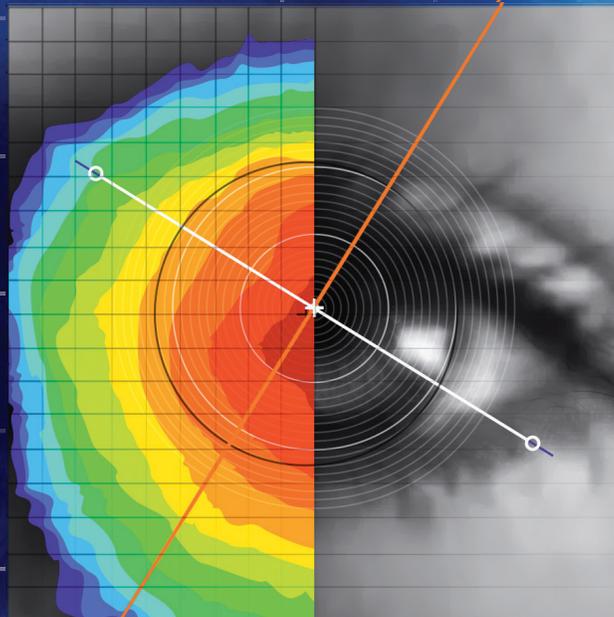


# Contemporary OrthoKeratology



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## **Dedication**

I was exposed to the benefits and potential of OrthoK in the infancy of my optometric career. This book is dedicated to those who shaped my initial interest in OrthoK many, many years ago through their insight, innovation, clinical skills and persistence.

Robert Barabas  
Irving Adler  
Richard Wlodyga

They would not recognize the state of OrthoK we are practicing today.

Special gratitude goes to my wife Judy who has been with me while in optometry school and for the duration of my optometric career. She always recognized that my work was my mistress. She has endured my passionate affair with Optometry and patient care which at times overflowed into our personal time and home life.

## **Acknowledgments**

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**BAUSCH + LOMB**

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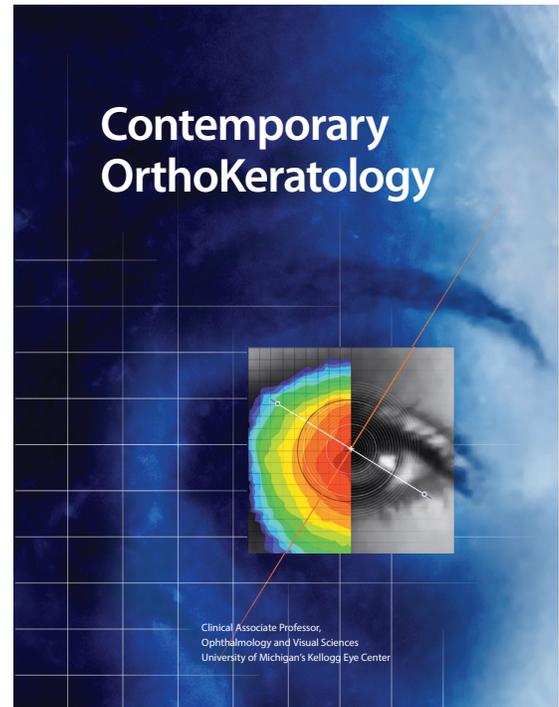
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# Contemporary OrthoKeratology

Michael J. Lipson OD FAAO FSLs

“The eye sees only what the mind is prepared to comprehend.”

Robertson Davies, *Tempest-Tost*

“Vision is the art of seeing what is invisible to others.”

Jonathan Swift

“We can’t change anything until we get some fresh ideas, until we begin to see things differently.”

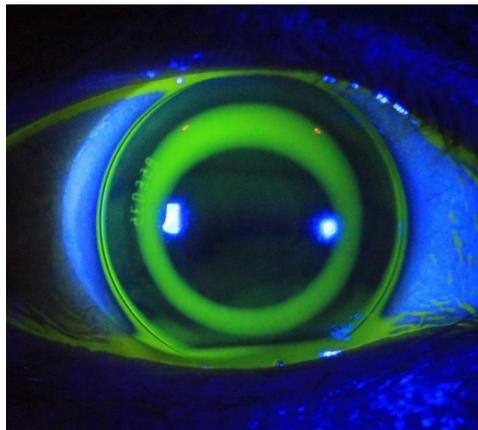
James Hillman

“Life’s too short not to try different things and to see what works for you and your body.”

Cory Booker

“If you really want to do something, you’ll find a way. If you don’t, you’ll find an excuse.”

Jim Rohn



*Figure 1-1. Slit lamp photograph of an OrthoK lens on eye with fluorescein*

Orthokeratology (OrthoK) is the practice of changing the curvature of the cornea with specially designed gas permeable (GP) contact lenses worn while sleeping to alter the refractive state of the eye and to temporarily improve the wearer’s unaided vision. It is unique in the field of eye care in that patients experience improved vision after the lens is removed and that the lens is not used during waking hours. It truly is a PROCESS in that it requires ongoing treatment, monitoring and care. This guide will detail all aspects of the process including its history, practice, regulation, technology, follow-up care, safety and how it affects patients. This guide is intended to serve as a source of pertinent information to practitioners learning about the process for the first time as well as a reference for those who have practiced OrthoK for some time. The information provided applies to all OrthoK patients and to all OrthoK lens designs. Training for fitting of specific OrthoK designs can be obtained from individual OrthoK lens designers and/or manufacturing laboratories (Appendix 1).

There will continue to be innovations that change the practice of OrthoK. It is strongly suggested that practitioners remain current with the latest OrthoK practices via continuing education from experienced practitioners in the field and from reputable industry sources.



# Chapter 1 – History/Background

The concept of intentionally changing the shape of the cornea with a contact lens to improve unaided visual acuity was fortuitously discovered by eye care practitioners in the early 1960's. Their clinical observations and discussions with patients wearing PMMA lenses indicated that unaided vision following removal of lenses was temporarily altered due to changes in the corneal curvature. Initial attempts to deliberately change refractive myopic error using rigid contact lenses were proposed by George Jessen using a technique that he named "Orthofocus".<sup>1</sup> The lenses and techniques at that time employed PMMA and early GP materials worn during waking hours. During the following two decades, OrthoK did not gain widespread acceptance either in the public or in the professional communities, partly due to resistance from the scientific community who maintained that altering the central cornea would not be safe. General eye care practitioners, in both optometry and ophthalmology, did not accept the procedure as being sound in the absence of clinical evidence that this process would not interfere with the structure and function of the cornea. At the time, only keratometry measurements and biomicroscope observations were available to evaluate, demonstrate and monitor corneal integrity and topographical changes. This primitive technology limited the ability to monitor lens positioning and other corneal changes during the procedure.

In the following 30 years, four major factors contributed to the development and understanding of OrthoK as we know it today. Those factors are:

- Development and use of videokeratography (computer-assisted corneal topography), now commonly referred to as simply "corneal topography"
- Development of new GP materials (higher oxygen permeability, improved surface wettability and improved stability)
- Computer-guided lathes enabling production of reverse geometry lens designs, which have a secondary peripheral curve(s) that are steeper than the central base curve
- Optical coherence tomography (OCT) allowing the thickness analysis of the individual layers of the cornea

# Corneal Topography



Figure 1-2 . Examples of various corneal topographers

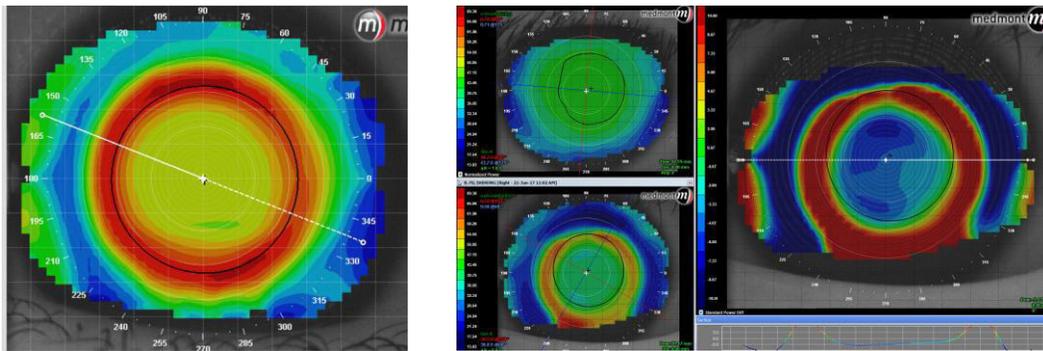


Figure 1-3 . Axial Map of Post-OrthoK  
 Top Left – Pre-treatment Tangential Map treatment Bottom  
 Left – Post-treatment Tangential Map Right – Difference (subtractive) Map

While corneal topography is currently commonplace and standard-of-care, it was not used in contact lens fitting or in OrthoK until the early 1980s, and it took years for its use to become widespread. As we now realize, corneal topography is required to fit and provide precise follow-up care for OrthoK patients. With OrthoK, it is necessary to measure and monitor the entire corneal surface to achieve the intended results. Sami El-Hage, OD, FAAO, is credited with being the first to use corneal topography to fit OrthoK lenses and to monitor the resulting corneal changes. <sup>2</sup>

Corneal topographer manufacturers have developed software that allows captured maps to be analyzed in more detailed ways for precise design and to monitor corneal changes during OrthoK.

The various types of topographical analysis include axial, tangential, elevation and difference maps. Technological advances currently allow the use of corneal topography for OrthoK to obtain accurate baseline measurements, determine initial lens selection, design initial lenses, monitor topographic changes after OrthoK lens wear and accurately monitor lens treatment/position over many years of lens wear. Chapter 4 provides a detailed discussion of topography. Today's standard of care dictates that the practice of OrthoK requires the use of corneal topography.

## New GP Materials

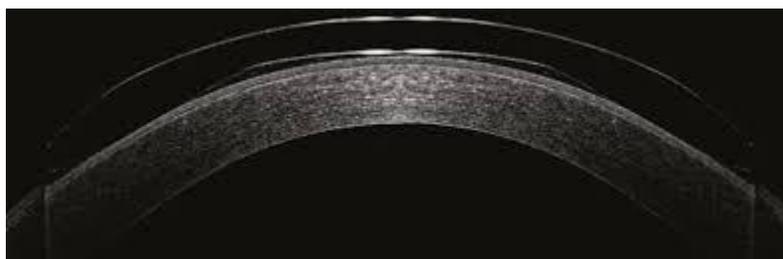
As contact lens material technology progressed, it became feasible to consider prescribing OrthoK lenses that were worn overnight while sleeping (Appendix 1). Current GP materials that are FDA-cleared for OrthoK are highly permeable (ISO/FATT Dk of 85 or higher). Both clinical and retrospective studies have demonstrated excellent safety with both children and adult OrthoK patients.<sup>3,4,5</sup> Improvement in GP lens materials has resulted in lenses with good surface wetting quality and has enabled the generation of lenses that feature multiple curves and parameters that remain stable.

## Computer-Guided Lathes

Innovation in manufacturing of contact lenses now allows laboratories to produce almost any lens geometry imaginable. The reverse-geometry design (mid-peripheral curves that are steeper relative to the base curve) was the first major innovation that led to modern OrthoK. Following that, aspheric designs, toric base curves, toric peripheral curves, double reverse designs and meridian-specific curves are now available.

## Optical Coherence Tomography (OCT)

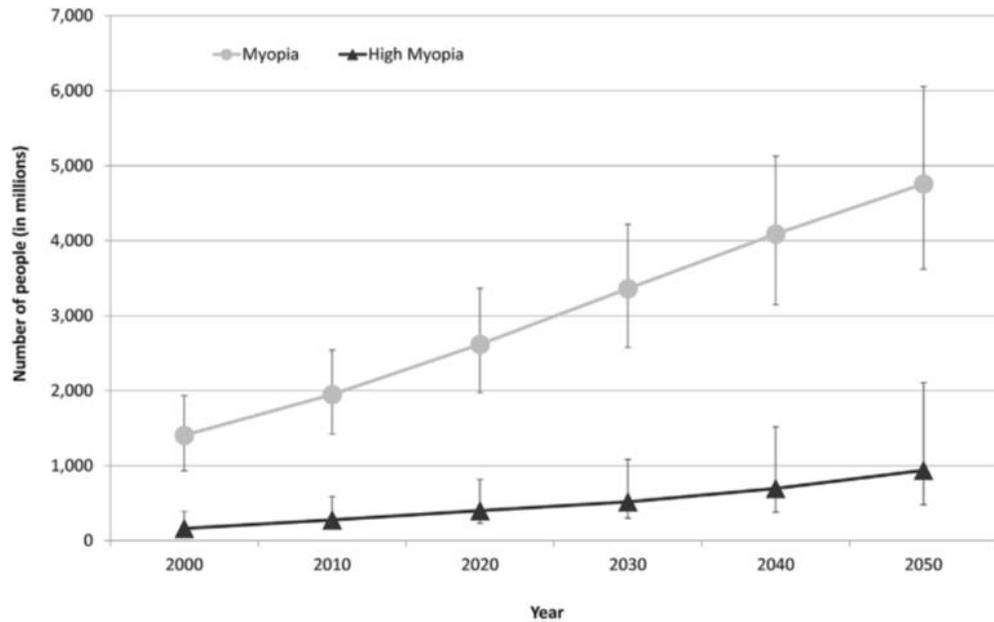
An OCT instrument is not necessary to clinically fit and monitor OrthoK patients but can provide detailed information regarding structural changes in the thickness of the individual layers of the cornea. This has added to the science and research data on OrthoK.



*Figure 1-4: OCT image of a cornea with an OrthoK lens on the eye*

Myopia (nearsightedness) is the most common ocular disorder affecting human beings, and it is increasing worldwide. In 2000, there were estimated to be 1.4 billion people with myopia in the world.<sup>1</sup> Projections from an extensive study on myopia trends show that there will be more than 4.7 billion myopic people (about 50% of the world population) by 2050.<sup>6</sup> More detailed observation shows significant national and regional differences in myopia prevalence.<sup>7</sup> For example, the prevalence of myopia in the US is estimated to be 42% of adults<sup>8</sup> to 96% of 19-year-old males in Korea.<sup>9</sup> In addition, the degree of myopia has increased worldwide such that the number of people who are highly myopic (more than 5.00D) is projected to increase from 163 million in 2000 to almost

1 billion (938 million) in 2050 <sup>6</sup> (Figure 1-5). High myopia carries an increased risk of vision-threatening problems such as myopic macular degeneration (40.6 times greater), retinal detachment (21.5 times greater for > 5.00D), glaucoma (14.4 times greater for > 6.00D) and cataract (3.3 times greater for > 6.00D).<sup>10,11</sup> In summary, myopia is more than just a refractive error; it is a public health issue that increases the risk of visual impairment.



**Figure 1-5.** Current and Projected Growth of Worldwide Myopia and High Myopia. Graph showing the number of people estimated to have myopia and high myopia for each decade from 2000 through 2050. The error bars represent the 95% confidence intervals. From Holden et al, 2015

Currently, OrthoK can be used to correct myopia, hyperopia, presbyopia and astigmatism (in the US, treating hyperopia and presbyopia are off-label applications). Alternatives to OrthoK include: spectacle lenses, daytime contact lenses (soft, GP and hybrid) and refractive surgery. OrthoK has been found to be safe and effective for adults and children, enabling wearers to enjoy clear vision without the need for vision correction during daily activities. Safety and corneal health with OrthoK are a worldwide concern; studies show an excellent record of safety.<sup>3,4,5</sup> Results of these studies indicate that use of OrthoK has less risk of microbial keratitis than overnight wear of soft lenses does. The most common complication is superficial keratitis during the first few days after starting OrthoK. This clinical observation is less common after the first week of wear.<sup>3</sup>

As mentioned above, the incidence and prevalence of myopia are increasing. Clinical observations and studies have also shown that once children are diagnosed with myopia, their degree of myopia progresses during their growth years. Extensive studies have been conducted to determine whether children progress more rapidly with one particular mode of correction as well as whether the rate of progression can be reduced with one modality of correction versus another. There are numerous studies evaluating the effect that OrthoK may have on the rate of myopia progression. Meta-analysis of these studies reports that OrthoK slows the rate of myopia progression between 40-60%.

## Why Should Practitioners Consider OrthoK?

The reasons why practitioners should prescribe OrthoK will be detailed in the chapters that follow. Features of OrthoK that are attractive to practitioners include:

- It provides an alternative option to correct myopia
- The potential to slow or stop progressive increase in degree of myopia
- Improvement of patients' perception of their vision-related quality of life (Chapter 2 -VRQOL issues)
  - Less dependence on vision correction
  - Fewer symptoms of discomfort during the day (itching, dryness, etc.)
  - Improved self-image
  - Fewer activity restrictions
  - Decreased concern about vision (loss of glasses/contacts and worsening vision)
- It expands the services offered by their office
- It attracts new patients
- It utilizes new optometric skills
- It allows practitioners to learn new procedures
- It creates a new income source for the practice

## Why Do Patients Want OrthoK?

Patients truly enjoy OrthoK for the reasons mentioned above. From the patient perspective, the most significant reason to pursue OrthoK is to enjoy good vision during waking hours without having to wear vision correction. Patients also report improved vision-related quality of life (VR-QOL). From clinical experience, practitioners report that many patients prefer to be free from glasses and/or have tried daytime contact lenses without ideal results. Finally, although not an approved indication, many patients/parents are attracted to the myopia control effect that OrthoK may provide.

# Chapter 2 – The Foundation of OrthoK

## OrthoK Lens Parameters and Nomenclature

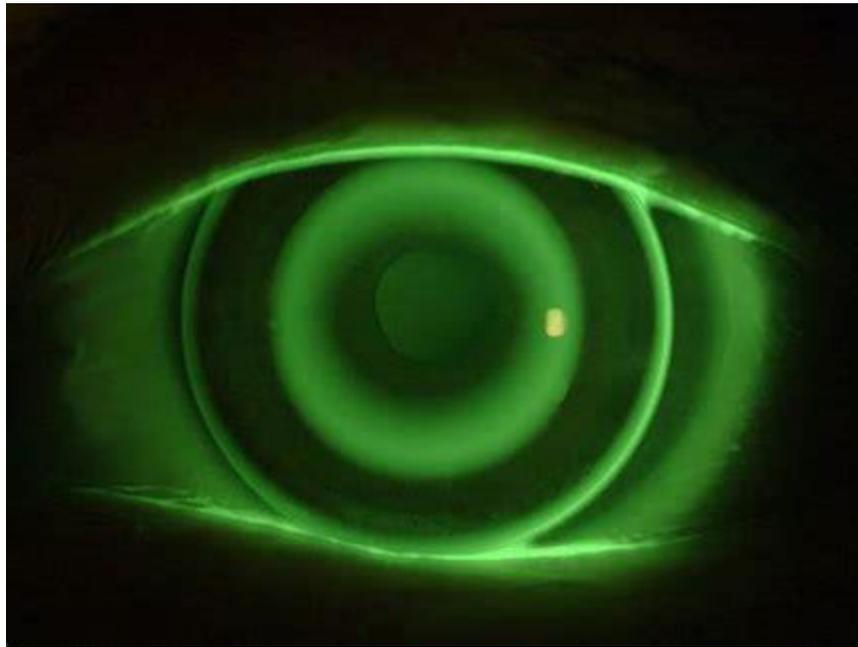
Even with the large variety of OrthoK lens designs available, all current OrthoK lenses have one thing in common: They all have at least one part of the posterior surface that is deeper (steeper) peripherally compared to the central area (reverse geometry). The back-surface design of an OrthoK lens that creates a controlled change in corneal shape has been subjected to the creative and clinically guided process of lens designers and manufacturers around the world. But as we look at each unique design, it is evident that they have more in common with each other than they have differences.

OrthoK lenses have various zones that are referred to with different terminology by each manufacturer. Table 2-1 shows a list of these zones with their various names.

### OrthoK Lens Parameter Chart

Parameter	Name	Other Name	Other Name	Abbreviation
Lens Diameter	Overall Diameter			OAD
Base Curve	Base Curve	Treatment Curve	Optic Zone	BC
Optic Zone Diameter				OZD
Reverse Curve Radius	Reverse Curve	Return Zone Depth	Fitting Curve	RC, RZD, FC
Reverse Curve Width				RCW
Alignment Curve Radius	Alignment Curve(s)	Landing Zone Angle		AC(1,2), LZA
Alignment Curve Width				ACW
Lens Thickness	Center Thickness			CT
Prescription	Power			Rx
Material				

*Table 2-1. Table of various OrthoK lens parameters with alternative names and abbreviations*



*Figure 2-2. Slit lamp photo of a typical fluorescein pattern with an OrthoK lens in place*

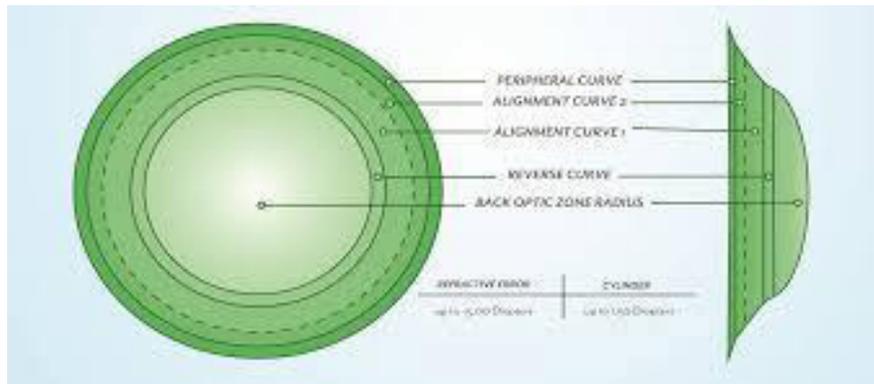
## OrthoK Lens Parameters - Function

The OrthoK lens zones described in Table 2-1 each play a different role in creating the desired corneal topographic changes. Most OrthoK lenses/designs have 4-5 distinct zones on their posterior surface (even more with some designs). The various designs of OrthoK lenses have many similarities, but the different manufacturers may use different nomenclature.

**Base Curve** – To improve unaided visual acuity in a myopic patient, the base curve (BC) is flatter (larger radius of curvature) than the central corneal curvature.<sup>12</sup> The difference in curvature between the lens and the cornea controls how much change occurs and, therefore, how much myopia is corrected. Though the corneal response is normally quite predictable, individual differences in response are observed. In general, the amount of myopia corrected is equal to the difference in curvature between the lens and the corneal curvature plus an adjustment factor (0.50 D-0.75 D) referred to as the Jessen Factor. For example, the base curve of an OrthoK lens for a -3.00 D myope with a central/apical corneal curvature of 43.50 D (7.76 mm), plus a 0.75 D Jessen factor, would be 39.75 D (8.49 mm) [ $43.50 - 3.00 - 0.75 = 39.75$ ].

**The Jessen Factor** is a theoretical amount of calculated over-correction required to result in full correction (plano manifest refraction). George Jessen is credited with determining this amount from initial experiences with OrthoK. The actual reason it is required is unknown but suggests that the corneal changes required to produce the desired refractive changes is not exactly 1 to 1. Although the 0.75 D amount is commonly used and generally well-accepted as valid, there are specific cases and specific designs for which a larger Jessen Factor (up to 2.00 D) is used.

In correcting myopia, the relative difference in curvature between the cornea and the less- curved (flatter) base curve creates an inward fluid force that results in a reduction in the central/apical corneal curvature, commonly referred to as flattening, producing a greater radius of curvature. This is graphically visible on the topography comparing the pre-treatment and post-treatment maps.



**Table 2-3.** Drawing depicting the various zones of an OrthoK lens. Courtesy of Euclid

**Optic Zone Diameter** - The diameter of the optic zone (OZD) can be changed to result in a larger or smaller area of central treatment. This may be a factor for some patients who have larger pupils and who may be more aware of glare in low-light conditions. OZD can be changed based on the amount of intended correction. Researchers are evaluating whether OZD has implications relative to myopia control, but this has yet to be confirmed. Each OrthoK lens design may use a different standard optic zone diameter or may have various optic zone diameters available. The average optic zone diameter for all designs is about 6.0 mm, with ranges between 5.0 mm and 6.9 mm.



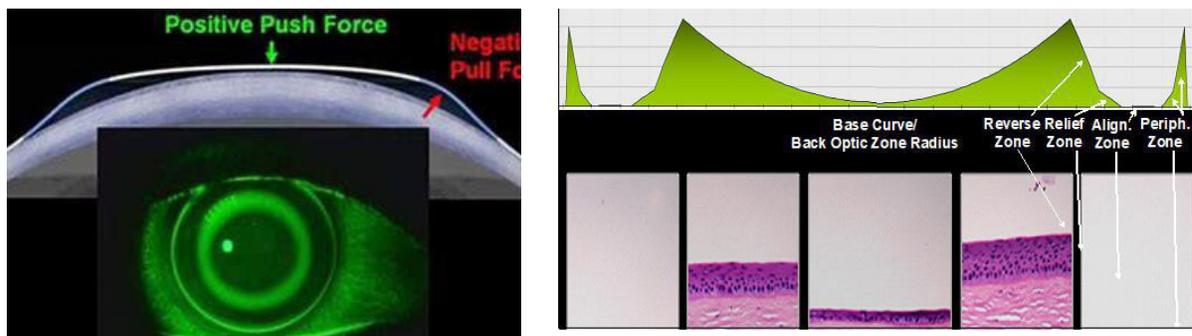
**Table 2-4.** Photo of an OrthoK lens showing the various zones

**Reverse Curve** – Located just peripheral to the base curve, the reverse curve (RC) is so named because it is steeper (shorter radius of curvature) compared to both the base curve of the lens and the central/apical curvature of the cornea. The radius of curvature of the RC varies with each design and is often considered to be proprietary. In general, the higher the degree of myopia—and therefore, the higher the intended change to the corneal curvature—the steeper the reverse curve needs to be. In most lens designs, the RC is spherical; but, to achieve the intended effect, some designs will incorporate toricity in this zone. The function of the RC is to create an outward (suction) fluid force to form a ring of corneal steepening around the central flattened zone. In addition, at the junction of the base curve and the reverse curve, the lens is farther (in height) away from the cornea. The reverse curve “returns” the lens closer to the cornea and helps provide better centration.

**Alignment Curve(s) –** Continuing peripherally, as the name suggests, the alignment curve (AC), or series of curves, is intended to align with the peripheral corneal curvature. This area of the lens serves multiple purposes. First is to support the majority of the weight of the lens and to distribute the fluid forces of the lens evenly 360° around the lens. Next, the alignment zone helps position the lens to maintain lens centration. Finally, this zone creates a semi-sealed environment under the lens to balance the fluid forces (the push- pull of the system). To achieve the intended effect, this zone can be customized to have a steeper or flatter radius of curvature (or planar angle) and to have various widths. In most lens designs, the AC(s) are spherical; but, to achieve even fluid forces in 360°, some eyes will require designs with toricity or asymmetric sagittal depth in this zone.

**Peripheral Curve(s) (PC) –** This area is designed to allow the most peripheral area of the lens to lift away from the cornea to avoid a complete seal-off of tear flow, allowing post- lens tear fluid exchange. Again, the curve, angle and width of the PC(s) can be specified as desired. This zone helps maintain lens comfort but generally does not contribute to the amount of treatment.

The change in corneal shape effected by OrthoK lenses does not result from mechanical pushing of the lens on the cornea but from the fluid forces created under the lens. These forces have been described as “squeeze film forces” created by the lens/cornea fitting relationship. There is an inward (push) force on the cornea in areas where the lens curvature is flatter than the curvature of the cornea. This results in an area of relative decrease in the radius of curvature (flattening). Conversely, there is an outward (pull) force on the cornea in areas where the lens curvature is steeper than the corneal curvature in that area. This results in a steepening of corneal curvature, seen as the classic “red ring” of steepening in the post-treatment tangential difference topography (see Chapter 4).

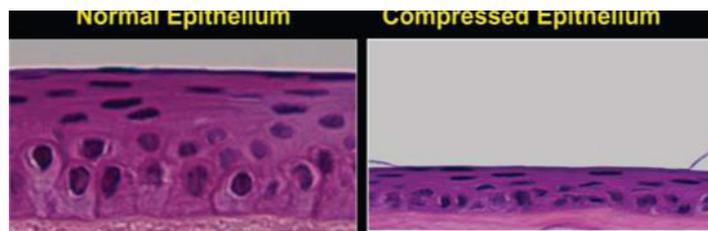


**Table 2-5.**

Left - Graphical representation of the central and mid-peripheral forces created by an OrthoK lens.

