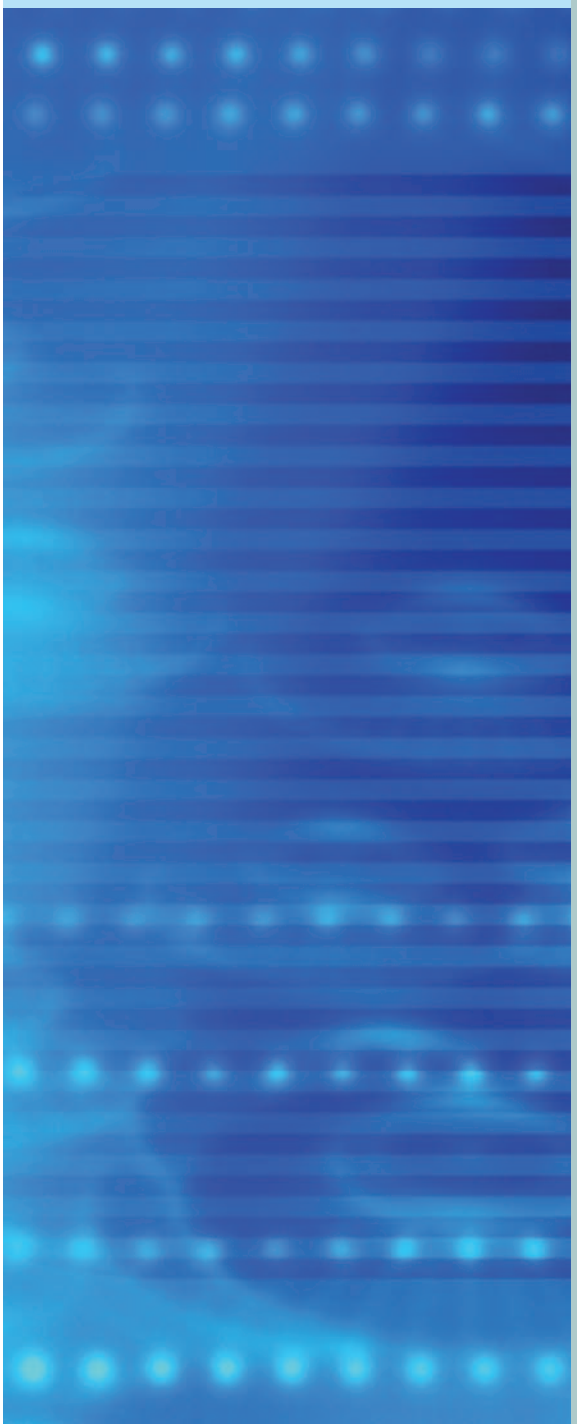


The OK® Lens E-System Design Certification Course

Supplement

Bausch & Lomb
Vision Shaping Treatment™

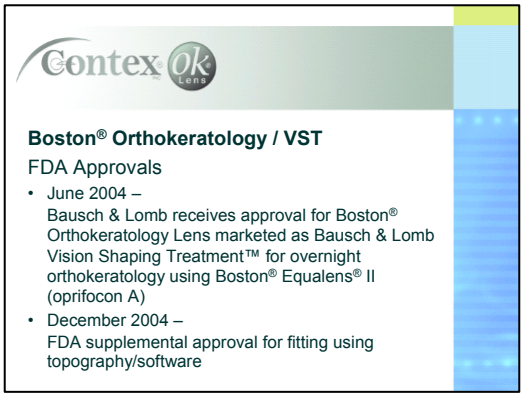
The Contex OK® Lens E-System Design for Vision Shaping Treatment Certification Course

Welcome to the Contex OK® Lens E-System Design Certification Course. This handout is designed to accompany the online or in-person certification process for this exciting product for contact lens corneal reshaping.

This handout supports the presentation you will watch that introduces you to Bausch & Lomb Vision Shaping Treatment™ for the temporary reduction of myopia and will provide you information and certify you on the OK Lens E System Design.

Please keep in mind that this certification test is not meant to take the place of detailed training on overnight orthokeratology and the OK Lens E System design.

Additional ongoing training is advised to increase your knowledge in managing patient care in this modality.



In June 2004 Bausch & Lomb acquired a premarket approval for the Boston® Orthokeratology Lens.

This is being marketed in the United States as the Bausch & Lomb Vision Shaping Treatment, or VST, for overnight orthokeratology using Boston® Equalens® II (oprifocon A) lens material.

Additionally, in December of 2004 a supplemental fitting approval that encompasses the use of corneal topography and/or software based designs was also received from the FDA.

It's important to note that Vision Shaping Treatment is not a lens design, but instead is a term to describe methods and designs for overnight orthokeratology.

With regards to vision shaping treatment this means that you have choices in high performance overnight orthokeratology lens designs and fitting methods and the use of the high Dk Boston Equalens II material.

Presently there are 4 designs that are being marketed under the Vision Shaping Treatment banner.

A unique feature of the Vision Shaping Treatment is that it offers you the flexibility to choose the fitting method that best suits you and your practice style.

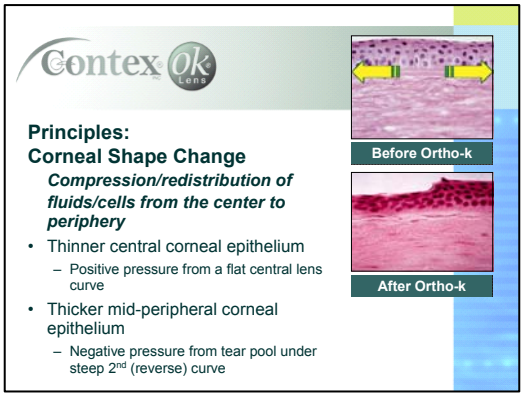
While corneal topography may not be necessary to select the initial lens in some of the vision shaping treatment design offerings, topography is considered essential to properly evaluate the ongoing progress in all designs.

The Boston Equalens II material has been available for a number of years in North American and has been FDA approved for extended wear since 1991.

It provides a significant amount of oxygen exchange having a Dk of 85 as measured by the ISO/Fatt polarographic method. Importantly, Equalens II provides excellent on-eye wetting resulting in a decrease of debris and surface deposit buildup.

