrected visual

## SUGGESTED SEQUENCE OF APPOINTMENTS

Visit #	Type of Visit	Tests Performed
1	Fitting Visit	UCVA, R, BCVA, ASE, T, AXL**, OR*
2	Dispense Visit	OR, BCVA, ASP, ASE, T
3	One-day Follow-up	tVA, RR, BCVA, ASE, T
4	One-week Follow-up	tVA, RR, BCVA, ASE, T
5	One-month Follow-up	tVA, RR, BCVA ASE, T
6	Three-month Follow-up	RR, ASE, T, AXL**
7	Six-month Follow-up	RR, ASE, T, AXL**
8	Annual Visit + Routine Eye Exam	RR, ASE, T, AXL**

**Table 1: UCVA (Uncorrected Visual Acuity); R (Refraction); ASE (Anterior Segment Evaluation); ASP (Anterior Segment Photography); T (Topography); AXL (axial length measurement); \*performed during diagnostic fitting; \*\*performed in cases of myopia management**

acuity, and staining assessment of the ocular surface are key metrics to monitor treatment effect. Review of care and handling procedures can be done quickly and ensure continued patient compliance and health and safety with overnight OrthoK. If patients are enrolled in a myopia management program in your office, quarterly or biannual ocular biometry measurements are helpful benchmarks to monitor treatment efficacy. (Table 1)

Outside of the suggested follow-up schedule, patients and/or caregivers need access to immediate care, or they need to know how to contact the office or the ECP directly, should problems arise.

### Care and Handling

Lens cleaning, disinfection, and handling should be reviewed at each visit. Hygiene, especially handwashing, must be stressed. Lens contamination due to care and

handling is the number one risk for complications associated with overnight wear of OrthoK lenses.<sup>3</sup> For young patients, establishing care routines is essential to help build consistency. Ask patients and/or caregivers to take pictures of their care/handling set-up at home and have them talk through their application, removal, and cleaning steps during follow-up visits. (Figure 5)

Before bed and with clean hands, either a caregiver or patient should remove the OrthoK lenses from the case, one lens at a time. The lens can be rinsed with saline (preferably non-preserved), and then a drop of non-preserved artificial tears can be placed into the bowl of the lens (optional step) and applied. Advise patients not to rub their eyes as this can dislodge the lenses. All solution in the case should be discarded at this time, and the case should be rinsed with saline and allowed

to air dry so that it is ready to use again in the morning. Although rare, the lens may fall out or shift while sleeping. If patients wake up in the morning and can see out of each eye, the lenses are correctly in place. After washing their hands, have your patient remove their OrthoK lenses. If they are prone to dryness in the morning, instruct the patient to instill a drop of non-preserved artificial tears into the eye to ensure adequate lens movement before removal with or without the aid of a small lens-remover tool. OrthoK lenses are then disinfected as recommended and placed in the corresponding side of the clean case. Disinfection can be performed with an all-in-one multipurpose GP solution or a hydrogen peroxide-based system.

### Back-up/Replacement OrthoK Lenses

It is recommended to have an OrthoK contact in place for each fit. OrthoK is an ongoing process that does not end upon dispense and finalization of lens parameters. Patients and/or caregivers need to understand the responsibilities of an OrthoK wearer and the commitment that goes into year one. This contract should include details regarding a backup pair of lenses, often offered at a discounted rate if a direct duplicate of finalized parameters is ordered and it is within the lab-specified warranty period. Outside of the warranty period, there will be costs associated with broken or replacement lenses. For broken lenses, advise the caregiver/patient that labs want to understand how they broke and often like to keep this information on file. Remind them to take photos of broken lenses and email them to your office for reference. To avoid disrupting the OrthoK treatment process, always encourage patients to have a backup pair. If a wearer has similar topographies and refractive

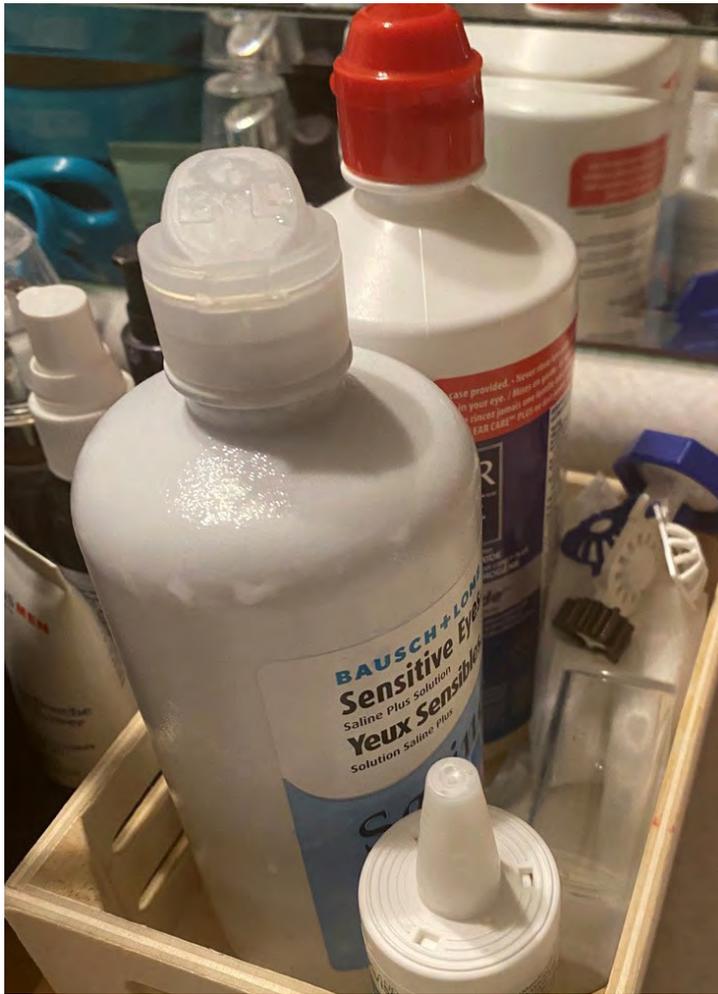


Figure 5. Patient's OrthoK workstation on the bathroom counter at home.

target correction in both eyes, have the patient bring their remaining OrthoK lens to the office and evaluate if it can be worn on each eye on alternating nights to ensure minimal washout and disruption of daily routines until the new lenses arrive.

### Annual Management Fees and/or Re-Fit Protocol

At the one-year mark, patients will require an annual exam to ensure that complete ocular health is assessed. An annual management fee can be applied to cover your chair time costs for ongoing OrthoK assessment in year two. This fee may include follow-up visits for the remainder of year two, or it can be independent with subsequent OrthoK follow-ups invoiced à la carte.