Courtesy of Paragon Vision Sciences

Right - Tear thickness profile (top) and corneal epithelial profile view (bottom) showing Central and mid-peripheral epithelial thickness changes after wear of a reverse geometry orthokeratology lens. Courtesy of E. Korszen and P. Caroline

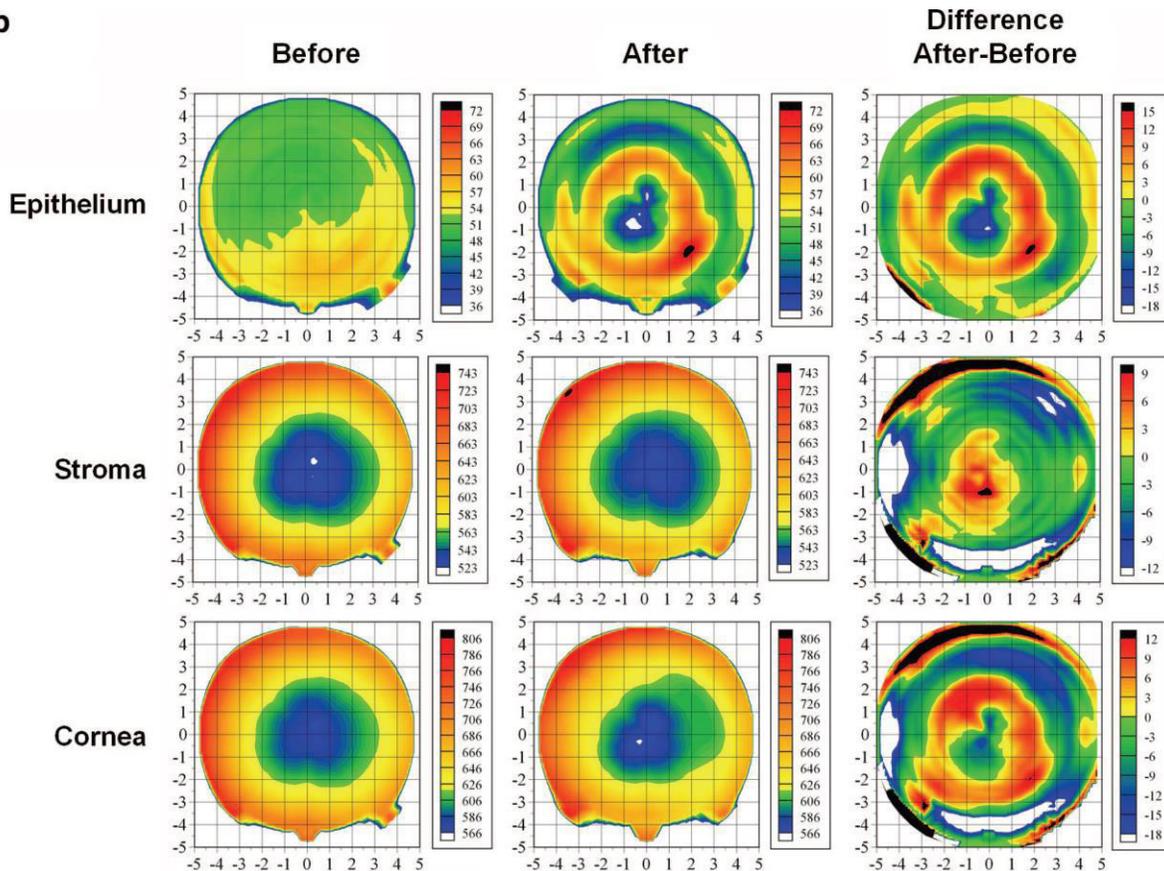


**Table 2-6.** Central corneal epithelial thinning after OrthoK. Choo et al.

Eye and Cont Lens 2004

Moving down to a cellular level, studies on the effects of OrthoK have demonstrated both corneal epithelial cell compression and possibly epithelial cell migration in the central cornea that results in a slight decrease in epithelial thickness and a topographic flattening. Mid-peripherally, OrthoK has been shown to produce thickening of the epithelium.<sup>13</sup> The combination of central epithelial thinning and mid-peripheral epithelial thickening creates a profile of corneal topography resulting in decreased myopia.<sup>14,15</sup> Studies of the effect of OrthoK on the corneal stroma have resulted in mixed findings. Some showed no stromal change, while others found implied stromal effects. Finally, changes in the corneal endothelium have not been demonstrated.<sup>16</sup>

**b**



**Figure 2-7.** OCT mapping of the thickness of individual corneal layers before and after OrthoK. Reinstein et al. *Optom Vis Sci* 2009

The next Chapter will discuss the effects of OrthoK on:

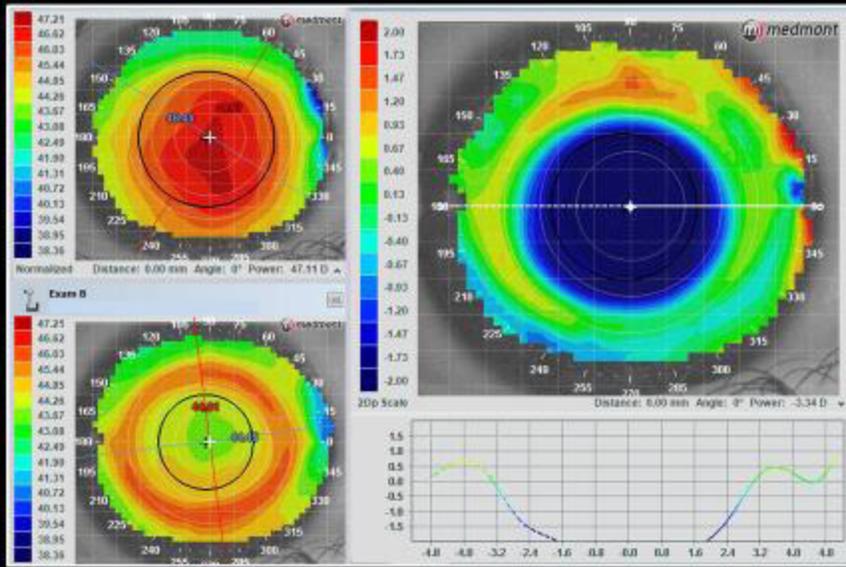
- Topography
- Visual Acuity
- Safety and Efficacy
- Wavefront Changes
- Vision-Related Quality of Life (VR-QOL)
- Dry Eye

## **Topography Changes in OrthoK**

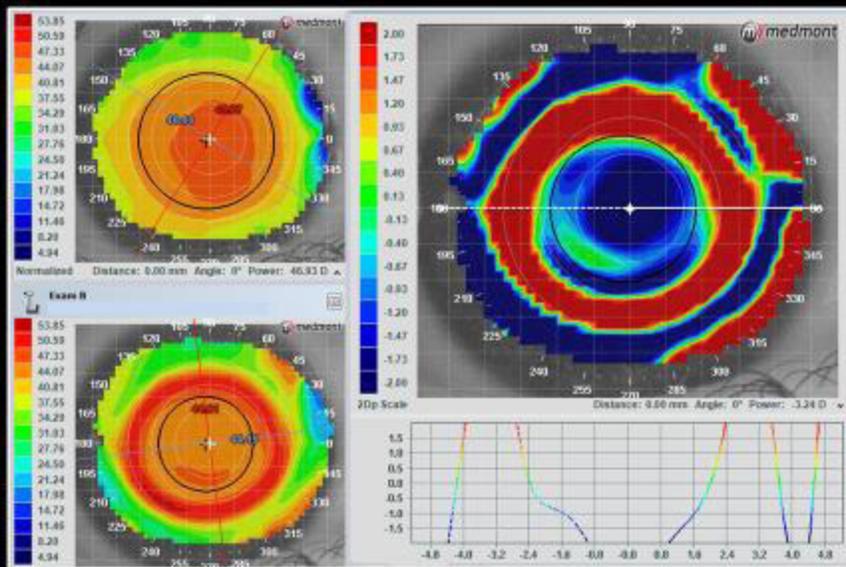
A corneal topographer is required for OrthoK. The mapping of the corneal surface provides essential information that aids in fitting, diagnostic evaluation and follow-up. At the initial fitting and evaluation, baseline topography provides a map of astigmatism, irregularities, asymmetry and eccentricity across most of the cornea. Taking the time to attain high-quality baseline maps is critical because they are the foundation to which changes in each subsequent visit's topography will be compared. Baseline topography provides data that will help with determining initial lens selection and lens design, and it provides information for designing lenses with compatible software. High-quality baseline maps can alert you to potential challenges and can help maximize first-lens success.

Typical topographic changes seen after OrthoK for myopia are central flattening surrounded by a ring of relative steepening. These changes are detailed in Chapter 4.

## Bulls-eye Subtractive Map Axial Interpretation: 2 Diopter Scale



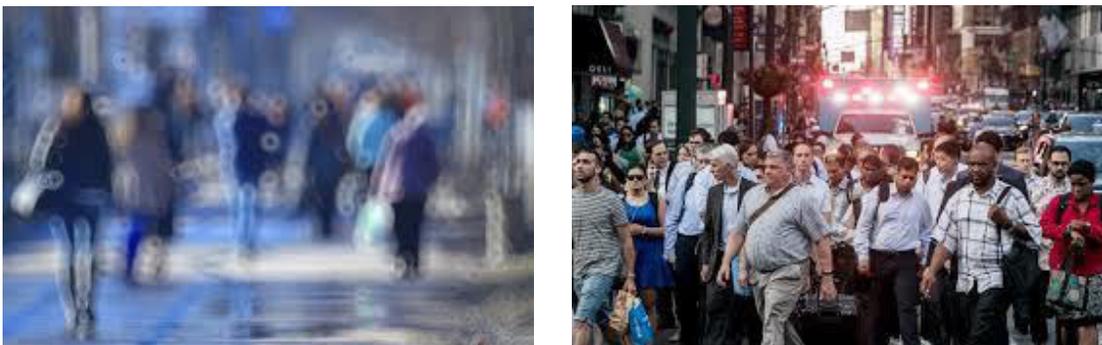
## Bulls-eye Subtractive Map Tangential Interpretation: 2 Diopter Scale



**Figure 2-8.**  
 Top - **Axial Difference Map** showing pre/post-OrthoK maps (left-top and left-bottom) with difference (subtractive) map on the right.  
 Bottom - **Tangential Difference Map** showing pre/post-OrthoK maps (left-top and left-bottom) with difference (subtractive) map on the right. Courtesy R. Kojima

## Visual Acuity Changes in OrthoK

Unaided visual acuity improves rapidly with OrthoK. Although each patient may respond slightly differently, many patients report good functional vision (20/40 or better) after only one night of OrthoK lens wear. Full correction occurs 3-10 days after starting OrthoK and usually results in excellent unaided visual acuity (92% 20/25 or better).<sup>17,18</sup> The number of nights of wear required to attain full correction depends on the degree of initial correction and the individual patient. After the full effect has occurred, patients report excellent unaided vision immediately upon lens removal in the morning that remains stable throughout all waking hours. Studies show that good vision can last up to 48 hours after lens removal.<sup>19,20,21,22</sup> While there are no detailed published reports on this, one study showed 90% recovery to baseline unaided visual acuity<sup>72</sup> hours after discontinuation;<sup>19,20,21,22</sup> another reported that complete recovery of all tested parameters (unaided visual acuity, refractive error, corneal regularity and contrast sensitivity) took 8 weeks.<sup>20</sup>



**Figure 2-9.**

*Left – representative image of unaided vision in a patient with moderate myopia.*

*Right – representative image of unaided vision in myopic patient after OrthoK.*

## OrthoK Is Temporary and Reversible

The corneal and refractive changes occurring after OrthoK are temporary. After patients have worn OrthoK lenses every night for about one month, good daytime vision usually lasts 12-48 hours after lens removal. Therefore, regular and consistent wear is required to maintain consistently good daytime vision, and patients must commit to wearing their OrthoK lenses every night as a routine. In long-term OrthoK wearers, if lens wear is discontinued, refraction has been shown to revert to baseline after 4-7 days.<sup>20,22</sup> Topographical changes after discontinuation of long-term OrthoK wear take longer to revert to baseline. One study showed a range of 2 weeks to 2 months for return to baseline topography.<sup>21</sup> In summary, both corneal and refractive changes occurring with OrthoK are temporary and reversible.

## Safety and Efficacy of OrthoK

There has been much discussion about the safety of OrthoK. Patient compliance and fitter knowledge are critical factors that contribute to its success and safety. Several decades ago, there were reports of serious side effects and vision loss associated with the use of OrthoK. This occurred in East Asia at a time (late 1990s and early 2000s) when the practice of OrthoK in that region was unregulated relative to practitioner training and the materials used to make OrthoK lenses. Additionally, detailed evaluation of these cases indicated that a significant cause of complications was related to poor instruction in or compliance with proper lens cleaning and disinfection practices.

Recent studies in the US and Asia have shown OrthoK to pose minimal risk.<sup>5</sup> In the largest follow-up study on OrthoK wearers, the risk of microbial keratitis (MK) with OrthoK use was found to be less than with overnight wear of soft silicone- hydrogel (SiHy) lenses.<sup>4</sup> This large post-approval study, showed that the risk of MK with OrthoK was 7.7 events per 10,000 patient-years of wear. For the children in this study (under 12 years old), the risk was 13.9 events per 10,000 patient- years of wear. This compared to 25.4 events per 10,000 wearers using SiHy lenses on an extended wear basis. Another study over a 4½ year period showed that the safety and efficacy of OrthoK was equal for adults and children under 12 years of age.<sup>3</sup> Additionally, an international meta-analysis on the safety and of OrthoK vs. soft lenses concluded that OrthoK poses minimal risk with less risk of serious complications compared to overnight wear of soft lenses.<sup>5,23,24,25</sup>

Both objective and subjective visual acuity as well as quality of vision with OrthoK has been studied in detail. Studies comparing visual acuity with OrthoK vs. contact lenses and glasses show visual acuity to be comparable with each mode of correction.<sup>3</sup> Subjectively, some patients feel that their overall vision is better corrected with OrthoK because no correction is worn during the day.<sup>23</sup> Some patients have reported decreased visual acuity with OrthoK later in the day. This experience is due to regression of the refraction improvements at 8-16 hours post-removal. This regression effect varies significantly from one patient to another based on the degree of the original refraction and individual corneal differences. Generally, the higher the degree of myopia in the original refraction, the more regressive changes are noted at the end of the day. That said, many patients with higher baseline refractions (higher than -4.50D) report consistently good visual acuity during all of their waking hours.

## Wavefront Changes in OrthoK

Finally, increased wavefront error with OrthoK may affect subjective quality of vision. Some OrthoK patients report increased awareness of night glare. This is due to the increase in spherical aberration created by OrthoK with larger pupil size in lower-light conditions.<sup>26,27</sup> Clinically, this can reduce contrast sensitivity. Pre- and post-OrthoK treatment studies show no effect on high-contrast visual acuity, but low-contrast visual acuity is reduced post-OrthoK. Pupil size affects overall wavefront aberrations for all patients. In OrthoK, in addition to pupil size, other factors affecting aberrations include treatment zone size, treatment zone decentration and consistently smooth treatment zone topography.



*Figure 2-10 Simulation of night glare created by spherical aberration*

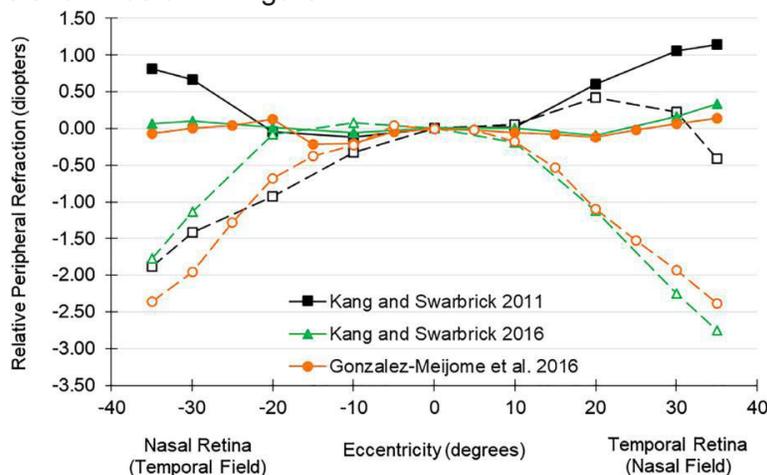
# Vision-Related Quality of Life Changes with OrthoK

Numerous attributes contribute to overall vision-related quality of life (VR-QOL). These include clarity of vision, fewer activity restrictions, freedom from correction, self-confidence, overall satisfaction with vision, and reduced eye-related symptoms (burning, itching, dryness, etc.). Patients using OrthoK report higher VR-QOL scores than when using spectacles or contact lenses worn during the day.<sup>28,29,30</sup> In a crossover study comparing OrthoK and soft contact lenses, after experiencing both modes of correction, about 70% of patients preferred to continue with OrthoK at the conclusion of the study.<sup>18</sup> In that same study, although objective visual acuity was insignificantly better with the soft lenses, subjectively, patients reported that their vision was better while using OrthoK. Other studies have shown higher VR-QOL scores in patients corrected with OrthoK vs. spectacles and soft contact lenses.<sup>28,29,30</sup>

There is one survey instrument that has been validated to assess and quantify VR-QOL with OrthoK. The 23-item “OrthoK and Contact Lens Quality of Life Instrument (OCL-QoL)”<sup>31</sup> questionnaire is precisely scored via Rasch analysis to show the beneficial effects of OrthoK for patients. The survey can be used in a variety of ways. For example, it may be given to individuals to compare their pre-OrthoK QOL score to their post-OrthoK score. It could also be used on age- and Rx- matched groups of patients to compare mean VR-QOL scores of a group of OrthoK wearers to a group of patients using another mode of vision correction. In multiple studies performed worldwide, the improved vision-related quality of life attributes most commonly mentioned by patients using OrthoK are 1) freedom from the need for vision correction during the day, 2) less activity restrictions and 3) less symptoms of discomfort, dryness and itchiness during the day. Other beneficial VR-QOL attributes of OrthoK include improved self-confidence, self-image, willingness to try new activities, overall satisfaction with vision, less worry about loss or damage of glasses and less dependence on correction.

## Peripheral Refraction

While OrthoK corrects the central refraction to improve unaided vision, it also changes the peripheral refraction from hyperopic (when corrected with spectacles) to myopic. This change in peripheral refraction creates the wavefront error changes mentioned above and is thought to be the mechanism by which OrthoK slows myopia progression. Studies demonstrating changes before and after OrthoK are shown below in Figure 2-11.



**Figure 2-11.** Spherical equivalent relative peripheral refraction (in diopters) measured by autorefractometry across the horizontal meridian of the eye from several studies before orthokeratology (solid lines with filled symbols) and after orthokeratology (dashed lines with open symbols). Square symbols = Kang and Swarbrick<sup>32</sup> (n = 16), triangle symbols = Kang and Swarbrick<sup>33</sup> (n = 19), circle symbols = Gonzalez-Mejome et al.<sup>34</sup> (n = 34). Courtesy of Nti and Berntsen, *Clin Exp Optom* 2019

## **Dry Eyes**

One advantage of OrthoK over soft lenses is that no lenses are worn during waking hours. Patients who experience dryness while wearing soft lenses may be excellent candidates for OrthoK. Many patients who switch from soft lens wear to OrthoK report fewer symptoms of dryness and discomfort during waking hours.<sup>18,28,29,30</sup> There are no published reports of dry eye patients having problems wearing OrthoK lenses while sleeping. Anecdotally, patients experiencing dryness with OrthoK have responded well to the use of lubricating drops before lens application, during lens wear, prior to lens removal and/or after lens removal.

# Chapter 3 – Initial Fitting

## Pre-fitting Exam

Prior to taking on a new OrthoK patient, a thorough baseline evaluation is crucial. This evaluation establishes all pre-fitting characteristics of the individual patient, details potential fitting challenges, sets expectations and lays the groundwork for every future encounter with that patient in what will often be a long-term relationship.



*Figure 3-1. Slit lamp evaluation prior to OrthoK*

## Pre-Fitting Consultation

Some OrthoK practitioners perform an “OrthoK Consult” with patients (and parents for minors) prior to the pre-fitting exam to assess factors that may influence the decision to commence the process for both patient and doctor. This consultation typically involves more discussion than testing. The discussion covers the basics of:

- Candidacy requirements
- Commitment required on the part of the patient (lens wear, follow-up, lens care, etc.)
- Features, benefits and discussion of the process
- Risk factors/potential adverse events
- Costs

**When patients do proceed with OrthoK treatment, each of these topics should be covered and reviewed in great detail using multiple methods: orally, through video presentation and in writing in the form of a thoroughly detailed informed consent document.**

## Baseline Exam

A thorough baseline exam is required and should include each of the following:

- Unaided visual acuity (monocular and binocular)
- Best-corrected visual acuity (monocular and binocular)
- Subjective refraction (cycloplegic refraction is helpful but not required)
- Corneal topography
- Horizontal visible iris diameter (HVID) or white to white (WTW) measurement
- Pupil size (mesopic, scotopic and photopic)

- Lid position/anatomy
- Slit-lamp evaluation
  - Eye lid condition
    - » Scarring, cysts, chalazia
    - » Meibomitis, blepharitis
    - » Trichiasis
    - » Entropion, ectropion
    - » Ptosis
  - Corneal evaluation (scarring, neovascularization, etc.)
  - Notation of any observations that may cause complications (pinguecula, melanosis, nevi, conjunctival vasculature, areas of scleral thinning, etc.)
  - Conjunctival evaluation (Papillary reaction, general or focal hyperemia)
  - Iris evaluation (nevi, irregular pigmentation pattern)
  - Evaluation of the crystalline lens



**Figure 3-2.** Photo of an eyelid margin with slight meibomitis



**Figure 3-3.** Anterior blepharitis.  
Courtesy of Medicinenet.com



*Figure 3-4. A benign melanosis of the sclera*

- Internal evaluation (dilated recommended)
  - Optic nerve cupping
  - Retinal health
  - Macular evaluation
- Intraocular pressure
- Axial length (not required, but important when considering myopia progression)
- External photography (helpful in documenting baseline observations of the lids, scleral attributes, blood vessels and scarring)
- Other potential testing (not required but may be helpful)
  - Anterior segment optical coherence tomography (AS-OCT)
  - Corneal thickness
  - Wavefront/aberration evaluation
  - Fundus photo and/or posterior OCT (helpful in monitoring subtle changes of retinal health due to myopia progression)

After the initial testing regimen is completed, the next step is a detailed and thorough presentation with a discussion of all issues involved in the process of OrthoK. This step is just as critical as the baseline testing because patient compliance and expectations (the doctor's and the patient's) are such an important part of the ultimate success for each patient.

## **Patient Candidacy: Refractive Status**

Of note, there is no age restriction (upper or lower) for OrthoK. Although the previously mentioned refractive parameters are approved indications for OrthoK, not all patients within those parameters will achieve ideal results. There are significant individual differences in quantity and quality of refractive response to OrthoK treatment. Practitioner experience with fitting specialty OrthoK designs may result in higher degrees of correction for individual patients.

In the US, FDA-approved indications for refractive status are:

- Vision Shaping Treatment (VST)<sup>35</sup>: myopia < -5.00D, astigmatism < 1.50D
- Paragon CRT<sup>36</sup>: myopia < -6.00 D, astigmatism < 1.75D

Prescribing OrthoK beyond these parameters is considered “off-label.” Off-label prescribing of medical devices is common in all fields of healthcare. With thorough explanation, discussion and written acceptance by the patient and/or parent/guardian, off-label usage is acceptable and at the discretion of the practitioner.

Outside of the US, refractive status beyond these parameters is at the discretion of the practitioner or relevant regulatory agencies.

## **Other (Practical) Candidacy Considerations**

### **Patient Motivation**

Undergoing the process of OrthoK is a commitment for patients. Individuals who wear OrthoK must be highly motivated to see without glasses during the day because lens wear is required for most nights. They should also be strongly motivated to learn how to apply and remove the lenses and be committed to consistently wearing and caring for their lenses as directed. Children being fitted with OrthoK should be as interested in OrthoK as their parents and the doctor are. If these considerations are not met, long-term success may be compromised.

### **Willingness to Comply with Instructions**

As practitioners, we like to think that patients will learn and comply with all of our recommendations and instructions. In reality, we know patients make their own adaptations to our instructions, take short cuts and adopt measures intended to save money. This may be more of an issue with patients who have previously worn other types of contact lenses. Starting at the initial evaluation and continuing through every follow-up visit, OrthoK practitioners should consistently convey a strong message that compliance with lens care and recommended follow-up visits is crucial with OrthoK use. In addition, explaining and detailing the potential risks of non-compliance may be helpful for some patients. Providing written materials with detailed care and use instructions is important. The following story illustrates the importance of the patient remaining compliant with prescribed lens care instructions and the importance of the practitioner prescribing and reviewing specific instructions.

## **Scenario of non-compliance**

*A 12-year-old Asian male had been successfully using OrthoK to correct his moderate myopia for the past 10 months. After returning from a family vacation, he misplaced his multi-purpose solution. Rather than informing his parents of this, he wore his lenses as normal but applied and stored them using tap water. The first few days went well for him, but after one week he noticed redness and burning in both eyes and more so in the right. His parents noticed the redness and brought him to the office for evaluation. Uncorrected visual acuity was 20/20 in each eye, as it had been at his last follow-up four months ago. Slit lamp evaluation showed slight inferior corneal staining, 2+ general hyperemia and moderate purulent exudate. He was diagnosed with bacterial conjunctivitis and started on antibiotic drops. A discussion about lens care regimen revealed his deviation from the recommended solutions and his use of tap water. Fortunately, he had no evidence of microbial keratitis. He had to discontinue wear of the OrthoK lenses for 3 days. Experiencing the complication, in combination with a review of the importance of adhering*

to the prescribed solutions and care techniques, will hopefully prevent future deviation from the prescribed regimen and complications.

## Patients who comply with proper lens care rarely experience complications.

On every follow-up visit, practitioners need to elicit feedback from patients to ensure that they are actually following through on those instructions. Ask patients open-ended questions to uncover specifically how they are wearing and caring for their lenses each day. Avoid questions such as, “Have you changed the solution regimen we started you on?” A better way to explore compliance would be more open-ended such as, “Tell me what solutions you are using at each step of the process.”

If you sense that a patient is unable or unwilling to comply, it may be necessary to have a serious discussion about whether OrthoK is right for him or her.

### Patient Hygiene

A critical habit that must be stressed for OrthoK patients is **handwashing** prior to lens application, removal or lens handling. It is recommended that handwashing be done with soap followed by thorough rinsing and then drying with a clean, lint-free towel. Rigorous eyelid hygiene is also required for patients who have a history of blepharitis or meibomitis; it is helpful for both initial and long-term success.

In addition, careful review of the products and routines for makeup, soaps and facial creams can help prevent problems with lens deposits.

### Communication with Doctor



**Figure 3-5.** Steps in lens care.

*Top Left - Washing hands prior to lens handling, application and removal.*

*Top Right – Lens application. Bottom*

*Left – Lens removal.*

Feedback from OrthoK patients during follow-up exams is necessary to diagnose potential problems with lenses, solutions, lens handling or lens fit. From the initiation of OrthoK, good communication between patient and practitioner should be encouraged and nurtured.

Practitioners must make patients aware that they need to answer all questions very honestly to provide as much information as possible to the practitioner. The communication should be detailed, candid and complete. OrthoK patients may enjoy the OrthoK process so much that they may be hesitant to share symptoms or problems, fearing that the practitioner may not allow them to wear

their lenses. Again, open-ended questions can create discussion that will help foster a successful and happy long-term relationship.

### **Normal Topography**

As thoroughly described in Chapter 4, a detailed discussion about baseline topography and its bearing on the overall difficulty and eventual success of OrthoK is important. Patients can relate to the patterns of the color maps and are often impressed by them.

## **Precautions/Contraindications**

There are individual differences in the degree to which each patient responds to OrthoK treatment. But clinical experience has identified a few known attributes that may contribute to decreased efficacy with OrthoK treatment. These include:

1. Significant corneal scarring – scar tissue creates an area of the cornea that is stiffer than normal corneal tissue is and may affect how the cornea responds.
2. Current wear of Gas Permeable (GP) lenses – these patients may not respond the same as someone who has never worn contact lenses. Current GP wearers should discontinue wear of their GP lenses for a significant period of time (4-8 weeks or longer until refractive and topographical stabilization is achieved) prior to starting OrthoK.
3. Soft contact lens (SCL) wearers – although not as much of an issue as with GP lenses, prior to commencing OrthoK, a period of time without wear of SCLs (1-2 weeks) will yield more predictable corneal and refractive changes.