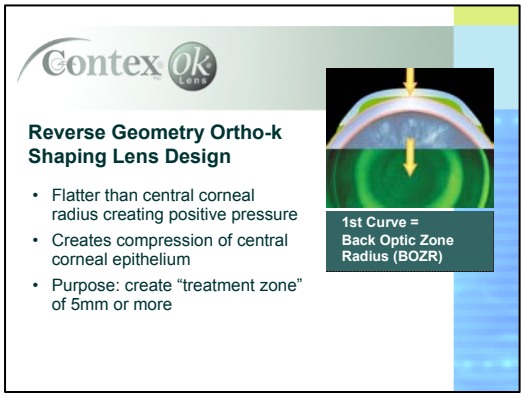
Uniquely, Boston Equalens II materials for overnight orthokeratology are available in distinctive colors to allow patients to easily discern which lens belongs in which eye.

A RED lens is used for the right eye and a YELLOW lens for the left. This allows the wearer to easily determine the proper lens for each eye and also ensures the prescriber is receiving the Boston lens material they expect.



In vision shaping treatment the change in corneal shape results from forces exerted on the tear film between the back surface of the lens and the cornea causing a gradual and steady compression and possibly a redistribution of fluids and epithelial cells under the lens from the center toward the periphery.

Specifically, the central corneal epithelium becomes thinner as a result of positive pressure under a flat central curve of the shaping lens, while the mid periphery becomes thicker due to the negative pressure created by the annular tear pool under a steeper second or reverse curve.

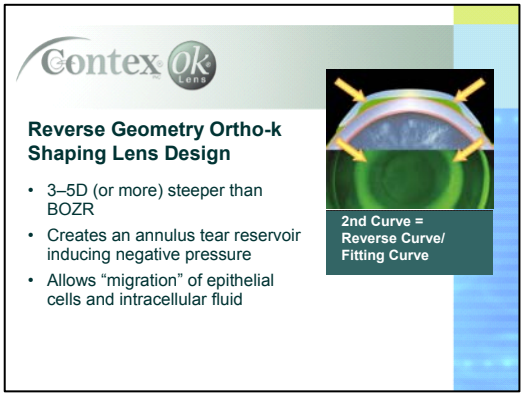


The back optic zone radius, also termed BOZR or base curve, is the first curve of Vision Shaping Treatment designs.

Calculated to be flatter than the central corneal radius, this curve provides positive pressure resulting in compression of the central corneal epithelium.

Generally the back optic zone diameter – termed BOZD - ranges from 6.0 to 8.0mm depending on the specific design – creating a treatment zone of 5.0mm or more.

Unlike the base curve in traditional GP designs this BOZR is used only to flatten the cornea and is not considered a fit factor.

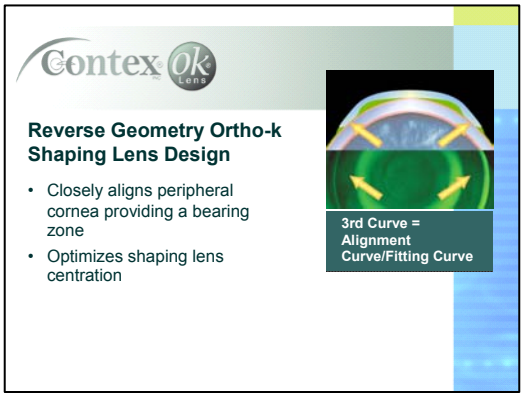


The second curve is most often termed the reverse zone and typically has a radius of 0.5mm to 1.0mm or is 3 to 5 diopters or more steeper than the back optic zone radius.

It forms an annulus shaped tear reservoir surrounding the central flat zone, inducing negative pressure

The reverse zone provides an area for the epithelial cells and intracellular fluid to collect.

This zone, comprised of one or more curves, is typically 0.6 to 1.0mm wide depending on the design of the shaping lens.

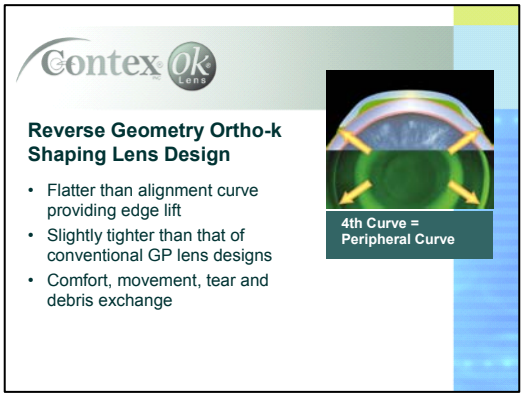


The third zone is the alignment zone.

This area is flatter than the reverse curve area and closely aligns the peripheral cornea providing a bearing zone to help the lens to center.

Its main function is the optimizing of lens centration. The fitting relationship can be modified by altering the angle or radius of the curve or curves, thus improving the lens centering characteristics.

It is generally 1.0 to 1.5 mm wide depending on the lens design.



The 4th curve or peripheral edge curve is flatter than the alignment curve, but slightly steeper than that of conventional lens designs - providing an edge lift adequate for lens comfort and movement, along with tear and debris exchange.

It is useful to understand the relationship between units such as microns, millimeters and diopters as these are the most commonly used to describe lens design.

Let's start the OK Lens E System Certification process. Here are the directions for completing your Answer Sheet.

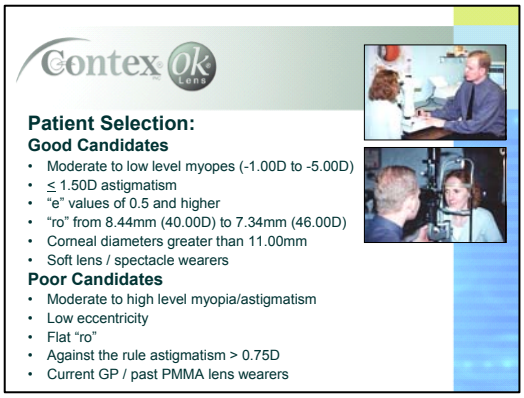
- *Be sure to completely fill-out the personal information at the top of the answer sheet. PLEASE PRINT LEGIBLY*
- *Choose the **best** answer from among those offered*
- *Mark your choice on the answer sheet by completely coloring-in the circle on the answer sheet*
- *If you decide to change your answer draw an "X" through the answer you do not want to be counted*
- *You will have approximately 30 seconds to complete each of the questions.*

Question 1: In which direction are the fluids and cells compressed or redistributed when a vision shaping treatment lens is worn?

Question 2: What is the value of topography in the course of ortho-k treatment?

Question 3: What is the function of the second fitting/reverse curve of the ortho-k shaping lens?

