Euclid Systems Corporation

Emerald™ Design Fitting Certification Course

Supplement

Bausch & Lomb
Vision Shaping Treatment™

The Euclid Systems Corporation Emerald™ Design for Vision Shaping Treatment Certification Course

Welcome to the Emerald 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 Emerald Design.

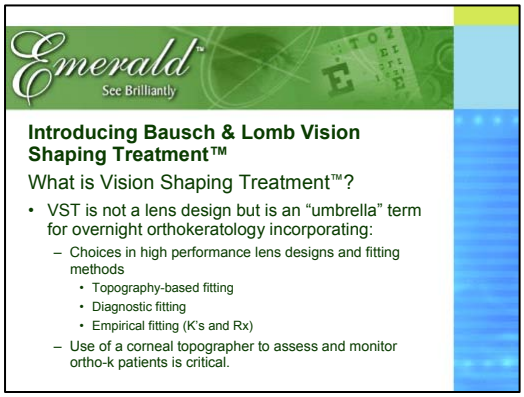
Please keep in mind that this certification test is not meant to take the place of detailed training on overnight orthokeratology and the Emerald Design.

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. We will describe each of these in a moment.

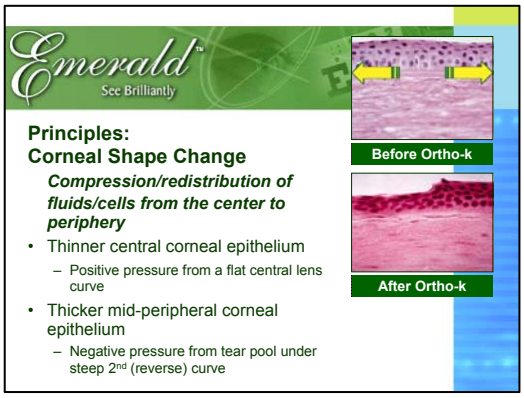
While corneal topography may not be necessary to select the initial lens in some of the vision shaping treatment design offerings, topography is considered essential to properly evaluate the ongoing progress in all designs.

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.

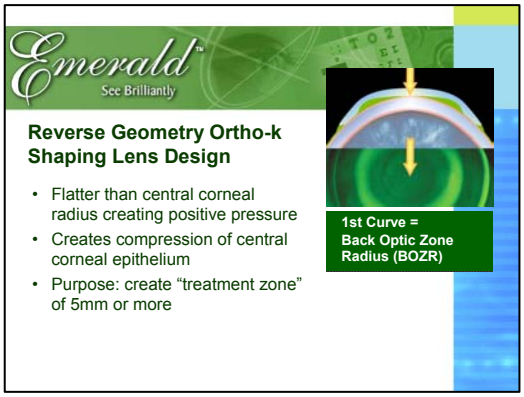
Uniquely, Boston Equalens II materials for overnight orthokeratology are available in distinctive colors to allow patients to easily discern which lens belongs in which eye.

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 created by the annular tear pool under a steeper second or reverse curve.

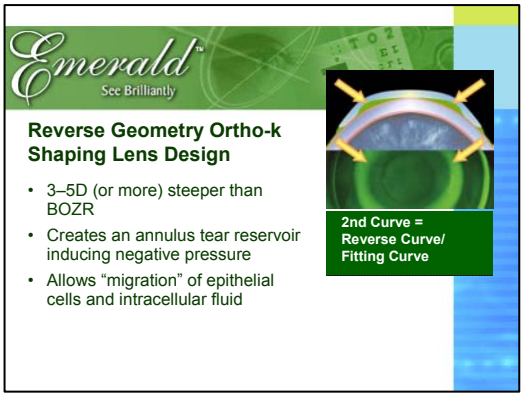


The back optic zone radius, also termed BOZR or base curve, is the first curve of Vision Shaping Treatment designs.

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.