### **Discussion of Possible Limitations (VA fluctuation)**

Although OrthoK wearers generally experience consistently excellent vision throughout their waking hours, some wearers experience minor fluctuations in acuity. This may manifest as a change in visual acuity at night compared to in the morning, a change from one day to the next or just randomly. These fluctuations may result from variable wearing time, debris under the lens creating corneal irritation, difficulty with lens removal or just an unusual sleeping position.

### **Discussion of Practitioner Expectations**

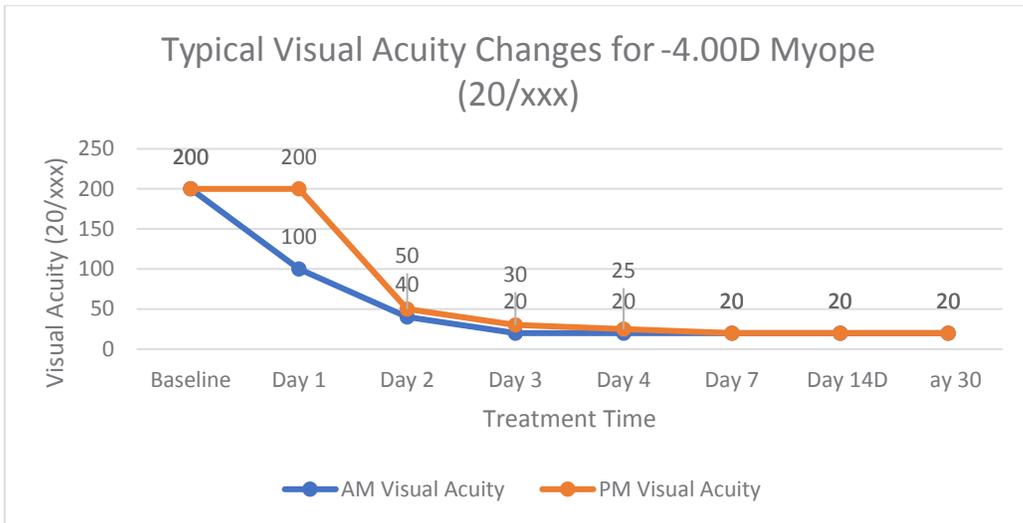
This part of the pre-fitting discussion is critical to ensure that patients know what the practitioner expects from them relative to compliance with follow-up care, lens care, communication with the doctor/office and what to do if complications occur. The patient must appreciate the importance of attending to all recommended follow-up visits and must accept responsibility for following the practitioner's prescribed lens care regimen. In addition, practitioners must establish comfortable and honest communication with OrthoK patients to ensure that patients discuss all of their symptoms and concerns with the practitioner. With this communication, patients are more likely to be compliant with practitioner recommendations regarding lens care and follow-up.

### **Discussion of the Expected Timetable for VA Improvement**

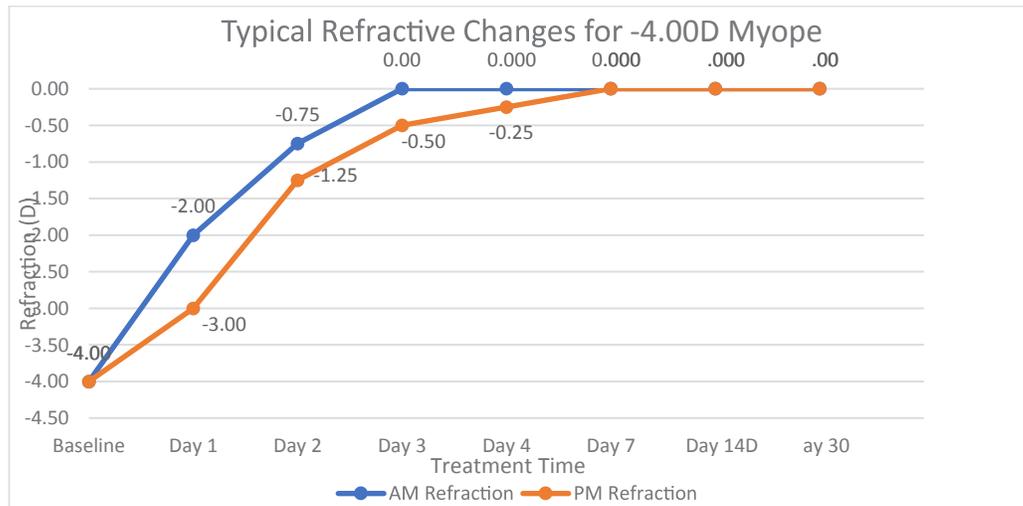
Practitioners should inform patients of what to expect regarding vision improvements and how to satisfy vision needs, especially during the first few days. It is important to balance the excitement of improved vision with a dose of reality regarding what most patients experience. For example,

12-year-old -3.00D myopes needs to know that after the first night of wear, they should not expect to have 20/20 acuity. In addition, they should be informed that it is normal for the vision that they experience immediately after lens removal to degrade during the day. For adults, the partial correction experienced after the first night or two can create difficulties with distance vision demands. A detailed discussion on how to best function during the visual transition of the first few days is important to satisfy normal visual functioning in school or with other activities. With partial correction, options include:

- No special treatment (just function with partially-corrected vision)
- Use an older pair of glasses with a lower prescription
- Use low-power soft CLs (Daily disposable)
- Use special adjustable-power glasses



**Figure 3-6.** Graph of typical response to visual acuity improvements with OrthoK for a -4.00 D myope in the morning and late afternoon



**Figure 3-7.** Graph of typical response to refractive improvements with OrthoK for a -4.00 D myope in the morning and late afternoon.

As shown in Figures 3-6 and 3-7 above, after 7-10 nights of OrthoK wear, vision should be consistently good during all waking hours. But, keep in mind there are individual differences in the rate of response to OrthoK as well as in the degree of refractive change. In general terms, the higher the baseline myopia, the longer it takes to achieve full correction. Immediately after lens removal in the morning, most patients experience full correction after two or three nights of wear. During the first week of OrthoK wear, daytime vision is expected to drop later in the day.

As a very general guideline, upon lens removal after the first night of wear, patients may show 1.50 D – 3.00 D of myopia reduction.<sup>20</sup> On the first day after starting OrthoK use, patients should be instructed to expect that distance vision will degrade throughout the day. By the time patients come for a 1-week follow-up visit, most will report good unaided vision for most of their waking hours.

## **Wearing Schedule**

Another important aspect of OrthoK is patient compliance with the prescribed wearing time and wearing schedule. For the first week of OrthoK wear, it is recommended that lenses be worn every night for 8-9 hours. For most patients, after the first week, a minimum of 7 hours of lens wear is necessary to maintain consistently good vision all day long. In the weeks, months and years of OrthoK wear that follow, many patients report that skipping a single night of wear has minimal effect on unaided vision during the following day. Skipping nights of OrthoK lens wear should be discussed in detail with the patient (and parents). Again, the practitioner should prescribe exactly when and how often the patient is allowed to miss a night of wear. Overall, to maintain consistently good unaided vision during all waking hours, OrthoK lenses should be worn the prescribed number of hours every night.

## **Eyelid Conditions/Hygiene**

Prior to initiation of OrthoK, a careful evaluation of eyelid health should be performed. If there is evidence of eyelid disease (Figures 3-2 and 3-3), it should be treated prior to commencing OrthoK treatment. Possible conditions that may affect OrthoK treatment include blepharitis, meibomitis, chalazia, ptosis, lid lag and incomplete eyelid closure while sleeping.

## **Allergies**

Allergic conditions, while not a contraindication for OrthoK, can create complications. These include increased mucous production and the potential for lens deposits, increased lens awareness due to papillary reaction and potential dryness in patients who are taking medication for allergies (oral and/or topical eye drops). As mentioned above, treatment and control of allergic response prior to initiating OrthoK is preferable.

## **Swimmers**

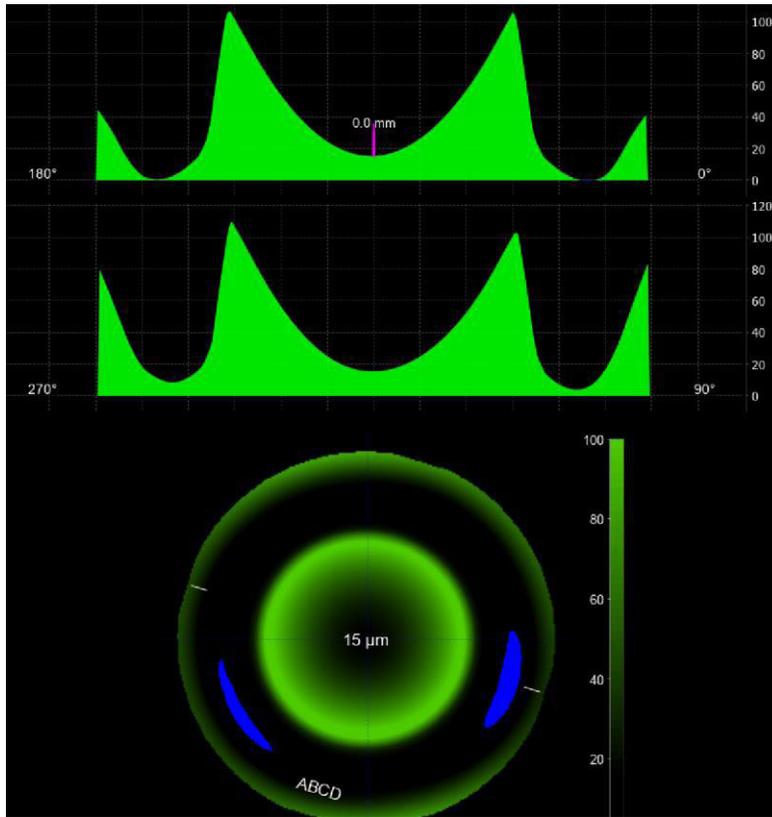
OrthoK wearers are involved in many activities, including swimming. Swimming in the evening, shortly before OrthoK lens application, can alter the normal tears (even with the use of goggles). It is helpful to prescribe artificial tears for use after swimming, prior to lens application or prior to removal.

## **Various Fitting Methods**

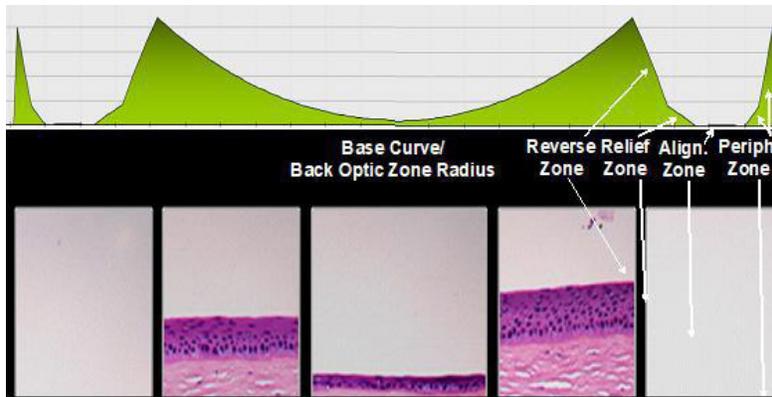
Depending on practitioner preference or the individual lens design, OrthoK lenses can be fit with a variety of techniques.

- Diagnostic Evaluation
  - Lenses with various specifications of known sagittal depth are evaluated with sodium fluorescein (NaFI)
  - Based on exam findings (keratometry, topography, manifest refraction, HVID, corneal eccentricity), a diagnostic lens is selected, placed on the patient's eye and evaluated with NaFI for centration, movement, treatment zone, reverse curve, alignment zone and edge lift
  - This method relies on the practitioner's judgment of the thickness and pattern of NaFI under the lens (see "Reading the Fluorescein" section below). Subsequently, the practitioner must modify the lens specifications to create the ideal fitting relationship
- Fitting Nomogram
  - This method uses two parameters (the spherical component of the manifest refraction and the flat K reading) to generate an initial trial lens

- Evaluation of the initial trial lens at the slit lamp with NaFI, as described above, determines whether this lens can be dispensed or whether modifications are necessary
- One manufacturer using this method offers the option of maintaining a stock of lenses for immediate dispensing
- Diagnostic Evaluation After One Night of Wear to Assess the Response to a Known Design
  - In this method, a small diagnostic set with specific parameters is dispensed for fitting characteristics only. These lenses are not designed for the target correction of each patient but are intended to evaluate the corneal topographic response to one night of wear
  - After the first night, fitting modifications are made based on corneal topography changes, and the target treatment is incorporated into the lenses ordered
- Topography-based Fitting/Design Software
  - This method uses corneal topography in combination with design software to simulate diagnostic fitting to prescribe custom-designed lenses
  - Using this method eliminates the need for diagnostic lens evaluation
  - The software will show the tear layer thickness profile of the proposed design in selected meridians of interest (Figure 3-6)
  - Of note, using this method requires excellent topography with the largest possible corneal area analyzed to most accurately design the ideal lens
  - Additionally, while the simulated fitting accurately predicts the dynamics between the lens and the cornea without lid interactions, it does not take into consideration the significant role of the interactions between the upper lid and the lens during overnight wear
- Empirical Fitting
  - Lenses are ordered from exam findings including refraction, keratometry, eccentricity from topography and HVID
  - Some manufacturers will ask for the above exam findings to design and manufacture the lenses using proprietary design features
  - Subsequent lens changes are made based on refractive and topographic results that are reported back to the manufacturer



**Figure 3-8.** Software-generated simulation of a proposed OrthoK design showing the tear layer thickness and the simulated NaFl pattern of that lens on the cornea.

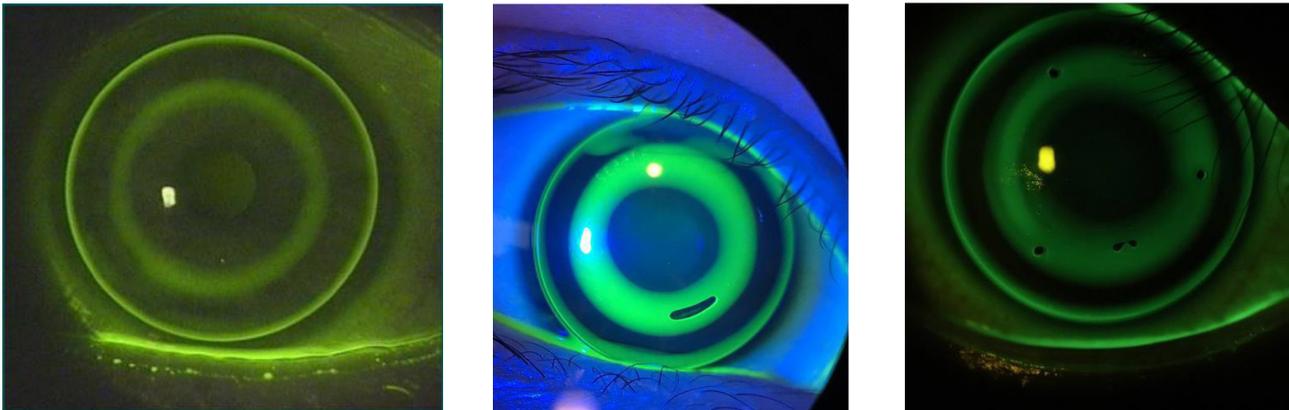


**Figure 3-9.** Tear profile (top) and corneal epithelial profile view (bottom) of a reverse geometry orthokeratology lens.  
 Courtesy of E. Korszen and P. Caroline

## Reading the Fluorescein

Slit lamp evaluation of diagnostic OrthoK lenses can be performed to evaluate the lens fitting characteristics. Although post-treatment topography tells us what effect the lens has had on the cornea, evaluation of the lens on the eye can further verify the proper fitting characteristics. After an OrthoK lens is applied to the eye and any initial tearing reaction has subsided, NaFI is applied to the upper bulbar conjunctiva using a paper fluorescein-impregnated strip. At this point, some patients are very sensitive to the feeling of their eyelid blinking over the edge of the lens. In these cases, instillation of one drop of a topical anesthetic helps minimize lens awareness to allow for better evaluation of the NaFI pattern. After applying a generous amount of NaFI, wait 1-2 minutes before evaluating to let the NaFI evenly disperse under the lens. Using the cobalt blue filter on the slit lamp, observe areas of high clearance, which will glow bright green, and areas with minimal clearance, which will appear dark. (Note: areas that appear black may still have a layer of tears under the lens because **a tear layer of less than 20 microns cannot be perceived at the slit lamp.**) In addition, supplemental use of a yellow Wrattan filter enhances the view of the NaFI to make its thickness easier to detect.

Sometimes it may be necessary to push some fluorescein under the lens to help get an adequate amount of dye under the lens, or the patient may need to blink firmly a few times to pump the NaFI under the lens.



**Figure 3-10.** Representative photos of NaFI patterns in well-fit OrthoK lenses. As seen here, the widths of specific zones may vary with the patient and/or the lens design. The bubbles evident in the center and right photos are not indicative of improper fitting. They are small and likely result from application with an insufficient amount of solution.

Courtesy of: M. Lipson

The ideal pattern will show a dark central area about 4 mm in diameter, which is created by the base curve/optical zone, surrounded by a ring of NaFI 1-2 mm wide under the reverse curve/return zone. Outside of that, another dark ring 1-2 mm wide should be evident under the alignment zone, and finally a small ring of glowing NaFI (about 0.5 mm) should be visible under the edge of the lens, demonstrating “edge lift.” Each of these areas are important to create an optimal OrthoK effect. The central zone should show uniform darkness throughout, indicative of uniform central inward fluid force. The ring of green glow under the reverse curve/return zone should appear of uniform width 360 degrees around, indicative of an outward fluid force. (Note: in cases in which toric reverse/return curves are prescribed, the NaFI pattern may show different widths in the vertical vs. the horizontal meridian.) The alignment zone should also show uniform width and uniform color around all 360

degrees. Good, solid alignment 360 degrees around is crucial. This area is responsible for lens centration and creates what has been called a semi-sealed lens environment.

In evaluating an OrthoK lens that has spherical alignment zones on a cornea with toricity, variable amounts of NaFI within that zone may be evident. This is most common when evaluating a spherical lens on a with-the-rule cornea in which the corneal elevation is lower in the vertical meridian; a slight bit of NaFI will be seen flowing under the alignment zone of the lens in the vertical meridian. In addition, a higher edge lift will be seen, particularly inferiorly. This inhibits a proper semi-sealed lens environment, negatively impacting the quality of treatment; a lens with poor alignment will often result in a poor treatment. In this case, to create an even NaFI pattern 360 degrees around, a VST lens with a toric return zone and/or a toric alignment zone or a Dual Axis CRT lens must be designed to create an ideal fit.

Observations at the slit lamp can verify topography findings and vice versa. But if the two observations are inconsistent, topography is more important and should be the priority. Corneal topography is the best tool to demonstrate true on-eye fitting characteristics with nighttime wear.

## **Lens Movement**

Another fitting characteristic that can be evaluated at the slit lamp is lens movement. There should be slight, but not excessive, movement observed with blinking (1-2 mm maximum). Excessive movement can be resolved with design changes (deeper return zone and alignment curves) and/or by increasing lens diameter.

## **Summary of OrthoK Fitting Techniques**

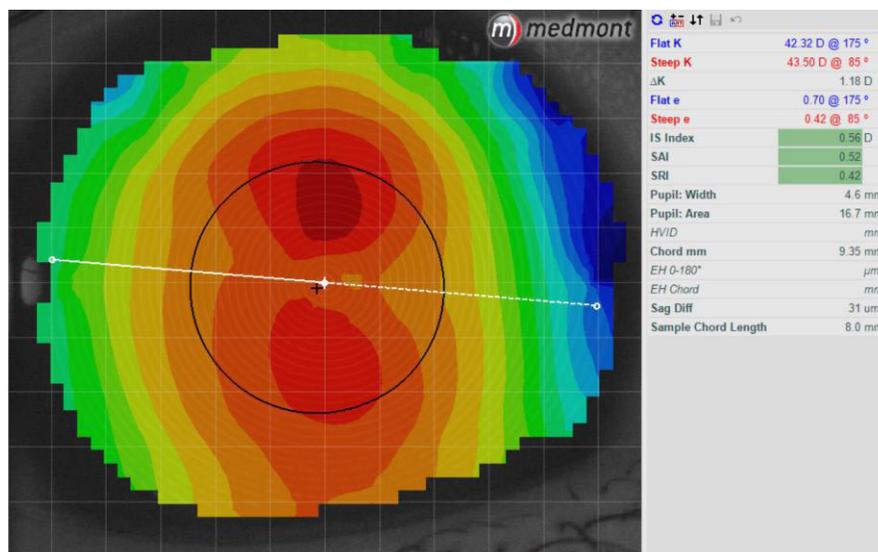
Each of the OrthoK fitting techniques requires diagnostic and problem-solving skills at the initial fitting, dispensing and follow-up visits. Success can be achieved with each system, but one modality may appeal to one practitioner and not to another depending on fitting experience, support staff and office routines. As you gain experience, you may become more comfortable with one particular system. However, over time, it is unlikely that one fitting system and/or one brand will be successful in fitting every patient.

## Table comparing the attributes of various methods of OrthoK fitting

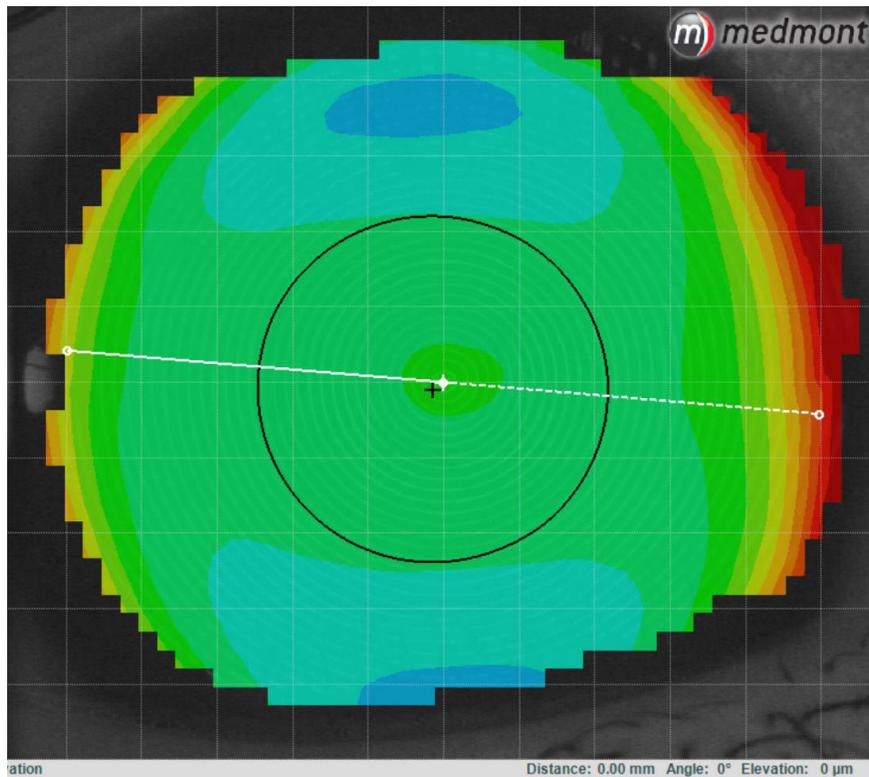
	Empirical	Diagnostic	Diagnostic after 1 night	Software designed	Nomogram
Advantage	Easy to Start	Need better diagnostic abilities and confidence	Seeing overnight lens position	Precision fitting	Good first lens selection
Advantage	No inventory	Patient experiences lens feeling	Higher success with first lens ordered	Higher success with first lens ordered	Less chair time
Advantage	Good initial success	More practitioner control		Totally customizable for unique cases	Short learning curve
Disadvantage	Dependent on consultant to modify	Learning curve for practitioner More chair time	Tease pt with one night of wear, then order lenses	Dependent on high quality topography	Requires diagnostic ability

# Chapter 4 – Topography

OrthoK, by definition, alters the shape of the cornea. As such, knowing the shape of the cornea at every stage of the process is imperative. Attaining high-quality topography at baseline aids in determining candidacy, initial lens selection and/or lens design. The baseline topography serves as a comparison for every future follow-up visit. The topography maps performed at follow-up visits are the basis for evaluating lens positioning as well as the size, consistency and degree of the treatment. In addition, localized changes in topography can indicate corneal abrasions from debris trapped under the lens or from trauma during application or removal.



**Figure 4-1.** Baseline corneal axial topography map of the right eye. Note the printout of the Sim Ks, E-Value (eccentricity) in the flat meridian and the steep meridian and sag difference (difference in corneal elevation between the flat and steep meridian at an 8 mm chord diameter, Courtesy of M. Lipson)



**Figure 4-2.** Baseline elevation map of the same eye as above. Note the lower (deeper) elevation superiorly and inferiorly, which is typical of an eye showing with-the-rule astigmatism  
 Courtesy of M. Lipson

By convention, topography maps are displayed in a color scheme/scale in which the areas in blue are flatter, red areas are steeper and green areas are in the mid-range. Most topographers have software that will display with a “normalized” scale to incorporate the range of curves on a particular cornea. With experience, there may be times when the practitioner may want to specify or customize the display ranges to better highlight the corneal changes.

A corneal topographer is mandatory to prescribe and monitor OrthoK treatment. Characteristics of a topographer necessary for the practice of OrthoK include:

1. A high degree of accuracy and repeatability.
2. Statistical analysis of repeated readings of apical radius, eccentricity, elevation, and sagittal height.
3. Various display maps: axial, tangential, and refractive power and curvature.
4. A “difference” or subtractive map function.
5. Pupil recognition/display of size and location.
6. A large area of corneal coverage with minimal interpolation or extrapolation.

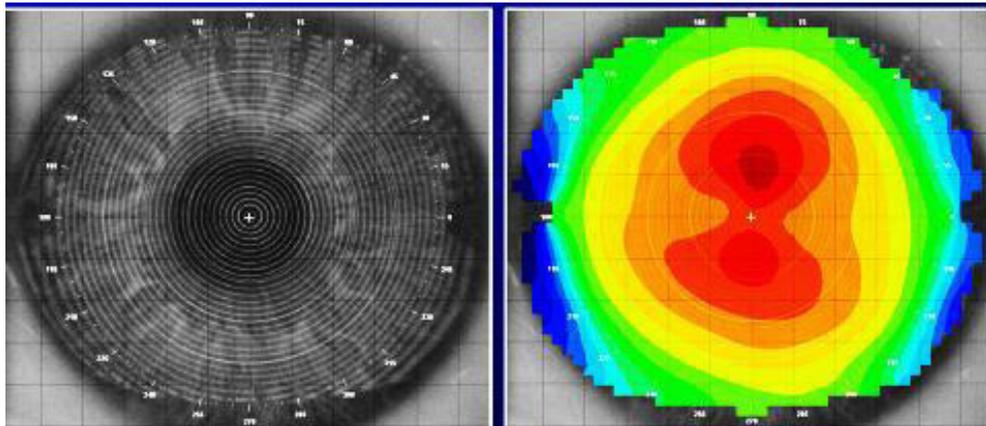
## Initial Topography Evaluation

This is an important time to remember that **placido-based topography is actually mapping the tear layer overlying the corneal surface.**<sup>37</sup> In most patients, a consistent tear film results in a reliable map of the actual corneal topography. But, when patients have dry eyes, corneal scarring, eye lid disorders or other anterior surface disorders, the topographer maps the irregular tear film rather than

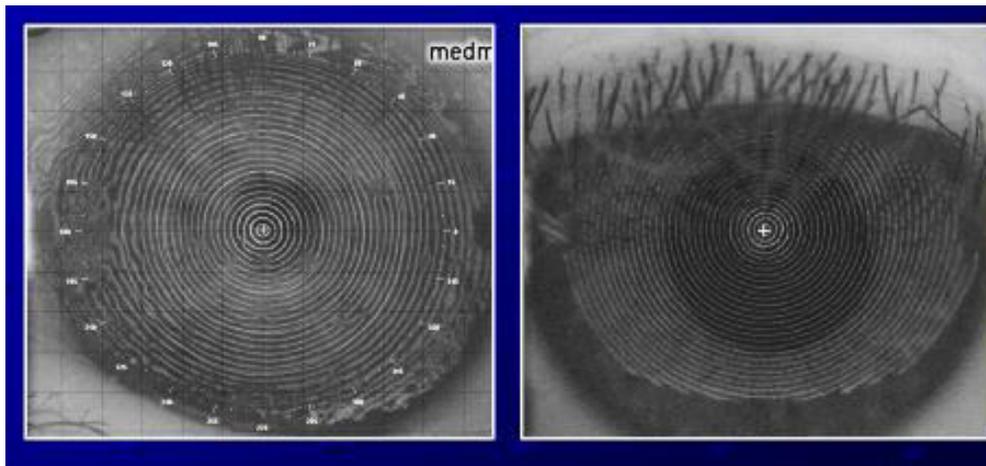
the actual corneal surface, which may result in topography maps that show topographic irregularities. This can impact the quality of the data if the process of capturing the topography requires a longer-than-normal amount of time and the patient is holding his or her eyes open for long intervals. This may result in tear thinning, dry spots or even excessive fluid volume due to reflex tearing.

