

Gelflex

Incorporating **ACL**



The Emerald™ Design Fitting Certification Course

Welcome to the Emerald Design™ Certification Course. This handout will provide you with information on the Emerald Design™ for Orthokeratology. 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. Some suggested contacts would be...

- Optometrists Association
- Orthokeratology Society of Oceania
<http://www.osa.net.au/>

Note: Topography is considered essential to properly evaluate the ongoing progress in all designs.

Boston XO material is used for Emerald Design™ lenses and provides a significant amount of oxygen exchange having a Dk of 100 as measured by the ISO/Fatt method.

In orthokeratology the change in corneal shape results from forces exerted on the tear film between the back surface of the lens and the cornea. This causes a gradual and steady compression under the lens from the centre 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.

Principles:
Corneal Shape Change

- Thinner central corneal epithelium
 - Positive pressure from a flat central lens curve
- Thicker mid- peripheral corneal epithelium
 - Negative pressure from tear pool under steep 2nd (reverse) curve

The back optic zone radius, also termed BOZR or base curve, is the **First Treatment curve/zone**. Calculated to be flatter than the central corneal radius, this curve provides positive pressure resulting in compression of the central corneal epithelium.

Reverse Geometry Ortho-k Shaping Lens Design

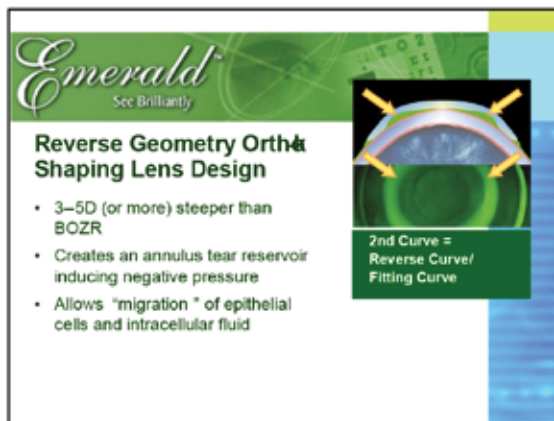
- Flatter than central corneal radius creating positive pressure
- Creates compression of central corneal epithelium
- Purpose: create "treatment zone" of 5mm or more

1st Curve = Back Optic Zone Radius (BOZR)

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 Treatment curve/zone** is most often termed the **Reverse curve/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.



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Reverse Geometry Ortho-k Shaping Lens Design

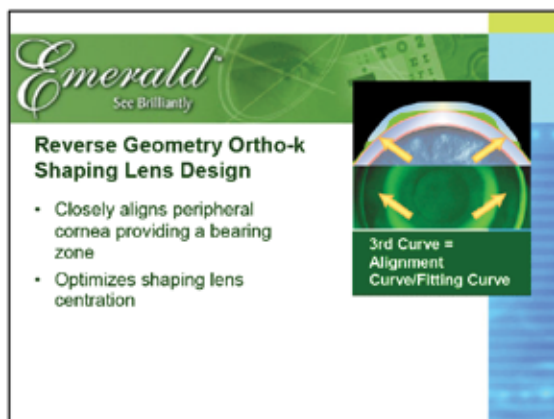
- 3–5D (or more) steeper than BOZR
- Creates an annulus tear reservoir inducing negative pressure
- Allows "migration" of epithelial cells and intracellular fluid

2nd Curve = Reverse Curve/ Fitting Curve

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 expand.

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

The **Third Treatment curve/zone** is the alignment curve/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.



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Reverse Geometry Ortho-k Shaping Lens Design

- Closely aligns peripheral cornea providing a bearing zone
- Optimizes shaping lens centration

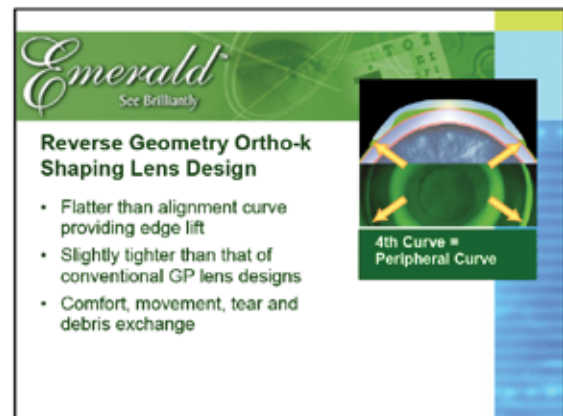
3rd Curve = Alignment Curve/Fitting Curve

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 **Fourth Treatment curve/zone** 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.