Question 4: What is the function of the third or alignment curve of the ortho-k shaping lens?



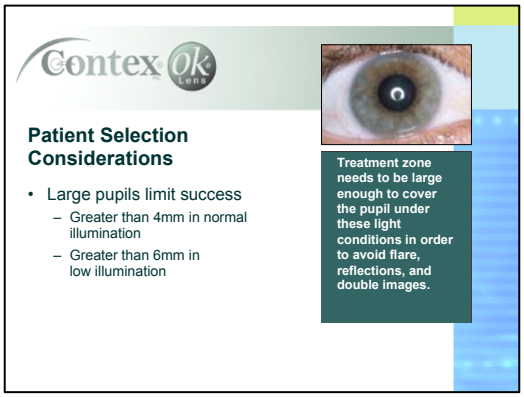
The range of myopic correction reduction approved with Vision Shaping Treatment is -1.00D to –5.00 Diopters.

The most successful ortho-k candidates are moderate to low level myopes whose corneal shapes have "e" values of 0.5 and higher, an apical radius

measurement between 40.00 and 46.00 diopters and corneal diameters greater than 11.00mm.

Beware of those patients with higher amounts of myopia, low corneal eccentricity measurements and flat corneas. Against the rule astigmatism greater than three quarters of a diopter can also be problematic, in that this reshaping process may induce even higher amounts of against the rule astigmatism. These types of patients may not be as well-suited for vision shaping treatment.

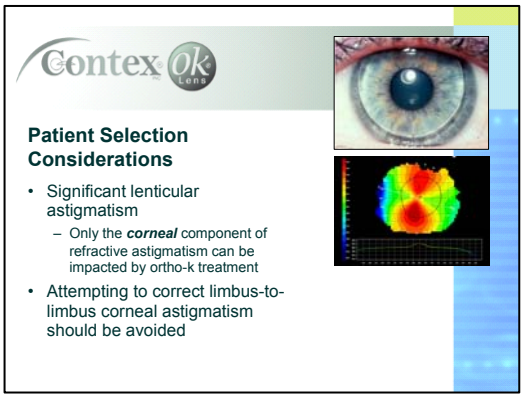
Also, proceed with caution with previous GP and PMMA lens wearers. These patients should remain out of their lenses until the corneal and refractive measurements have stabilized, often 2 to 4 weeks or more.



Evaluate the pupil size accurately in both normal and dim illumination.

Depending on the amount of attempted myopic reduction, the expected treatment area in overnight orthokeratology is usually 5 to 6mm in size.

Therefore, patients with pupils greater than 5mm in normal illumination and/or greater than 6mm in low illumination may not be suitable candidates. Large pupils may result in haloes, glare, or peripheral distortion in dim lighting conditions.



The effectiveness of ortho-k treatment is reduced where there is significant internal or lenticular astigmatism.

Note any potential residual astigmatism by comparing the cylinder component of the spectacle Rx to the amount of corneal astigmatism measured by central keratometry. Since vision shaping treatment affects corneal astigmatism only, avoid cases where residual astigmatism may be greater than 0.75D.

Also, limbus-to-limbus corneal astigmatism may result in a less effective ortho-k procedure. In these cases the fitting relationship is altered in the periphery and lens rocking may occur. Visually, the net result is that full myopic reduction is not achieved or the treatment regresses quickly.

It is advisable to avoid those patients that have any active ocular infections.

Patients with severe corneal irregularity from injury, surgery or a condition such as keratoconus or a corneal dystrophy should also be avoided.

Also note patients who have demonstrated an allergic response to lens care products that would be used in vision shaping treatment.

Question 5: What is the generally accepted maximum "against-the-rule" astigmatism that can be attempted with ortho-k fitting?

Question 6: What is the maximum amount of myopic reduction that Vision Shaping Treatment is approved for by the FDA?

Question 7: Why may patients with large pupils experience problems with ortho-k?

Question 8: Why is lenticular astigmatism a potential problem when fitting ortho-k shaping lenses?

Patient compliance is an important factor in the success of Vision Shaping Treatment patients. Here are a few important tips.

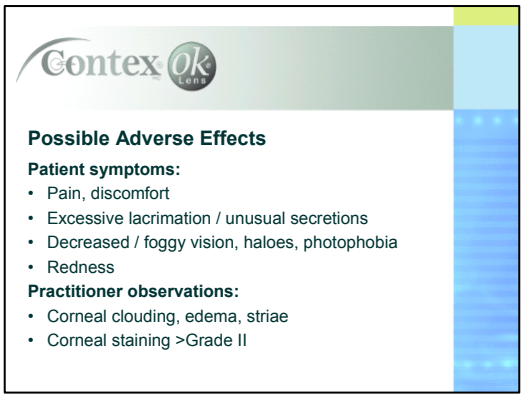
There is no need to remove the shaping lenses if awoken during the night - but upon awaking in the morning it is advisable that patients instill a few drops of the recommended rewetting solution and wait a few minutes before attempting to remove their lenses.

Of greatest importance is that the patient should check that the shaping lens is moving prior to lens removal.

While removal of Vision Shaping Treatment lenses is usually not a problem for the patient in some cases, due to the larger lens diameter, it may be necessary to employ the use of a DMV lens remover.

Be sure to advise your patients to contact your office if they have difficulty removing the lenses.

Also, remind the patient to use only the recommended approved GP lens care products with their Vision Shaping Treatment lenses.

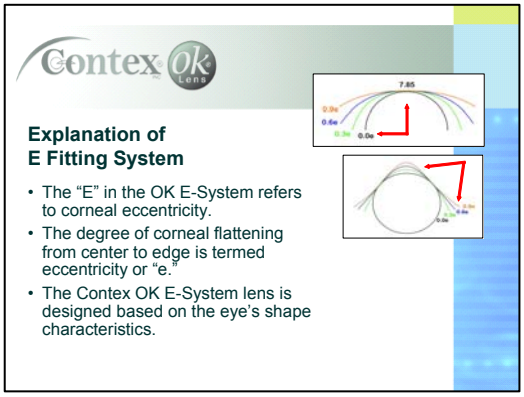


Patients should be advised to discontinue reshaping lens wear and call your office immediately if they experience pain, discomfort, excessive tearing or any of the other symptoms described on this slide.

Vision shaping treatment should also be discontinued if you observe any corneal hypoxia or staining greater than Grade 2.

Question 9: Which patient symptoms with vision shaping treatment are of most concern to the contact lens practitioner?