The treatment effect of OrthoK lenses may deteriorate as the lenses get older, thus the ECP should recommend that a replacement pair be ordered at this time. A higher than expected residual refraction measured at the one-year visit can easily be remedied with a new set of OrthoK lenses in the habitual parameters. If necessary, a re-fit may be required if a wearer has discontinued lens wear on their own (minimum of three weeks), if lens wear is no longer comfortable, or if the treatment effect is significantly off from the expected outcome. ●

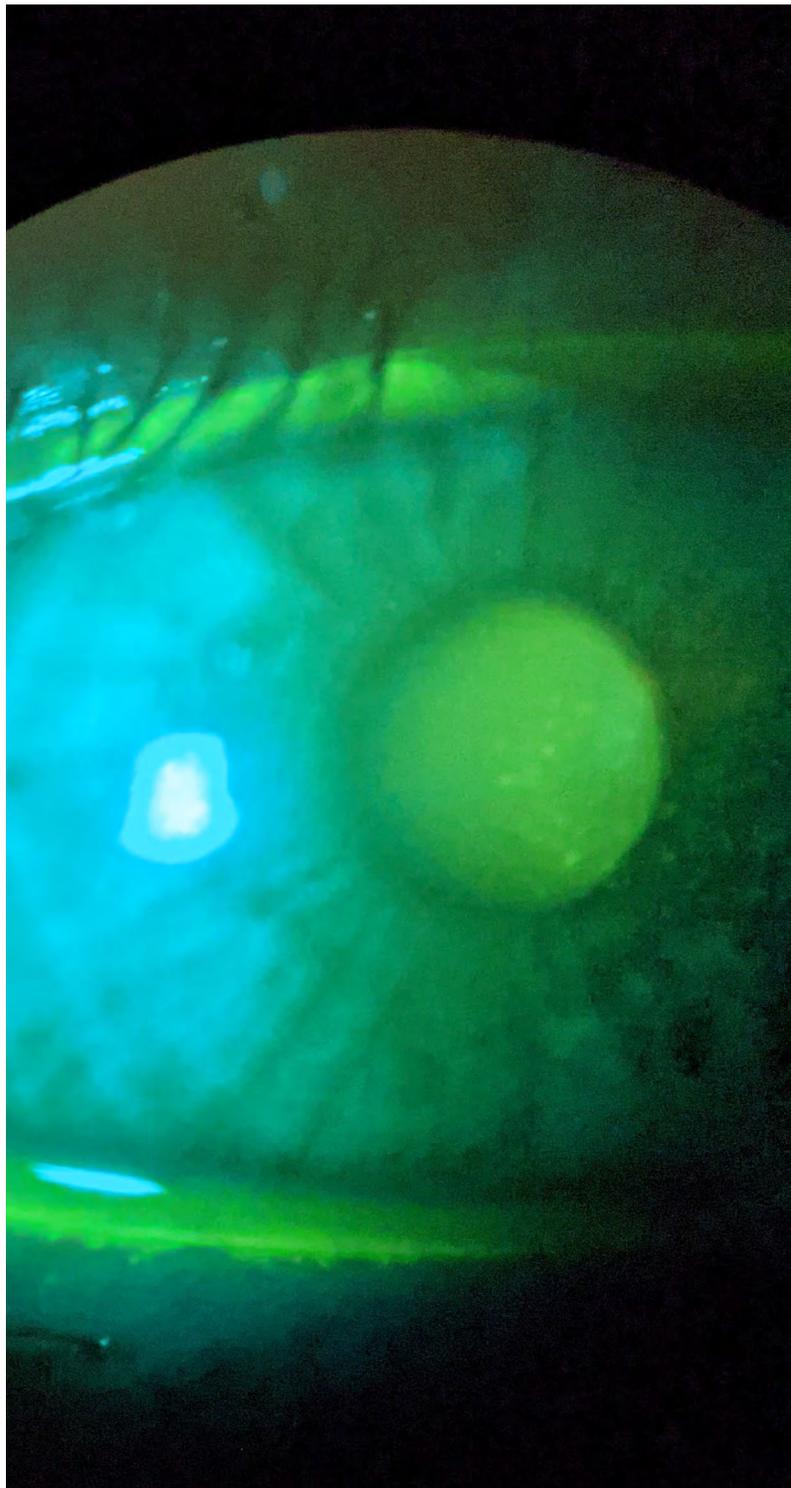


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# Managing Orthokeratology Complications

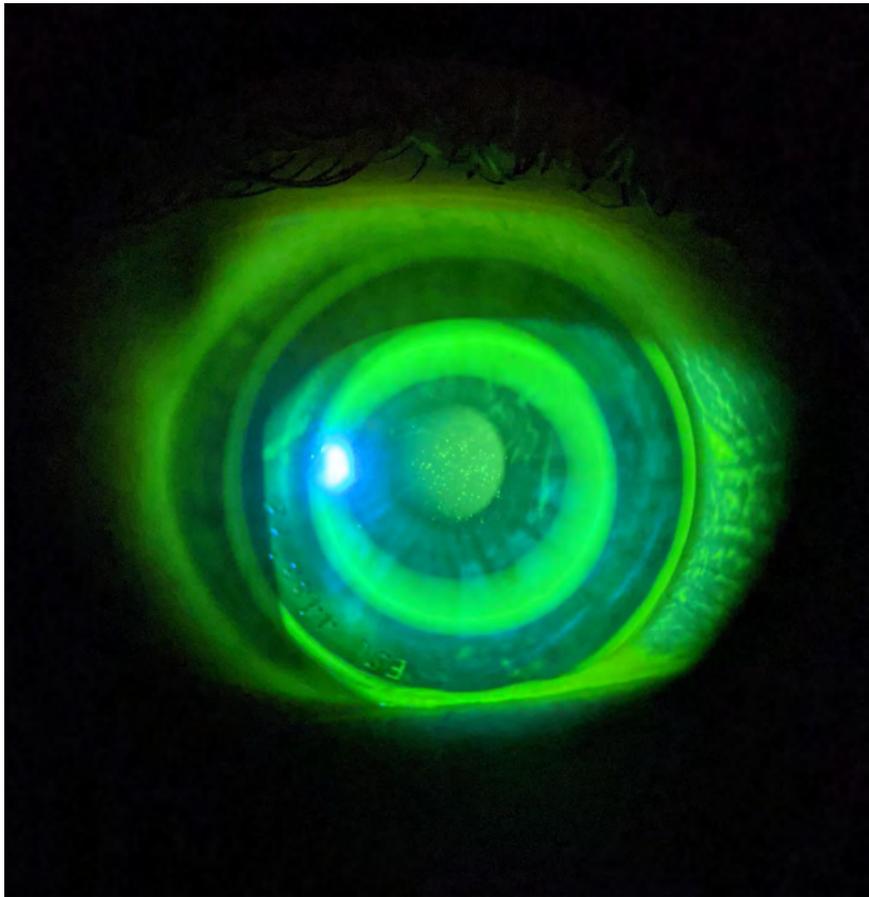
By Stephanie Fromstein, OD, and Bruce Koffler, MD



**W**hen discussing the management of orthokeratology (OrthoK) complications, it is necessary to note that overnight wear of these lenses has been shown to be both safe and effective in the management of myopia.<sup>1</sup> This is reflected by a body of evidence from hundreds of publications strongly indicating the safety of this technique in both children and young adults.<sup>2,3</sup> Also true, however, is that introducing any contact lens into the ocular environment changes the physiological and pathological milieu, with studies reflecting that up to 29% of OrthoK lens wearers will experience some form of adverse event.<sup>4</sup> In following the literature, the vast majority of these events are mild, transient, and reversible, with the incidence of severe complications with OrthoK clocking in at 4.0-6.9%.<sup>5</sup> Factors associated with increased risk of complications were high myopia, younger age, and allergic conjunctivitis, with only high myopia being significant.<sup>4</sup>

Many patient (or perhaps more accurately, parental) concerns on the safety of OrthoK stem from a relatively sizeable and significant outbreak of microbial keratitis across several countries in the early 2000s.<sup>6</sup> Comprised predominantly of acanthamoeba infections, these outbreaks were found to be secondary to

**Central staining after orthokeratology lens removal.**



Central staining as viewed underneath orthokeratology lens with fluorescein instilled.

improper lens care, as well as the use of contaminated tap water for lens cleaning and storage.<sup>2</sup> With improved protocols and care compliance, rates of microbial keratitis have steadily declined such that OrthoK no longer appears to present increased risk compared to the same over-night wear pattern of our more established silicone hydrogel contact lenses.<sup>7</sup> Furthermore, the risks of this technique must be weighed not only against the other myopia management tools in our toolbox – including multifocal contact lenses and atropine – but should also be balanced with the inherent risk of doing nothing, as the deleterious effects of high or even moderate amounts of myopia have been well established.<sup>4</sup> With this in mind, here are the potential complications and the techniques for their management.