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Reverse Geometry Ortho-k Shaping Lens Design

- Flatter than alignment curve providing edge lift
- Slightly tighter than that of conventional GP lens designs
- Comfort, movement, tear and debris exchange

4th Curve = Peripheral Curve

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.

The range of myopic correction reduction approved is -1.00D to -5.00 Diopters.



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Patient Selection:

Good Candidates

- Moderate to low level myopes (-1.00D to -5.00D)
- ≤ 1.50D astigmatism
- "e" values of 0.5 and higher
- "ro" from 8.44mm (40.00D) to 7.34mm (46.00D)
- Corneal diameters greater than 11.00mm
- Soft lens / spectacle wearers

Poor Candidates


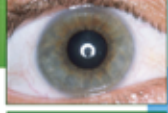
- Moderate to high level myopia/astigmatism
- Low eccentricity
- Flat "ro"
- Against the rule astigmatism > 0.75D
- Current GP / past PMMA lens wearers

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 ortho-k.

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. Even soft lens wearers must cease wear for up to 1 week.

Patient Selection Considerations



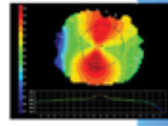
- Large pupils limit success
 - Greater than 4mm in normal illumination
 - Greater than 6mm in low illumination

Treatment zone needs to be large enough to cover the pupil under these light conditions in order to avoid flare, reflections, and double images.

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.

Patient Selection Considerations

- Significant lenticular astigmatism
 - Only the *corneal* component of refractive astigmatism can be impacted by ortho-k treatment
- Attempting to correct limbus-to-limbus corneal astigmatism should be avoided

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 ortho-k 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.




Patient Selection: Contraindications

- Active corneal infections of cornea, acute/subacute inflammation of anterior chamber
- Disease, injury, abnormality affecting cornea, conjunctiva, eyelids
- Severe dry eyes
- Corneal hypoesthesia
- Any condition exacerbated by contact lens wear
- Allergy to any ingredients in care solutions

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 ortho-k treatment.





Care and Maintenance

- *It is important for the wearer to check that the lenses are moving before attempting removal.*
- Instill several drops of rewetting solution just before sleep and upon waking.
- In some cases, a DMV remover may be required.
- Instruct patients to contact office for guidance on management of bound lenses.

Patient compliance is an important factor in the success of ortho-k patients. Here are a few important tips.

There is no need to remove the 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 lens is moving prior to lens removal.

Whilst removal of lenses is usually not a problem for patients. 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 lenses.

Possible Adverse Effects

Patient symptoms:

- Pain, discomfort
- Excessive lacrimation / unusual secretions
- Decreased / foggy vision, haloes, photophobia
- Redness

Practitioner observations:

- Corneal clouding, edema, striae
- Corneal staining >Grade II

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

Ortho-k treatment should also be discontinued if you observe any corneal hypoxia or staining greater than Grade 2.

Now that we have discussed some general principles regarding ortho-k 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 Design™ lens is recommended for patients with the following characteristics:

Patient Selection

- Spherical Rx -1.00 to -5.00 Diopters
- WTR cylinder \leq 1.50 Diopters
- WTR cylinder = $\leq \frac{1}{2}$ the Sphere Rx
- ATR cylinder = ≤ 0.75 Diopters

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 $\frac{1}{2}$ 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.

Patient Selection Considerations

- Marginal Dry Eye
 - Treat the dry eye first
 - Will tend to deposit more
 - May increase chance of lens adherence
- Chronic Dry Eye
- IOP outside normal range

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.