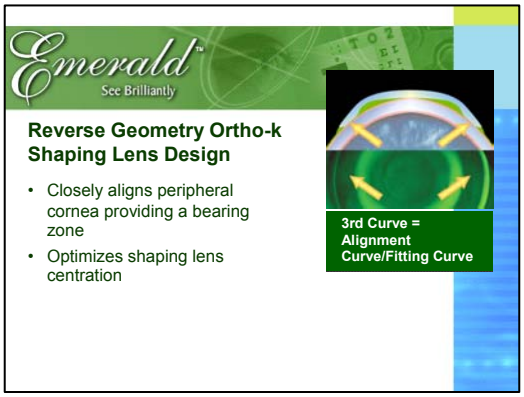


The second curve is most often termed the reverse zone and typically has a radius of 0.5mm to 1.0mm or is 3 to 5 diopters or more steeper than the back optic zone radius.

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.



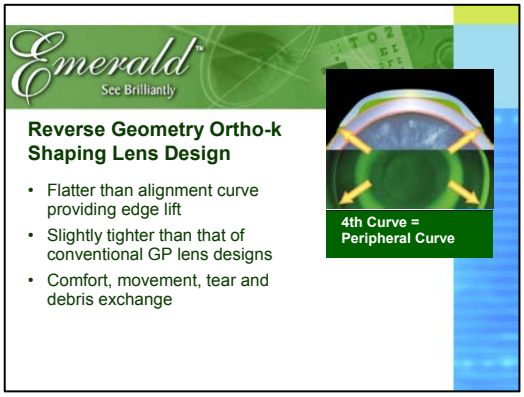
The third zone is the alignment zone.

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 Emerald Design Certification process. Here are the directions for completing your Answer Sheet.

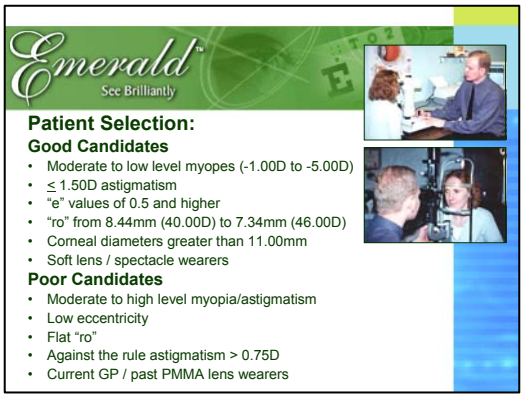
- *Be sure to completely fill-out the personal information at the top of the answer sheet. PLEASE PRINT LEGIBLY*
- *Choose the **best** answer from among those offered*
- *Mark your choice on the answer sheet by completely coloring-in the circle on the answer sheet*
- *If you decide to change your answer 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?

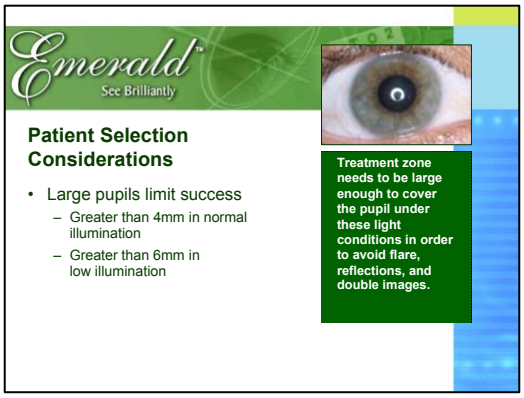


The range of myopic correction reduction approved with Vision Shaping Treatment is -1.00D to –5.00 Diopters.

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.

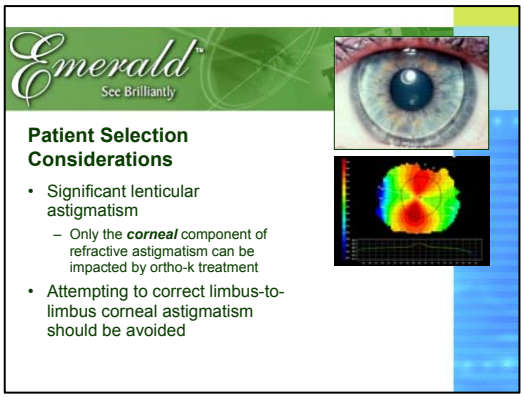
Beware of those patients with higher amounts of myopia, low corneal eccentricity measurements and flat corneas. Against the rule astigmatism greater than three quarters of a diopter can also be problematic, in that this reshaping process may induce even higher amounts of against the rule astigmatism. 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.