### Corneal Staining

By far, the most common complication of OrthoK is damage to the ocular surface in the form of corneal staining.<sup>8,9</sup> Up to 29% of wearers will experience some corneal staining, primarily mild or moderate (up to a Grade 2 on the Efron scale).<sup>2,4,10</sup> Myriad etiologies may cause this, including thinning of the central corneal epithelium, improper OrthoK fitting, corneal hypoxia, hypersensitivity to cleaning and disinfecting solution, mechanical abrasion caused by the buildup of protein deposits on the back surface, binding, and/or incorrect removal of a bound lens in the morning.<sup>11</sup>

Given the multitude of etiologies and the relative ubiquity of staining complications, it is helpful to examine the staining pattern to help narrow down the source.<sup>2</sup> A diffuse staining pattern often points to

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**The most common complication of OrthoK is damage to the ocular surface in the form of corneal staining.**

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a more generalized underlying condition such as lid conditions, preservative sensitivity, or dry eye. Peripheral indentation rings may denote a tight or immobile OrthoK fit. A central staining pattern is often associated with binding. OrthoK alters both the viscosity and thickness of the post-lens tear film, which can, in the absence of adequate movement and tear exchange, make the lens more adherent to the cornea upon awakening.<sup>2</sup> Lens removal of an adherent lens may lead to unintentional sloughing of a few epithelial cells leading to central staining that may be associated with symptoms of pain, discomfort, and/or redness. Lid and negative hydraulic pressure have also been implicated in this effect, which may be why the effect tends to be more pronounced in higher myopes who tend to have a tighter fitting lens.<sup>2</sup> Lens deposits (especially protein) can also lead to increased lens binding. The result is mild staining or a superficial abrasion upon lens removal.

When managing staining with OrthoK wear, anything more significant than a Grade 2 on the Efron scale should signal that the patient temporarily discontinue OrthoK wear to avoid more serious adverse events such as a deeper abrasion or a corneal ulcer. Initiate treatment of moderate to severe staining with an age-appropriate broad-spectrum topical

antibiotic and lubrication with artificial tears. Advise patients to stay out of the lenses until resolution. If the presumed etiology is an issue with fit, modification to encourage movement and tear exchange should be employed; this most often involves flattening of the tertiary and/or peripheral curves to loosen the lens on the eye. Recommend that patients use a lubricating solution (in the form of an artificial tear or a gas permeable conditioning solution) upon application and before removal to ensure the lens is mobile. Given the more detrimental effects on higher myopes, consider partial correction in recalcitrant cases. If the staining is central and acquired after several months of wear, cleaning with an in-office cleaning solution to remove deposits resolves a great many of these cases and can lengthen the lifespan of a well-fitting lens. Examination of lens fit, staining pattern, and detailed case history can help point in the direction of the correct etiology and management option.

### Dry Eye

As mentioned, OrthoK wear impacts tear components, with the tear film all but guaranteed for disruption by the foreign entity. This leads to increased evaporation and thinning of the tear film.<sup>8</sup> Incomplete blinking may further exacerbate this tear disruption, though this effect is minimized as patients wear OrthoK with their eyes primarily closed. Incomplete nighttime eyelid closure must also be checked. While there can be initial excessive tearing,<sup>17</sup> basal tear secretion tends to decrease over time along with decreased corneal sensitivity. All of which is to say that OrthoK can lead to contact lens dryness and discomfort, as reflected in an increased Ocular Surface Disease Index (OSDI) after six months of wear.<sup>17</sup> In patients wearing

OrthoK, it is thus prudent to monitor both signs and symptoms of dry eye and treat each accordingly. Treatment involves the staged approach to management and treatment outlined in the [TFOS DEWS II report](#). Most pediatric OrthoK patients find significant relief in signs and symptoms with Stage I therapy, including ocular lubricants, lid hygiene, warm compresses, and identifying possible dietary and medicinal modifications that may be beneficial. Some of these treatment strategies can and should be employed before ever fitting the

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**Children with  
allergic conjunctivitis  
are more likely to  
develop myopia  
sooner than children  
without it.**

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patient in lenses, especially where the patient has significant signs or symptoms of dry eye on initial examination. Providing potential OrthoK patients with a dry eye survey at their consultation can help direct your evaluation and therapy appropriately, as well as monitor for exacerbations with lens wear.

### Allergic Conjunctivitis

One can hardly speak about dry eye without noting the association of allergic conjunctivitis. This association is especially unfortunate because their respective management can be counterproductive (e.g., allergy medications notoriously dry out the ocular surface). However, the underlying inflammation in both conditions makes the association less surpris-

ing. It creates a role for anti-inflammatory therapy in the form of high-level topical steroids or lower-acting immune modulators in managing both conditions.

The association of OrthoK with allergic conjunctivitis does, however, seem to go a little deeper. Children with allergic conjunctivitis are more likely to develop myopia sooner than children without it.<sup>18</sup> In a chicken-or-egg discussion reminiscent of keratoconus, the question becomes whether there is a mechanical component to myopia (due to eye rubbing), or conversely, whether patients with atopy are also predisposed to nearsightedness. Regardless of the what-came-first debate, however, a need to properly manage allergies, especially in the context of myopia development or myopia progression, seems to be a clear-cut conclusion. Treatment at a minimum should include a topical antihistamine/mast-cell stabilizer in patients with signs or symptoms of ocular allergy. Given the crossover with dry eye, also recommend an artificial tear, which may be chilled in the refrigerator to provide cooling relief. Severe cases of atopy should discontinue lens wear and be managed with the aforementioned therapy plus a topical steroid. Patients should be aware that it may be several months before they can return to OrthoK wear and should be offered alternative means of refractive correction.

### Infectious Keratitis

A more serious concern of OrthoK is microbial or infectious keratitis,<sup>2,12</sup> as the overnight ocular ecosystem allows for concentration and proliferation of the normally unproblematic lid flora.<sup>2,13</sup> The risk of microbial keratitis in OrthoK is similar to that of other overnight wear modalities and has been reported between 4.0 and 13.0/10,000 patient years of wear.<sup>6</sup> *Pseudomonas* and *acanthamoeba* are the

most common keratitis-causing culprits,<sup>14</sup> though serratia, fungal infections, staphylococcus, and nocardia infections are also reported in the literature.<sup>15</sup> Given that these ocular occupants traditionally do not cause issues, it follows that some other process is likely diminishing corneal epithelial cells defenses – be it mechanical or hypoxic – predisposing them to infectious invasion.<sup>13</sup> Bacterial keratitis should be managed with an in-office loading dose and subsequent therapeutic dose of a broad-spectrum antibiotic in addition to hourly lubrication. Consider cycloplegia as well to improve comfort. Central or vision-threatening ulcers should be cultured before treatment is initiated; if this technique is not available at your practice, immediately refer the patient, especially in the case of pediatric keratitis. Refer any treated ulcer that does not improve as expected to a corneal specialist, as it may be a fungal or acanthamoeba infection.

