SMARTLENS™

FITTING GUIDE

THE NEXT GENERATION OF SCLERAL LENS DESIGN

KATT DESIGNGROUP

Original Boston Materials

SPECTRUM INTERNATIONAL

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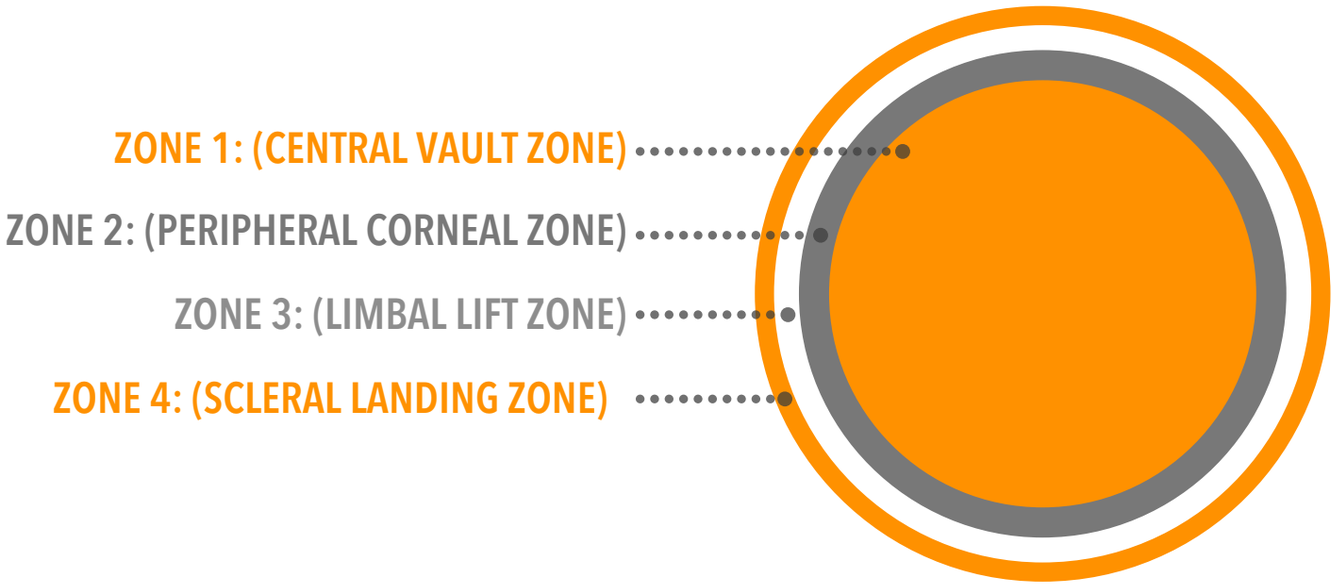
SMART 4 ZONE SCLERAL LENS DESIGN

The SMARTLENS™ is a new generation of vaulting scleral lens which incorporates numerous unique features unlike any other, making it the smartest scleral lens design.

SMART 4 ZONE INDEPENDENTLY CONTROLLED ZONES



Utilizing a proprietary **SMART 4 ZONE** lens design, the **SMARTLENS™** is incredibly forgiving in fit with a high first fit success rate.

When needed, each zone can be highly customized for the most complex of corneal and scleral shapes, making it the smartest lens design in the market.

The SMARTLENS™ construction allows it to be successful on normal corneal shapes as well as highly irregular post-surgical, diseased, trauma and bulging conditions. Practitioners have a wide range of fitting options from symmetric, toric and asymmetric landing, variable lens diameters, single vision, aberration control and multifocal optics.

The SMARTLENS™ provides practitioners with a scleral lens that can fit virtually any eye shape or condition with both efficiency and success.