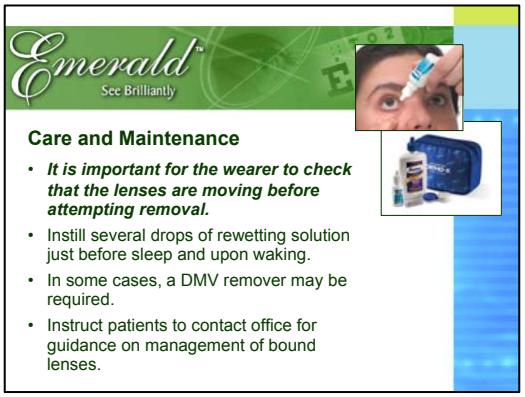
Also note patients who have demonstrated an allergic response to lens care products that would be used in vision shaping treatment.

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.

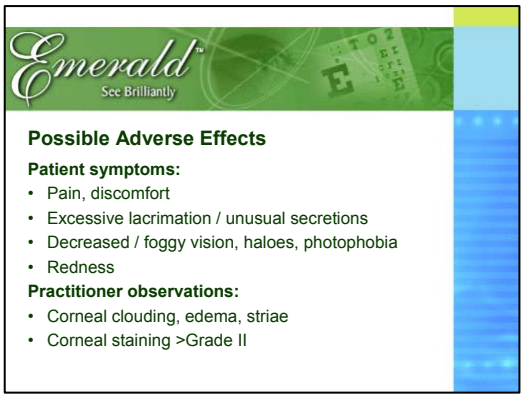
There is no need to remove the shaping lenses if awoken during the night - but upon awaking in the morning it is advisable that patients instill a few drops of the recommended rewetting solution and wait a few minutes before attempting to remove their lenses.

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.



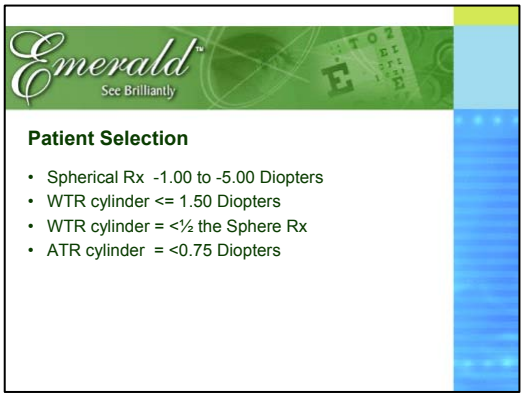
Patients should be advised to discontinue reshaping lens wear and call your office immediately if they experience pain, discomfort, excessive tearing or any of the other symptoms described on this slide.

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 Emerald Design works.

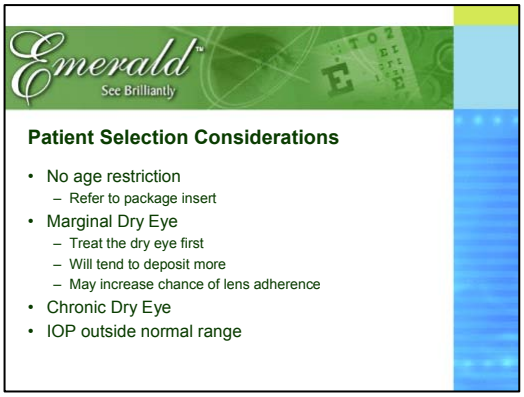


First let's reinforce some statements regarding patient selection. When considering the refractive error, the Emerald lens is recommended for patients with the following characteristics:

A myopic spherical component between –1.00 and –5.00 diopters combined with with the rule cylinder of up to 1.50 diopters. It is recommended that the with

the rule cylinder be no more than ½ the amount of the spherical correction.

Also consider that against the rule cylinder greater than 0.75 diopters will tend to cause lateral lens decentration problems and should be avoided.



There are currently no age restrictions in overnight orthokeratology. Please refer to the Emerald package insert for further information.

Patients with clinical dry eye may have difficulty obtaining consistent results and may be prone to SPK, deposits, and lens adherence.

Where dry eye conditions exist, the condition should be treated before the procedure is begun.