Acanthamoeba keratitis is not only the most severe adverse event associated with OrthoK lens wear,<sup>6</sup> but it is also significantly overrepresented in the literature. OrthoK wearers represent only 1% of the vision correction population, while 13% of acanthamoeba cases have a history of OrthoK wear.<sup>16</sup> Thus, while rare, OrthoK appears to be a notable risk factor in the development of this sight-threatening condition. Given this over-representation, early diagnosis of these patients, who often have ocular pain that far exceeds their limited clinical findings, is critical in getting the patient timely care and preventing visual loss. When treatment of OrthoK-related keratitis does not respond as anticipated to therapy, acanthamoeba should be high on your differential diagnosis, and an appropriate referral should be made immediately.

Risk factors for acanthamoeba keratitis

are: wearing OrthoK, sleeping while wearing lenses, and topping off lens solution. While the first two are non-negotiable given this type of lens treatment, the importance of proper lens care in minimizing this significant complication is clear. Repeatedly educate patients about how to properly care for their lenses. This includes cleaning with appropriate solutions, avoiding tap water in any stage of the lens cleaning process, proper cleaning, replacing the lens case (often a breeding ground culprit), and using a new solution every day. Write and reiterate instructions, and verify compliance with case history at each visit. Given the association of acanthamoeba infections with poor lens care, as the old adage goes: an ounce of prevention is worth a pound of cure; investment in patient education on proper lens care can reduce or eliminate the risk of this severe complication.

### Benign “Complications”

Finally, there are several benign “complications” noted on clinical examination of our OrthoK patients. These include an iron ring thought to be associated with tear stagnation (similar to a Fleischer ring in keratoconus), which is heavily correlated to the length of treatment.<sup>15</sup> Anecdotally, virtually every patient who has been wearing OrthoK lenses for a year or more will have this finding, which is best seen with the cobalt blue filter. Fibrillary white lines may also be observed in the sub-basilar plexus, which are thought to represent prominent nerve fibers, and which require no treatment.<sup>15,19</sup> Photo documentation may be valuable for monitoring these benign findings over time.

### Long-term Considerations

Long term, there appear to be minimal changes in pertinent measurements after discontinuation of therapy. There is no

significant change in epithelial or corneal thickness, endothelial or morphological features, as well as other corneal biomechanical properties.<sup>2,21</sup> No observable impact on meibomian gland structure after two years of lens wear has been noted.<sup>17</sup> There is an increased but transient change in higher-order aberrations,<sup>22</sup> much like you would observe in refractive surgery.<sup>15</sup> Even eight weeks or more after discontinuing OrthoK wear, there is a mild hyperopic shift<sup>23</sup> and increased corneal toricity/refractive astigmatism.<sup>15,24</sup> This is due to a lingering flattening of the flat meridian. As with other complications of OrthoK, this effect is more pronounced in higher myopes, patients who start wear earlier, and those with a longer course of treatment.<sup>24</sup>

### Conclusion

Overall, the complications of OrthoK are relatively minor with well-established treatment protocols. Clinical skills can help to minimize these risks by ensuring a healthy ocular surface before treatment and an ideal fit. Clinical diligence in terms of written instructions, care and compliance, and routine follow-up is also invaluable. In doing so, the conscientious practitioner allows for observing complications early and managing them appropriately. While OrthoK does introduce risk factors that other myopia control modalities do not, adverse events tend to be mild. Many would argue these risk factors and adverse events are outweighed by the benefits of a well-established and trusted myopia control technique. OrthoK lens use must be selected with an eye both to appropriate patient (and parent) selection and viable alternatives given the specific situation. If OrthoK is the best approach to your patient, forge ahead with the confidence that you have chosen a safe and effective means of myopia control. ●



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# Combination Therapy: Orthokeratology + Low-Dose Atropine\*

Monica Jong, PhD, BOptom

**O** rthokeratology (OrthoK) is a clinical technique that uses specially designed rigid corneal lenses worn overnight to reshape the cornea, which leads to central flattening and midperipheral steepening, temporarily reducing or eliminating refractive error during the daytime.<sup>1</sup> OrthoK has also been reported to be one of the most effective non-drug treatments for myopia control and is thought to slow myopia by providing myopic defocus to the peripheral retina.<sup>2</sup> It can slow axial elongation on average 0.25 to 0.27 mm over two years.<sup>3-5</sup>

Atropine is a non-selective muscarinic antagonist, and receptors are found throughout the eye, including the ciliary body, retina, and sclera.<sup>6</sup> The mechanism by which atropine slows eye growth is not known. Atropine has a dose-response relationship, with high concentrations resulting in a greater slowing in axial elongation and an increase in adverse effects such as photophobia, near accommodation loss, and pupil dilation.<sup>7</sup> Low-dose atropine

at 0.01% concentration has been used most widely to slow myopia progression, but the recent LAMP study confirmed suspicions that 0.01% atropine is not effective in slowing axial elongation, and that 0.025% and 0.05% are better clinically with little rebound and adverse effects.<sup>8-10</sup> Over three years of treatment, the dose-response was evident with axial elongation on average 0.50±0.40 mm, 0.74±0.41 mm, and 0.89±0.53 mm for 0.05%, 0.025%, and 0.01% atropine, respectively.<sup>10</sup> The corresponding increase in spherical equivalent refractive error was -0.73±1.04D, -1.31±0.92D, and -1.60±1.32D for 0.05%, 0.025%, and 0.01% low-dose atropine, respectively. The limited studies examining combination therapy have been mainly OrthoK with the addition of 0.01% atropine.

Although 0.01% monotherapy is not clinically effective alone, when used in combination with OrthoK, early studies report enhanced treatment effect compared with OrthoK alone.<sup>11</sup> One school