### Obtaining Good Maps

Prior to taking on a new OrthoK patient, acquiring a high-quality map is critical. Some topography units have software to evaluate the quality of the captured image, but knowing what to look for without the software is helpful. First, look for a large area of coverage without interference from eyelids or eyelashes. The more data collected, the better the overall map to assess the whole cornea. First, detailed observation of the raw image of the placido rings can indicate the overall quality of the capture. For example, incomplete rings or overlapping rings would indicate a poor-quality capture, which yields a poor-quality representation of the true corneal topography that the color map may not show.



**Figure 4-3.** Placido ring reflections (left) and axial color map (right) showing excellent quality of ring reflections and a high-quality capture of corneal topography



**Figure 4-4.** Placido images from topographic captures that are not ideal:  
Left – poor tear quality resulting in distorted rings (ring jam) and poor representation of true topography  
Right – small aperture due to lid interference resulting in incomplete data

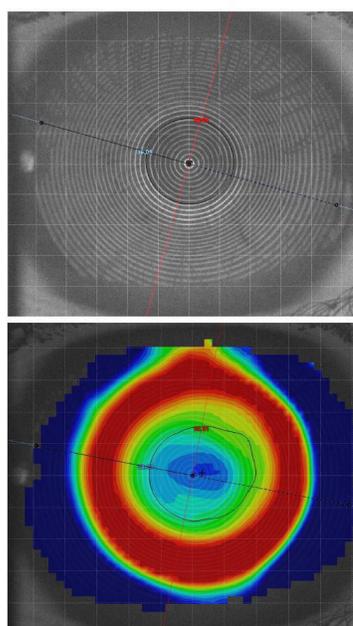
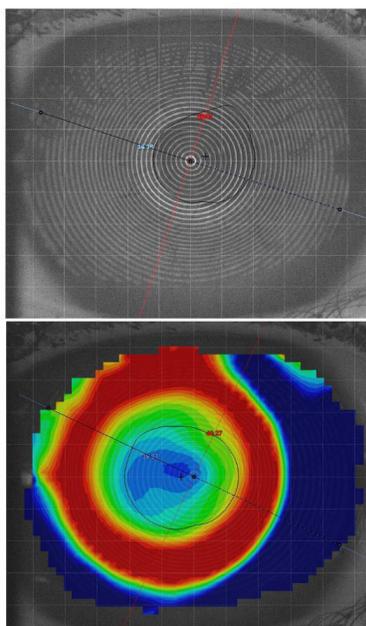
## Helpful tips for attaining high-quality topography maps

1. Ensure the largest possible opening of the eyelids to attain the largest possible area of corneal exposure; this may require help from the patient, parent or another assistant.
2. Use a low-viscosity lubricating drop in the eyes just prior to performing topography.
3. Take multiple maps to evaluate centration, smoothness and consistency between maps (repeatability).
4. Evaluate maps to ensure that there are no holes or blank spots (missing data).
5. Evaluate the placido images to ensure that there are smooth ring reflections with no ring overlap (ring jam).
6. Evaluate maps to verify that there is no interference from the eyelids or eyelashes.

## Summary of the features of a good topography capture:

1. The majority of the cornea is displayed on the color map.
2. The placido rings are all clear and free of overlap.
3. No holes or gaps in the readout.
4. The color patterns have smooth transitions from one area to another.
5. Lids and lashes do not interfere in the display and are well beyond the edge of the map.
6. Good centration. The color display should be centered relative to the geometrical center of the cornea. Special techniques are required to achieve a well-centered topography map due to the fact that most topography instruments instruct patients to fixate at the center of the target. This technique will produce a map of the cornea that is centered on the visual axis, which is usually nasal to the geometrical axis. The difference between the visual axis and the geometrical center of the cornea is called **Angle Kappa**. To address this difference, the patient should be instructed to fixate on a spot that is slightly horizontal to the center target.

For example, with a Medmont topographer, for the right eye, the patient should be instructed to fixate 1-2 rings left of center (for the left eye, fixation should be 1-2 rings right of center). This method should be used for baseline and for all post-treatment topography captures. An example of this is shown below in Figure 4-5.



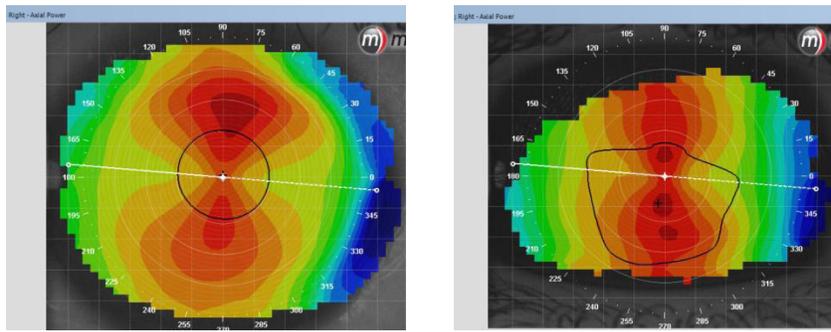
**Figure 4-5.** All images are of the same eye

*Left Top - Placido image of the left eye with the patient fixating at the center of the fixation target (note that the end of the rings is much closer to the limbus in the left part of the photo, nasally)*

*Left Bottom - Tangential map of the left top image indicating slight nasal decentration*

*Right Top - Placido image of the same eye with the patient fixating 1 ring to the right of center. (Note the better centration of the ring pattern)*

*Right Bottom - Tangential map of the right top image indicating well-centered treatment*



**Figure 4-6.** Photo of pre-treatment topography of two different captures  
 Left – full map coverage  
 Right – data is missing superiorly and inferiorly due to lid interference

## Data Acquired from Topography

**Simulated K Readings (SimK)** – this is the minimum and maximum corneal curvature of an area 3 mm in diameter, the two principal meridians, 1.5 mm from the geometrical center of the cornea. The exact point of data collection may be slightly different for individual topography units. This is comparable to the readings acquired from a manual keratometer.

**Corneal Eccentricity (e-value, Q, p or Shape Factor)** – this is the rate of shape change moving from the center of the cornea to the periphery. It is most commonly called eccentricity (e). The reading is expressed based on a formula that includes the central and peripheral curvature and the distance from the center, or chord length. A normal, untreated corneal shape usually becomes less curved (flatter) toward the periphery. Some topographers express the result as a single “averaged” number, but it is helpful to know the eccentricity of each principal meridian and to know the chord length at which the eccentricity is calculated. As a reference, “0.00 e” represents a perfect sphere (no flattening from center to periphery); an ellipse is between 0.00 and 1.00, 1.00 is a parabola and > 1.00 is a hyperbola. The e-value is also an indicator of corneal sagittal height. Corneas with lower e-values are more spherical and have a greater sagittal height, while corneas with higher e-values are more elliptical and have a lower sagittal height.

**Shape Factor** is a measure of corneal asphericity and is defined as  $e^2$ . Q is another way of expressing shape corneal asphericity ( $Q = -e^2$ )

Each topographer expresses eccentricity and/or asphericity in its own unique way. Ask your topographer’s technical staff to explain how they calculate this display and how to use this for OrthoK fitting.

**Horizontal Visible Iris Diameter (HVID)** – a capture of the topographic image also takes a standardized photo of the eye that can be analyzed with calipers to attain a very accurate reading of the corneal diameter through software or manipulated calipers.

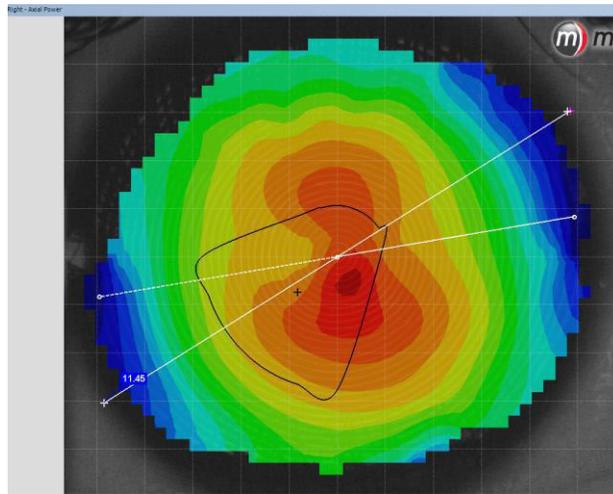


Figure 4-7. Topographic map showing measurement and notation of iris diameter (line from 2 o'clock to 8 o'clock)

**Corneal Indices** – These are software-dependent analyses of the patient’s topography compared to a pre-analyzed group of “normal cornea” patients. Generally, these grade the degree of irregularity and/or the degree of asymmetry. These indices are generally found on all topographers, but the numbers are unique to each device, and indices from one device cannot be compared to the indices from another.

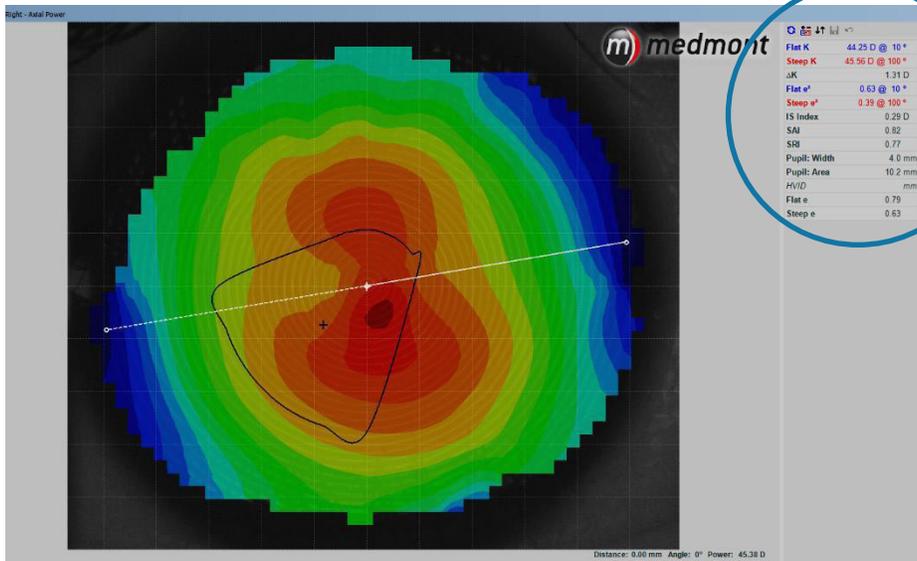


Figure 4-8. Normal topography with numerical values and indices in the upper right corner

Flat K	45.01 D @ 1°
Steep K	46.63 D @ 91°
ΔK	1.61 D
Flat e²	0.34 @ 1°
Steep e²	0.29 @ 91°
IS Index	0.20 D
SAI	0.33
SRI	0.44
Pupil: Width	6.0 mm
Pupil: Area	30.4 mm²
HVID	mm
Flat e	0.58
Steep e	0.54

Figure 4-9. Typical display of indices

Values assessed generally include:

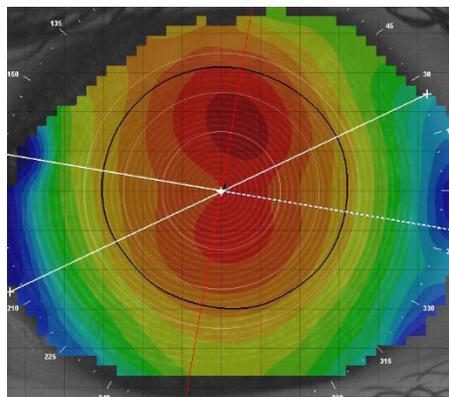
- Flat K, steep K
- Amount of astigmatism and axis
- Eccentricity (some software calculates one number as an average vs. others that provide the e-value of both the flat axis and the steep axis)
- Pupil size – in Figures 4-7 and 4-8, the patient had a very dark iris, which can create difficulty in automatically measuring the pupil
- HVID – some are automatic while others require manual measurement
- Indicators of regularity vs. irregularity:
  - I-S difference – this is a Keratoconus index looking at the difference in curvature at a specified vertical distance between the inferior and superior areas of the cornea. The I-S index represents the average power in the inferior hemisphere (I) against the average power in the superior hemisphere (S). The difference is given as a dioptic value. The greater the number, the greater the asymmetry
  - Symmetry/Asymmetry – this is an indicator of the vertical and horizontal symmetry of the corneal surface. The opposing oblique meridians are compared against each other to determine the degree of asymmetry. A perfectly spherical cornea would have a value of 0.0. The greater the asymmetry between opposing meridians, the higher the SAI value
  - Regularity/Irregularity – this is an indicator of how the topography compares to a normal/regular corneal shape. This index weights its assessment to the pupil and determines irregularity of surface curvature. The greater the value, the greater the irregularity

**Again, each topographer has its own individual indicies that it specifies as normal vs. abnormal.**

**Pupil Size** – As described above, the image acquisition typically captures a very accurate pupil size. It is measured with the software and is part of the reported data.

## Candidacy – The Good/Difficult/Poor

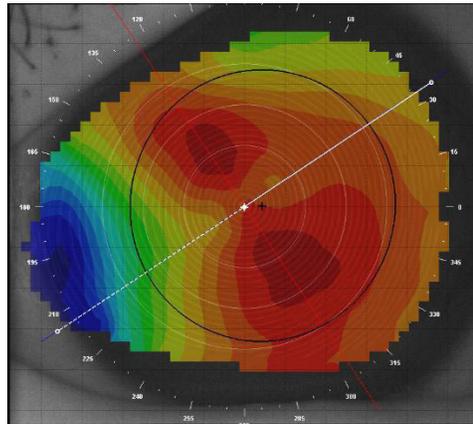
Baseline topography is the foundation upon which all future OrthoK evaluations are based. But even before the start of the process, topography may help us identify challenging patients, those who may not be good candidates or even those for whom OrthoK may be contraindicated.



**Figure 4-10.** Pre-treatment topography showing slight asymmetry and high eccentricity (horizontal ecc = 0.78, vertical ecc = 0.65)

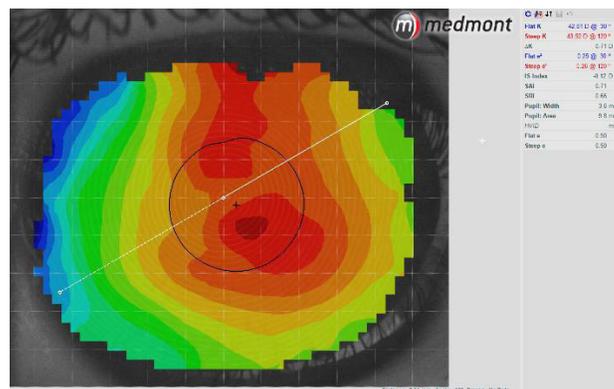
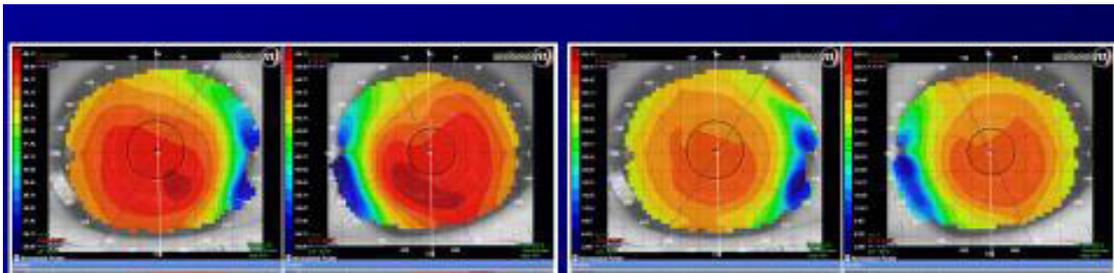
Topographic characteristics that are important in making these distinctions include:

**Irregular Astigmatism** – Evaluated visually and/or with software indices, this is manifested in topographic asymmetry (vertical, horizontal or just not regular). This is not always a contraindication but will make it more challenging to achieve an ideal endpoint visual acuity.



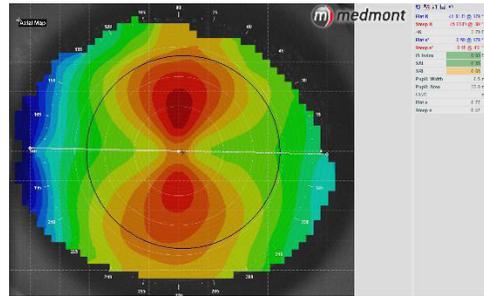
**Figure 4-11.** Pre-treatment topography showing oblique and slightly irregular astigmatism

**Significantly Decentered Apex** – Even if great care is taken to center the mapping, some patients show a decentered apex. This is not a contraindication but may present a challenge to achieving ideal lens centration.



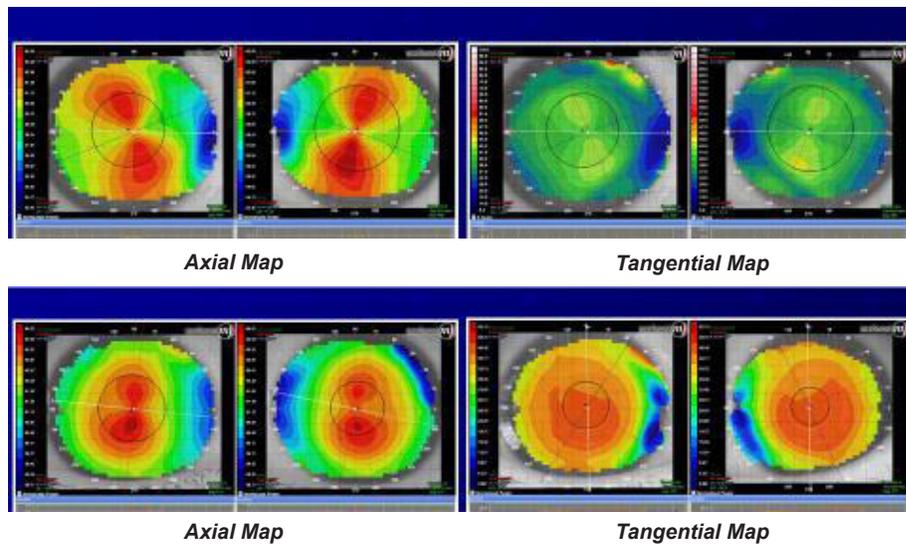
**Figure 4-12. Axial Maps:**  
Top - Spherical cornea with a decentered apex  
Bottom - Pre-treatment topography showing irregular astigmatism and a decentered apex Courtesy of R. Kojima

**High Astigmatism** – As evidenced in the refraction and with topography. It can be challenging to “sphericalize” the cornea with OrthoK to eliminate high degrees of astigmatism in both the refraction and the topography.



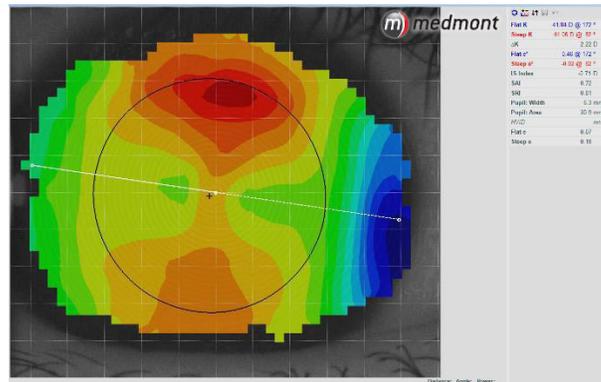
**Figure 4-13.** Pre-treatment topography showing high astigmatism (~3.00D)

**Central vs. Limbus-to-Limbus Corneal Astigmatism** – Not all astigmatism is the same on the cornea. Some patients show astigmatism in the center of the cornea that is decreased or returns to an almost spherical shape in the periphery (central astigmatism). Others show the astigmatism pattern continuing over the whole cornea (limbus-to-limbus astigmatism). Differentiating these two entities is important because it will dictate the fitting characteristics of the lenses; the central astigmatism cases may do well with spherical designs, while the limbus-to-limbus astigmatism cases will likely require designs with toric alignment zones and/or toric reverse curves to land evenly on the toric corneal surface (see Chapter 2).



**Figure 4-14.** Top image – Limbus-to-Limbus Astigmatism (~3.75 D corneal cyl)  
 Bottom image – apical astigmatism (~0.75 D corneal cyl)  
 Courtesy of R. Kojima

**Topographic Asymmetry** – When viewing topography, some topographers automatically print out indices for asymmetry. But even gross observation will be able to pick up vertical or horizontal asymmetry. Prior to considering this, carefully look at the maps to ensure that the placido image is in the geographic center of the eye. Often, the fixation positioning will produce an image that is slightly decentered. As mentioned previously, to achieve ideal centration of the image, you may have to instruct the patient to look slightly to the right or the left of the fixation target. If topography shows asymmetry with a centered placido image, it will be more challenging to achieve ideal lens centration with OrthoK and more challenging to produce the ideal OrthoK effect.



*Figure 4-15. Pre-treatment topography showing astigmatism and mild asymmetry*

## **Axial vs. Elevation vs. Tangential Maps**

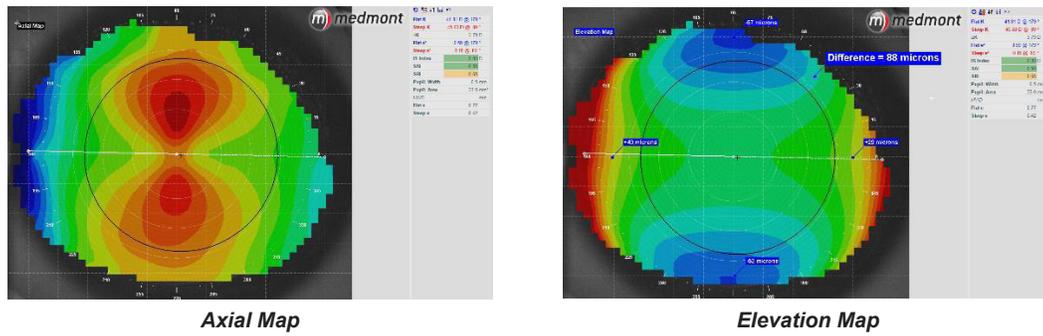
Familiarity with the foundations of topography is important to aid in diagnostic evaluation of OrthoK patients. Each brand of topographer may be slightly different, but the basic maps remain constant:

**Axial Map** – This is the most commonly used map and provides the most general representation of the corneal contour relative to the optical axis.

**Elevation Map** – This map is helpful in evaluating the height of the cornea and, specifically, the height difference between different areas of the cornea. Readings are displayed as height relative to a reference sphere calculated by the topographer and described as the “best-fit sphere.” This is an important feature in the design of toric alignment and peripheral curves in cases involving astigmatism (as described above).

**Tangential Map** – Sometimes called an “instantaneous map,” this map highlights areas of the cornea where sudden changes in corneal shape occur. In OrthoK, this is particularly important to distinguish the position of the flattened treatment zone that transitions to the steeper area under the reverse curve (the so-called “red ring”).

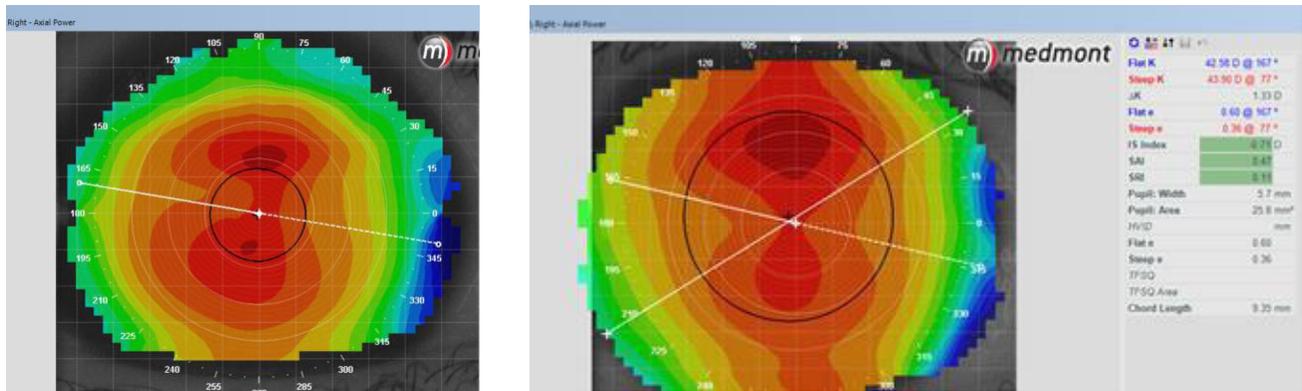
**Difference Map** – This takes the latest map and compares it to any specified previous map (baseline or other reference map); it displays the change from the reference map to the latest map. It is a very important map that shows exactly what changes have occurred from the baseline or after any lens modifications. It is usually displayed using the axial or tangential maps.



**Figure 4-16.** Two maps of the same patient with moderate with-the-rule astigmatism  
 Left image - axial map showing the power or radius of the cornea  
 Right image - elevation map showing the vertical/horizontal elevation difference  
 (88 microns at an 8 mm chord)

## Ideal corneal topography for an OrthoK candidate will have the following features:

1. A well-centered map with the apex near the geometrical center of the cornea.
2. Vertical and horizontal symmetry.
3. An average apical radius (41.00 – 45.00 D).
4. A low amount of with-the-rule astigmatism (less than 1.50 D).
5. An average amount of eccentricity (0.25 to 0.80).



**Figure 4-17.**  
 Left Photo - Example of an ideal topography map for an OrthoK candidate  
 Right Photo - Example of a more difficult OrthoK case with limbus-to-limbus astigmatism and asymmetric topography

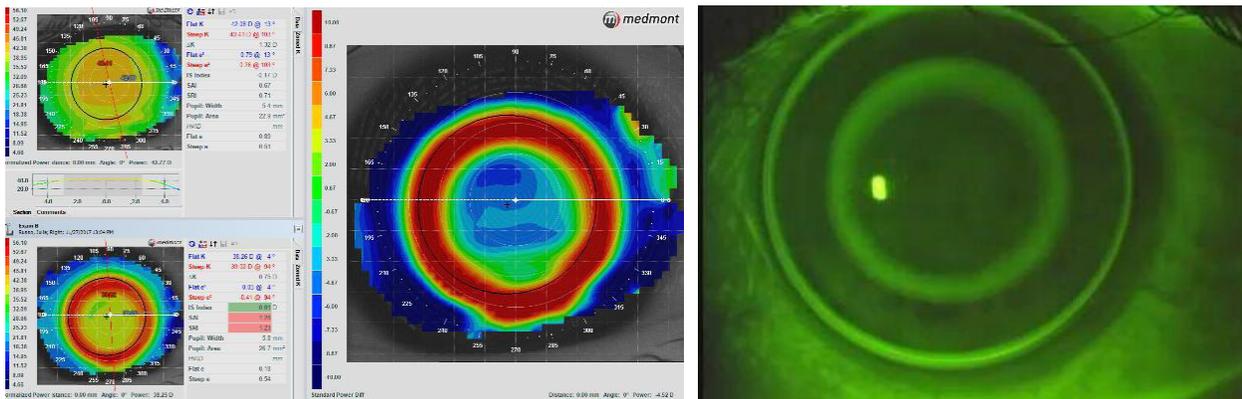
# Post-Fitting Topography Assessment

**Centration** – Centration of an OrthoK lens is one of the most important fitting characteristics necessary to provide optimal visual results. No matter what you observe with regard to lens position in the open eye, the topography tells the story of where the lens is positioned while sleeping. The location of the treatment will indicate whether a change in lens is needed and the type of lens modification required. **To evaluate the location of the treatment zone, it is best to use a tangential difference map.**

**Difference Maps** – As described above, in addition to looking at the post-wear topography, the difference map will provide an excellent display of the exact location and quantity of changes that have occurred.