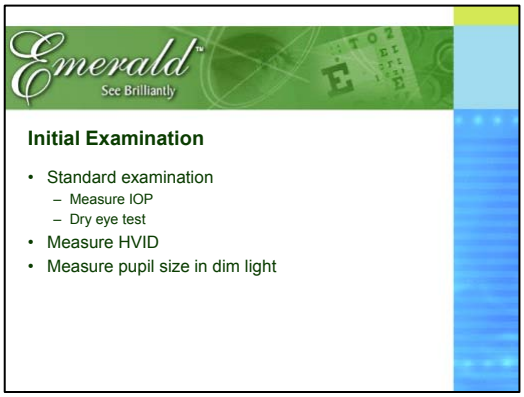
You should not proceed if the patient is diagnosed with chronic dry eye or if the intraocular pressure is outside the normal range. With a high intraocular pressure, the cornea will not respond; if it is too low the patient will not obtain good holding time on their visual acuity.

At the initial exam, use a well calibrated Keratometer to obtain K readings. For follow-up visits you will need a topographer, phoropter or autorefractor, and a yellow Wratten filter for your slit lamp to accurately assess the fluorescein pattern and corneal integrity. Keratometry is not recommended after the lenses have been worn since clinical studies have shown no correlation between the change in K-readings and the uncorrected visual acuity.

There currently is no standard by which all topographers can be calibrated. So, there could exist a great deal a variation between these instruments.

For this reason simulated K's from most topographers may not be accurate enough to base the lens design upon.

Numerous ortho-k fitting nomograms used over a long period of time have established that keratometers can be universally calibrated and used to successfully fit contact lenses for orthokeratology. However, It is strongly recommended that initial topography be used routinely to screen for corneal abnormalities and to establish a baseline.
A phoropter or well calibrated Autorefractor is necessary for determining the prescription and a slit lamp is required for evaluating the lens and the cornea.



The initial exam must include: Standard eye examination to measure the refraction and to obtain "K" readings.

The horizontal visible iris diameter, also termed HVID, should be measured. This is used in the Emerald design to determine the optimum lens diameter.

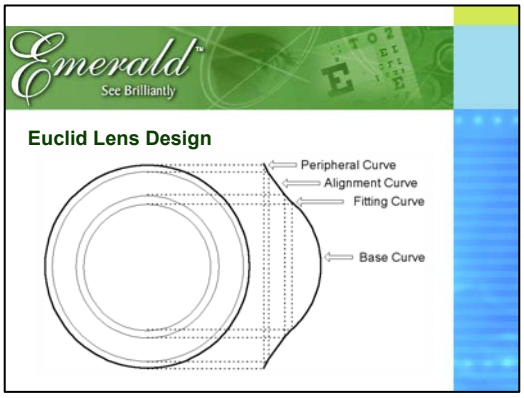
Pupil size should be measured in dim light. If the pupils are larger than 7mm the patient may not be an ideal candidate, especially if they spend considerable time in dim illumination.

It is critical to be sure of your measurements for accurate lens design. Instrument calibration should be regularly checked and multiple readings are always suggested.

Review the patient data and the topography maps. Repeat any numbers that don't make sense.

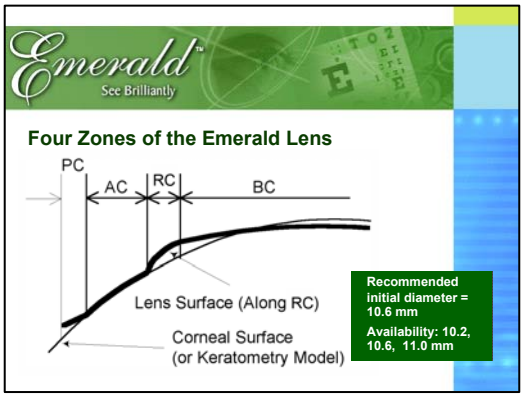
Question 11: Which of the following patients would be considered a *poor candidate* to be fitted with the Emerald Vision Shaping Treatment Design?

Question 12: The recommended data needed for designing an Emerald lens is:



With the Emerald design all of the parameters are determined by a series of computer calculations performed by Euclid Systems, based on the patient refraction and keratometry data, and horizontal visible iris diameter as they are supplied by you, the practitioner.