Instruments Required

Initial Exam and Follow-up

- **Calibrated Topographer**
- Corneal Topographer for screening & baseline record
- Phoropter or Autorefractor
- Slit Lamp
- Yellow Wratten Filter

At the initial exam, use a calibrated Topographer to obtain Sim 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.

Topography is 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.

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Initial Examination

- Standard examination
 - Measure IOP
 - Dry eye test
- Measure HVID
- Measure pupil size in dim light

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.

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Euclid Lens Design

Peripheral Curve
Alignment Curve
Fitting Curve
Base Curve

With the Emerald Design™ all of the parameters are determined by a series of computer calculations.

Which are based on the patient refraction, topography 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 Design™ overnight ortho-k lens is a four-zone (second zone can comprise one or more curves) reverse geometry design whose purpose is to reshape the cornea when worn overnight (while sleeping) to temporarily reducing the need for daytime myopic correction.

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Four Zones of the Emerald Lens

PC AC RC BC

Lens Surface (Along RC)
Corneal Surface (or Keratometry Model)

Recommended initial diameter = 10.6 mm
Availability: 10.2, 10.6, 11.0 mm

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.

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Select Alignment Curve Radius & Position

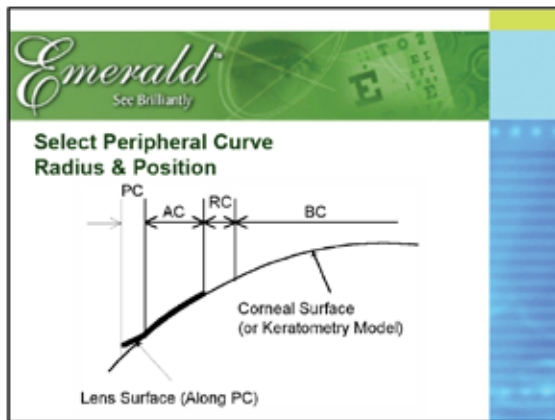
AC RC BC

Lens Surface (Along AC)
Corneal Surface (or Keratometry Model)

An Alignment Curve is chosen that is equal to the Flat "K" reading

This curve can be steepened or flattened as specified by the practitioner to allow the Alignment Curve to be parallel to the cornea as closely as possible in this area.

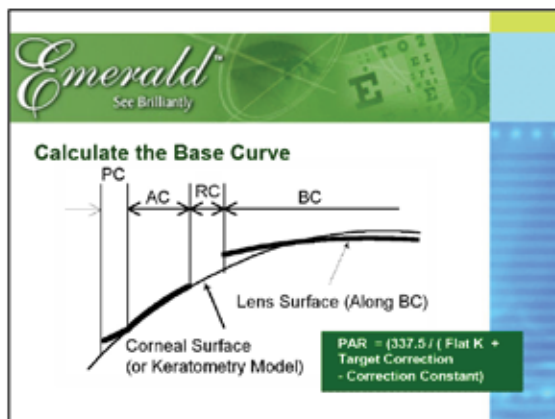
Initially, an alignment curve radius is chosen that is equal to the Flat "K reading. If the alignment curve is too flat, the lens will ride high. If it is too steep the lens will ride low.



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.

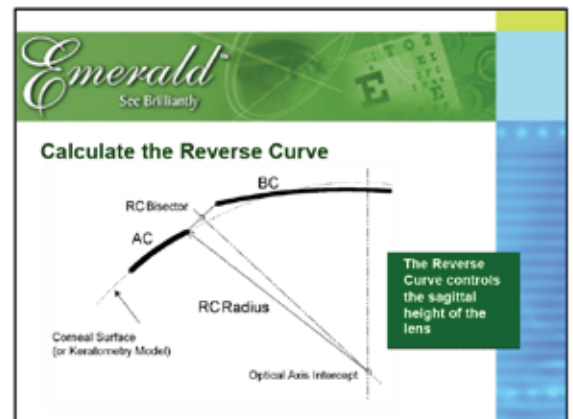
The third step in the design is to calculate the appropriate base curve or Posterior Apical radius also termed (PAR) to allow for the treatment of the patients myopia.



In the case of the Emerald Design™ 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 final curve to be calculated is the Reverse Curve. The Reverse Curve is calculated 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.