Question 10: What is the most important observation that the wearer should make prior to attempting removal of their ortho-k shaping lenses after waking?

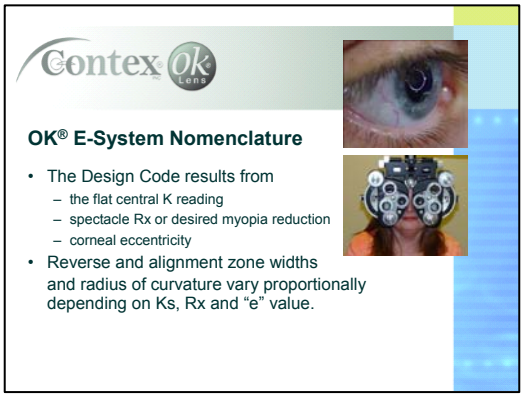


Now that we have discussed some general principles regarding Vision Shaping Treatment let's look at the details of how the Contex OK Lens E-System works.

For the appropriate candidate, the OK Lens E-System is a very safe approach to eliminating the need for eyeglasses. The "E" in the OK E-System refers to **"**corneal eccentricity" and signifies the design's reshaping fitting philosophy.

The degree of corneal flattening from the center to the periphery is termed eccentricity. This eccentricity, or "e" value is a key fitting factor in the OK E-System design as it affects the sagittal depth or height of the lens to cornea fitting relationship.

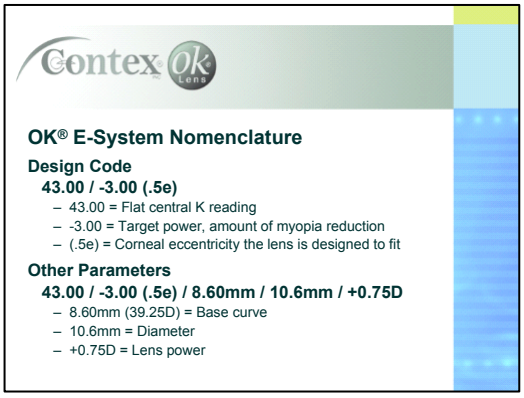
The Contex OK E-System takes into consideration the differences in corneal eccentricity, with each lens designed to the unique shape characteristics of the eye undergoing orthokeratology treatment.



The OK- E System uses a unique method to describe the lens parameters - referred to as the design code. The design code relates to the shape and refractive requirements of the cornea rather than the parameters of the lens.

This allows practitioners to design the lens based on the central k reading, refraction or desired myopia reduction, and corneal eccentricity.

In the design code, the reverse and alignment zone widths and radius of curvature are not listed since they vary in equal proportions depending on the ocular measurements.



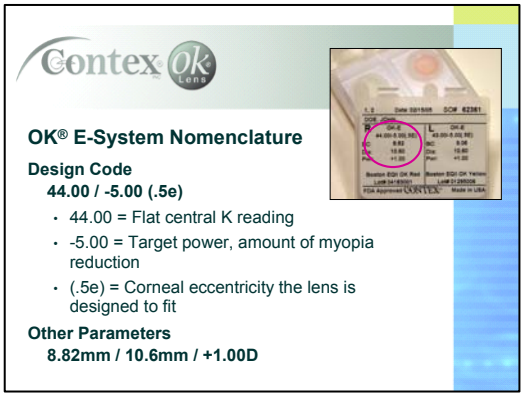
Let's review how the design code appears. In this example the first number in the design code, 43.00 diopters, refers to the flat central K reading. This is the original or pre-fit "K" reading and should not be changed. The only time this value would change is when using inventoried lenses and a lens with a different flat K value is used to change the fitting relationship.

The second number, -3.00, is known as the Target Power. This number indicates the desired amount of myopia reduction to be achieved. The target power controls the base curve or back optic zone radius which in turn controls the amount of myopia reduction.

The third number in the code is **.5E** and represents the corneal eccentricity that the specific lens is designed to fit. The average corneal eccentricity is .45 to 0.55, therefore, when using Ks and Rx to choose the initial lens the default e value is 0.5. If topographical data is available the e-value from the topography plus the offset value from the Contex topographer reference table may be used.

In addition to the design code, the other parameters provided on the lens packaging are the base curve, overall lens diameter and lens power. In general the base curve also known as the back optical zone radius or BOZR is determined by subtracting the target power in diopters plus an additional 0.75 diopters from the flat central K reading.

The recommended diameter is 10.6mm. The recommended lens power is +0.75D if the desired amount of myopia reduction is -3.87D or less. Alternatively, in those cases where the myopia correction is -4.00D or higher choose a lens power of +1.00D.



In this example the first number in the design code, 44.00 diopters, refers to the flat central K reading.

The second number, -5.00, is the Target Power and the number indicates the desired amount of myopia reduction to be achieved. Also, for powers greater than 4.00D it is not necessary to compensate for vertex distance as this adjustment is factored into the design.

The third number in the code is .5e and represents the corneal eccentricity that the specific lens is designed to fit.

The other parameters provided on the lens packaging are the base curve, overall lens diameter and lens power. Since the desired myopia correction is higher than -4.00, the lens power is +1.00.

Question 11: The "E" in Contex OK® Lens E-System refers to the corneal eccentricity. How is the corneal eccentricity defined?

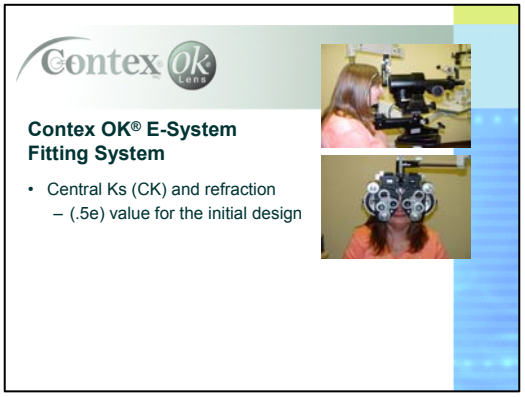
Question 12: The 1st number in the Contex OK® Lens E-System Design Code refers to what?

Question 13: The 2nd number in the Contex OK® Lens E-System Design Code known as the Target Power refers towhat?

Question 14: The 3rd number in the Contex OK® E-System Design Code refers to what parameter?

The initial OK-E Fitting System LENS can be chosen by various methods: Central K's and refraction - Central K's, refraction and topography or with a dispensing inventory set.