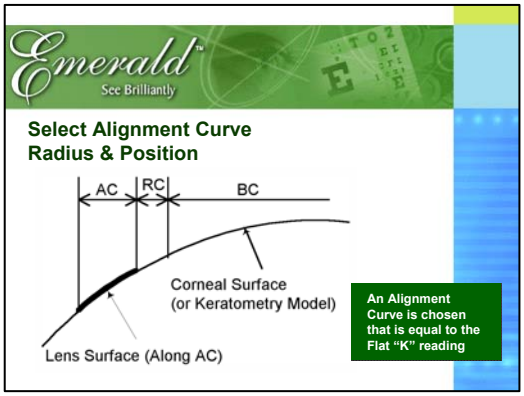
Importantly any of the curves can be adjusted if necessary to achieve the maximum effect.



The Emerald overnight ortho-k lens is a four-zone reverse geometry design whose purpose is to reshape the cornea when worn overnight (while sleeping) to temporarily reduce the need for daytime myopic correction.

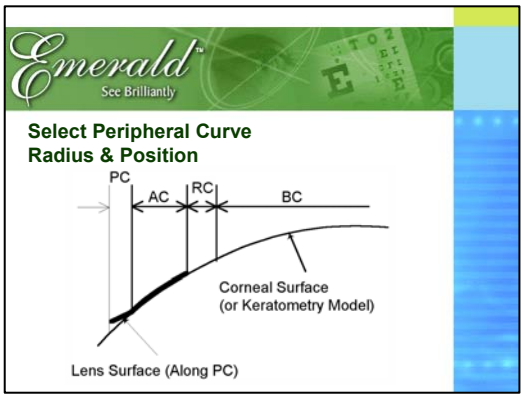
The first step is to determine the optimum diameter. This will ultimately affect the width of the alignment curves as well. The standard diameters are 10.2, 10.6 and 11.0, although diameters greater than 11.0 mm can be manufactured. The 10.6mm diameter is recommended initially. Consider an initial diameter of 10.2mm if the flat keratometer readings are steeper than 45.00 diopters or if the corneal diameter is smaller than 11.5mm, Select an initial diameter of 11.0mm if the cornea is spherical or there is "Against the Rule" Astigmatism.

The key to success is to choose a diameter that will provide corneal coverage up to approximately 0.4mm from the edge of the lens to the limbus. This will provide the best lens centration. If the lens decenters nasally or temporally during sleep, the lens diameter should be increased.



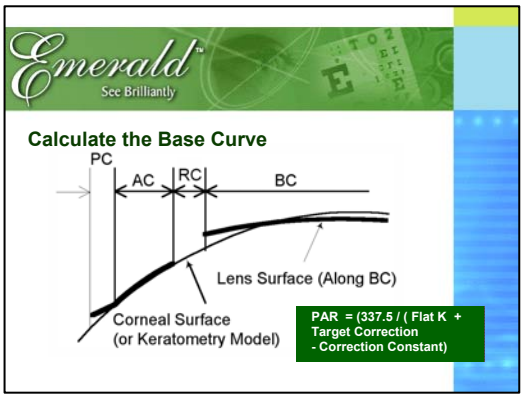
The alignment curve is calculated next. This curve is used to center the lens – a critical part of the successful procedure. This curve can be steepened or flattened as specified by the practitioner to allow the Alignment Curve to parallel the cornea as closely as possible in this area.

Initially, an alignment curve radius is chosen that is equal to the Flat "K reading. If the alignment curve is too flat, the lens will ride high. If it is too steep the lens will ride low.



The peripheral curve provides edge lift to the lens allowing for adequate tear exchange, debris removal, and to allow for lens movement.

The standard peripheral curve is an 11.50 mm radius that can be customized as needed.

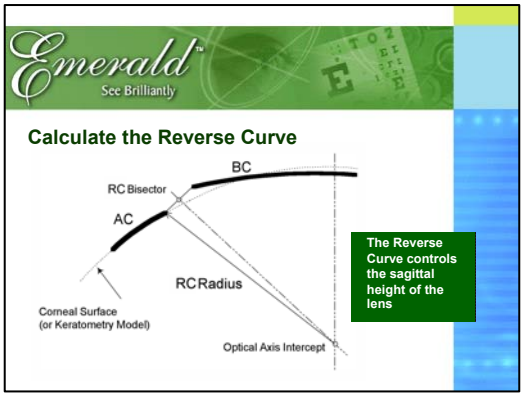


The third step in the design is to calculate the appropriate base curve or Posterior Apical radius also termed (PAR) to allow for the treatment of the patients myopia.