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.

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.



Follow-Up Schedule


- Next Day
 - As early as possible, usually within several hours of lens removal
- One Week
 - Morning visit
- One Month (Record time of visit)
 - Late in day (6-8 hours after lens removal)
- Six Months (Record time of visit)
 - Late in day (6-8 hours after lens removal)

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.

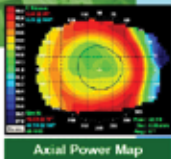
At one month and six months, the patient should be seen later in the day (6 to 8 hours after lens removal) to determine how long the treatment is 'holding'.

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



Follow-Up: Axial Maps

- Global / aerial view of cornea
- Tends to ignore (smooth) variations of corneal surface
- Estimate eccentricity (e), shape factor, and asphericity
- Apical radius (R_0) is calculated from axial map
- Most referred to for fitting and follow-up



Axial Power Map

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 (R_0) 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.



Follow-Up: Tangential Maps

Also called "Instantaneous / True" maps


- Represents the actual local radius of curvature and dioptric value of the cornea without "smoothing"
- Detects small variations in corneal contour and their exact locations
 - central islands (steep spots)
 - divots (flat spots)



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.

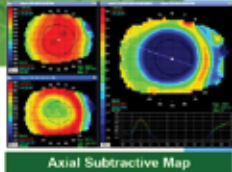
This allows for comparison of the alteration to corneal shape and power caused by the ortho-k lens.



Follow-Up: Subtractive (Difference) Maps

Subtractive (Difference) maps:

- Measure the difference between the pre and post fit corneal topography
- Allow comparison of corneal shape and power changes to subjective refraction and VA

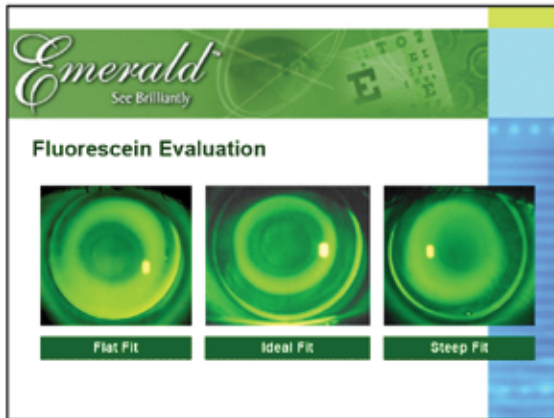


Axial Subtractive Map

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.



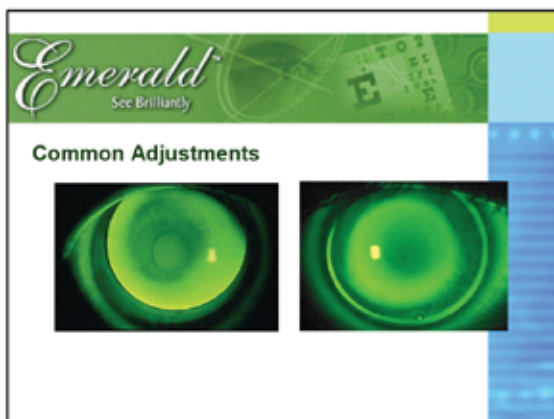
Here we observe a complete bearing area in the center and bright annulus of fluorescein under the reverse curve.

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.

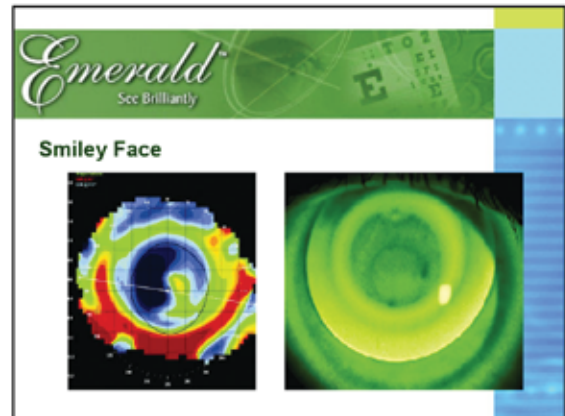
The flat-fitting lens on the left has a very wide Reverse Curve zone that shows fluorescein spreading into the alignment curve. This indicates an ortho-k lens that has a sagittal depth that is too low and an Alignment Curve that is too flat.