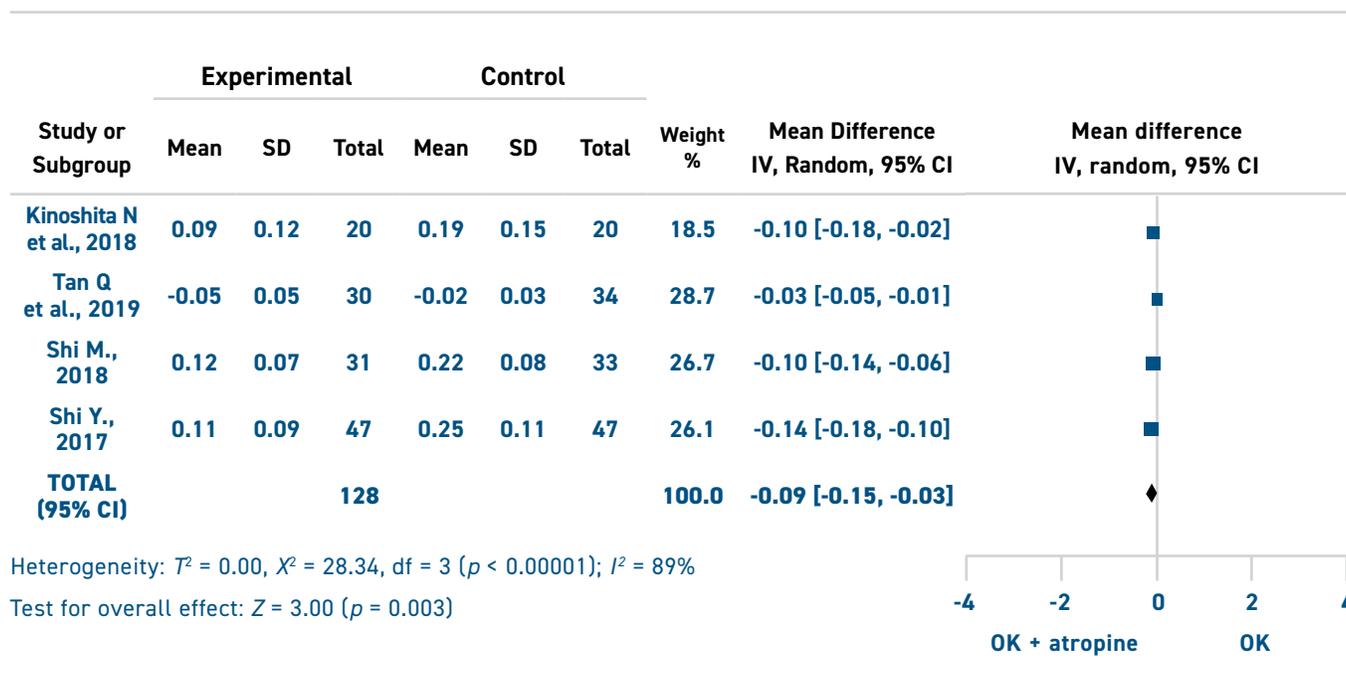


Figure 1. Forest plot of the comparison of change in axial length (AL). Orthokeratology = OK; confidence interval = CI. Adapted from Wang et al. 2021.<sup>15</sup>

\*considered off-label use for myopia control in many parts of the world

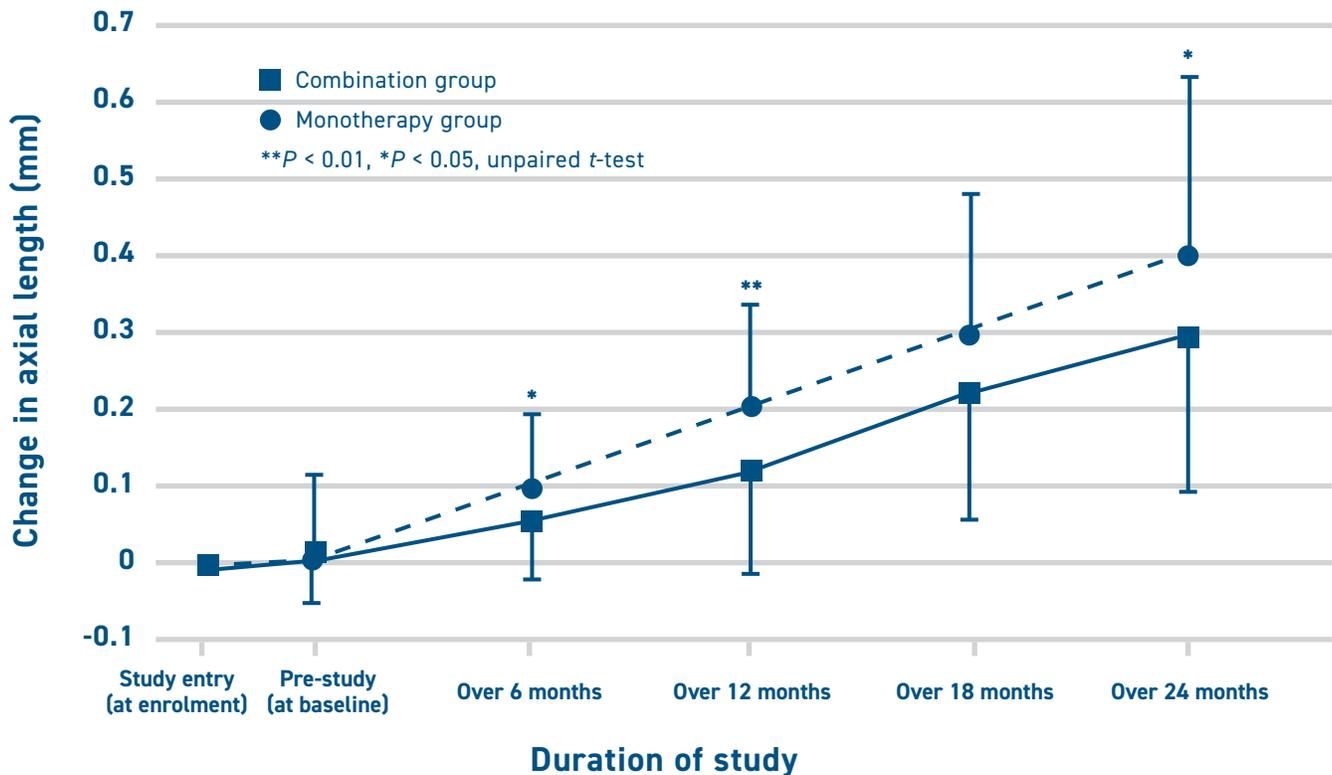


Figure 2: The change in axial length in OK and 0.01% atropine combination group versus OK-only group adapted from Kinoshita et al.<sup>12</sup>

of thought is that the slight pupil dilation from the low-dose atropine enhances the effect of the myopic defocus reaching the peripheral retina, or that higher order aberrations play a role.<sup>12-14</sup> The underlying mechanisms are still not well understood and remain subject to further research.

### Research Studies in OrthoK Combined with 0.01% Low-Dose Atropine

To date, there are a limited number of studies of relatively short duration reporting the efficacy of combination therapy. Figure 1 shows the results of the recent meta-analysis by Wang et al.,<sup>15</sup> which examined combined OrthoK with 0.01% atropine, and which included four prospective randomized studies with a total of 267 children with myopia between -0.50D to -6.00D, ranging in age from 6 to 16 years old from Hong Kong, China, and Japan. The studies were one to twelve months in duration.<sup>15</sup> The control group for the studies were OrthoK alone.

Overall, Wang et al.<sup>15</sup> reported that the mean axial length of the 128 subjects in the combination therapy had statistically significantly reduced elongation by 0.09 mm after one year of treatment. (Figure 1)

The longest combination study to date was by Kinoshita et al.,<sup>12</sup> a study that enrolled 80 Japanese children aged 8 to 12 years with a spherical equivalent of -1.00D to -6.00D. A total of 73 subjects completed two years in the study. Axial length increase was less in the combination therapy group ( $0.29 \pm 0.20$  mm) versus the monotherapy group on average ( $0.40 \pm 0.23$  mm). (Figure 2)<sup>16</sup> The difference was statistically significant. The enhanced treatment efficacy was seen to reduce from approximately 50% to 30% at the end of the first year to the end of the second year.

In a sub-group analysis, Kinoshita et al.<sup>12</sup> found that combination therapy achieved better slowing in axial elongation in those with lower initial myopia and was not linked to age. This effect has

not been observed in other prospective<sup>17</sup> or retrospective<sup>18,19</sup> combination studies, which had slightly different age and refractive error ranges.