## Patterns – Superior, Inferior, Central Island, Superficial Punctate Keratitis –

Lenses that are not performing ideally will show various topographic patterns. For example, a superiorly decentered lens will show an inferior arc of steepening beyond the treatment zone (the so-called “smiley face”).



**Well-Centered Treatment**

**Figure 4-18.**

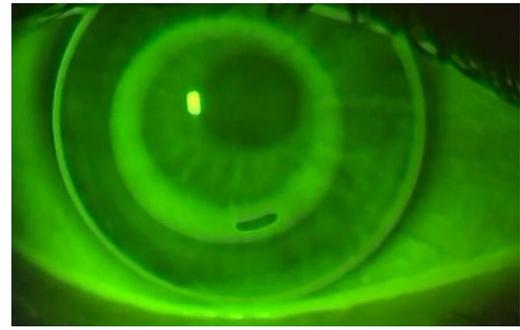
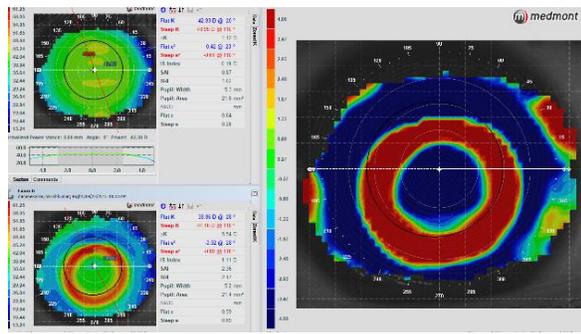
Left - Pre/Post-OrthoK tangential difference map showing a well-centered treatment and an ideal result  
Right – Slit-lamp photo with NaFl of a well-centered OrthoK lens - Slit lamp photo courtesy of C. Norman



**Superior Decentration**

**Figure 4-19.**

Left - Pre/Post-OrthoK tangential difference map showing superior decentration - Courtesy of R. Kojima  
Right – Slit-lamp photo with NaFl of a superiorly decentered OrthoK lens - Slit lamp photo courtesy of C. Norman

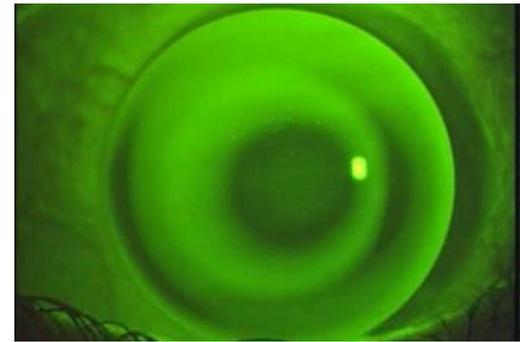
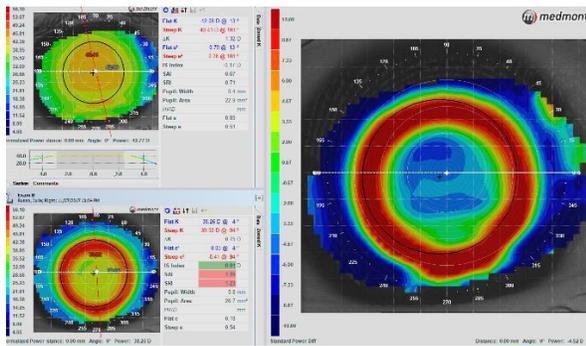


**Inferior Decentration**

**Figure 4-20.**

*Left - Pre/Post-OrthoK tangential difference map showing inferior decentration*

*Right – Slit-lamp photo with NaFl of an inferiorly decentered OrthoK lens - Slit lamp photo courtesy of C. Norman*



**Lateral Decentration**

**Figure 4-21.**

*Left - Pre/Post-OrthoK tangential difference map showing lateral decentration*

*Right – Slit-lamp photo with NaFl of a laterally decentered OrthoK lens - Slit lamp photo courtesy of C. Norman*

Conversely, an inferiorly decentered lens will show a superior arc of steepening beyond the treatment zone (the “frowny face”).

OrthoK lenses that have too much sagittal depth or that do not create a uniform tear film in the treatment zone may create a generalized flattening across the treatment zone with a small area centrally that is steeper than the surrounding area; this is called a “central island.”

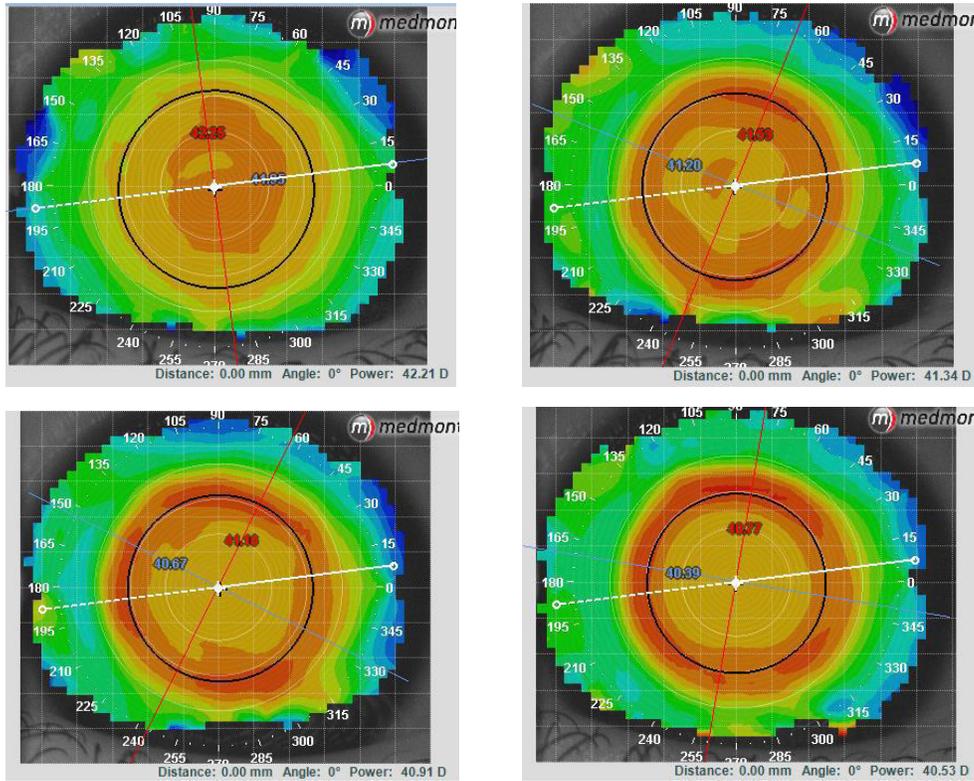
If the OrthoK lens has an insufficient tear layer under the lens, this could create surface irritation resulting in superficial punctate keratitis (SPK). On topography, this would show up as a very irregular, non-uniform color pattern. It is not the visibly smooth pattern seen in a normal cornea or in one that is responding well to OrthoK.

**Lateral Decentration** – Post-wear topography that shows nasal or temporal decentration may be a challenge to alleviate. This can occur due to lens design issues, unique baseline topography (decentered apex, asymmetry) or effects of the eyelids. The first step to alleviate lateral decentration would be to increase the sagittal depth of the lens (return zone and/or alignment zones). In addition, changes in overall lens diameter may minimize lateral decentration. Increasing the overall diameter may help to increase corneal coverage, or it may be necessary to decrease the diameter to avoid areas of high elevation.

For more details on topography, consult the textbook on Orthokeratology by John Mountford.<sup>38</sup>

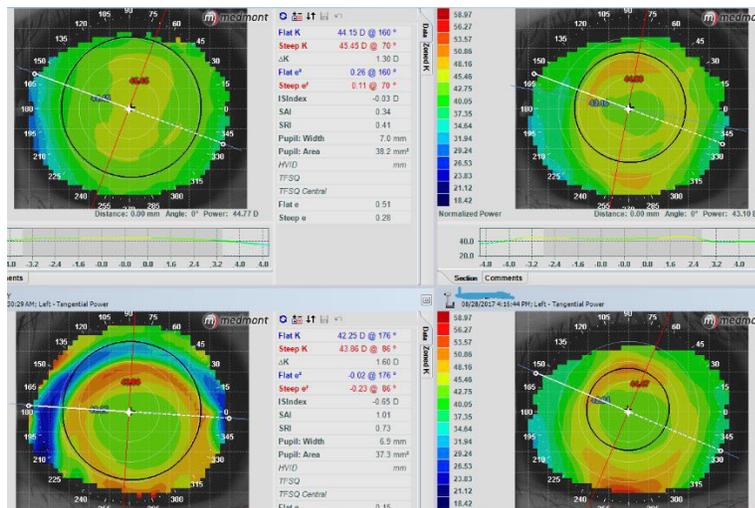
# Trends in topography changes during OrthoK

Sequential topography at various time points during the process of OrthoK can indicate ideal treatment vs undesired results. The maps below show the topographical trend for a well-centered case. Note the more defined treatment zone and mid-peripheral ring of steepening from baseline to 1 month.



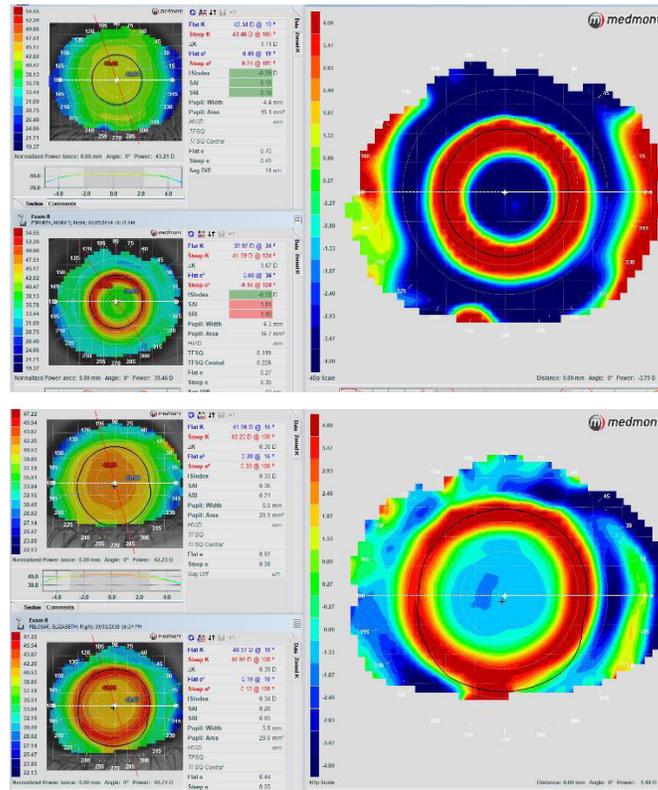
**Figure 4-22.** Tangential maps of a patient over time  
 Top Left - Baseline  
 Top Right - 1 Day  
 Bottom Left - 1 week  
 Bottom Right - 1 month. Note the increase in definition of the central treatment zone (M. Lipson)

In cases demonstrating decentration in the first few days of OrthoK, the trends show the decentration becoming more pronounced over time (Figure 4-23).



**Figure 4-23.** Tangential maps showing early decentration becoming more evident over time  
 Top Left - Baseline  
 Top Right - 1 day  
 Bottom Left - 1 week  
 Bottom Right - 3 weeks

Treatment zone size as viewed with post-treatment topography may vary with lens design, degree of baseline correction and individual patient response. Figure 4-24 shows tangential difference maps with distinct differences in two patients who are both very successful with excellent unaided acuity.



**Figure 4-24.**  
 Top – Tangential difference map with small treatment zone  
 Bottom – Tangential difference map with large treatment zone



# Chapter 5 – Lens Care/Handling

Always stress the importance of **handwashing prior to lens handling!**

A patient's hands touch the contact lenses, the lens case, the eyelids and the eyes. Handwashing can minimize the risk of introducing contaminants to each of these components. Research has demonstrated that this is an important routine that must be followed to minimize the chance of long-term lens-related complications. Use of anti-bacterial soaps that are not oil-based is recommended.



*Figure 5-1. Thorough handwashing is a necessary routine*

## Contact Lens Disinfection and Wear Solutions

Lenses are exposed to contaminants from the patient (hands and eyelids), airborne particles in the environment, the lens storage case and potentially anything else with which the lenses come in contact (i.e., water, saliva). As OrthoK lenses are worn while sleeping, if lenses are not properly disinfected, there is a significant potential for contaminated lenses to contribute to ocular infection. Proper techniques to disinfect lenses are not difficult to perform but must be followed with precision and consistency. Approved care systems to disinfect gas-permeable (GP) OrthoK lenses include:

- **GP Multipurpose Solutions** (e.g., B+L Boston Simplus, Menicon Unique pH) Some have separate cleaning and wetting solutions and some are all-purpose and contain both in one bottle. Care should be taken to avoid abrasive cleaners on high-Dk Orthok materials
- **Peroxide-based Systems** (e.g., Alcon ClearCare, CooperVision Refine One Step, Johnson & Johnson Oxysept). These systems provide both disinfection and oxidative surface cleaning. They have been associated with a lower risk of eye infections and are especially good for patients with allergies or other sensitives. Care should be taken with new wearers who may need another solution to rinse the lenses during application and removal practice

Some patients are highly sensitive to solutions with a preservative. These patients may find it helpful to rinse their lenses with a preservative-free saline solution prior to application to avoid reactions to multipurpose solutions. In addition, it may be better for some patients to use a preservative-free saline solution on the lens prior to application.

Each of these systems will provide effective lens disinfection, but individual patients may find that one particular system cleans better for them or feels more comfortable for them than another system does.

## Additional Cleaning Options

The patient's routine lens care system should maintain lenses in a like-new condition for up to a year. But, some patients have more lipids or proteins in their tears, and so even with good technique and compliance with the prescribed lens care regimen, lens surface deposits can occur. In such cases, supplemental cleaning agents may be needed. These include:

- Surfactant cleaners (e.g., Miraflow, Walgreens Extra Strength Cleaner)
- Protein Removers (e.g., Boston Liquid Enzymatic Cleaner, Menicon Progent)

These additional cleaners may be used bi-weekly or monthly to better remove surface deposits. It is recommended to use stronger cleaners after lens removal in the morning to minimize the chance of getting any residual cleaner in the eye.

## Supplemental Solutions

There are various over-the-counter (OTC) solutions available for use with OrthoK lenses. Some are specifically designed for use with contact lenses, and others are designed as artificial tear supplements but work well in the eye or on the lenses for OrthoK patients.

### Pre-Application of Contact Lenses

Even after adaptation to lens wear, some OrthoK patients experience significant lens awareness each night at application. This can be minimized by use of a lubricating eye drop in the eye prior to lens application. Patients should be educated to instill a drop onto the eye and then wait about 20-30 seconds before applying the lenses. This process helps flush out any debris or mucus that may be in the eye and adds an additional layer of lubrication prior to lens application. This can become part of the daily routine. For patients with allergies or sensitivities, it is helpful to use a non-preserved artificial tear.

### With Contact Lenses On Eye

Some patients report symptoms of dryness while wearing OrthoK lenses. Lubricating drops that are indicated for use with contact lenses can be used on the eye while lenses are worn to alleviate this feeling. OrthoK patients should be advised to apply the lenses just before they go to sleep and to remove them when they wake up to minimize wearing lenses while the eye is open.

### Pre-Removal of Contact Lenses

Dryness can occur when lenses are worn while sleeping due to less lens movement and tear exchange. Patients should be advised to instill one drop of an artificial tear solution in the eye before removing the lens, as this can make the lens easier to remove and can minimize potential problems with lens adherence. For most patients, this is recommended as a routine procedure.

### The Lens Case

Even though the lens case has disinfecting solution inside, the case itself can become contaminated. Biofilms can form in the case and harbor microbial growth.

**Cases used with GP or multipurpose solutions should be replaced every 3-4 months.**

**Cases used with peroxide systems should be replaced every 2 months.**

## **NO TAP WATER ON LENSES**

Tap water is not sterile. Studies have shown the potential risks of tap water exposure to the lens or lens case. <sup>39</sup>The most serious of these risks is the development of infectious keratitis (i.e., Acanthamoeba, Pseudomonas, Serratia). It is imperative that the patient understands the importance of letting tap water touch the lens case or the lenses. not letting tap water touch the lens case or the lenses.



*Figure 5-2. Tap water should never touch the lens*

## **Application/Removal and Care Education**

Proper education and instruction at lens dispensing and at follow-up visits is essential for long-term success with OrthoK.

### **Introductory Video**

Having the patient watch a video of how to apply and remove OrthoK lenses can be a great first step in providing a visual demonstration of what to expect. The video should show proper technique for handwashing, handling and holding the lens, body position and how to hold the lids open. There are free videos available from the Gas Permeable Lens Institute and some orthokeratology lens manufacturers, or you can make your own video.



*Figure 5-3. Demonstrate digital rubbing of both surfaces of the lens*

## One-on-One Training

Once the patient has seen the instructional video, an individual training session is always necessary to ensure that the patient attains all of the skills essential for long-term success and that he or she begins with good lens care habits. During these one-on-one sessions, each patient may have to slightly adapt techniques due to his or her unique eye shape, orbital bone anatomy or manual dexterity. An experienced technician/assistant can supervise and ensure that the patient is competent and confident about every aspect of lens handling and care.



*Figure 5-4. One-on-one training of application and removal*

## Written Instructions for Home Reference

After the patient watches the video and completes the one-on-one training, it is important to also dispense written instructions that review everything that the patient needs to know about lens care and handling. These written instructions should have information that reinforces the verbal training given in person but may also contain:

- Frequently asked questions and answers including when not to wear lenses (i.e., when eyes don't look or feel healthy)
- Links to web sites with additional information
- How to handle emergencies (pain, blurred vision, redness)
- After hours contact information for the doctor/office

## Review at Follow-up

During the first few follow-up visits, to ensure that patients have learned and are proficient and compliant with proper handling procedures, patients should be asked to demonstrate their application, removal and cleaning procedures.

## Summary

Long-term success with OrthoK depends on careful hand hygiene and compliance with the prescribed routine of cleaning, disinfection and handling of the lenses. Use of solutions that are effective and compatible with a patient's eyes is required to provide the patient with excellent visual acuity, maintain a clear and healthy cornea and keep the patient as comfortable as possible while wearing lenses.

## Final Consideration

It may be helpful for patients to purchase a spare pair of lenses in case of lens loss or breakage. Spare lenses should be stored wet in a multipurpose or gas permeable solution. With long-term storage, the solution in the case should be changed every 2 weeks.

# Chapter 6 – Follow-Up Care



Figure 6-1. OrthoK check up

## Schedule

Following dispensing of OrthoK lenses and a thorough education and training on lens application, removal and cleaning/disinfection, the patient should be instructed on when to return for follow-up care. As patients leave their dispensing and education visit, they should know how to apply, remove and care for their lenses, exactly when to apply the lenses, the prescribed hours of wear, and they should have an appointment for follow-up.

A suggested “normal” follow-up schedule is:

- **The morning** after their first night of wear; after the first-day visit, subsequent visits may be done in the morning or afternoon
- One week after the start of lens wear
- One month after the start of lens wear
- Three months after the start of lens wear
- Six months after the start of lens wear
- After that, annual exams resume 6 months later. Annual exams should be done for all OrthoK patients, and many patients may require check-ups every 6 months



Figure 6-2. Schedule follow-up exam times

If the patient does not respond as expected or if lens changes are made, additional follow-up visits are indicated. After a lens change is made, follow-up should be done after about one week. This allows enough time for the new lens to have its intended effect but is a short enough time to make further corrections if necessary.

## The First Follow-up Visit – After the First Night of Wear

To evaluate the patient's reaction to the first night of wear, it is best to see the patient the following morning (less than 2 hours after lens removal). Some practitioners advocate that patients wear the lenses into the office to evaluate the lens position and movement. They can then evaluate the cornea immediately after lens removal. An informal poll of experienced OrthoK practitioners showed that most prefer to have patients remove their lenses immediately after waking and see them early in the morning.

The improved vision that patients experience after the first night of wear is quite exciting for the patient and the practitioner. This is the biggest one-night change that the patient will experience! Encourage their excitement, but also take the opportunity to reinforce the importance of follow-up care and lens care issues.

## Follow-Up Testing

Each OrthoK follow-up visit should include:

- History – report from the patient regarding the quality of his or her unaided vision, the time elapsed before regression is noticed, wearing time, comfort and any issues involving application and removal
- Unaided Visual Acuity – monocular and binocular
- Slit-lamp Evaluation – to assess corneal integrity, staining, tear film stability, inflammatory events and conjunctival injection (see chapter 7 for complications)
- Corneal Topography – to assess lens positioning relative to the pupil and corneal regularity
- Manifest Refraction
- Evaluation of lens condition – at practitioners' discretion
- Review of Lens Care Regimen



*Figure 6-3. Slit lamp evaluation at follow-up exam*

## Annual Exam Testing

Annual exams should include all of the above as well as intraocular pressure, internal eye health evaluation, axial length measurement (if done at baseline) and careful assessment of lens condition.

## Review of Lens Care

It is critical to ensure that the patient remembers all of the details that your office has taught him or her regarding lens care and cleaning as well as any other adjunctive agents or procedures.

Rather than asking “yes/no” questions, ask patients to verbalize the protocol that they follow including the solutions that they are using and in what order.

With the excitement of starting OrthoK and the multiple steps to learn, patients sometimes forget one or more small steps. **REINFORCE YOUR PRESCRIBED LENS CARE ROUTINE AT EVERY VISIT!**



*Figure 6-4. Demonstrate proper cleaning and disinfection*

## Next Visit

At every visit, the last thing that patients should hear from you is when you want to see them next. Pre-appointment of follow-up visits is essential.

Remember that OrthoK is a PROCESS. It requires ongoing care. You and your patients should know exactly when you want to see them and what they are expected to do in between visits as well as what to bring to the next visit. Written instructions may help patients retain and follow your recommendations with greater fidelity.

## Unscheduled Visits

On occasion, patients will experience complications with OrthoK use. These can be minor or potentially serious. Patient education includes a discussion of the signs and symptoms associated with adverse events. Patients should understand what to do if these occur.

This may seem obvious to practitioners, but patients do need to be educated on these issues. Patients should monitor:

- Vision – monocularly for clarity, glare and distortions
- Comfort – while wearing lenses and without lenses
- Appearance – redness or swelling

In other words, they should LOOK GREAT, SEE GREAT, FEEL GREAT!! (see chapter 7 for complications)



*Figure 6-5. Look Great - See Great - Feel Great*

In the normal course of OrthoK, patients may experience slight vision fluctuations, a slight feeling of discomfort or a little redness. Most of these are normal and self-limiting. But, patients must be educated to differentiate potentially sight-threatening occurrences from self-limiting ones, and they should know when to call the office and should be encouraged to contact the office when in doubt.

Examples of some serious symptoms that require an urgent office visit include:

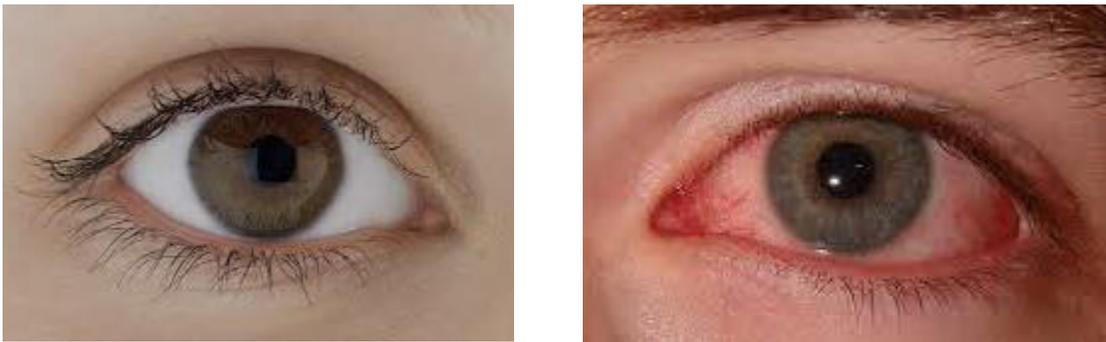
- Eye pain lasting more than 30 minutes after lens removal
- Significant light sensitivity
- Significantly blurred vision for more than one day
- Significant redness

# Chapter 7 – Complications/ Troubleshooting/Problem Solving

Contemporary OrthoK lens wear is a safe and effective alternative modality to correct refractive error. Although most OrthoK patients rarely experience complications associated with OrthoK lens wear, occasionally a patient will experience a problem. This next chapter details potential issues associated with OrthoK treatment and how to best handle them.

## Important note about making changes to lens parameters

This problem-solving chapter includes recommended changes to lens parameters to correct fitting issues and/or to improve unaided vision. When changes are being made during the first 1-2 weeks of OrthoK treatment, patients may immediately switch from one lens to the next without interruption of normal nightly wear. But, when changes are being made at any time after 2 weeks, it is best to have the patient discontinue lens wear for 5-7 days prior to commencing wear of the new lens to allow the cornea to return to baseline levels. This process is particularly relevant when the issue relates to lens decentration, as the decentered topographic changes may create a pattern that will affect any subsequent lens in a similar way. When the cornea is allowed to return to baseline, assessing the fit of the new lens will be more accurate. New lens parameters are much more likely to create improved centration with the baseline topography compared to when worn with treatment changes from a decentered treatment zone.



**Figure 7-1.**

*Left – Clear eye and eye lids*

*Right – Generalized redness, requires investigation into the cause*

# Patient Complaints and Symptoms

This table summarizes patient issues, reasons for the issues and suggested steps to remedy the issues. Additional details are described below the table in a textual format.

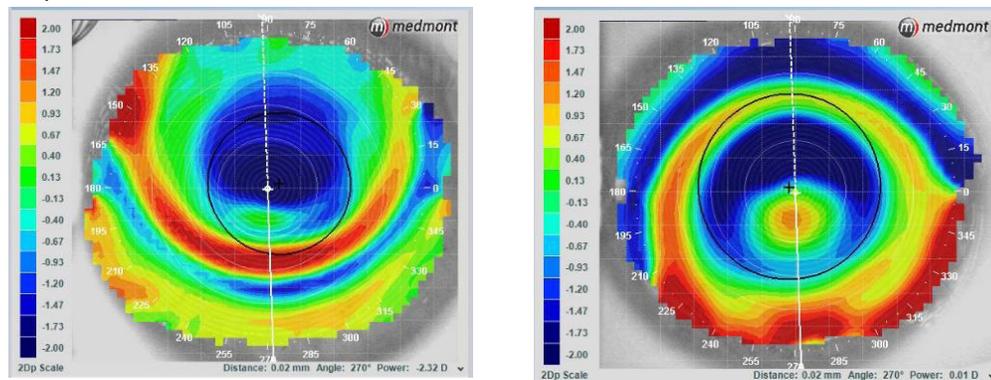
Patient Issue/Symptom	Reasons for Issue	Steps to Resolve
Unacceptable Visual Acuity	Under-correction Central island Small treatment zone	<ul style="list-style-type: none"> <li>Flatten BC by amount of under-correction</li> <li>Lower lens sagittal depth by reducing sagittal depth of reverse curve and/or flattening alignment curve</li> <li>Increase optic zone diameter and/or reduce the sagittal depth of the lens</li> </ul>
	Over-correction Decentered treatment zone	<ul style="list-style-type: none"> <li>Steepen BC by the amount of over-correction</li> <li>1) increase overall lens diameter, 2) increase lens sagittal depth, 3) prescribe toric reverse and/or alignment curves to create more uniform bearing 360° around and 4) adjust widths of reverse and/or alignment curves to increase bearing area</li> </ul>
Night Glare/Halos	Small treatment zone relative to pupil size Decentered treatment zone Large pupils	<ul style="list-style-type: none"> <li>Re-design with larger treatment zone diameter</li> <li>Lower lens sagittal depth by reducing sagittal depth of reverse curve and/or flattening alignment curve</li> <li>Prescribe Brimonidine bid to reduce pupil size</li> </ul>
Night Glare/Halos	Small treatment zone relative to pupil size Decentered treatment zone Large pupils	<ul style="list-style-type: none"> <li>Re-design with larger treatment zone diameter</li> <li>Lower lens sagittal depth by reducing sagittal depth of reverse curve and/or flattening alignment curve</li> <li>Prescribe Brimonidine bid to reduce pupil size</li> </ul>
Variable Vision	Inconsistent wearing time Lens deposits Unusual sleeping position Difficulty with lens application/removal	<ul style="list-style-type: none"> <li>Educate patient about prescribed wear time</li> <li>Clean lenses thoroughly</li> <li>Remind patients not to rub their eyes</li> <li>Assure proper techniques for lens handling</li> </ul>
Patient Issue/Symptom	Reasons for Issue	Steps to Resolve
Lens Awareness	Excessive lens movement Small lens diameter Tight eyelids Allergies Adaptation times differ	<ul style="list-style-type: none"> <li>Modify lens design with thinner edge profile</li> <li>Prescribe larger diameter lens</li> <li>Design lens with lower edge lift</li> <li>Treat allergies with antihistamine or steroid drops</li> <li>Advise that some patients take longer to adapt</li> </ul>
Stinging/Burning	Solution incompatibility Chemical or contaminants from fingers Lens deposits	<ul style="list-style-type: none"> <li>Prescribe preservative-free care system</li> <li>Prescribe preservative-free solution for application</li> <li>Educate patient on proper handwashing; review thorough lens cleaning; instill lubricating drop prior to application</li> </ul>
Application/Removal Issues	Failure to place lens on center of cornea; applying too much pressure at application Failure to hold lids open wide enough Excessive pressure with removal device; excessive lens movement while removal device is in contact with the lens on eye	<ul style="list-style-type: none"> <li>Review application/removal technique</li> <li>Ensure proper holding of lids</li> <li>Ensure proper pressure and technique with removal device</li> </ul>

## Visual Acuity

While most patients enjoy excellent vision after lens removal, some will state that their vision is not clear enough. Careful evaluation will determine whether there is more that can be done to improve vision or whether the patient has unrealistic expectations.