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INTRODUCTION TO SMARTLENS™

16 LENS DIAGNOSTIC FITTING SET

Central Thickness of .30 on all lenses

(2) 15.0mm DIAMETER SYMMETRIC LENSES		
Sag. µ	Base Curve	Power
3.400	8.65	+3.00
3.800	8.04	0.00

(7) 15.5mm DIAMETER TORIC LANDING LENSES		
Sag. µ	Base Curve	Power
3.200	8.65	+4.00
3.400	8.65	+3.00
3.600	8.45	+2.00
3.800	8.04	0.00
4.000	7.50	-2.00
4.200	7.03	-4.00
4.800	6.75	-10.00

(7) 16.5mm DIAMETER TORIC LANDING LENSES		
Sag. µ	Base Curve	Power
3.800	8.44	+2.00
4.000	8.44	0.00
4.200	8.04	-2.00
4.400	8.04	-4.00
4.600	8.04	-6.00
4.800	8.04	-8.00
5.200	7.34	-12.00

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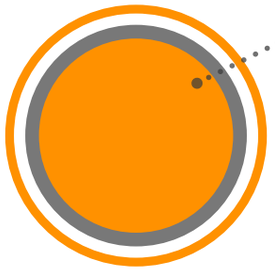
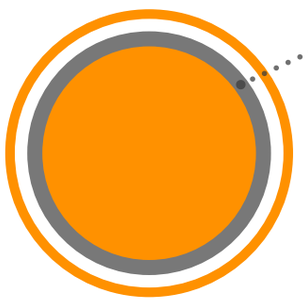


ZONE 1: (CENTRAL VAULT ZONE)

The 1st zone in the SMARTLENS™ uses a radius of curvature to follow the natural curve of the central corneal. The function of Zone 1: (Central Vault Zone) is to clear all central corneal tissue. It is not typical to require adjustments to this zone, however, the base curve can be steepened or flattened when desired to create more or less central vault.

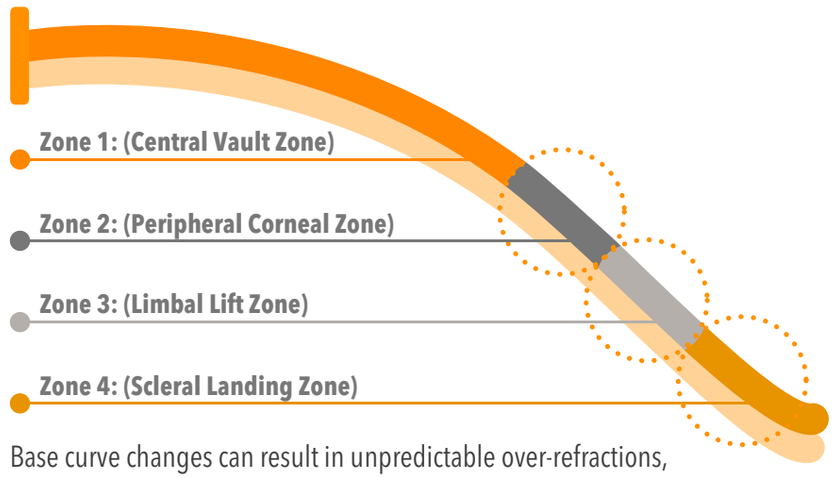
As an example, steepening the center two zones does not steepen the outer two zones or visa versa. Each zone can be altered separately from the adjacent zones. This provides an exceptional level of customization when required on the most challenging of eye shapes.



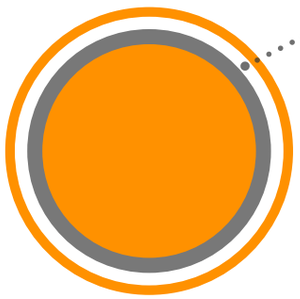
ZONE 2: (PERIPHERAL CORNEAL ZONE)

The 2nd zone in the SMARTLENS™ uses the **SMART 4 ZONE** technology to run parallel to the peripheral corneal surface. The Zone 2: (Peripheral Corneal Zone) is meant to clear or vault the peripheral corneal tissue. This zone can be altered positively or negatively to raise or lower the vault through this zone and Zone 1.