### Adverse Effects

The most commonly seen adverse effects were mild corneal staining and conjunctivitis. Less frequent were: central corneal staining, mainly related to OrthoK lens wear; mild photophobia outdoors in those undergoing combination therapy; corneal infiltration; and mild superficial punctate keratopathy.<sup>15</sup> No significant changes in uncorrected distance visual acuity, intra-ocular pressures, and corneal epithelial cell density have been reported.<sup>15</sup>

There is a slight risk of microbial keratitis with overnight OrthoK wear.<sup>20</sup> Thus, carefully monitoring pediatric patients is important, including reinforcing hygiene, such as handwashing, cleaning OrthoK lenses, safe storage of OrthoK lenses, and regular replacement of OrthoK lenses.<sup>21</sup>

To date, rebound in myopia progression with combination treatment has yet to be studied. One way of reducing the potential for rebound is to continue myopia management into the late teens or early adulthood when there is less risk of myopia progression.<sup>22</sup>

## Conclusion

Short-term studies suggest that the addition of 0.01% atropine to OrthoK

enhances the treatment effect in myopia control,<sup>15</sup> and only one study has reported two-year results so far.<sup>12</sup> All the studies have been conducted in East Asian children. More studies are required to understand the responses of other ethnicities to combination therapy, the long-term safety and efficacy, the mechanism of action, and any potential rebound effect. Take care with formulation to ensure stability of the atropine. Consider

higher concentrations to optimize the balance between treatment efficacy and side effects. Nonetheless, early evidence suggests that adding 0.01% atropine to OrthoK enhances treatment efficacy compared with OrthoK alone. Assessing the benefits of myopia management versus the risks,<sup>23</sup> combination therapy could be considered if monotherapy is not effective in pediatric patients with progressing myopia.<sup>22</sup> ●



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# Managing the Business of Orthokeratology

By Azinda Morrow, OD, FAAO



**Myopia progression is best assessed by axial length measurements using an optical biometer.**

**O**rthokeratology (OrthoK) is an incredibly rewarding and creative niche of myopia management patient care, and it is growing ever more popular in today's optometric community. Ultimately, incorporating OrthoK into one's practice setting can be both profitable and fulfilling, but prior to being a thriving OrthoK practice, there are numerous factors to consider. Although there may be hesitancy when determining how to best proceed, by understanding the business management of an OrthoK practice, many difficulties can be avoided by moving thoughtfully and conscientiously.

## Considerations Before Initiating OrthoK at Your Practice

Depending on your clinical background or expertise, OrthoK may be a foreign concept to you and your staff. Unlike standard soft contact lenses or other custom-made specialty lenses, OrthoK involves primarily fitting children using a reverse geometry design that is worn overnight.<sup>1</sup> These key aspects will require the doctor to become trained in proper OrthoK fitting, troubleshooting, follow-up schedules/protocols, and most importantly, safety. There are numerous conferences with wet labs that can train optometrists in these areas.

Every company will require eye care providers to complete an online certification to fit their OrthoK designs. Establishing an account and a relationship with an OrthoK manufacturing company is necessary to begin the fitting process. During the fitting process, whether someone is a new or seasoned OrthoK prescriber, lab consultants can be easily reached by phone or email to help with cases that may require assistance.

Choosing a company to work with and a lens design can also require thought, as various laboratories choose the initial OrthoK design differently. Some companies have an in-office fitting set similar to a standard fitting set for many soft lenses. In addition, complementary fit guides provided with these sets help guide a provider in selecting the initial diagnostic lens and help with in-office troubleshooting. Other companies, however, provide empirical or topography-based OrthoK designs, allowing providers to use data gained from previously performed examinations to order a tailor-made design for the patient. The primary benefit of in-office fitting sets is that they allow patients to experience OrthoK before initiating the process, and step-by-step troubleshooting can be performed in-office prior to the initial order. Alternatively, empirical orders allow for early patient-specific customization, tend to have high first-lens success, and are space-savers in-office, as stock lenses are unnecessary.

Specialized equipment may also be required depending on the practice's current patient base. To effectively fit and troubleshoot OrthoK, a corneal topographer

is necessary. Although initial fitting and ordering can be achieved with autokeratometry values, additional vital data during the fitting process, such as centration and treatment size, can only be determined and assessed with topographical maps. Secondly, although OrthoK fitting can be performed for older patients not requiring myopia management, virtually all children will require an assessment of myopia progression, which is best achieved by axial length measurements using an optical biometer.<sup>3</sup> Fortunately, topographers and biometers can be used for several other patient populations rather than simply for OrthoK patients. In addition, as myopia management care has become more popular, multiple instrument companies are developing “myopia devices” that include autorefraction, corneal topography/

tomography, and axial length measurement capabilities in one device.

Depending on the provider’s comfort level, well-trained staff and technicians can perform many tasks. Once an OrthoK company account has been established, initial orders and/or fitting and data acquisition, such as lens over-refraction, manifest refraction, and topography can be delegated to staff. Other elements of OrthoK care that staff can assist with include lens application and removal training and patient education on proper cleaning and care of the lenses.

### Implementing an OrthoK Protocol

How you implement OrthoK into your practice may differ depending on your practice setting. For those eye care professionals new to offering myopia management, creating a myopia “protocol” for



Proper documentation is essential to make all families aware of the regulatory nuances.

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seeing these patients is imperative, especially in a multi-doctor practice, to ensure proper management and monitoring over time.<sup>4</sup> Aspects to consider from a clinical perspective are how often to assess for progression, what testing should be completed at each visit, which treatment options the office will offer, and other considerations.

From a practice management perspective, because myopia management is not currently covered under vision care insurance, each practice may choose between various methods for charging patients for these services. Some practices may choose to bill annual comprehensive examinations to vision care insurance and charge patients for additional services using an a la carte method. However, because regular follow-up visits are required for OrthoK, many practices may choose to bundle all



Depending on the provider's comfort level, well-trained staff and technicians can perform many tasks.

management and/or contact lens procedures and imaging services (topography and/or biometry) into a single global fee covering a specific period. For example, for an OrthoK patient, an annual global fee may include:

- initial baseline data acquisition (annual

comprehensive exam)

- OrthoK fitting appointment (whether with an in-office fitting set or once the lens has been ordered)
- one-day, one- to two-week, and one-month follow-up appointments

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- additional appointments for potential lens changes (lens dispenses/follow-ups)
- six-month myopia progression evaluation

As children are mainly available during late afternoon and evening hours during the week, and on the weekends, if your practice is not open during these hours, it is important to consider whether to expand clinical care to these times. Providers can choose to have myopia management incorporated into their general clinic schedule, or have a separate “myopia management” clinic during the week. Depending on who in your practice is comfortable with examining children, their availability, and patient volume, each office may choose to do this differently.

### Effective Communication

Effective patient communication is also vital for all members of the OrthoK-prescribing team, including staff and technicians. Although OrthoK is widely accepted as being efficacious for myopia management, proper explanation of the risks, advantages, and alternatives to the process is critical. In addition, at this time, there are only two

myopia management interventions that are FDA approved in the United States. First is the CooperVision MiSight 1 day, a soft contact lens that has been proven to minimize progression of refractive error and axial elongation. The second is Johnson & Johnson Vision’s Acuvue Abiliti Overnight Therapeutic Lenses for Myopia Management, which have been approved for myopia management, although they have not been indicated for slowing axial elongation.