Reasons for unacceptable VA:

- Under-correction – manifest refraction without lenses shows residual myopia
- Central Island – an uneven treatment zone creates uneven corneal changes
- Small treatment zone – may create a limited central area of clear vision associated with symptoms of halos and glare
- Over-correction – manifest refraction shows significant hyperopia
- Decentered treatment zone – creates imperfect central optics through the pupil, resulting in inadequate vision correction



**Figure 7-2.**

*Left - Topography map showing a superiorly decentered treatment zone*

*Right – Inferiorly decentered treatment zone AND a central island*

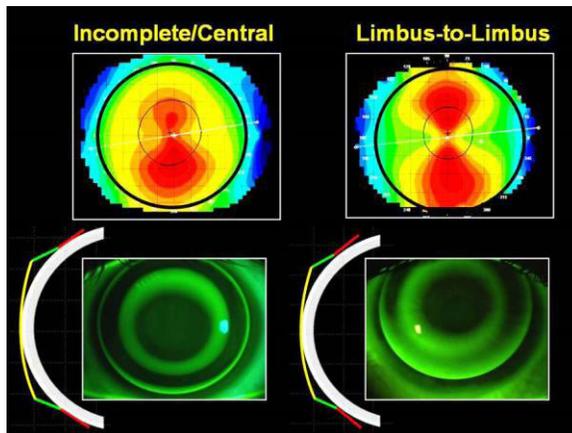
*Courtesy of E. Korszen and P. Caroline*

To correct unacceptable VA: (the specific modifications listed apply to OrthoK for myopia only)

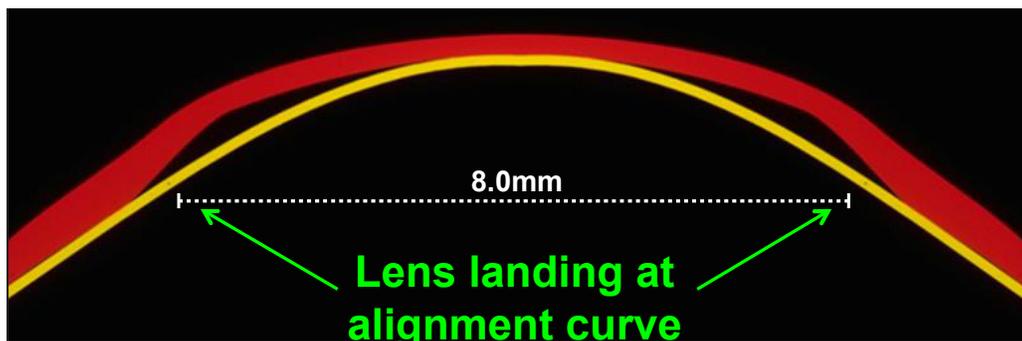
- Under-correction – flatten the base curve (BC) by the amount of the under-correction
- Central island – reduce the lens sagittal depth by decreasing the depth of the reverse curve and/or by flattening the alignment curve(s)
- Small treatment zone – order a lens with a larger optic zone diameter and/or reduce the sagittal depth of the lens
- Over-correction – steepen the BC by the amount of the over-correction
- Decentered treatment zone (part 1) - there are various combinations of modifications to improve lens centration: 1) increase overall lens diameter, 2) increase the lens sagittal depth, 3) prescribe toric reverse and/or alignment curves to create more uniform bearing in all meridians and 4) adjust the widths of the reverse and/or alignment curves to increase the bearing area

Note: For customized options, contact the consulting service of the individual manufacturer/designer on how to change parameters to create the desired changes.

- Decentered treatment zone (part 2) - One of the most common reasons for lens decentration is a lens with a spherical alignment curve landing unevenly on meridians of different elevation. This problem is alleviated by designing lenses with toric reverse curves and/or toric alignment curves to land evenly on the cornea in the areas of highest and lowest elevation. Although there are no rigorous, published studies on this, clinical experience suggests that a toric lens may be required when the corneal elevation difference of the primary meridians is 25-30 microns or more at an 8 mm chord diameter (see Figures 7-3 and 7-4)



**Figure 7-3.** The difference in vertical and horizontal elevation of the cornea can create uneven bearing in the alignment zone (lower right). These images show a spherical lens on two different types of astigmatism: left-central corneal astigmatism; right-limbus-to-limbus astigmatism  
 Courtesy of P. Caroline



**Figure 7-4.** Ortho-k lenses “land” on the eye at the alignment curve. A corneal height differential of 30 $\mu$  between the two primary meridians at a chord length of ~8.0 mm suggests that a toric lens will improve landing 360° around. Courtesy of E. Korszen and P.Caroline

Note: With unexplained over- or under-correction, it may be necessary to discontinue lens wear, allow the eyes to return to baseline and verify all baseline readings of manifest refraction, topography, over-refraction with diagnostic lenses and all lens fit calculations.

### Night Glare/Halos

Patient awareness of glare and halos can occur with OrthoK. Patients report this more often in the first 2 weeks of the OrthoK process, but these symptoms tend to diminish with time. It is more of a problem for adults when driving at night. In most cases, lens parameters can be adjusted to minimize these symptoms.

Reasons for night glare/halos:

- Treatment zone is smaller than the pupil size
- Decentered treatment zone – the optics are not centered over the pupil
- Physiologically large pupils

To correct night glare/halos:

- Change the lens design - use a larger optic/treatment zone (i.e., change from 6.0mm to 6.4mm)
- If the NaFl pattern or topography shows a smaller-than-ideal treatment zone size, change to a lens with less sagittal height, lowering the reverse curve and/or flattening the alignment zone
- Although it is “off-label,” some patients may find relief from halos and night glare with the use of Brimonidine eye drops, twice daily, to reduce the pupil diameter

### **Variable Vision**

OrthoK patients occasionally describe changes in their clarity of vision from morning to night or from one day to the next. Individual differences in patient response after lens removal cannot always be accounted for with fitting adjustments. However, careful evaluation of the wearing schedule, the condition of the lenses, corneal topography and corneal integrity will help identify the potential source of this problem.

Reasons for variable vision:

- Inconsistent wearing time – this may cause vision to drop off earlier in the day
- Lens deposits – this may cause minor irritation to the cornea that could impair acuity
- Unusual sleeping position – if patients sleep in a face-down position or lay on their hand in a way that places unwanted pressure on the eye, it can affect lens position and create irregular topographic changes
- Difficulty with lens application/removal – central staining of the cornea can result from the trauma of protracted efforts to apply or remove lenses. Also, if the eyes are dry in the morning, removal can cause corneal trauma/staining that may affect visual acuity

To correct variable vision:

- Educate the patient on the importance of consistent wearing time for a minimum of 7 hours per night
- Clean lenses thoroughly – use additional cleaning/surfactant agents and/or change to a different care system
- Remind patients not to rub their eyes while in bed. Although this may be difficult to control while sleeping, the power of strong suggestion may help
- Ensure proper technique of lens application and removal. If lenses are difficult to remove in the morning, use of lubricating drops in the eyes followed by gently massaging the lens through the closed upper lid prior to removal may be helpful. In some patients, modifying the lens to have a higher edge lift may also be necessary

## **Lens Awareness**

Commonly, during the first few nights of OrthoK lens wear, patients may be aware of the lens. This is mostly due to the sensation of the lid blinking over the edge of the lens. During the first week, most patients adapt to the lens awareness and can become quite comfortable with lens wear while their eyes are open. However, a few patients can experience significant ongoing lens awareness. Very rarely, patients will complain about lens awareness while their eyes are closed.

Reasons for lens awareness:

- Excessive lens movement
- Lens diameter is too small
- Edge lift of the lens is too high
- Tight eyelids
- Allergies (allergic patients can be more sensitive)

To correct lens awareness:

- Modify the lens design to create a thinner edge profile
- Increase the overall lens diameter
- Lower the lens edge lift
- Treat signs of allergy with antihistamine or steroid drops
- Inform patients that there are individual differences in adaption
- Instruct patients to close their eyes and go to sleep immediately after lens application

## **Stinging/Burning**

Stinging and burning are not common if proper techniques are used for lens care and lens application.

Reasons for stinging/burning:

- Solution incompatibility
- Introduction of chemicals or contaminants from fingers during lens application or removal
- Lens deposits

To correct stinging/burning:

- Prescribe the most compatible and comfortable lens solution for patients to use long- term
- Educate patients to ensure thorough handwashing prior to handling the lens. Instructions are to wash hands thoroughly with antibacterial soap. Rinse thoroughly to remove all traces of hand cream, dust, dirt or lint from the fingers, as these could become trapped under the lens and cause discomfort. After handwashing, avoid touching any other surfaces and avoid touching clothing, the face or anything that may transmit other chemicals or contaminants
- Use a lubricating eye drop in the eye prior to lens application

## Application/Removal Issues

Although taken for granted, improper application or removal can detrimentally affect the outcome of OrthoK.

Reasons for application/removal issues:

- Failure to place the lens directly on the center of the cornea
- Applying too much pressure at application
- Failure to hold the lids open wide enough
- Too much pressure with the lens removal device
- Too much movement of the lens on the eye while in contact with the lens removal device

To aid in application/removal:

- Review and refine application and removal techniques via one-to-one instruction, video demonstration and written instructions.
- Ensure proper technique of holding the eyelids and the lens.
- Provide customized instruction and hints to ensure accurate, first-time lens application on the center of the cornea.
- Ensure proper pressure and placement of the lens removal device.

## Lens Fitting and Compliance Issues

There are various clinical observations that may be detected by practitioners during follow-up visits that may create problems for patients. Some of these cause no symptoms for the patient.

### Topographic Signs

**Centration of Treatment Zone** – this is a key factor for both long- and short-term success of OrthoK lens wear. As such, corneal topography should be performed at every follow-up visit to evaluate lens centration. Lens positioning can be evaluated with axial maps but is more dramatically visualized with tangential maps. What lens modifications will improve a decentered treatment zone depend on the direction of the decentration.

- SUPERIOR decentration
  1. Increase the overall lens diameter.
  2. Increase the sagittal depth of the lens.
  3. Prescribe toric reverse and/or alignment curves to create more uniform bearing 360° around.
  4. Adjust the widths of the reverse and/or alignment curves to increase the bearing area.
- INFERIOR decentration
  1. Decrease or increase the overall lens diameter depending on the HVID.
  2. Decrease the lens sagittal depth.

3. Prescribe toric reverse and/or alignment curves to create more uniform bearing 360° around.
  4. Increase or decrease the widths of the reverse and/or alignment curves, allowing more lid control to pull the lens up.
- LATERAL decentration (NASAL OR TEMPORAL)
    - Increase the overall lens diameter.
    - Increase the lens sagittal depth.
    - Prescribe toric reverse and/or alignment curves to create more uniform bearing 360° around.
    - Adjust the widths of the reverse and/or alignment curves to increase the bearing area.

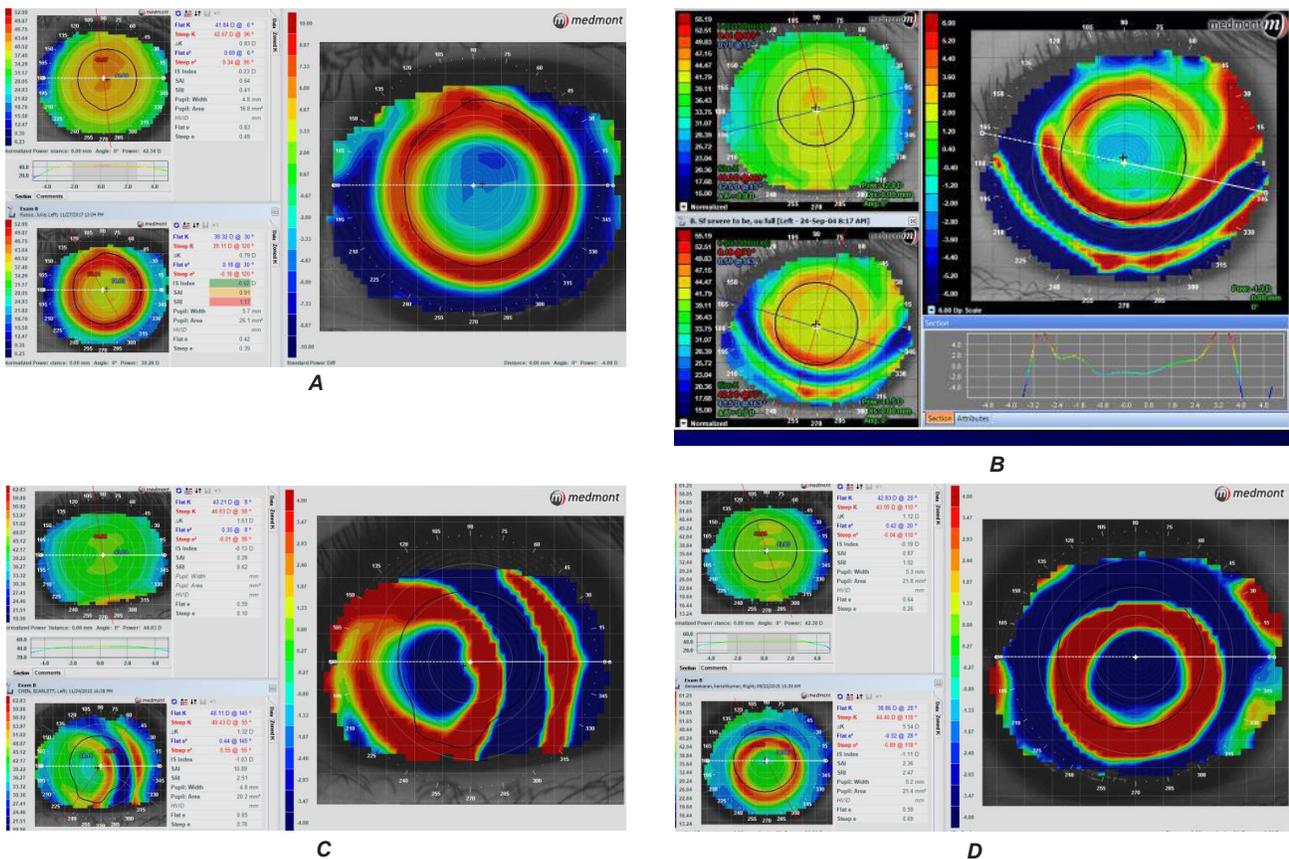
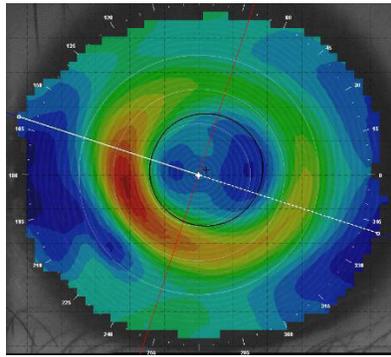


Figure 7-5. Four tangential difference maps after 1 week of OrthoK lens wear.

- A – Ideal Centration of treatment zone
- B – Superior decentration of treatment zone
- C – Lateral decentration of treatment zone
- D – Inferior decentration of treatment zone

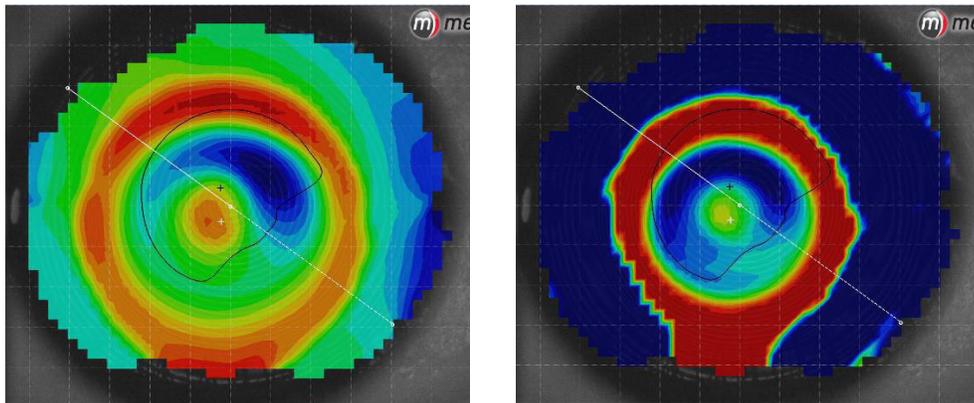
**Treatment Zone Size** – a small treatment zone can cause unwanted visual disturbances such as halos, glare and flare, which may be especially problematic for patients in low-light conditions such as night driving. A larger treatment zone size may be achieved by:

1. Using a larger optic/treatment zone.
2. Reducing the sagittal depth of the lens by reducing the depth of the reverse curve and/or by flattening the alignment curves.

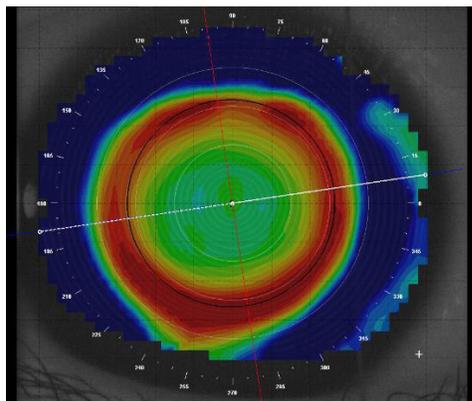


**Figure 7-6.** Post-OrthoK axial topography showing a small treatment zone that is slightly decentered

**Central Island** – This characteristic is visible on topography when there is a definite small central area of steepening within a flatter treatment zone. Central islands are caused by a fitting relationship in which there is too much sagittal depth that produces a non-uniform central tear thickness under the lens. Careful evaluation of the actual curvature of this island is necessary to determine whether it is flatter than the pre-treatment curvature. A true central island will be equal to or steeper than the original central curvature.



**Figure 7-7.**  
 Left - Post-OrthoK axial topography showing small central island  
 Right - Post-OrthoK tangential topography showing small central island



**Figure 7-8.** Post-OrthoK tangential map after lens modification to eliminate a central island

To eliminate a central island, decrease the sagittal depth of the lens by reducing the depth of the reverse curve and/or the alignment curves.

## **Corneal Staining – Superficial Punctate Keratitis (SPK)**

Corneal staining is the most common slit-lamp finding that practitioners will observe in OrthoK patients.<sup>20</sup> When evaluating the cornea in the morning after the first night of OrthoK lens wear, slight SPK can be observed in a majority of patients. Typically, this is seen as superficial keratitis that stains with NaFl. Minor staining is thought to be part of the eye's initial adaptation to overnight wear. The staining should not affect the patient's vision or comfort and generally resolves during the first week of lens wear.

If SPK is observed after one month of lens wear, it is important to identify the cause and take steps to minimize or eliminate it. Causes of chronic SPK include:

- Lens deposits
- Chemical sensitivity reaction from preservatives in lens solutions
- Debris trapped under the lens during wear (endogenous or exogenous)
- Localized area of excessive lens bearing (central or peripheral)
- Difficulty removing the lens in the morning due to dryness and/or minor lens adhesion effects

Steps to alleviate SPK:

1. Ensure proper cleaning techniques.
2. Change to a different care regimen (i.e., peroxide-based system).
3. Prescribe a preservative-free solution to use at lens application.
4. If the SPK appears to be lens-induced, reassess the fitting parameters to identify areas of excessive bearing. In cases of central SPK, it may resolve by increasing the sagittal depth of the lens. In cases of peripheral SPK, it may resolve by making the alignment curves flatter or by making the edge lift higher.
5. Some patients show significant improvement of chronic SPK with the use of preservative-free lubricating drops in the eye just prior to lens application and/or just prior to removal.
6. Use of special lens cleaning agents and protein removers (such as Menicon Progent).

## **Hyperemia**

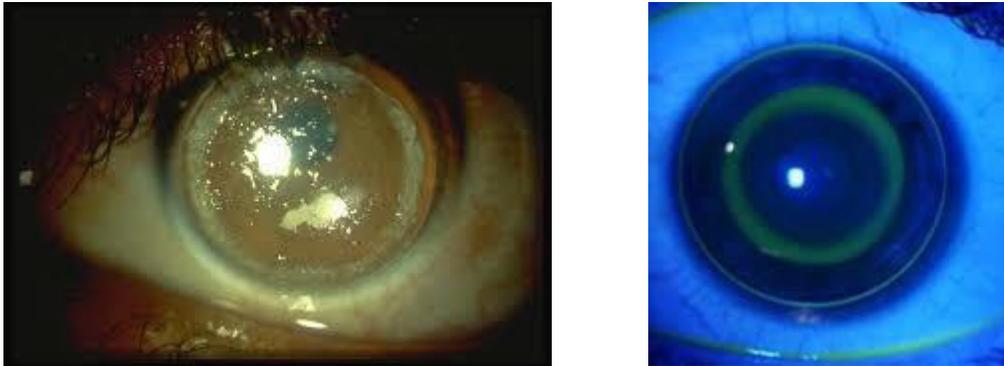
Red eyes are an uncommon finding with OrthoK lens wear. Even in patients with SPK, most patients do not show significant redness. When redness does occur, in addition to the same causes of SPK, conjunctivitis (i.e., bacterial, viral, chemical and allergic) must also be considered.

Resolution of redness includes the same possible modification mentioned above for SPK. But, if conjunctivitis is the diagnosis, careful evaluation should be done, as with any contact lens patient, to make a precise diagnosis to initiate proper treatment.

## Lens Deposits

Deposits on lenses can cause various problems during the course of OrthoK. The source of lens deposits may be the patient (i.e., protein, mucus or oils) or from external factors (i.e., makeup, makeup remover, oil-based hand/face lotions, soaps, sprays and airborne particles).

Careful cleaning after each night of lens wear is important to prevent deposits. Also, handwashing and rinsing is the first step in establishing good hygiene habits. Additional surfactants and special cleaning agents may be necessary for some patients to maintain a clean, wettable lens surface.



**Figure 7-9.**

*Left- OrthoK lens with significant anterior surface deposits. Courtesy of Bausch.com*

*Right- OrthoK lens with clean, wettable anterior surface. Courtesy of M. Lipson*

New surface treatments are available to make the surface more wettable and thus more resistant to deposition.

## Summary of Problem Solving

Alleviating undesired complications during the process of OrthoK is an art that improves with experience. Unacceptable vision, comfort or lens position can often be improved after careful clinical observation and detailed patient questioning. But, even experienced practitioners can benefit from the assistance of a fitting consultant from the lens manufacturer. When contacting the lens manufacturer/consultant, be prepared to communicate as much detailed observation as possible regarding the lens fitting characteristics and the patient response. It is particularly useful to be able to export pre- and post-treatment topography maps to the consultant for problem-solving advice.



# Chapter 8 – Practice Management

It is required that eye care professionals are trained and certified before prescribing overnight OrthoK lenses in their practice. Certification is attained from each OrthoK lens manufacturer for their specific lens design.

In addition, the practitioner and staff must take steps to ensure that they and the office are prepared and equipped to successfully offer OrthoK to patients.

## Office Preparation

As discussed in Chapter 1, OrthoK is a PROCESS. Just as we ask patients to be committed to the process, the practitioner and the entire office must embrace the process. Training and education for the practitioner and for all office personnel is essential. A successful OrthoK practice requires a thorough understanding of the physiology, science, mechanics, practical and practice management aspects of the process. In addition, as discussed previously, certain instrumentation and equipment is required and others helpful for successful OrthoK fitting.

### Practitioner Education

Practitioners have a number of resources to tap into when beginning the process of learning OrthoK. These include:

- OrthoK lens manufacturers offer online resources, lab consultants, training materials and workshops for specific lens designs
- National, regional and local meetings offer lectures, wet labs and workshops. Some include:
  - Vision By Design (VBD) – annual meeting of the American Academy of Orthokeratology and Myopia Control (AAOMC) – [www.orthokmeeting.com](http://www.orthokmeeting.com)
  - Global Specialty Lens Symposium (GSLs) – [www.gslsymposium.com](http://www.gslsymposium.com)
  - Training from private, specialty groups or individuals
- Webinars are offered by various groups/organizations
- Online Resources provide additional information, references and a library of lectures/webinars
  - Gas Permeable Lens Institute – GPLI – [www.gpli.info](http://www.gpli.info)
  - Contact Lens Manufacturers Association – [www.clma.net](http://www.clma.net)
- Colleagues/Mentors – Valuable information can be gained by talking with a colleague or friend who has experience in getting started with OrthoK

### Staff Education

While education and training for the practitioner is important, it is equally important for the office staff, receptionists, technicians and assistants.

- Educational resources for staff mirror those offered for practitioners as mentioned above
- It is critical that staff members are comfortable with all lens care and handling procedures and that they are able to convey those skills to patients. If staff members are candidates,

they should be encouraged to undergo OrthoK for themselves to experience every aspect of the process

- After the entire office team has been trained in all aspects of fitting and follow-up, ongoing in-office training is necessary to ensure that all new information and procedures are well-rehearsed and completely coordinated

## Equipment

### Mandatory

- Corneal topographer
- Diagnostic fitting lenses (if required for the chosen fitting system)
- Lens inspection devices (magnifier, radiuscope, lensometer)
- Lens care systems
- Lens accessories for lens application, removal and cleaning

### Optional

- OCT (optical coherence tomography)
- Photography – video and/or still imaging equipment
- Lens modification equipment for lens polishing
- Scan biometry

Other - Other equipment used for OrthoK is already commonly in eye care offices. It is listed here as a reference.

- Slit lamp (w/cobalt filter)
- Fluorescein strips
- Wratten filter
- Starter lens care kits
- Dedicated space in the office for lens handling education/training
- Equipment to play video instructions
- Burton lamp (handheld blue light)

## Choosing Your First Patients

Once your office and staff are equipped and prepared, consider fitting your family, staff members and their families and friends first. When they become OrthoK wearers, they become resources for referrals. It also provides potential patients with confidence when they see those close to the practitioner endorsing the process. Simultaneously, it provides the practitioner with the experience and the confidence necessary to work with patients routinely seen in the practice. However, keep in mind that, although it is convenient to fit family and staff members, they often do not possess the same motivation for OrthoK as do patients who view myopia correction with OrthoK worthy of their time and funds.

Beyond your family, friends and staff, your first OrthoK patients should be straightforward, “easy cases.” These include patients with low myopia and normal/regular topography who are highly motivated and will comply with your instructions.

## Discussing OrthoK as an Option

After your comprehensive exam and while presenting your findings, all prescription options, including OrthoK, should be presented. For example, when you have a patient such as 9-year-old “Mia,” who complains of blurred distance vision and is found to be myopic, your summary to her and her parents



*Figure 8-1. Talking with parent and child about OrthoK*

might be something like the following:

“Mia is near-sighted and needs help to see better for distance. We can do that with glasses or contact lenses worn during the day or with special contact lenses worn only while sleeping.”

Currently, many parents are not aware of OrthoK, so hearing about a mode of correction “worn only while sleeping” will usually pique their curiosity and prompt them to ask follow-up questions to learn about the details of OrthoK. This is your opportunity to describe the process and highlight the benefits that OrthoK can provide.