This allows practitioners to choose a fitting method that fits in with their patient flow and fitting philosophies.

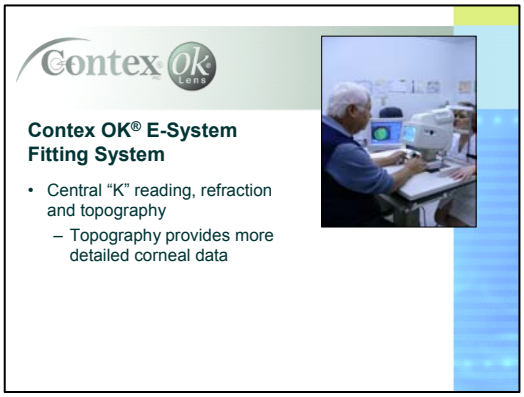


One philosophy is based upon central K readings and the refraction.

Take these measurements, then simply call or fax them into Contex to place the order.

Our experienced consultants will assist you in designing a lens.

When using this method a .5 corneal eccentricity value is used as it reflects the average corneal eccentricity of most eyes. After the evaluation of the initial lens, adjustments to the fitting relationship and the e value can be made.



Another option is to combine the keratometric and refractive measurements with corneal topography.

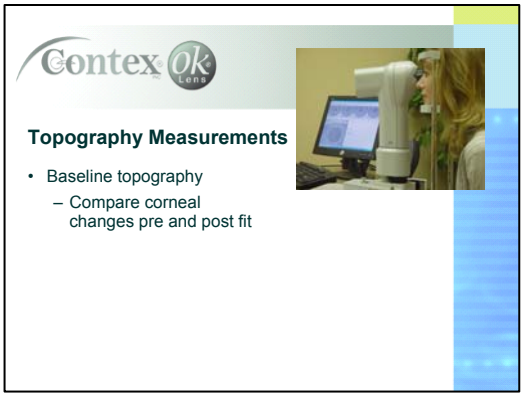
Topography measurements provide more detailed corneal data including the eccentricity measurements for the individual eye.

This fitting method provides a more customized approach to the lens selection process.

Dispensing from an inventory set is yet another option, allowing for immediate lens selection.

This fitting process decreases the number of visits and chair time by allowing small parameter changes that will improve the fitting relationship to occur immediately.

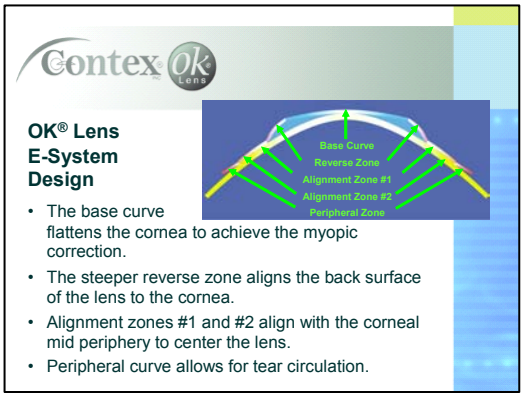
Inventory fitting is the recommended method. While certification is required for fitting the OK Lens, inventory sets are not required to begin fitting.



Baseline topography measurements should be taken for all potential OK E-System patients.

While the topography data acquired may not always be used for the initial lens selection, it will be used later to compare with post fit maps as a means of understanding what corneal changes have taken place during the orthokeratology treatment.

They are also beneficial if changes need to be made to the initial lens design.



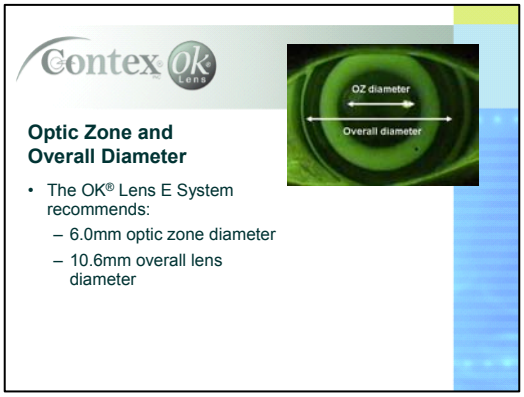
The OK E-System is comprised of four and five zone lenses. Each zone is made up of one or more curves and has a specific function.

In the OK-E system the Base Curve does not play a significant role in fitting - as in fitting conventional GP lenses - but instead is responsible for flattening the cornea to achieve the desired myopic correction.

Adjacent to the base curve, the steeper Reverse Zone forms a tear reservoir where excess tears and displaced corneal epithelial tissue may settle. The reverse zone is also designed to bring the back surface of the lens into proper alignment with the cornea.

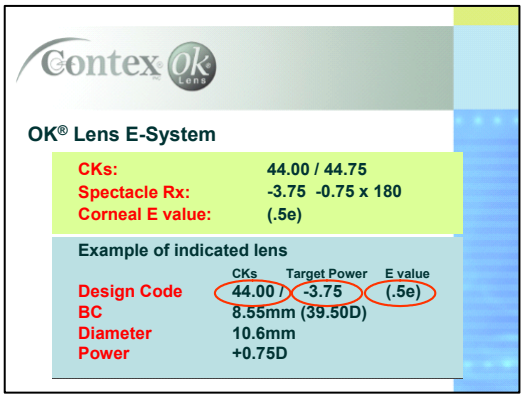
Next is the Alignment Zone #1. This area is calculated to align with the mid periphery of the cornea and to keep the lens centered and positioned properly on the cornea. For higher myopes or patients with flat corneas and low e values a second alignment zone may be added for improved corneal alignment.

The fifth curve is the Peripheral zone. Its purpose, as with other GP lenses, is to allow for tear circulation and debris removal under the lens.



The recommended optic zone diameter is 6.0 mm. In some cases such as for larger pupils, the optic zone can be increased to 6.5mm or 7.0mm to reduce flare or glare.

For optimal lens centration a 10.6mm lens diameter is suggested, however other diameters are available. For example a 10.0mm lens may be indicated for children or those patients with steep corneas.



Let's look at a fitting example. The central K readings are 44.00/44.75.

The spectacle prescription is -3.75 -0.75 x 180 and the corneal E value derived from corneal topography is: .5

In this example the first indicated lens will have a design code of 44.00/-3.75 (.5e). The lens would

have a 8.55mm or 39.50D base curve, 10.6mm diameter and +0.75D power. The “44.00” designates the flat central K reading that this specific lens is designed to fit. The “-3.75” represents the number of diopters of myopia that the lens is designed to reduce. In the Contex OK Lens E-System this is called the “Target Power.” Typically the target power is equal to the refraction.