Because of these complexities, proper documentation is essential to make all families aware of the regulatory nuances and ensure all questions and concerns are answered and discussed before initiating myopia management treatment. Detailed and thorough informed consent discussion and off-label use agreement forms should be presented to all families prior to initiation of fitting and management.<sup>4</sup> Information that should be discussed prior and listed on these forms include:

- definition of off-label and explanation of all treatment options
- risks, benefits, and alternatives of treatments offered and that long-term risks

are not known

- outline of fitting and follow-up schedule, including long-term myopia management
- acknowledgment of understanding that controlling the progression of myopia is not guaranteed
- acknowledgment that the parent and/or guardian wish to proceed

An example of an informed consent form available at the following link:

- [University of California, Berkeley College of Optometry, Myopia Control Clinic, Informed Consent for Treatment](https://www.berkeley.edu/college-of-optometry/myopia-control-clinic/informed-consent-for-treatment)

### Final Considerations

Our eye care community continues to learn about the benefits of initiating treatment for all myopic and pre-myopic children with continued research efforts and patient management. OrthoK can provide a fully customized patient experience. Still, regardless of the treatment option chosen, myopia care is a critical and impactful means to offer innovative treatment for our patients and their families. ●



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# RESOURCES: Everything You Need to Know About Orthokeratology

By Jennifer Harthan, OD, FAAO, FSLs, and Michael Lipson, OD, FAAO, FSLs

**T**o be successful with orthokeratology (OrthoK), practitioners must have a broad understanding of the existing evidence-based literature, current prescribing trends, and updates in diagnostics and lens designs utilized for myopia management. This comprehensive resource guide will enhance the practitioner's knowledge of orthokeratology and myopia management to assist in their clinical practice. Follow the links below to access the vast information available on these topics.

## PEER-REVIEWED JOURNALS

These peer-reviewed journals contain evidence-based literature relevant to contact lenses, orthokeratology, myopia management, and clinical research.

- [Contact Lens and Anterior Eye](#)
- [Cornea](#)
- [Eye & Contact Lens](#)
- [Investigative Ophthalmology & Vision Science](#)
- [JAMA Ophthalmology](#)
- [Journal of Cataract and Refractive Surgery](#)
- [Journal of Contact Lens Research and Science](#)
- [Ophthalmic and Physiological Optics](#)
- [Optometry and Vision Science](#)

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## BOOKS

These books can provide valuable insight into your orthokeratology and myopia management clinical practice.

- [Clinical Manual of Contact Lenses 5th Edition](#) (by Edward S. Bennett and Vinita A. Henry)
  - This book covers all modalities of contact lenses, including orthokeratology.
- [Contemporary Orthokeratology](#) (by Michael Lipson)
  - This book covers all facets of the practice of orthokeratology.
- [Orthokeratology: Principles and Practice](#) (by J. Mountford, D. Ruston, and Trusit Dave)
  - This resource demystifies the subject of orthokeratology and provides practical information for all those interested in the technique.
- [The Orthokeratology Handbook](#) (by D. Todd Winkler and Rodger T. Kame)
  - This book provides a step-by-step approach to explaining how to prescribe orthokeratology.

## WEBSITES/NEWSLETTERS/BLOGS

Newsletters and blogs highlight relevant topics and research related to orthokeratology and myopia management.

- [Review of Myopia Management](#)
  - [I-site Newsletter](#)
  - [My Kids Vision](#)
  - [MyMyopia](#)
  - [MIVISION](#)
  - [Myopia Profile](#)
  - [Orthokeratology News and Research](#)
- 

## SOCIAL MEDIA GROUPS

Social media can provide a great way to connect and discuss orthokeratology and myopia management with other practitioners.

- [American Academy of Orthokeratology and Myopia Control](#)
  - [European Academy of Orthokeratology and Myopia Control](#)
  - [International Academy of Orthokeratology and Myopia Control](#)
  - [Ortho-K Lens Specialists](#)
  - [Ortho-K Marketing and Public Awareness](#)
  - [Orthokeratology Society of Oceania](#)
- 

## PROFESSIONAL ORGANIZATIONS AND SOCIETIES

These professional organizations and societies offer resources and continuing education for practitioners. Many have archives of resources and webinars available.

- [American Academy of Optometry](#)
- [American Optometric Association Contact Lens and Cornea Section](#)
  - [Clinical Report: Myopia Management](#)
- [American Academy of Orthokeratology and Myopia Control](#)
- [Brien Holden Vision Institute](#)
- [British Contact Lens Association](#)
- [Contact Lens Society of America](#)
- [Cornea & Contact Lens Society of Australia](#)
- [European Academy of Orthokeratology and Myopia Control](#)
- [European Federation of the Contact Lens Industry](#)
- [GP Lens Institute](#)
- [International Myopia Institute](#)
- [Orthokeratology Society of Oceania](#)
- [World Council of Optometry](#)

## CONSULTING ORGANIZATIONS

These organizations provide education and insights for practitioners interested in implementing myopia management and orthokeratology into their practices.

- [Hoot Myopia Care](#)
  - [OK Love Myopia Control Experts](#)
  - [Treehouse Eyes](#)
- 

## SYMPOSIA

These meetings provide education and opportunities to highlight new research and technology. Attendance at these meetings is an excellent way to network between practitioners and industry.

- [American Academy of Optometry Annual Meeting](#)
  - [American Optometric Association Annual Meeting](#)
  - [Global Specialty Lens Symposium](#)
  - [Vision By Design](#)
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## PROFESSIONAL PUBLICATIONS

Professional publications are a great way to learn about orthokeratology and myopia management from key opinion leaders.

- [Review of Myopia Management](#)
  - [Orthokeratology in Practice – Contact Lens Spectrum](#)
  - [Review of Cornea & Contact Lens](#)
  - [Review of Optometric Business](#)
  - [Review of Optometry](#)
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## PROFESSIONAL PODCASTS

Podcasts present relevant information and updates regarding orthokeratology and myopia management in an innovative conversational format.

- [The Corrected View: An Ortho-K and Myopia Control Podcast \(AAOMC\)](#)
- [The Knowns & Unknowns of Myopia Management \(AAOMC\)](#)
- [The Myopia Podcast](#)
- [The Myopia Exchange](#)
- [The Bright Eyes Podcast: Advice for Healthy Vision of All Ages](#)

## DIAGNOSTICS

	Company	Device
Topography	Alcon	<a href="#">EH290 Eye Map</a>
	Bausch and Lomb	<a href="#">Orbscan</a>
	EasyScan USA	<a href="#">Cassini Total Corneal Astigmatism</a>
	Medmont	<a href="#">Meridia and E300</a>
	Nidek	<a href="#">OPD-Scan III</a>
	Oculus	<a href="#">Pentacam AXL*</a>
	Oculus	<a href="#">Myopia Master</a>
	Oculus	<a href="#">Oculus EasyGraph</a>
	Optikon	<a href="#">Keratron</a>
	Optikon	<a href="#">Scout Keratron#</a>
	Tomey	<a href="#">TMS-4N</a>
	Topcon	<a href="#">Aladdin M*</a>
	Topcon	<a href="#">CA-800</a>
	Tracey	<a href="#">iTrace*</a>
	Visionix	<a href="#">Visionix VX120/130*</a>
Zeiss	<a href="#">Atlas 9000</a>	
Tomography	Oculus	<a href="#">Pentacam HR*</a>
	Oculus	<a href="#">Pentacam AXL*</a>
	Ziemer Group	<a href="#">Galilei G6*</a>
Biometry	Haag-Streit	<a href="#">Lenstar/Lenstar Myopia</a>
	Oculus	<a href="#">Pentacam AXL</a>
	Oculus	<a href="#">Myopia Master</a>
	Topcon	<a href="#">Aladdin</a>
	Topcon	<a href="#">MYAH</a>
	Visionix	<a href="#">Visionix VX120/130*</a>
	Zeiss	<a href="#">IOLMaster</a>
Ziemer Group	<a href="#">Galilei G6*</a>	

\*combination #no longer available

Having the proper diagnostic tests in your office to successfully manage myopia is vital. Assessing the cornea's curvature, shape, and elevation is essential for orthokeratology design selection. Measuring refractive error and axial length is critical before and during treatment to monitor progression.