In cases where an oblate cornea exists, this zone can be used to create a reverse geometry shape. Or in bulging eyes, it can be increased to raise the peripheral corneal vault.



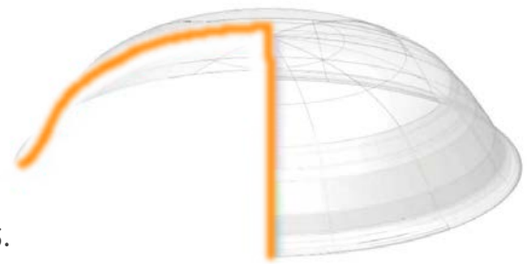
Base curve changes can result in unpredictable over-refractions, whereas raising or lowering the Zone 2: (Peripheral Corneal Zone) specifically alters the sagittal height. In the diagnostic set, the Zone 2: (Peripheral Corneal Zone) varies as the sag values change.



ZONE 3: (LIMBAL LIFT ZONE)

The 3rd zone in the SMARTLENS™ also uses the **SMART 4 ZONE** technology to vault th ough the sensitive limbal anatomy and link the lift in Zone 2 (Peripheral Corneal Zone) to the landing in Zone 4 (Scleral Landing Zone).

The Zone 3 is typically altered when extra limbal vault is required. Increasing or decreasing Zone 3 will raise or lower the central two zones of the lens. When making Zone 3 changes that might adversely affect the apical clearance, a modification to the Zone 1 or Zone 2 can be altered to neutralize or compensate for these adjustments.



NOTE: All positive (+) step zone adjustments increase the overall depth of the lens. Conversely, all negative (-) step adjustments to the zones decrease the overall sagittal depth of the lens. The Zone 2 (Peripheral Corneal Zone) and Zone 3 (Limbal Lift Zone) are controlled by SMART 4 ZONE technology. More forgiving and easily adjusted when we need to increase or decrease elevation. Smart!

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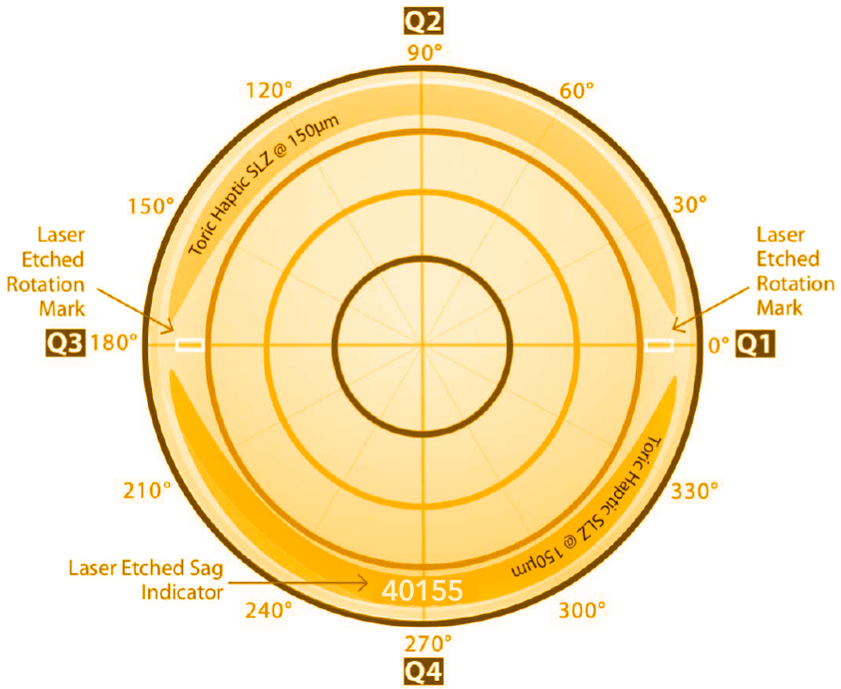
ZONE 4: (SCLERAL LANDING ZONE)

The Zone 4 uses a propietary shape that's designed to distribute its pressure over a broad surface area. It is uniquely designed to be forgiving based on the wide range of scleral angles it may land on. And it can be easily adjusted to suit an extremely high or low scleral angle.