In the case of the Emerald™ lens, this curve will be flatter than flat K by the amount of myopia being targeted for correction, plus an additional 0.75D to allow for the corneal shape regression that will occur upon lens removal. This induced hypermetropia should allow excellent, device-free visual acuity for the wearer's waking hours.

Unlike a regular GP lens, the Emerald design Base Curve has no effect on the centration of the lens.

The formula to calculate the posterior apical radius "par" is shown on the screen.



The final curve to be calculated is the Reverse Curve. The Reverse Curve is calculated by Euclid to connect the base curve to the alignment curve and provide the appropriate area for reshaping.

This curve controls the sagittal height of the lens. It can be flattened to decrease the sagittal height and eliminate central islands or vaulting.

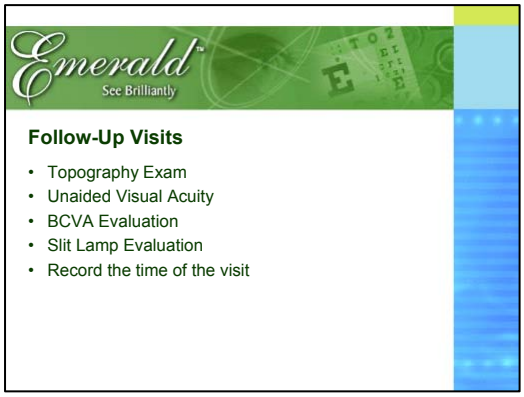
Conversely, centration improves steepening this curve thereby increasing the sagittal height.

Question 13: Which description best identifies the Euclid Emerald Ortho-k Design?

Question 14: The initial recommended Emerald lens diameter is:

Question 15: The Emerald design typically uses an Alignment Curve radius that is:

Question 16: What parameter change would likely be required if an Emerald design lens decenters horizontally?



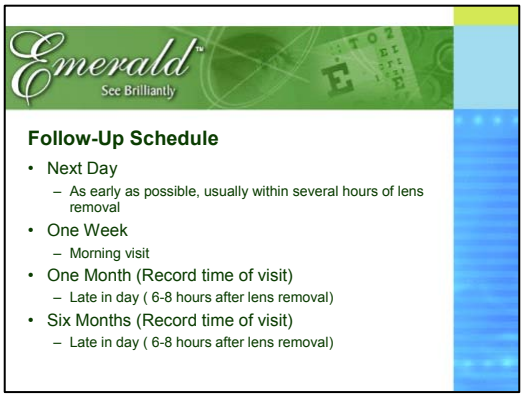
The tests listed here should be performed on each follow-up visit. This information is valuable if a lens parameter change is required.

It is not unusual to see mild SPK of a mechanical nature when the lenses are first worn. It should resolve during the day and not re-occur with any frequency.

SPK can also occur if the lenses become coated with protein. Since the lenses are designed to closely fit the cornea, tear exchange is minimal and patients must take special care to keep the lenses clean.

Always record the time of visit.

When you call for consultation at Euclid, you will be asked to provide this information in order to determine what change is necessary to improve the vision shaping treatment.



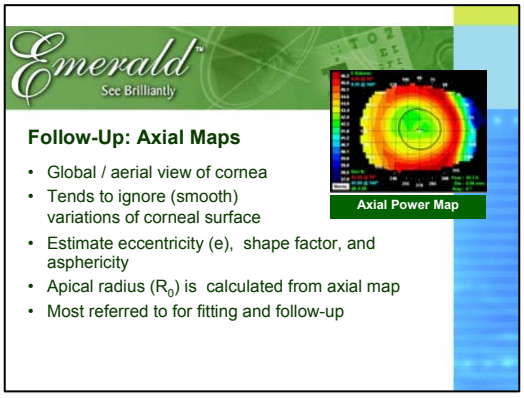
Once the patient's ortho-k lenses have been dispensed, the follow-up process begins. The patient should be instructed to bring their lenses to every visit so you can check the lenses for cleanliness and defects.

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 in the morning again, not wearing the lenses.

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".