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. Please call Australian Contact Lenses for advice on correcting any fit issues.

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

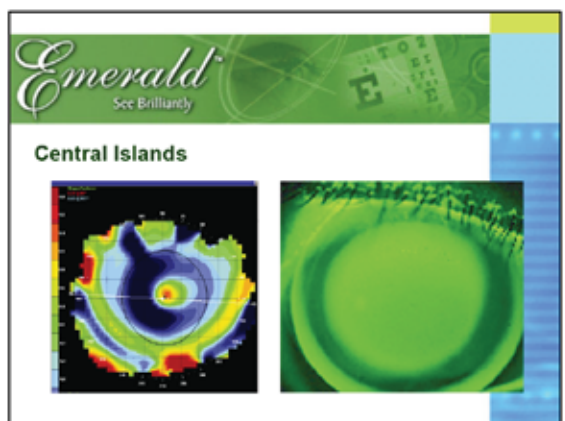


A "Smiley Face" topography map usually indicates that the sagittal height of the shaping lens is too low. The area of treatment (applanation) is positioned too high, causing a flattening of the superior cornea. The usual remedy for resolving this type of fitting problem is to increase the sagittal height of the lens.



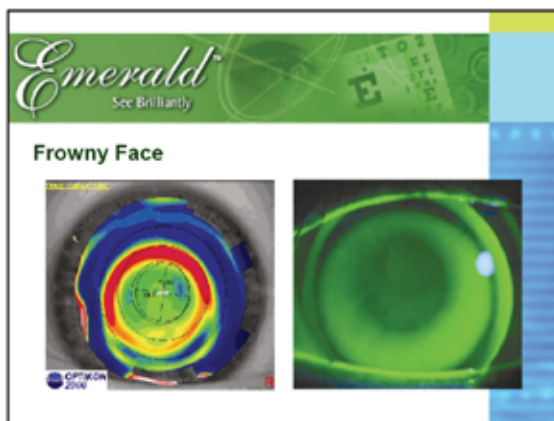
This may be accomplished by steepening Reverse Curve radius and/or increasing Reverse Curve width, and/or changing base curve radius.

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 resolve this fitting problem. Accomplish this by flattening the Reverse Curve radius, and/or decreasing the Reverse Curve width, and/or changing base curve radius.

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

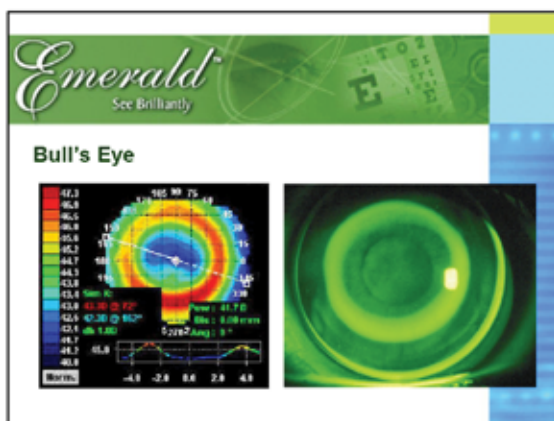


Because of the excessive sagittal height, the shaping lens is centering low and is not able to raise to position over the central cornea.

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

This may be 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.

In summary, Emerald Design™ lenses have been clinically proven to provide an excellent lens choice for overnight Ortho-K.

The figure shows the Emerald logo at the top left. Below it, the text 'Summary of Benefits' is displayed. To the right of the text is a list of five bullet points. The Emerald logo is also visible in the background of the slide.

Summary of Benefits

- Clinically proven procedure
- Non-surgical alternative for myopia management
- Safe procedure with few, if any, complications
- Reversible, with corneal shape returning to baseline after discontinuing lens wear
- Easy adaptation with only overnight wear required
- No daytime wear of corrective lenses needed

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 Emerald Ortho-k Certification Course and congratulations on completing this certification program.