OrthoK can also be discussed with patients at every step of the office visit, including at the reception desk. When checking in, patients/parents can be asked routinely whether they are at the office to start the OrthoK process. If patients/parents inquire about OrthoK, it’s a perfect opening to explain the process and direct them to ask the doctor whether they may be a candidate for OrthoK. Similarly, OrthoK can be mentioned during every phone call with patients inquiring about the office or making an appointment.

During preliminary testing, technicians/assistants should ask whether patients are aware of OrthoK, suggest that they may be a candidate and direct them to ask the practitioner for more details.

## Printed Materials

Practitioners should also develop office literature/information sheets for patients to keep for their reference. Collect detailed information on OrthoK to create custom pages for your office that answer commonly asked questions about the process. Additional information sheets should provide data on research that supports the safety and efficacy of OrthoK as well as links to web sites for patients to find additional information on the process (see details below). (Appendix 2)

### **Fitting Agreement - informed Consent** (Sample - Appendix 3)

This is a critical document to have when initiating the process of Ortho K. It serves multiple purposes that will benefit the doctor, the patient and the practice by spelling out the procedural details of the process. It puts all aspects of the procedure in writing as a reference for future use. Both patients and parents should be encouraged to read and understand the entire document. In addition to the full version of the agreement, it is advisable to have a simplified version (an assent to treat) of the agreement written specifically for children. Children should be asked to read and sign the agreement to help stress the importance of their role regarding compliance and the long-term safety of the process. Its content should include:

1. Details about the diagnostic and fitting process
2. Other options for correcting vision
3. Risks and benefits of the process
4. Recommended follow-up schedule
5. Responsibilities of the doctor regarding the ongoing care of the patient
6. Responsibilities of the patient to ensure ongoing success
7. What constitutes an adverse reaction
8. What to do if an adverse reaction occurs
  - How to contact the office during office hours
  - How to contact the doctor/office after office hours
9. Fees, including details of what is included and what is not
10. Policies on lens replacement/spare lenses
11. Discontinuation of the process, including the refund/exchange policy with specific times and amounts
12. An acknowledgment that they have read, understand and agree to the terms spelled out in it

### **QA Sheet** (Appendix 4)

A customized collection of commonly asked questions with detailed answers might include:

- How OrthoK works
- How lenses are worn
- Background on the process
- Costs

- Safety
- Web sites for additional info

**Summary of Clinical Studies** – with references, if desired, that discuss the procedure’s:

- Safety
- Efficacy
- Myopia Control Discussion of Fees

## Discussion of Fees

Each practice should set its fees for OrthoK at a level that reflects the value of the service to the patient and to the practitioner. Some practices establish a global or “package” fee that includes all OrthoK-related services for a specified period of time, while others have elected to itemize the services on an individual basis. In addition, each practice must decide on whether all OrthoK patients should have the same fee or whether they choose to have tiered levels of fees based on the complexity of the case.

Considerations in determination of fees include:

- Total chair time required for standard OrthoK fitting
  - Comprehensive baseline exam
  - OrthoK fitting and dispensing
  - Instruction on lens handling and care
  - Follow-up visits for a designated period of time (3-12 months)
- Topography at every visit and any other diagnostic testing
- Lens Fee (some offices include a spare pair)
- Expertise and specialized training of the practitioner and office staff
- Responsibility that the practitioner assumes for the eye health of the patient

Fees should also be clearly outlined in the fitting agreement and should provide the following information:

- What is included. Examples of what may be included are office visits directly related to OrthoK, testing, procedures, lenses, lens exchanges
- What is not included. Examples of what may not be included are office visits unrelated to OrthoK (i.e., injury on the soccer field), broken lenses, lost lenses
- For what time period. For each of the services included, a specified time period must be defined. For example, you might say that office visits directly related to OrthoK are included for X months after the start of OrthoK. Or, that lens exchanges to improve the vision or fit will be done without additional charge during the first X months after starting OrthoK.
  - Annual Service Fee

Some offices have developed an annual service fee for ongoing care of OrthoK patients that includes a specified number of routine visits (i.e., comprehensive annual visit and a brief check at 6 months) and

new lenses. Some practitioners feel that using the annual service fee encourages better compliance with practitioner recommendations for follow-up because the fees are paid ahead of time. Others will continue on a fee-for-service basis in which charges are made for the exams and lenses at the time they are done.

## Practice Management

Fitting patients with OrthoK lenses that exhibit ideal centration and provide excellent unaided vision requires a grasp of various clinical skills. Managing the patients, parents and office requires a completely different set of skills.

### Managing Patients

At the initial fitting (see Chapter 3), patients starting OrthoK, especially children, need reassurance that you will be there for them to teach them the skills to care for and handle their lenses and that you are committed to their success. Patients need to know:

- What to expect from OrthoK in terms of vision, comfort and appearance
- When to contact your office and what to look for to monitor their vision and eye health status
- What OrthoK does so that they can tell their friends about the special process they are undergoing
- The potential for complications and compliance with prescribed follow-up care

### Managing Parents

Parents need to know:

- That you are committed to the eye health and safety of their children's eyes
- What to expect from you and your office
- What to expect from their child
- What services are covered by the fees they pay and what services carry additional fees



**Figure 8-2.** Scheduling appointments for OrthoK patients requires careful planning to maintain a smooth office and patient flow

## Managing the Practice

- OrthoK is different from other vision correction options, and managing it in practice is also different in the following ways:
- Managing an OrthoK practice requires special care and preparations.
- Scheduling considerations – allocating time in the daily schedule for OrthoK consultation visits, initial exams, instructional sessions, follow- up visits and urgent visits is different than for other types of visits.
- Presentation of fees and policies is different than for traditional contact lenses and glasses.
- Answering inquires about OrthoK takes special training for all office staff.

## Summary of OrthoK

### Advantages of OrthoK

- No correction needed during waking hours <sup>18</sup>
- Less symptoms of dryness/discomfort compared to soft lenses <sup>18,28,29,30</sup>
- Fewer activity restrictions <sup>18,28,29,30</sup>
- More self-confidence <sup>18</sup>
- Reversible and adjustable <sup>20,21,22</sup>
- Temporary (can go back to original rx) <sup>20,21,22</sup>
- May slow myopia progression in children <sup>40,41,42,46,47</sup>

### Disadvantages of OrthoK

- More spherical aberration/Increased night glare <sup>26,27</sup>
- Potential for vision fluctuations <sup>18</sup>
- Requires consistent wearing time
- Temporary – requires ongoing lens wear <sup>20,21,22</sup>

### Potential Risks with OrthoK

- Corneal irritation/abrasion <sup>23,24</sup>
- Infection <sup>23,24</sup>

### OrthoK Compared to Other Refractive Options

- Better vision-related quality of life (VR-QOL) compared to glasses and soft lenses <sup>3,28,29,30</sup>
- No correction needed during waking hours
- Comparable visual acuity to soft lenses <sup>3,18</sup>
- Comparable VR-QOL to LASIK <sup>43</sup>
- Comparable subjective visual acuity to LASIK <sup>43</sup>
- Fewer activity restrictions than with contact lenses worn during the day or glasses <sup>3,28,29,30</sup>

As OrthoK becomes more popular with patients and practitioners, more research continues to be performed on all aspects of the process. In addition, new designs and materials are being developed to improve outcomes. As stated in a summary article by Cho et al. from 2008 that still holds true today, “It is therefore important that practitioners keep abreast of latest developments in OrthoK and continue to improve their OrthoK practice to provide quality service to their patients.”<sup>44</sup>

Educational programs and new studies are ongoing. Attend these programs to stay informed as to the latest findings and clinical practices. An impressive review article by Nti and Berntsen<sup>45</sup> on OrthoK was recently published that summarizes the scientific literature involving all aspects of OrthoK.

OrthoK brings impressive benefits to patients but carries with it small risks. Learn as much as you can, stay informed and keep up with new technology. ENJOY !!

#### Appendicies

- Listing of OrthoK designs
- Sources for additional information and studies
- Sample fitting agreement/assent
- Question and Answer Sheet
- Myopia management discussion

# Chapter 9 – Roundtable Discussion

Panel Discussion By World-Renowned Experts on the Use of OrthoKeratology for Managing Myopia and Myopia Progression

In June of 2019, a panel discussion on the use of OrthoKeratology to manage myopia and myopia progression took place. The following is a transcript of that discussion. It includes the state of evidence-based studies and personal experiences on this topic.

## Participants

Michael J. Lipson OD FAAO FSLs – moderator

Maria Liu OD PhD MPH MBA FAAO – Associate Professor, University of California, Berkeley

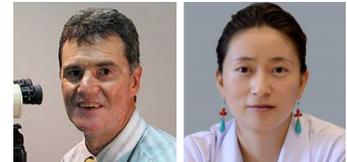
Russell Lowe OD FAAO – Professor, University of Melbourne, Australia

Earl Smith OD PhD – Professor and former dean at University of Houston, College of Optometry



*Michael*

*Earl*



*Russell*

*Maria*

## Michael:

My name is Michael Lipson. I'm an associate professor at University of Michigan. I'll be moderating this discussion tonight and I have experience in clinical research as well as clinical care. We also have Earl Smith with us, professor, former dean at University of Houston and a pioneer with studies on the optical and environmental effects on change in axial length. Russell Lowe, a professor at University of Melbourne, Australia. He's a clinician and a researcher and we're also lucky to have Maria Liu, associate professor, University of California Berkeley. She's also the director of the Myopia Clinic at University of California Berkeley. Welcome. And I feel honored to be gathered with you as friends and colleagues to discuss the role of Ortho K in managing myopia progression with you tonight. I thank you for taking time from your busy schedules to share these experiences and your expertise. So let's start with you Earl. Your animal studies kind of set the stage for the clinical practices that we're prescribing today in the clinic. Your studies have influenced where Ortho K fits into the current myopia management picture.

## Earl:

Well, let me just start by saying it's not just our research. It's research in laboratories around the world using a variety of different animals. And the research in large respect is very much in agreement. It shows some fundamental things about the mechanisms that regulate eye growth. And all of our current optical treatment strategies that we use in myopia management essentially rely on the operational properties of these mechanisms. And the key properties that are important for myopia management is that we know that axial length growth is regulated by the eyes effective refractive status. In essence, optical defocus. And in particular we know that imposed myopic defocus can actively slow eyeball growth, reduce myopic shifts and in some cases actually produce hyperopic shifts. And we also know that visual signals from the periphery influence this because the periphery of the eye is so much larger than the central retina.

**Earl:**

Visual signals in the periphery can dominate and all of our optical treatment strategies, and in particular Orthokeratology, takes advantage of that. Orthokeratology by the nature of the corneal changes that are produced imposes myopic defocus, primarily in the periphery depending on where the treatment zone starts. But the key thing is, it produces a high amount depending on the refraction, but it can produce a very high amount. And if it's inside the pupil you produce competing, simultaneous defocus across the entire eye, a myopic defocus which is a very, very strong signal for inhibiting growth. I think that is one of the things, there are a couple things, I think that stand out about Orthokeratology in terms of optical management.

**Earl:**

Another thing that is important with Orthokeratology is that, that the therapeutic optical effects are in place all day long. It's constant. But I think equally important is the optical treatment effects of Orthokeratology are fixed on the eye. So as the eye looks around the world, the optical treatment zone and its changes in power don't move relative to the visual axis, and that allows the eye and the brain to adapt very rapidly to what would be very disturbing. In contrast, similar optical effects in a spectacle lens would be very difficult to adapt to. So there's a lot of advantages about Ortho K, but the key point is that it produces myopic defocus, a lot of it over a large part of the eye.

**Michael:**

That's great. We're going to circle back to that in a few minutes because that's going to become important for some of the later discussion. But I'd like to move on a little bit right now with Russell. You have clinical experience and research results that really support the use of Ortho K on a clinical basis in kids. Now in a clinical setting, when do you start discussing or prescribing Ortho K? Is there definition by age or by level of myopia or even the family history?

**Russell:**

Michael, I discuss treatment options for myopia management with all young myopes and the families and the conversation is generally biased toward OrthoK being the premium treatment that we offer at our office. Both age and level of myopia are key considerations but they are not absolute deal-breakers, per se. We have found that some very young patients, even as young as five or six years, can sometimes be excellent candidates for OrthoK whereas older children at age nine or ten may be less suitable for a variety of reasons that may relate to personality, parental support and a host of factors really.

**Russell:**

I generally prefer to delay instituting OrthoK treatment until the manifest myopia is greater than one diopter or 1.50D. I think it's important that the child becomes aware of the significant improvement in their unaided visual acuity with the treatment. The positive reinforcement of improved unaided eyesight gives the reward for effort

**Michael**

In other words, they can appreciate the bigger difference in post-treatment vision vs. pre- treatment vision.

**Russell:**

Yes. We have an imperative to treat myopia as early as possible but with OrthoK, that's not always practical in my opinion.

**Michael:**

Okay. Well that leads into some of the other modalities that we might prescribe for patients. And Maria has worked with various modalities in managing myopia progression. And I guess for you, Maria, the question might be, what kind of scenarios or what type of patients do you prefer to prescribe Orthokeratology for myopia management?

**Maria:** So if I was the one making the decision, I certainly would prefer fitting patients with OrthoK with relatively lower level of myopia compared to prescribing daytime multifocal soft lenses. And age wise I tend to feel a little bit more comfortable fitting Ortho K lenses in younger children compared to daytime lenses because that really requires the complete independence of handling the lenses without parent's guidance. And in terms of decision making, it's really not my preference but I do feel a very strong predisposition to Ortho K lenses from Asian ethnicity, especially parents as first generation immigrants.

**Michael:**

Okay.

**Maria:**

And I do want to make a special note. We have heard from multiple conferences that some people are saying, Ortho K lenses do not control myopia at a lower level of myopia as effectively as compared to a moderate level of myopia. Because theoretically speaking for each diopter of a central corneal flattening, we can only achieve a one diopter of a paracentral steepening, which is the myopia retardation dosage. This is actually not true. By choosing different designs, by manipulating the parameters of the lenses, we're able to achieve different levels of paracentral steepening where the amount of myopic defocus with the same level of central corneal flattening, and certainly with our data from Berkeley Myopia control clinic, we're not seeing Ortho K being less effective in controlling progression of myopia in a low myope.

**Michael:**

Well, that's great. I think that's important information for all of us to know because sometimes we hear a lot of this at the meetings and start to accept it. So it's good to hear that you have experienced that even the low myopes in Ortho K are showing significant management of their myopia progression. Basically, one other issue is, how do we really monitor myopia management techniques that we are using like Ortho K? Meaning I'd like each of you to share your thoughts on the efficacy of Ortho K to slow the refractive changes as well as axial length changes. And any one of you can enter in here.

**Earl:**

Okay.

**Michael:**

Earl, go ahead.

**Earl:**

There is a large and growing body of evidence that clearly shows that Orthokeratology most importantly slows axial elongation rates; refractive errors are less often reported in Ortho K studies of course because of the alterations in corneal power that actually produce the improvements in vision in a myopic child.

**Michael:**

In other words, we'd have to have the patients stop wearing lenses to really get a true refractive assessment.

**Earl:**

Yes, that's it. But the most important thing is I think everybody agrees that the reason we want to slow the progression of myopia is that as the eye becomes longer, there are structural changes that put the eye at risk for a variety of conditions that can cause significant visual impairment, permanent visual impairment. So limiting axial elongation rates are really what we want to do.

**Michael:**

Okay. Russell, do you have anything to say on that?

**Russell:**

Yes, Michael. From a clinical perspective, it's very difficult to get a firm handle on the efficacy of any individual treatment. Overall, we rely on limited evidence from a relatively small number of clinical studies mostly conducted over a relatively short time frame. However, when it comes to the patient in your chair, you don't know the rate at which that patient may progress without OrthoK treatment. Patients who show active progression during Ortho K treatment may have progressed at a much faster rate without that treatment. We tend to assume that the patient has been less successful but we do not have access to a valid comparator. We then have to manage the expectations with the patients and their parents.

**Michael:**

Okay. Great point.

**Russell:**

You have to have confidence in the chosen modality. It is the best treatment we can offer within the constraints of our current knowledge. And if I can just add another point to the discussion, safety and efficacy often tend to be discussed as separate issues in contact lens care in general and in OrthoK in particular. I think, in reality, these two important aspects of treatment are very closely linked.

**Russell:**

Patients who comply fully with our safety instructions for lens care and hygienic lens handling methods usually achieve higher levels of unaided visual acuity from day to day and they exhibit well developed

topographical map patterns. If we can succeed in motivating patients to be more compliant with the instructions for lens care and management we will simultaneously promote a greater chance of improvement in the longer term efficacy.

**Michael:**

That's a great point. Thanks for the clinical perspective on that important issue. Maria, I think you can also talk to the point about monitoring axial length increases. After you discuss that, it might also be a great segway to a discussion on your experience and research on the overall safety of Ortho K.

**Maria:**

So I want to add a little bit more about the evaluation of the efficacy of Ortho K in myopia control. I do believe we need to have both refractive data and the axial length data because they're actually giving us slightly different information. Refractive data certainly is cleaner. There is a pretty strong association between the level of myopia and the risk of a related complications. While the axial length is the most direct variable related to excessive scleral stretching, its correlation with refractive change is confounded by the physiological axial growth seen in younger myopes. More specifically, in younger age, especially if we're talking about an age range of six to 10 years old, the data tends to be a little bit noisy. And that is because at that age, the ocular structure is still undergoing a lot of physiological change.

**Maria:**

So the overall axial length is probably a combined product from an overall growth of the eyes that's not related to myopia progression (ie. age-related physiological growth) as well as the myopia progression related axial elongation. So that may actually add some noise in really helping us quantify the exact efficacy in myopia control. So every year when I talk to parents about the exact efficacy of Ortho K lenses in controlling their children's myopia, I tend to present both refractive data and the axial length data to hopefully let them understand at this point, just seeing a certain level of axial length elongation doesn't necessary mean there is a definitive myopic progression.

**Michael:**

And how are you defining or how are you assessing refractive data in your Ortho K patients?

**Maria:**

So there are several things we can do. Obviously, the most accurate way of doing refractive data would be the auto refraction over their own lenses or over our trial lenses of the same base curve. I've used that as the most objective way of looking at their refractive data.

**Michael:**

Okay. And then if you can kind of jump into the safety issue that Russell started talking about. You published a study a few years ago, a meta-analysis study on safety of Ortho K. Can you comment on that?

**Maria:**

So long term safety of Ortho K lenses certainly has to have combined efforts from three different directions. The number one factor deals with proper fitting of the lenses. The improper selection of the lens parameters significantly reduced the safety of long-term lens wear. This is actually happening a lot in China. The Ortho K practitioners in China, their level of training, level of experience and varies so dramatically that you will see some very experienced doctors pretty much having a very good understanding of almost all of the designs available on the market, versus some other doctors treating thousands of patients without really understanding what they're doing. So the proper fitting, proper parameter selection is the number one key factor.

**Maria:**

And the second key factor is the compliance from the daily application and removal as well as the maintenance of the lenses. And the third important factor is the adherence to the routine follow ups. This is also seen in more of the cases I see in China. It's not uncommon for patients to be fitted with Ortho K lenses, graduated from this fitting program and not coming back for follow up for a couple of years. And usually those are the cases that if you hear from the patients or parents, there are usually some serious events going on.

**Michael:**

Okay. I think in talking, I'd like to address this conversation to a doctor who is about to consider taking on Orthokeratology to manage myopia progression. I hear two concerns from new practitioners. Number one, it's a lens that's worn while sleeping, and number two we're working primarily with children. So safety certainly has to be of high priority. How would you address that to a potential doctor who is about to undertake Ortho K? Either Earl or Russell, do you want to comment on that?

**Earl:**

Maria or Russell. I'm not the right person for that one.

**Michael:**

Okay.

**Russell:**

There are a number of attendant risks associated with any contact lens system that involves overnight wear. There are potential lens contamination issues associated with handling and placement onto the eye shortly before going to sleep. On the other hand, those risks are reduced with GP lenses compared to soft lenses. Overall the evidence suggests overnight Ortho K has about the same risk of microbial keratitis as daily wear of soft contact lens being in the order of about three or four per 10,000 eye years. That is a great safety record with OrthoK but we have to work hard to achieve it. As Maria said, an essential part of it is regular follow-up.

**Russell:**

On the topic of safety, I am a great advocate of safe lens removal, a frequently overlooked aspect of care. It's important to ensure That the lenses are not bound to the ocular surface upon waking before attempting lens removal. I make a point of advising my patients at routine follow-up visits. They

should first look closely at their eyes in the mirror and if necessary, instill a lubricant eye drop into the eye and gently nudge the lens using the lower eyelid margin to release the binding before removal. I've seen one or two patients develop pain to the point of wanting to discontinue treatment simply because of not knowing how to remove the lenses safely.

**Michael:**

That's a great point regarding safety. I guess I can relate my own personal experiences here is that when I talk to patients as well as other doctors, I certainly can report on the studies that are out there in terms of the safety record that Ortho K has had, which is very, very good. But I also try to relay my own personal experiences in our practice, which basically reiterates what you were saying. As long as we have a patient who is really compliant with the care of the lenses, following our instructions and coming in for follow ups that we have really not had any serious problems. So that's great. Maria, any other comments before we leave this topic?

**Maria:**

Yes. So I have two more points to add. The first point is, some parents or some doctors are confused between the extended wear of soft lenses versus the overnight wear of Ortho K lenses. Even though Ortho K lenses are worn overnight, the eyes are taking a good break during the day. This is very different than wearing the soft lenses nonstop for seven days or even longer. Additionally, my most important recommendation for the practitioners who just started fitting Ortho K is to start with low prescription. The higher the myopia, the more challenging the fit is and it's more challenging for the long term fitting consistency and the centration of the lenses.

**Maria:**

This is something that's happening more in China because China currently does not have any other alternatives such as topical Atropine of various concentrations or daytime multifocal contact lenses. As a result, a lot of parents are electing to fit their kids fitted with OrthoK even though the prescription is really high. And I see a lot of doctors are fitting Ortho K lenses even with a prescription of -8D or even -10D. Again, the recommendation I would like to give to the beginning practitioners is to start with low prescription. And certainly, that's going to drastically improve the safety of OrthoK lens wear.

**Michael:**

That's great. Thank you. Those are important points that are important clinically. I hear these kinds of question very often from practitioners that do not currently fit OrthoK. Also I think while we're on this topic, related to this, as patients are hearing about OrthoK for the first time, discussions regarding the risks of Ortho K versus the potential benefits of Ortho K come up. I think one other thing I'd like to discuss tonight is not only the risks of Ortho K versus the benefits, but the risks of not doing any form of myopia management and the discussion that we have with our patients on that. I know Earl you're a little less clinically oriented right now but Russell or Maria, please chime in on that.

**Russell:**

Many families who are referred to my clinic seem to have a good idea in advance that it's important to try to limit the myopia and they refer to it as keeping "the degree" as low as possible. But they do not fully understand why. So I like to tell them a little about myopia being the consequence of unwanted

growth of the eyeball. And why it's important to try to reduce or prevent further elongation or growth of the eye. I do my best to avoid making it sound too scary.

**Russell:**

The aim is to encourage patients to pursue a treatment for their personal benefit. But we don't want to frighten people into treatment. The message, although well intended, needs to strike a balance. For example, a large increase in the relative risk of an uncommon occurrence may be insignificant and needs to be put into perspective by also quoting the absolute risk. Does that make sense?

**Michael:**

Yes, good point. I think one of the studies that gets quoted often at meetings is that the projection is that if we were to slow myopia progression by 50%, which Ortho K usually is able to get close to, that would result in about 90% less high myopes, less patients developing this high myopia. And I think that can be a strong message to parents. This relates to what you were saying.

**Maria:**

Michael, can I add one more thing?

**Michael:**

Sure. Go ahead.

**Maria:**

Yeah. So in terms of this risk benefit analysis, we also need to take a look at the opportunity cost or the relative risk of prescribing conventional single vision spectacles. Are we really doing no harm by fully correcting myopic children with the conventional design, single vision spectacle, and especially as those with higher prescriptions? We all know just from the inherent nature of the spectacle design with negative lenses, the higher the prescription, the more negative power it has in the periphery of the lenses. And combined with a relatively more prolate shape of the eyeballs in higher myopes, those two factors will actually induce a lot of hyperopia in the periphery when the central vision is fully corrected. And from animal and experimental myopia models, we know that hyperopic defocus, whether it's imposed throughout the whole retinal field or, it's only to the peripheral retinal field, is a trigger for accelerated eye growth. So we really need to think back in asking ourselves, are we actually doing no harm by fully correcting a myopic child with conventional single vision spectacle.

**Michael:**

Okay, that's a good observation that most practitioners can relate to. I think going back to what you said before relative to the patient's awareness of this, whether it be their ethnic background that they're more familiar with managing myopia progression and exposing Ortho K to new patients who have never heard of it before, sometimes can be a little overwhelming to these patients.

**Maria:**

Exactly.

**Earl:**

I think Russell is right. You don't want to frighten people, but this is a public health issue and reducing the progression rate will go a long way to increasing the likelihood that your patients will have good vision for a longer period of their lives. And that's something that we can't lose sight of and you have to think of a way to emphasize that issue to the decision-makers in health care administrations. In particular, that preventative management techniques can have very long term and very significant potential public health benefits for the patient.

**Michael:**

Those are great points because I think the perception publicly is that myopia is more of a nuisance whereas we know from what we have seen in our patients and what we have read in the studies, that myopia truly is a disease process and that predisposes patients to very serious vision threatening complications later in life. So the public health issue becomes more important as the prevalence of myopia becomes greater and these kids are becoming myopic much younger. In my practice, I tend to discuss one other issue that I talk about with patients besides myopia management. I've done studies on vision-related to quality of life. While these kids are enjoying the myopia control or myopia management benefits of Ortho K, they're also enjoying the freedom from their vision correction during the day. Also, their eyes seem more comfortable and they have other less tangible benefits like less worry, less activity restrictions and a little more self-confidence. So I don't know if any of you have clinical stories about these kinds of issues that have come into play with your patients. I certainly do. Russell?

**Russell:**

The standout scenario for me was a 14 yr old female whose family had recently immigrated to Australia from China. The parents wanted their child to be treated with OrthoK and had avoided spectacle correction for fear that the glasses would damage their daughter's eyes. Turns out she was -8.00D R and L with no previous correction! You can only begin to imagine the change in this young person's life with OrthoK partial correction in the order of -6.50D in each eye.

**Russell:**

Many of our young patients tell us before they commence treatment that they rarely wear their glasses. They maybe put them on when they need to in the classroom. But often times they don't wear their glasses in a social context. They prefer not to. They prefer to promote the look of not having to rely on glasses.

In terms of quality of life, I think we have very happy patients and families as well. The parents are happy. Children continue OrthoK as adults because they've been in treatment for such a long period of time, well over 10 years in a number of cases with some approaching 15 years of treatment. And many of these successful children have no intention of moving on to any other modality in the future, as long as they can continue with their OrthoK, that's the way they want to continue throughout life.

**Michael:**

I agree. Anything else on that Maria?

**Maria:**

Yeah. So I just have one more thing to add. In addition to the profound impact on the children's self-esteem, improving the blurry vision and the dependence on optical corrections, I do have to say at least in China, this is a very unique thing. Being myopic in the early developmental stage significantly limits, students career choices and a lot of students self-selected out of certain occupations because they have blurry vision. And in China, for example, if you want to become an employee of a government agency, you'll have to have certain level of uncorrected vision. This is a very unique and interesting requirement from Chinese government. And so a lot of students are actually undergoing refractive surgery prematurely even knowing that their prescription is still changing. They do so just to satisfy the requirements of those career choices. And I've had so many patients wearing OrthoK lenses feeling so grateful that they don't have to actually go into a permanent treatment but still able to actually meet the requirements for those types of career selections.

**Michael:**

Oh, that's great. I think more and more of that is going to present in the United States as well. We're seeing more of that now anyways. I don't know if there are other points that we need to make on this right now, but Ortho K really is something that personally I'm confident talking to patients about in terms of the efficacy in providing good vision and the efficacy of slowing down myopic progression. Earl you commented on something that I have felt very strongly about over the years, which is that with Ortho K, the optical effects we create are in play 100% of the time. They're always there whereas with soft lenses, you may get different kinds of distortions and patients can not necessarily wear the soft lenses all their waking hours.