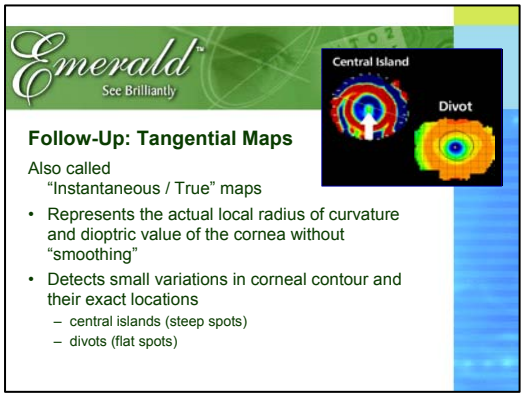
It is important to record the time of visit on all follow-ups.



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. for fitting and for comparison during follow-up exams.

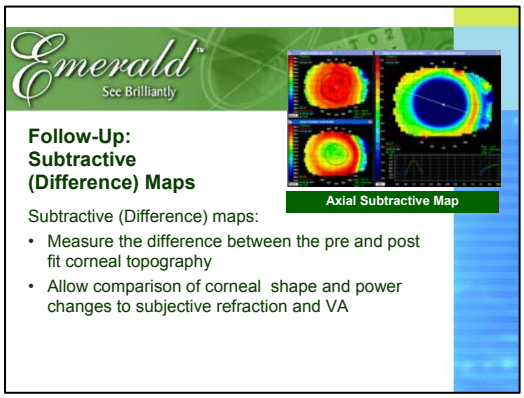
The apical radius at point zero (R0) is derived from this map as well. It is also the map most referred to



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.

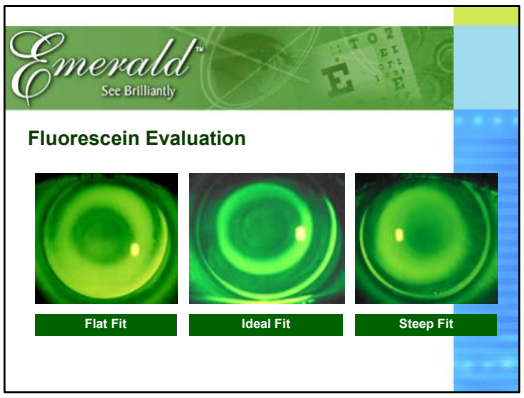


A subtractive plot or difference map, measures the difference between the pre and post fit cornea topographical maps.

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 subtractive plots are considered the most effective method for analyzing the ortho-k effect on the cornea.



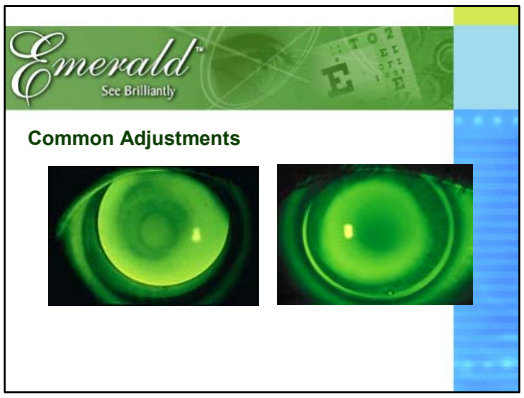
The lens shown in the center represents an ideal fit.

Here we observe a complete bearing area in the center and bright annulus of fluorescein under the reverse curve.

We note an even, broad distribution of fluorescein in the alignment zone showing a precisely aligned lens, with a complete smaller zone of fluorescein under the peripheral curve.

The flat-fitting lens on the left has a very wide Reverse Curve zone that shows fluorescein spreading into the alignment curve. This indicates an ortho-k lens that has a sagittal depth that is too low and an Alignment Curve that is too flat.

The lens on the right has a sagittal height that is too high resulting from an Alignment Curve that is much too steep causing the lens to lift (vault) the cornea. Both the left and right lenses should not be dispensed to a patient. Place a call to a Euclid Emerald Consultant for advice to correct the problem.