The .5e represents the corneal eccentricity this lens is designed to fit. Other E values may be used when needed. For example, a .55e would indicate a .55 corneal eccentricity, which would be a looser lens than the .5e.

Prior to beginning the fitting process it is recommended that your keratometer is calibrated to ensure accurate readings for the best fitting results.

The slit lamp is necessary to evaluate lens fit and corneal integrity.

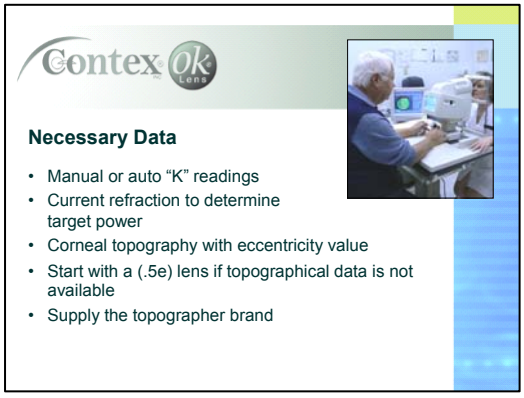
While a topographer isn’t necessary to order the initial lens, it is recommended that a baseline topography map is taken to evaluate the results at the follow up visits. Also, the pre-fit topography assists with ruling out poor candidates and predicting the amount of myopia reduction that can occur.

Contex OK® Lenses can be fit using any brand topographer. We have analyzed most topographers to determine the necessary data from each brand. Simulated K’s from the topographer should be within +/- .25 diopter of the manual or automated keratometry readings. In our experience the manual or automated K results are more consistent than the simulated K's of the corneal topographer.

For lens design and consultation, topography maps and parameters can be e-mailed to topomaps@contexusa.com. You can also fax maps in color to the number listed in the graphic above.

Since the fluorescein pattern in ortho-K fitting has many subtle nuances, use a yellow Wratten filter to accurately evaluate the fine details.

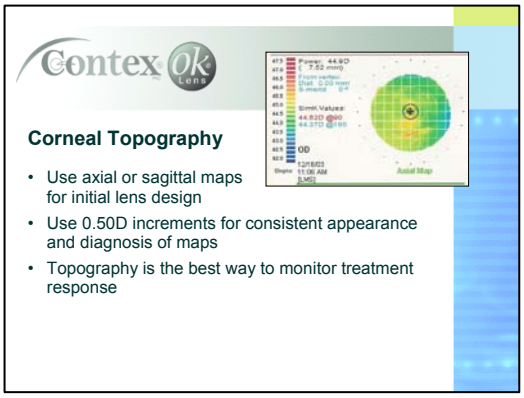
Although it doesn’t provide as large an image as the slit lamp a Burton lamp may also be used. Its advantage is that it allows you to easily assess and compare both eyes at the same time.



At the initial fitting it is necessary to perform keratometry readings and a current refraction should be done to determine the proper target power.

The eccentricity value can be determined by topography or if there is no topographer available start with a (.5e) lens.

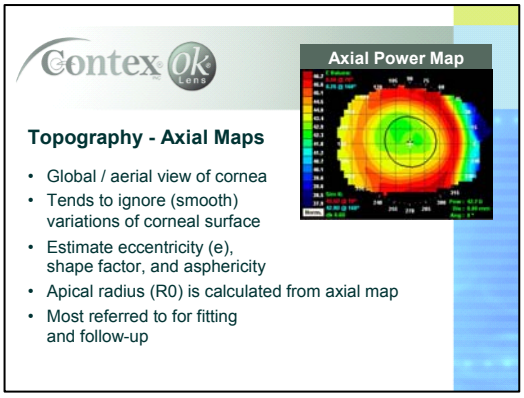
It is important to supply Contex the brand of the topographer you are using when ordering the lenses.



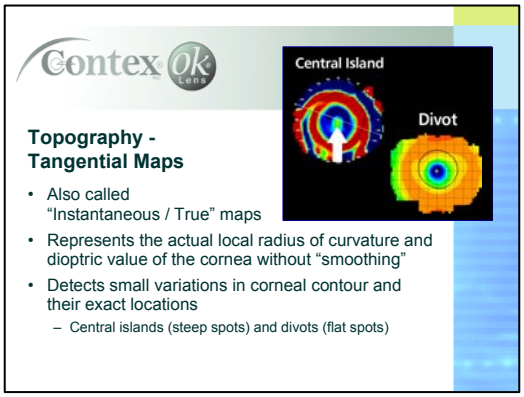
Axial or sagittal topographic data is preferred for fitting the initial lenses. In general, tangential topography is only useful for demonstrating corneal changes to the patient once the treatment has begun.

It is also recommended to set your topographer to display in ½ diopter increments for A consistent appearance and diagnosis of maps. If the diopter increments are too large, for example 3 diopters, the map may only show three colors. In comparison, if 1/4 diopter increments are used there will be twice as many colors as in a 1/2 diopter map. Therefore the 3 diopter increments shows no detail while the 1/4 diopter increments show too much.

Topography is the best way to monitor treatment response for overnight Contex OK lenses.



Topography is really the key to determining how the lens is fitting and how the treatment is progressing.



The axial map provides an aerial or global view of the cornea and tends to ignore slight variations in the corneal surface.

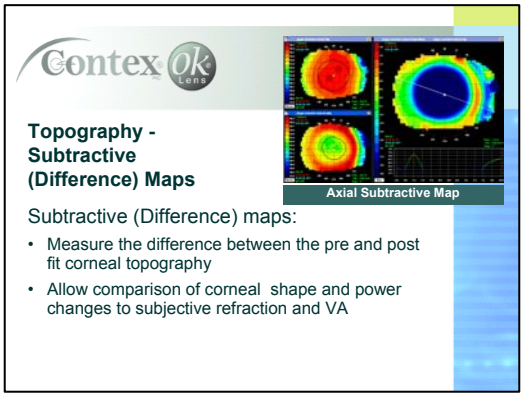
This map provides data on corneal eccentricity ("e"), shape factor, and asphericity.

The apical radius at point zero (R0) is derived from this map as well. It is also the map most referred to for fitting and for comparison during follow-up exams.

The tangential map represents the actual local radius of curvature at any point on the cornea.

The tangential radius map is useful for detecting small variations in corneal contour like central islands and divots induced by steep and flat lenses respectively.