**Earl:**

Well I think one of the things, I'm not sure I explained this well, but the optical effects are fixed in place on the cornea. So when the eye moves, the cornea moves with it. And so the treatment zone moves with the line of sight. Whereas if you have a contact lens, even a relatively tight fitting contact lens, the lens is going to move. And so if you have a treatment zone, it's position can vary, the pupil is going to change size and position. That doesn't necessarily deter you from wearing the lens but it can interfere with vision.

**Earl:**

And I can guarantee you if you try to design a spectacle lens that would produce the same optical effect as Ortho K you'd have a lens that no one could wear because you'd have variations in spectacle magnification across the entire field. And so eye movements or head movements would cause differential movement across the visual field, whereas with Ortho K, that's not the case. The brain adapts exceedingly rapidly to things that are very constant over time. And so I think one of the reasons Ortho K is very much accepted, despite the fact that the optical profiles are really interesting, is that the brain basically adapts because those changes in optics are constant over time.

**Michael:**

Very well stated, thank you for clarifying that. I don't know if there are other factors, but as an overall summary, what we've talked about tonight suggests that Ortho K is safe. It does significantly slow myopic progression and axial length increases, and it's a good alternative to glasses and contact

lenses as a refractive correction. So I think it's going to show continued growth and continued use in terms of managing myopia and as an alternative to glasses and contacts. If any of you have other burning points relative to Ortho K and how it can be used to manage myopia progression in kids and why it's an advantage, I would like you to summarize your feelings on that now.

**Russell:**

Michael, I would like to add one further point. Brien Holden reminded us that 25% of progressive myopes worldwide are normally sighted at age 20 years. In other words, late or adult onset myopes are a significant group of people. They are often highly motivated and they are often outstanding candidates for Ortho K. So it's not just about the kids. We have slightly older folks out there that stand to gain from limiting myopic progression.

**Michael:**

Okay. So just to clarify, that was 25% of adult myopes have normal vision at what age?

**Russell:**

At 20 if I remember correctly. It has become a surprisingly large subgroup of myopes.

**Michael:**

Wow.

**Russell:**

We tend to forget about late onset myopia, but it's a significant subgroup of myopia.

**Michael:**

So it's not just for little kids then.

**Russell:**

Not exclusively for little kids.

**Michael:**

Okay.

**Maria:**

Michael, I have another point to add.

**Michael:**

Good, go ahead.

**Maria:**

Which is not related to patients for practice management. I do want to make sure we are all making harder effort in training practitioners at earlier stage of their career. Currently Ortho K practice is considered as an advanced contact lens specialty. And most of third and fourth year OD students do not get much exposure in fitting or doing follow-ups on Ortho K patients. I do believe we really need to

expose optometry students as soon as they are engaged in clinic or even trying to provide workshops for them so that they can actually fit each other and gain experience with these really fascinating lenses and treatment as early as possible in their career.

**Michael:**

Okay. I think what you are saying is that Ortho K needs to establish itself as a solid subject in the curriculum.

**Maria:**

Yeah, I think it does need repeated exposure at different level from observational, from personal wearing experience and from fitting the lenses with guidance until they can fit the lenses and perform troubleshooting independently. It does take repeated exposure for someone to achieve a comfortable level of fitting the lenses. And I think our current way of training Ortho K practitioners in US could be improved by given interns earlier and repeated exposure.

**Earl:**

I think a key point there is that Orthokeratology should be mainstream. It's not something that should be relegated to specialty practices. It is something that is one of a few techniques that have been proven to be effective in managing myopia progression. And that's so important that I really agree with Maria. This is something where the schools need to up their game a bit and ensure that their students are getting those kinds of experiences so they're confident that they can do that when they graduate.

**Michael:**

I think that's a great point. I would love to see that happen. I'd love to be part of that somehow to get the schools to establish Ortho K as a mainstream part of the curriculum and as a part of our profession. But the schools are under a time constraint. I know the earlier we're involved, the better. But obviously if the schools make time for Ortho K in the curriculum they've got to take it from somewhere else.

**Earl:**

That's always the challenge. And you see every school moving in the direction of having myopia management clinics and that is becoming the rule and it's something that is terribly important for our profession to embrace.

**Michael:**

Wow. I think you guys have made really good points here, and I think it establishes that Ortho K is a valuable part of managing myopia and probably in my mind it's the preferred modality right now although even with other modalities that are in use, OrthoK has significant advantages both with efficacy, safety and compliance.

I really want to thank each of you. The information you discussed has provided some great insight into Ortho K and its use in managing myopic progression. If you have any other points to make, now's the time to do it.

**Earl:**

I'm good.

**Russell:**

I'm good. Thanks Mike.

**Maria:**

Yeah, I'm good too.

**Michael:**

Thank you very, very much. I appreciate your time and efforts on this and we'll be talking to each of you very soon.

**Michael:**

Great group and good friends. Thank you.

**Earl:**

Bye now.

**Maria:**

Bye.

**Michael:**

Goodnight and Thank you!

**Russell:**

Bye from me.

# References

1. Jessen\_G, "Orthofocus Techniques," *Contacto*, 1962;6:200.
2. El Hage\_S, "Photokeratoscopy and Controlled Keratoreformation," paper presented at the International Symposium of Ophthalmological Optics, Tokyo, Japan, May 1978.
3. Lipson MJ. Long-term Clinical Outcomes for Overnight Corneal Reshaping in Children and Adults. *Eye Cont Lens*. 2008;34:94-99.
4. Bullimore MA, Sinnott LT, Jones-Jordan LA. The risk of microbial keratitis with overnight corneal reshaping lenses. *Optom Vis Sci* 2013;90:937–944.
5. Liu YM and Xie P. The Safety of Orthokeratology—A Systematic Review. *Eye Cont Lens* 2016;42: 35–42.
6. Holden BA, Fricke TR, Wilson DA, et al. Global prevalence of myopia and high myopia and temporal trends from 2000 through 2050. *Ophthalmology*. 2016;123(5):1036-1042.
7. FrenchAN, Morgan IG, Burlutsky G, et al. Prevalence and 5- to 6-year incidence and progression of myopia and hyperopia in Australian schoolchildren. *Ophthalmology*. 2013;120:1482–1491.
8. Vitale S, Sperduto RD, Ferris FL III. Increased prevalence of myopia in the United States between 1971–1972 and 1999–2004. *Arch Ophthalmol*. 2009;127:1632– 1639.
9. Jung SK Lee JH Kakizaki H Jee D. Prevalence of myopia and its association with body stature and educational level in 19-year-old male conscripts in Seoul, South Korea. *Invest Ophthalmol Vis Sci* . 2012; 53: 5579–5583
10. Holden BA, Jong M, Davis S, Wilson D, Fricke T, Resnikoff S. Nearly 1 billion myopes at risk of myopia-related sight-threatening conditions by 2050 - time to act now. *Clin Exp Optom*. 2015 Nov;98:491-493.
11. Flitcroft DI. The complex interactions of retinal, optical and environmental factors in myopia aetiology. *Prog Retin Eye Res*. 2012 Nov;31:622-660.
12. Caroline, PJ. Contemporary orthokeratology. *Cont Lens Ant Eye*. 2001;24:41 – 46.
13. Swarbrick HA, Wong G and O'Leary DJ. Corneal Response to Orthokeratology. *Optom Vis Sci*. 1998;75:791-799.
14. Haque S, Fonn D, Simpson T and , Jones L. Corneal and Epithelial Thickness Changes After 4 Weeks of Overnight Corneal Refractive Therapy Lens Wear, Measured With Optical Coherence Tomography. *Eye & Contact Lens*. 2004;30: 189–193.
15. Reinstein DZ, Gobbe M, Archer TJ, Couch D, and Bloom B. Epithelial, Stromal, and Corneal Pachymetry Changes during Orthokeratology. *Optom Vis Sci*.2009;86:E1006-E1014.
16. Yoon JH and Swarbrick HA. Posterior Corneal Shape Changes in Myopic Overnight Orthokeratology. *Optom Vis Sci*. 2013;90:196-204.
17. Charm J. Orthokeratology: clinical utility and patient perspectives. *Clin Optom*. 2017;9:33-40.
18. Lipson MJ, Sugar A, and Musch DC. Overnight Corneal Reshaping versus Soft Disposable Contact Lenses: Vision-Related Quality-of-Life Differences From a Randomized Clinical Trial.

Optom Vis Sci 2005;82:886–891.

19. Kobayashi Y, Yanai R, Chikamoto N, et al. Reversibility of Effects of Orthokeratology on Visual Acuity, Refractive Error, Corneal Topography, and Contrast Sensitivity. *Eye Cont Lens*. 2008;34:224-228.
20. Barr JT, Rah MJ, Jackson JM, et al. Orthokeratology and corneal refractive therapy: A review and recent findings. *Eye Cont Lens*. 2003;29:S49 –S53.
21. Soni PS, Nguyen TT, Bonanno JA. Overnight orthokeratology: Refractive and corneal recovery following discontinuation of reverse geometry lens. *Eye Cont Lens* 2004;30:254 –262.
22. Barr JT, Rah MJ, Myers W, et al. Recovery of Refractive Error After Corneal Refractive Therapy. *Eye & Contact Lens*. 2004;30:247–251.
23. Dart JK, Radford CF, Minassian D, et al. Risk Factors For Microbial Keratitis With Contemporary Contact Lenses: A Case-Control Study. *Ophthalmology* 2008;115:1647-1654.
24. Morgan PB, Efron N, Hill EA, et al. Incidence Of Keratitis Of Varying Severity Among Contact Lens Wearers. *Br J Ophthalmol* 2005;89:430-436.
25. Schein OD, McNally JJ, Katz J, et al. The Incidence Of Microbial Keratitis Among Wearers Of A 30-Day Silicone Hydrogel Extended-Wear Contact Lens. *Ophthalmology* 2005;112:2172-2179.
26. Berntsen DA, Barr JT and Mitchell GL. The Effect of Overnight Contact Lens Corneal Reshaping on Higher-Order Aberrations and Best-Corrected Visual Acuity. *Optom Vis Sci* 2005;82:490–497.
27. Hiraoka T, Okamoto C, Ishii Y, et al. Mesopic contrast sensitivity and ocular higher-order aberrations after overnight orthokeratology. *Am J Ophthalmol* 2008;145:645–655.
28. Hiraoka T, Okamoto C, Ishii Y, et al. Patient Satisfaction and Clinical Outcomes After Overnight Orthokeratology. *Optom Vis Sci* 2009;86:875–882.
29. Queirós A, Villa-Collar C, Gutiérrez AR, et al. Quality of Life of Myopic Subjects With Different Methods of Visual Correction Using the NEI RQL-42 Questionnaire. *Eye & Contact Lens* 2012;38: 116–121.
30. García-Porta N, Rico-del-Viejo L, Martín-Gil A et al. Differences in Dry Eye Questionnaire Symptoms in Two Different Modalities of Contact Lens Wear: Silicone-Hydrogel in Daily Wear Basis and Overnight Orthokeratology. *BioMed Research International*. 2016; Article ID 1242845, 9 pages <http://dx.doi.org/10.1155/2016/1242845>.
31. MacAlinden C and Lipson MJ. OrthoK and Contact Lens Quality of Life Questionnaire (OCL-QoL). *Eye and Contact Lens*. 2017;Published Ahead-of-Print. doi: 10.1097/ICL.0000000000000451.
32. Kang P, Swarbrick H. Peripheral refraction in myopic children wearing orthokeratology and gas permeable lenses. *Optom Vis Sci* 2011; 88:476–482.
33. Kang P, Swarbrick H. New perspective on myopia control with orthokeratology. *Optom Vis Sci* 2016; 93:497–503.

34. Gonzalez-Meijome JM, Faria-Ribeiro MA, Lopes-Ferreira DP et al. Changes in peripheral refractive profile after orthokeratology for different degrees of myopia. *Curr Eye Res* 2016; 41: 199–207.
35. US Food and Drug Administration, Center for Devices and Radiological Health. Summary of Safety and Effectiveness, Premarket Approval Application Supplement. June 14, 2004 Available at: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=p010062> accessed March 27,2019.
36. US Food and Drug Administration, Center for Devices and Radiological Health. Summary of Safety and Effectiveness, Premarket Approval Application Supplement #P870024/S43. January 18, 2002. Available at: <http://www.fda.gov/cdrh/pdf/P870024S043b.pdf> Accessed March 27,2019.
37. Mejía-Barbosa Y and; Malacara-Hernández D. A Review of Methods for Measuring Corneal Topography. *Optom Vis Sci.*2001;78:240-253.
38. Mountford J, Ruston D and Dave T. *Orthokeratology: Principles and Practice*. Philadelphia, PA: Butterworth-Heinemann, Elsevier Ltd; 2004.
39. Cope JR, Collier AS, Rao MM, et al. Contact Lens Wearer Demographics and Risk Behaviors for Contact Lens-Related Eye Infections — United States, 2014. *MMWR Morb Mortal Wkly Rep.* 2015;64:865-870.
40. Swarbrick HA. Orthokeratology review and update. *Clin Exp Optom.* 2006;89:3:124–143.
41. Sun Y, Xu f, Zhang T, et al. Orthokeratology to Control Myopia Progression: A Meta-Analysis. *PLoS ONE* 10(4):e0124535. doi:10.1371/journal.pone.0124535
42. Si J-K, Tang K, Bi H-S, et al. Orthokeratology for Myopia Control:A Meta-analysis. *Optom Vis Sci* 2015;92:252-257.
43. Rah MJ, Bailey MD, Hayes J,et al. Comparison of NEI RQL–42 Scores in LASIK vs. CRT Patients. *Invest Ophthalmol Vis Sci* 2004;45: E-Abstract 1578.
44. Cho P, Cheung S-W, Mountford J and White P. Good Clinical Practice In Orthokeratology. *Cont Lens & Ant Eye.*2008;31:17–28.
45. Nti AN and Berntsen DA. Optical changes and visual performance with orthokeratology. *Clin Exp Optom.*2019; Published Ahead-of-Print. DOI:10.1111/cxo.12947
46. Lipson MJ, Brooks MM, Koffler BH. The Role of Orthokeratology in Myopia Control: A review. *Eye Contact Lens* 2018;44:224–230.
47. Lipson, MJ and Koffler BH. Orthokeratology for Managing Myopia Progression in Children. *Advances in Ophthalmology and Optometry.* 2019;4:75-87. Book Chapter, Section 2, Pediatrics. <https://doi.org/10.1016/j.yaoo.2019.04.004>

# Appendix 1 – OrthoK Designs and Materials

## OrthoK Lens Manufacturers/Suppliers

OrthoK Designs-Manufacturers			
Brand Name	Manufacturer	Fitting method	FDA License
BE Retainer	ABB/Precision Technology	Topography/Diagnostic Evaluation	B&L/VST
CKR	Optivision Inc.	Topography/Design Software	B&L/VST
Contex- OK E-System	Contex Inc.	Empirical/Topography	B&L/VST
CRT, CRT Dual Axis	Paragon Vision Science	Nomogram/Empirical/Design Software	
DreamLens	Art Optical/Blanchard/Tru-Form	Empirical	Paragon CRT
Emerald, Sapphire	Euclid Systems Inc.	Empirical	B&L/VST
Fargo	GP Specialists	Empirical	B&L/VST
Forge	Eyesspace/Custom Craft	Topography/Design Software	B&L/VST
GOV	GP Specialists	Empirical/Diagnostic Evaluation	B&L/VST
iSEE	GP Specialists	Fitting Calculator	B&L/VST
MiracLens	MiracLens LLC	Empirical	B&L/VST
Night Move	Gefflex/Advanced Corneal Engineering	Empirical	B&L/VST
NightLens-Wave Contact Lens System	MetroOptics/X-Cel Contacts	Topography/Design Software	B&L/VST
OrthoFocus	Progressive Vision Technologies	Empirical/Topography	B&L/VST
RG4	Paragon Vision Science	Nomogram/Empirical	Paragon CRT
Super Bridge/E-Lens Overnight Orthoker	E&E Optics	Fitting Nomogram	B&L/VST
Vipok	E&E Optics	Fitting Nomogram	B&L/VST

Compiled by Michael J. Lipson OD FAAO Updated 7/8/2019

## Gas Permeable Materials with FDA indication for Overnight OrthoKeratology

Name	Manufacturer	Colors	Material	DK	License
Boston Equalens 2	Bausch & Lomb	Red, Yellow, Clear, Blue, Green	Fluorosilicone Acrylate	85	VST
Paragon HDS100	Paragon Vision Sciences	Autumn Red, Clear, emerald green, sapphire blue, yellow	Fluorosilicone Acrylate	100	CRT
Menicon Z	Menicon	Autumn Red, Clear, emerald green, sapphire blue, yellow	Fluoro-Siloxanyl Styrene	163	CRT

- VST package insert available at: <https://www.bauschsvp.com/Portals/207/assets/8147001%20Boston%20VST%20Ins%20US%20WILM.pdf>
- VST information available at: <http://www.bausch.com/ecp/our-products/orthokeratology/vision-shaping-treatment>
- ParagonCRT information available at: <https://www.paragonvision.com/faq/>



# Appendix 2 – OrthoK Resources

## The American Academy of Orthokeratology and Myopia Control

<https://www.orthokacademy.com/>

### **For the Practitioner**

Doctor Locator

Becoming a Fellow

Online store

Meeting Info

### **For the Patient**

Find an OrthoK Doctor

Info on OrthoK

Info on Myopia

Frequently Asked Questions

## The Gas Permeable Lens Institute

<https://www.gpli.info/>

Education • Information Resources • Webinars

## Contact Lens Manufacturers Association

<https://www.contactlenses.org/orthok.htm>

Information on OrthoK for patients and practitioners

## International Myopia Institute

<https://www.myopiainstitute.org/>

Links to published papers on myopia and myopia management Information on myopia from international panel of experts

## All About Vision

<https://www.allaboutvision.com/contacts/orthok.htm>

Questions and answers about OrthoK

## PubMed

<https://www.ncbi.nlm.nih.gov/pubmed/?term=orthokeratology>

Government web site listing published studies on OrthoK

## Clinical Trials.gov

<https://clinicaltrials.gov/ct2/results?cond=Myopia&term=&cntry=&state=&city=&dist=>

Listing of clinical trials - ongoing and recruiting

## Google Scholar

[https://scholar.google.com/scholar?hl=en&as\\_sdt=0%2C23&q=orthokeratology&oq=ortho](https://scholar.google.com/scholar?hl=en&as_sdt=0%2C23&q=orthokeratology&oq=ortho)

Listing of studies published on OrthoK

**Bausch Health**

<https://www.bausch.com/ecp/our-products/orthokeratology>

Information on VST

**Paragon Vision Science**

<https://www.paragonvision.com/>

Information on CRT

Information on Myopia

Find an Eye Doctor

# Appendix 3 – Sample Consent/Fitting Agreement

OrthoKeratology, also referred to as OrthoK, Corneal Reshaping, Corneal Refractive Therapy (CRT) and others, is a process of wearing specifically designed contact lenses worn only while sleeping to temporarily reshape the front surface of the cornea to reduce refractive error and allow for good unaided vision during waking hours. In addition to improving unaided vision, a growing body of evidence in the scientific literature suggests that use of OrthoK may slow the progression of nearsightedness in some children. However, the United States Food and Drug Administration (FDA) has not specifically approved any contact lens to slow myopia progression. All OrthoK lenses prescribed at this office have been approved for wear by the FDA to correct refractive error, but not specifically to slow the progression of nearsightedness.

I understand that while these contact lenses are FDA indicated to correct refractive error, they do not have FDA indication for slowing the progression of nearsightedness. Prescribing these lenses to slow myopia progression is an “off-label” indication. I further understand that there is no guarantee or assurance of any treatment outcome for my child and that these contact lenses may not slow the progression of nearsightedness. \_\_\_\_\_ Initials

## Benefits of OrthoK vs. Risks

I understand that OrthoK contact lenses are medical devices prescribed as one option for correcting my vision. Other options include spectacle lenses (glasses), traditional contact lenses or refractive surgery. Optical alternatives to control increasing degree of myopia also includes soft multifocal contact lenses.

Soft multifocal contact lenses are typically prescribed for people over 40 years of age to correct both distance and near vision. When prescribed for children, studies show they slow myopic increases to a similar degree at OrthoK.

I understand that OrthoK lenses are worn overnight to temporarily change the shape of the front of the eye (cornea) and that lenses must be worn regularly to maintain these changes. In electing to pursue OrthoK, I understand there are significant benefits along with some risks.

Benefits of OrthoK	Risks of OrthoK
Good vision without correction during the day	Possible Infection
May slow increasing degree of myopia	Possible sensitivity reactions
Improved Vision-related Quality of Life	Redness/Itching
Less Activity Restrictions	Corneal Abrasion
Better Self-Image	Discomfort

Although the chance of an eye infection is very low (about one case per 1100 years of wear), it is greater for OrthoK lenses than daytime contact lens wear because the contact lens is worn overnight.

I understand that if I follow the recommended care instructions and wear schedule that I will significantly reduce my chance of experiencing the risks noted above. I also understand that following the recommended care and wearing schedule does not guarantee I will not experience any of the risks mentioned above. \_\_\_\_\_ Initials

**Your responsibility** to us is to keep the recommended follow-up schedule, to pay the fees in full and to inform us of any changes in vision or comfort.

**Our responsibility** to you is to assure your best eye health and best vision utilizing our experience and the latest available technology.

**Fees and Payment:** The fee for the OrthoK procedure is a specialty evaluation and is not covered by insurance. The evaluation includes the initial eye exam, corneal mapping, eye health evaluation, special test procedures, diagnostic fitting, all follow-up visits needed during the first 6 months, one pair of lenses and any necessary lens exchanges during the first 6 months. Fees are due in full prior to commencing treatment.

The total fee varies with the complexity of your unique condition.

The fee for your case is: \_\_\_\_\_

**Replacement cost of lenses is .....specify costs, exchange policy, lost or damaged lenses and any other situations relative to the cost of lenses**

**Recommended follow-up evaluations.....specify your recommended schedule of routine follow-up visits.**

**Also specify that if additional visits are required, what types of visits are included in the fees that have been paid and which are not included**

**Any other relevant office policies .....**

**If I experience pain, discomfort or reduced vision with contact lenses, I will (office name) promptly. I understand all the instructions I have been given regarding the care, wearing and follow-up involved in OrthoK. If I have questions in the future, I know I can reach the doctor or a technician at OFFICE PHONE**

**After business hours, eye pain should be evaluated by an eye care professional. Calling the above number after business hours – describe your emergency procedures and urgent contact phone/text/ etc.**

I understand the risks and benefits of the process of OrthoK. I agree to follow the recommendations made by Dr. \_\_\_\_\_ and his staff regarding lens wear, follow-up care and lens care.

Child's name (print): \_\_\_\_\_

Parent's name (sign): \_\_\_\_\_

Date: \_\_\_\_\_

Dispenser's name (sign): \_\_\_\_\_

# Appendix 4 – Commonly Asked Questions/Answers

ORTHOKERATOLOGY (ORTHO-K)  
OVERNIGHT CORNEAL RESHAPING (OCR)  
CORNEAL REFRACTIVE THERAPY (CRT)

## What is OrthoK?

The names above are different names for the same process. OrthoK is the use of special-design contact lenses to change the shape of the cornea to temporarily correct myopia (nearsightedness). It is an alternative to glasses, LASIK or traditional contact lenses.

## How are lenses worn?

Lenses are worn while sleeping (7-8 hours) and removed upon waking. **Most people enjoy clear vision all day with no correction needed.** In many cases, only one set of lenses is required.

- Lenses must be worn regularly to maintain vision improvements. If lens wear is discontinued, vision will return to the original prescription in 3-7 days.

## What kind of lenses are used?

Specially designed, highly breathable (gas permeable) contact lenses.

## How long does it take?

Unaided vision improves after the first night of wear. As you consistently wear lenses, your unaided vision remains good all day long. Full effect takes an average of 7-10 days.

## How often do I need to be checked?

You will be checked when you pick up lenses, the next day after your first night of wearing the lenses, then, one week later, one month, three months and six months. After that, we check your eyes and vision every six months.

## What should I bring with me to my OrthoK check?

You must bring all of your OrthoK lenses and solutions to each visit. Your lenses should be clean and ready to be checked. It is recommended to bring them in your travel case in the bag that was provided to you.

## Can the lens get lost in my eye?

No. The lens can move off-center, but it can't go "behind" the eye. There is tissue and muscle that surrounds the eye, preventing this from happening.

**Who are the best candidates?**

Generally, moderately nearsighted people of any age who wish to improve their vision and be free of vision correction during the day. Also, children becoming more nearsighted who want to slow or stop progressive changes. Patients with low amounts of farsightedness are also good candidates.

**What if I break or lose a lens?**

Ideally, you should have a spare set of lenses. If not, call our office immediately. Some lenses can come in 2-3 days and others may take up to 2 weeks.

**What is the cost for OrthoK?**

In most cases, the cost is \$xxxx which includes an initial comprehensive exam, one pair of lenses, contact lens fitting, corneal topography, evaluation and follow-up care for six months.

More complex cases and those with higher prescriptions have higher fees, between \$xxxx and \$xxxx determined at time of consultation.

Replacement/spare lenses for are \$xxx/lens. Custom/complex designs are \$xxx- xxx/lens.

**How often to lenses need to be replaced?**

The maximum lifetime of OrthoK lenses is (x) years. This assures best vision comfort and eye health. Often the replacement lenses are made with the same specifications as the current lenses.

**What do I do if I can't find the solutions in stores?**

Often times these solutions can be found in stores such as Target, Walmart, Costco, and pharmacies. The solutions can also be found on Amazon. If you are still having trouble finding solutions, never pick new ones on your own. ALWAYS make sure to contact our office first.

**Does Orthok stop progression of nearsightedness (myopia)?**

Many studies have shown that children wearing OrthoK lenses have slower myopic progression compared to those wearing glasses. In addition to the studies, our clinical experience shows individual differences in rate of myopic progression in OrthoK-wearing children. Some continue to progress while others show little to no progression.

**(An alternative here might be a summary of a few studies)**

We were part of a large, national multi-center controlled study to look at the question of whether OCR does have an effect on stopping or slowing myopic progression over a five year period in children aged 9-13. The study ran from 2007-2012. Results showed significant reduction of myopic progression, similar or better than other published studies on the effect of OrthoK on myopic progression.

Internet References:

<https://www.orthokacademy.com/>

<https://www.gpli.info/>

<https://www.myopiainstitute.org/>

<https://www.allaboutvision.com/contacts/orthok.htm>

<https://www.bausch.com/ecp/our-products/orthokeratology>

<https://www.paragonvision.com/>

<https://www.myopiacare.org/>

<https://www.myopiaprofile.com/about/>

[https://journals.lww.com/claojournal/Fulltext/2018/07000/The\\_Role\\_of\\_Orthokeratology\\_in\\_Myopia\\_Control\\_A.5.aspx](https://journals.lww.com/claojournal/Fulltext/2018/07000/The_Role_of_Orthokeratology_in_Myopia_Control_A.5.aspx)



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## Contemporary Orthokeratology

This book covers all facets of the practice of Orthokeratology. From getting started to advanced fitting challenges and problem-solving, it is intended as a knowledge base for novices just learning about the process as well as a reference for those experienced in the practice of OrthoK.

It opens with a section on history and development of the process of OrthoK, then covers the foundation of knowledge and skills needed for the practice of OrthoK. It then moves through the initial evaluation, candidacy and fitting. A lengthy chapter is devoted to extensive examples of corneal topography. This includes text and numerous graphical examples for tips on how to utilize topography for diagnostic evaluation of pre- and post-treatment maps.

Discussion of careful follow-up care, lens care and handling as well as a large section on trouble-shooting and problem-solving is included. Finally, there is a section on the basics of practice management in the practice of OrthoK. Also included is a special supplemental feature; a transcript of a discussion the author had with international experts on the topic of managing myopia with OrthoK.

All in all, it's a source for the current knowledge base of all aspects relating to the practice of OrthoK.

## About the Author

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Dr. Michael Lipson is an optometrist/associate professor at University of Michigan. He has been involved in Orthokeratology in its various forms since 1975. 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 specialty contact lens and research topics. Dr. Lipson developed a validated questionnaire to assess vision-related quality of life for all types of vision correction, including OrthoK. He is an independent consultant to the specialty lens industry emphasizing OrthoK education. He is a fellow of the American Academy of Optometry and the Scleral Lens Education Society. He is on the GPLI Advisory Board, served as Vice-President of the Scleral Lens Education Society and on the Scleral Lens Education Society Board for many years.

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