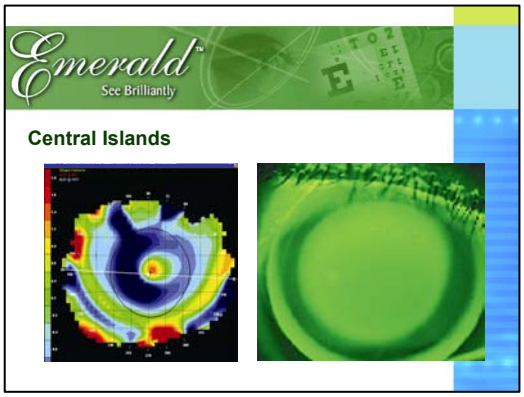


This next section will deal with evaluating and correcting fitting/shaping problems.

A “Smiley Face” topography map usually indicates that the sagittal height of the shaping lens is too low. The area of treatment (applanation) is positioned to high, causing a flattening of the superior cornea.

The usual remedy for resolving this type of fitting problem is to increase the sagittal height of the lens. This may be accomplished by steepening Reverse Curve radius and/or increasing Reverse Curve width, and/or changing base curve radius.

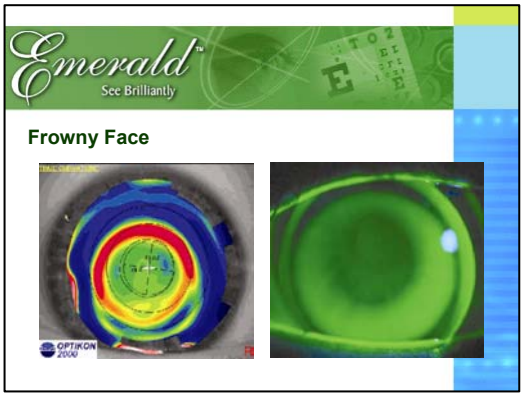
The Euclid Emerald Consultant can assist in making the proper adjustment.



A “Central Island” topography map usually indicates that the sagittal height of the shaping lens is too high. There is excessive pressure on the peripheral cornea that causes an uneven central treatment zone to form, affecting unaided visual acuity.

It is usually necessary to decrease the sagittal height of the lens to resolving this fitting problem. Accomplish this by flattening the Reverse Curve radius, and/or decreasing the Reverse Curve width, and/or changing base curve radius.

Once again, the Euclid Emerald Consultant can assist in making the proper adjustment.

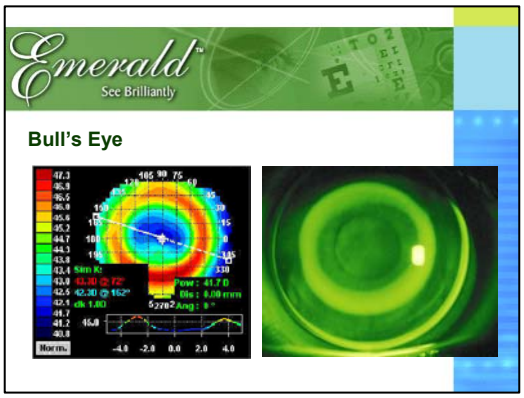


A “Frowny Face” topography map usually indicates that the sagittal height of the shaping lens is too high.

Because of the excessive sagittal height, the shaping lens is centering low and not able to raise to position over the central cornea.

Decrease the sagittal height of the lens to fix this fitting problem.

This may accomplished by flattening Reverse Curve radius, and/or decreasing the Reverse Curve width, and/or changing base curve radius.



A “Bull’s Eye” topography map indicates that the treatment is progressing properly. The treatment zone is centered properly over the central cornea and the area of flattening (applanation) is taking place uniformly, as desired.

In the beginning, this treatment zone may be well-centered, but small.

As long as the zone position is central and unaided visual acuity remains good, the patient should be monitored for progression and stabilization of the treatment zone over the next 1 or 2 weeks.

Question 17: A Subtractive or Difference map is used to determine:

Question 18: A “Central Island” topography map would indicate that the Emerald lens:

Question 19: A “Smiley Face” topography map would indicate that the Emerald lens:

Question 20: A “Bull’s Eye” topography map would indicate that the Emerald lens:

In summary, Emerald™ lenses have been clinically proven to provide an excellent lens choice for Overnight OrthoK as part of the VST system.

It is an excellent, safe, non-surgical alternative for management of myopia with few, if any, complications.

The procedure is reversible with the cornea returning to baseline after discontinuing lens wear.

Thank you for taking the Euclid Systems Emerald Ortho-k Certification Course and congratulations on completing this certification program.