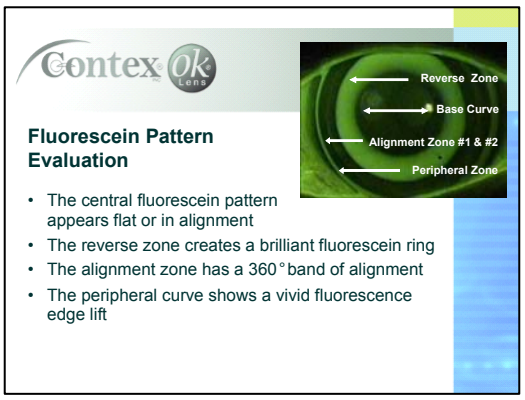
The tangential map provides better visualization of the exact location of a corneal defect.



A subtractive plot or difference map, measures the difference between the pre and post fit cornea topographical maps.

This allows for comparison of the alteration to corneal shape and power caused by the ortho-k shaping lens.

These changes can then be compared to subjective refraction and visual acuity. For this reason difference maps are considered the most effective method for analyzing the ortho-k effect on the cornea.

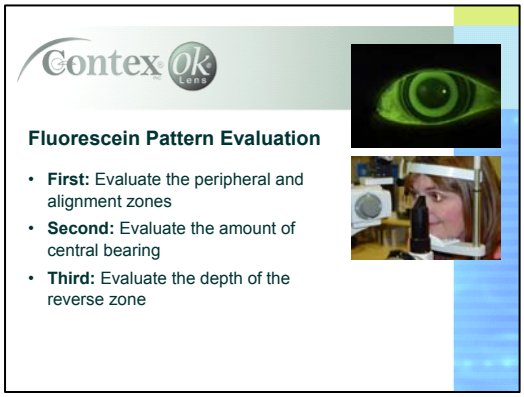


When observing the optimal fluorescein pattern, the center of the lens, typically shows a 3-5mm central area that appears flat, either showing a lens to cornea bearing or alignment relationship.

The reverse zone that creates a narrow .4 to 1.0 mm brilliant pooling ring, is also referred to as a reverse curve, fitting curve or tear reservoir.

The alignment zone aligns the mid-peripheral cornea, thereby helping the lens to center. If the alignment zone is fit properly there should be a .8 to 1.2 mm, 360 degree band of alignment.

In the OK E-System the peripheral zone utilizes a true aspheric peripheral curve. A more vivid fluorescence is seen because of the edge lift needed to promote tear exchange.

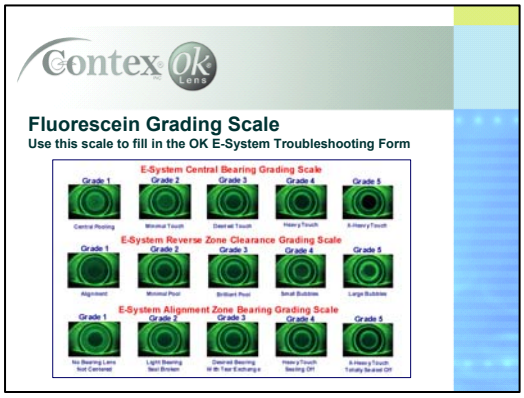


When evaluating the fluorescein pattern, begin observing the lens from the outside in to the center of the lens. First, evaluate the peripheral and alignment zone to determine the amount of edge lift and the degree of alignment bearing.

Next evaluate the amount of central bearing.

And finally, evaluate the depth of the reverse zone.

To assist you with an easier method of accessing the lens fit , our unique fluorescein grading scale defines all zones with a 1 to 5 bearing to clearance grade with a grade 3 being optimum.



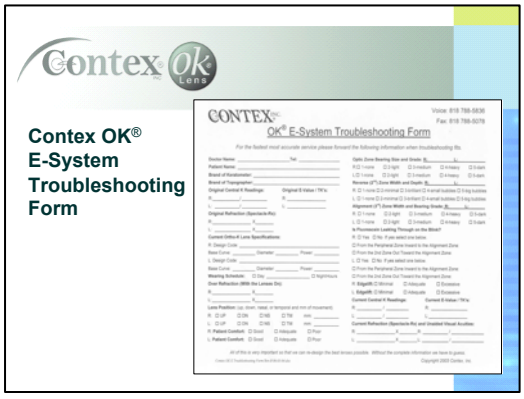
The grading scale is intended for use with well centered lenses. Poorly centering lenses should be assessed on center by manually centering the lenses with the lower lid and fingertip.

Question 15: What parameter of an OK® E-System lens controls the amount of myopia reduction?

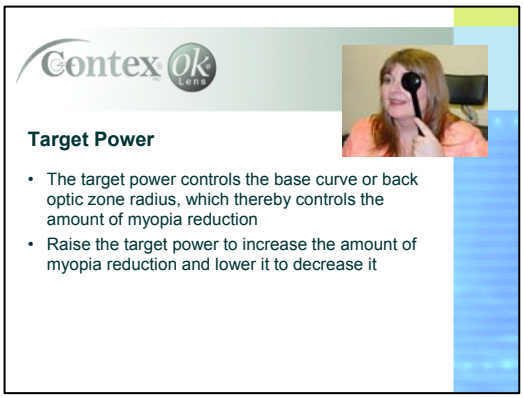
Question 16: Which zone(s) should be evaluated first while performing fluorescein analysis?

Question 17: In order to achieve consistency in topographical map output, it is recommended that your topographer be set at what incremental value?

Question 18: When using the OK® E-System Fluorescein Grading Scale, what grade is optimum?

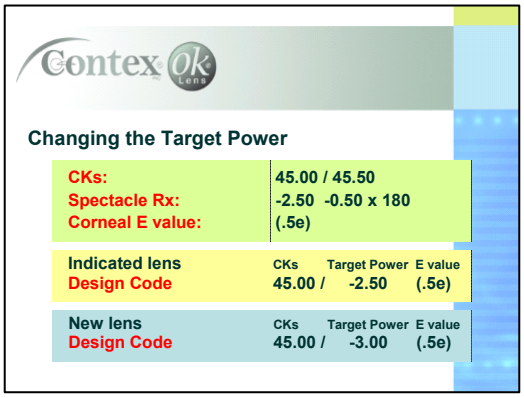


Our grading system works together with the OK® E-system troubleshooting form. This form has been developed to evaluate problems in a logical manner and can be easily faxed or sent to our lens consultants for fast and accurate assessment. To avoid having to complete the original data more than once, copies should be kept in the patient file that includes the original patient data.