- Topography
  - Corneal topography characterizes the shape of the cornea. Most corneal topography devices use Placido ring analysis for the tear film to capture anterior corneal curvature measurements.
- Tomography
  - Corneal tomography provides three-dimensional imaging of the anterior and posterior corneal surfaces along with corneal thickness distribution. Corneal tomography is beneficial for the diagnosis and monitoring of disease progression.
- Biometry (axial length)
  - Measuring axial length is essential to determine the associated risk of pathology, predict the risk of myopia development, and evaluate the effectiveness of myopia management treatment. This is one of the most important devices to have for orthokeratology practice.

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## ORTHOKERATOLOGY MANUFACTURING LABORATORIES

Each orthokeratology design offers unique features. Choosing a manufacturing laboratory is based on practitioner preference. The manufacturing laboratory is a partner invested in the success of your practice and patients. Consultants are essential to the orthokeratology process and offer years of experience to aid fitting and troubleshooting. Many have created resource libraries complete with webinars and instructional videos for patients and practitioners.

- [ABB Optical Group](#)
- [Acculens](#)
- [Art Optical Contact Lens](#)
- [Advanced Vision Technologies](#)
- [Bausch + Lomb](#)
- [Blanchard](#)
- [Contamac](#)
- [Contex](#)
- [CooperVision Specialty EyeCare](#)
- [Essilor Custom Contact Lens Specialists](#)
- [Euclid](#)
- [Eyespace/Custom Craft](#)
- [GP Specialists](#)
- [Johnson & Johnson Vision](#)
- [Metro Optics](#)
- [Menicon](#)
- [Paragon](#)
- [Precision Technology Services](#)
- [TruForm Optics](#)
- [WAVE](#)
- [X-Cel Specialty Contacts](#)

# SPONSORS

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### COOPERVISION

-  [coopervisionspecialtyeyecare.com](http://coopervisionspecialtyeyecare.com)
-  800-528-8279 (USA and Canada)

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### ART OPTICAL

-  [artoptical.com](http://artoptical.com)
-  800-253-9364

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-  [carecredit.com](http://carecredit.com)
-  800-859-9975 (press 1, then 6)

## SUPPORTING SPONSOR



### WAVE CONTACT LENS

-  [wavecontactlenses.com](http://wavecontactlenses.com)
-  855-655-2020

## SUPPORTING SPONSOR



### XCEL SPECIALTY CONTACT

-  [xelspecialtycontacts.com](http://xelspecialtycontacts.com)
-  800-241-9312

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### EUCLID

-  [euclidsys.com](http://euclidsys.com)
-  800-477-9396

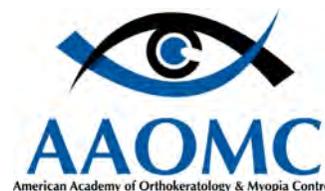
# PROFESSIONAL ORGANIZATIONS

Review of Myopia Management *would like to thank the following organizations for endorsing OrthoK 2022: The Orthokeratology Education Initiative.*



## AMERICAN ACADEMY OF ORTHOKERATOLOGY AND MYOPIA CONTROL

The [American Academy of Orthokeratology and Myopia Control](#) strives to present an open forum allowing members to learn and interact with other members and find a safe environment absent of the interests or agendas of any one person, group, or company.



Through workshops, courses, and fellowship programs, the AAOMC allows members to grow in competence and demonstrate this ability to their peers and the public. Through innovations, the AAOMC forwards the science of orthokeratology and myopia control.

The AAOMC (formerly the OAA) was founded in 2002 by a group of concerned educators, researchers, and clinicians based in the United States. The organization has grown in scope since its formation at the first Global Orthokeratology Symposium. In the last two decades, with the launch of the fellowship program and the landmark Vision By Design education symposia, the academy has completed one part of its mission in educating the eye care community and the public about orthokeratology. Membership in the AAOMC is open to any licensed professional who has an interest in the specialty of orthokeratology and myopia control. This includes: doctors of optometry and ophthalmology, opticians, researchers, educators, and students.

## THE GAS PERMEABLE LENS INSTITUTE

The [Gas Permeable Lens Institute](#) (GPLI) is a 501(c)(3) non-profit organization dedicated to providing eye care professionals and students with unbiased educational and practice-building resources and programs pertaining to GP and custom soft contact lenses.



Since 1985, the Institute has been nationally recognized by leaders in the contact lens profession and education system, providing focused webinars, clinical programs, hands-on workshops, innovative online resources, and more. In 2022-23, the GPLI will be introducing a series of comprehensive modules to help the novice fitter feel comfortable in evaluating and fitting GP lenses, membership programs for eye care professionals and students, and an expansion of corneal and scleral workshops for optometry students. GPLI helps students, residents, and eye care professionals gain the experience they need to provide patients with the advantages of GP and custom soft lenses.

## CORNEA & CONTACT LENS SOCIETY OF AUSTRALIA



Originally founded as the Contact Lens Society of Australia (CLSA) in 1962, the CLSA's goal was to improve the standard of prescribing and fitting of contact lenses in Australia.

As the scope of optometry and eye health care expanded, in 2008 the CLSA became the [Cornea & Contact Lens Society of Australia](#) (CCLSA), reflecting the broader interests and skills of members, including optometrists, ophthalmologists, academics, researchers, students, registrars, and industry.

The CCLSA continues to evolve in order to remain relevant, vibrant, and dynamic.

From humble beginnings, the CCLSA today has a solid and expanding membership network and counts among its members some of the leading eye care professionals in the field.

CCLSA continues to promote education, research, professional development, and networking. At the leading edge of innovative methods of sharing, mentoring, and learning, the CCLSA demonstrated a rapid COVID-19 response and roll-out of webinars, position statements, business support, face mask access, and special offers.

The CCLSA has provided over \$AU650,000 in research awards since 1973 and continues with multiple annual awards.

The CCLSA is unique in Australia by including ophthalmology, optometry, and industry in its membership and by offering free membership to students and reduced fees for part-time/non-practicing members and recent graduates.

The CCLSA is a friendly and collegial organization: A place for like-minded experts in the field and novices alike to receive and share the very best education in contact lenses, vision correction, and eye care management, including the ocular surface, anterior eye, and therapeutics, in order to grow, network, and continue to elevate individual and collective skills in patient care.

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## INTERNATIONAL ACADEMY OF ORTHOKERATOLOGY & MYOPIA CONTROL



The [International Academy of Orthokeratology & Myopia Control](#) (IAOMC) was founded in 2011 at the first international congress of the organization in Orlando, Fla. This completed the goal of uniting the world under one umbrella first conceived in 2002 at the first Global Orthokeratology Symposium in Toronto, Canada. The principal leadership at the time, representing America (Cary Herzberg, OD, [American Academy of Orthokeratology & Myopia Control](#)), China (Peiying Xie, MD, [International Academy of Orthokeratology Asia](#)), and Europe (Marino Formenti, OD, [European Orthokeratology Academy](#)), formed the three pillars of the organization. Over time, the organization has grown to seven sections (ALOCM Latin America, AOC-AOMC SE Asia, BIPOK India, OSO Australia/New Zealand). Today, the IAOMC has over 10,000 ophthalmologist and optometrist members worldwide. Among its many notable accomplishments are yearly annual meetings hosted by each section on a rotational basis and the first protocols adopted for orthokeratology/myopia management.