As mentioned earlier in the description of the Design Code, the flat central K reading, refraction and corneal eccentricity dictate the lens design. The Target Power controls the base curve or back optic zone radius which in turn controls the amount of myopia reduction.

To increase the amount of myopia reduction, raise the target power. To decrease the amount of myopia reduction lower the target power.



Consider an example; In which the central K readings are 45.00/45.50. The spectacle prescription is -2.50 -0.50 x 180 and the corneal E value is .5

In this example the first indicated lens will have a design code of 45.00/-2.50 (.5e)

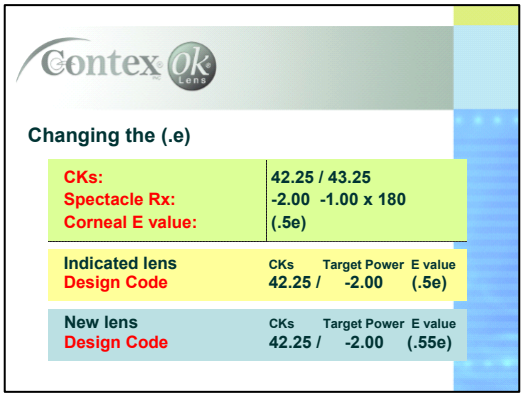
If an additional -0.50D of myopia is to be corrected, simply add a 0.50D to the -2.50 target power, so the new target power is -3.00D. The target power controls the base curve or back optic zone radius which thereby controls the amount of myopia reduction.

The eccentricity in the design code refers to the original or pre fit corneal eccentricity. A lens may be fitting too tightly if the fluorescein evaluation shows bubbles in the reverse zone or when a lens exhibits seal off.

The lens may be fitting too loosely when minimal fluorescein pooling is seen in the reverse zone or when the alignment zone shows minimal or no bearing.

If the lens is too tight or loose the “e” of the lens is raised to loosen the lens fit, and lowered to tighten it.

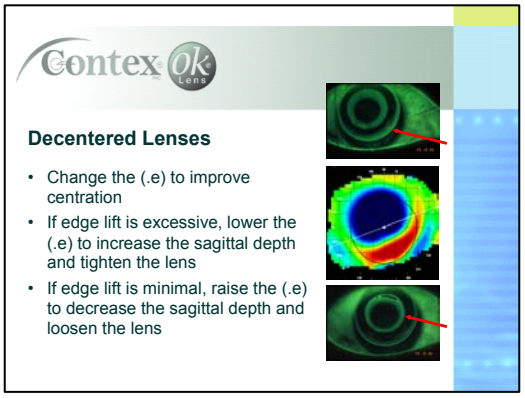
To make a significant change in the fit, a minimum .05 change in the e-value is necessary. The .05 e-value change results in approximately 10 microns of change.



Let’s look at an example of how these changes work. Consider that the central K readings are 42.25/43.25. The spectacle prescription is -2.00 -1.00 x 180 and the corneal E value is .5

In this example the first indicated lens will have a design code of 42.25/-2.00 (.5e).

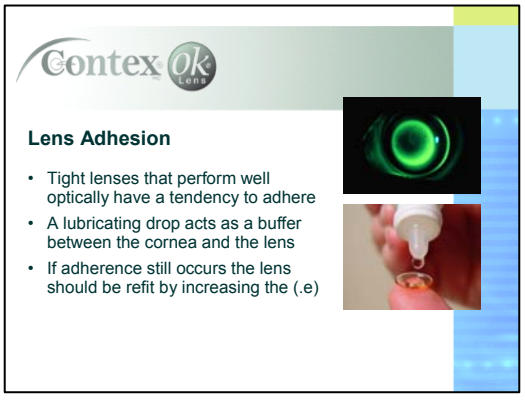
If this is a tight fitting lens consider loosening the lens fit by increasing the e-value .05e or approximately 10 microns. This will result in a new lens with a design code of 42.25/-2.00 (.55e). Conversely if this lens was fitting loosely, decrease the e-value by the same amount.



Changing the e value also improves lens centration.

If edge lift is excessive, lower the (.e) to increase the sagittal depth and tighten the lens.

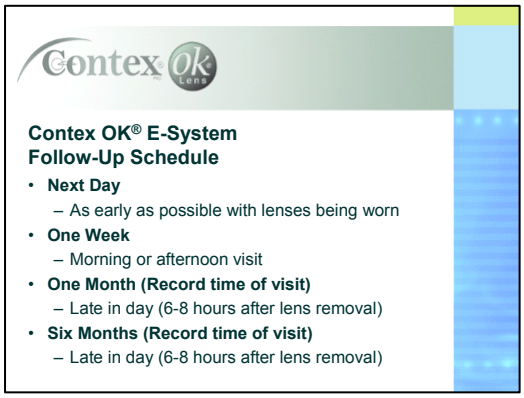
If edge lift is minimal, raise the (.e) to decrease the sagittal depth and loosen the lens. Typically once the lens has the correct "E" value it will center, but if this fails an increase in overall lens diameter may be necessary.



Lenses that perform well optically, but are somewhat on the tight side, can have a tendency to adhere.

It is recommended to use a lubricating drop as a buffer between the cornea and the lens. We recommend that the drops be put in the bowl of the lens and then applied to the eye.

If adherence still occurs, the lens is too tight and should be re-fit by increasing the "e"



Once the patient's ortho-k lenses have been dispensed, the follow-up process begins.

On the first follow-up visit, the patient should be seen early in the morning, either with the lens on or within 2 hours of removal.
At One Week you will see the patient again, either in the morning or afternoon but without lenses being worn. This visit will provide an idea of how much treatment effect is taking place.

At one month and six months, the patient should be seen later in the day (6 to 8 hours after lens removal) to determine how long the treatment is 'holding".

It is important to record the time of visit on all follow-ups. Also, the patient should be instructed to bring their lenses to every visit in case you want to inspect the cleanliness or quality.

Question 19: Which lens parameter(s) in the Contex OK® Lens E-System Design Code are changed to tighten or loosen the lens?

Question 20: What lens parameters in the Contex OK® Lens Design Code are changed to improve centering of the lens?

That's it – you have completed the Contex OK Lens E-System Design Certification Test. This certification is the first step to begin fitting overnight orthokeratology in your practice.

Thank you for choosing the OK E-System Design by Contex.