Lens Thickness

The standard center thickness (CT) of the SMARTLENS™ GP is: **.30mm** Standard or **300** (µm). Available in .01mm steps.

SMARTLENS™ diagnostic and custom lenses in the primary diameter ranges have a **Toric Haptic Periphery (THP).**



15.0mm Dx Lenses have a spherical periphery and a 2-digit sag indicator (ie: 40) and 15.0mm as diameter indicator.
15.5mm Dx Lenses have a 125µm toric haptic periphery and a 2-digit+T sag indicator (ie: 40T) and 15.5mm as diameter indicator.
16.5mm Dx Lenses have a 150µm toric haptic periphery and a 4-digit sag. indicator (ie: 4000) and 16.5mm as diameter indicator.

360º

- The inclusion of the toric haptic periphery provides alignment on the sclera
- Aids in the lens centration
- Axis stabilizer in case of Cylinder correction

The **SMARTLENS™** is not meant to sit on any specific axis, so the rotation indicating hash marks denote the flat axis of the lens.

Upon insertion, **SMARTLENS™** will automatically find the flattest meridian of the sclera and remain rotationally stable on that axis.

The majority of the time, the scleral flat meridian will not line up with the flat K or refractive axis, so it is important to note the axis where the lens finds its rotational stability.

Noting the axis of the flat meridian insures that the correct axis is compensated for when front surface cylinder is required. The lens sag is laser etched.

SELECTING THE RIGHT DIAGNOSTIC LENS FOR YOUR PATIENT

SMARTLENS™ FITTING TECHNIQUE

HVID and topography are useful, and **a diagnostic fitting set is required.**

HOW? The SMARTLENS™ is designed to vault the whole cornea and rest on the sclera.

DIAGNOSIS FITTING STEPS:

- **HVID** MEASUREMENT
- **DETERMINE CONDITION (EYE DEPTH):**
NORMAL, MEDIAN, OR HIGH SAG HEIGHT
- **SELECT DIAGNOSTIC:** 15.0mm, 15.5mm OR 16.5mm TRIAL
BASED ON HVID AND CONDITION
- **PREPARE LENS:**
CLEAN AND RINSE

SMARTLENS™ PARAMETERS

Zone Adjustments: Each zone of the **SMARTLENS**™ can be adjusted to customize the lens for each individual eye.
Often the trial parameters will need few changes other than power. However, when faced with odd shaped surfaces, the **SMARTLENS**™ allows for a wide range of adjustments to each zone, including: Limbal and Scleral zone toricity, Quad Specific and Front Toricity when needed.

Base Curve Range: 5.72 – 9.64mm (59.00 – 35.00D)
Diameter Range: 14.5 – 17.0mm (0.1mm increments)
Power Range: ±30.00D (0.25D steps)
Cylinder Range: up to -5.00D
Axis: 1-180
Dual Depth Axis: 0-360
Zone 2 (PCZ): +/-15 in steps of 25µ

Zone 3 (LLZ) : +/-15 in steps of 25µ
Zone 4 (SLZ) : +/-15 in steps of 25µ

Zone 3 and Zone 4 (LLZ/SLZ) Toricity: +15 in steps of 25µ
Quadrant Specific: +/-15 in steps of 25µ (independent control of each of the 4 zones)

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SMARTLENS™ FITTING TECHNIQUE

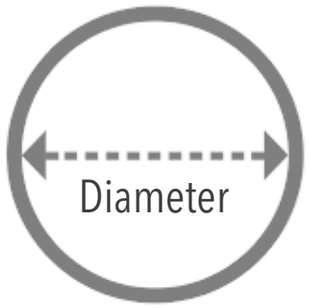
STEP 1

Measure the size of the horizontal visible iris diameter (HVID) to calculate which diagnostic diameter may be most appropriate for the patient. Add 3.5mm to the HVID measurement to determine the closest diagnostic lens diameter or choose the larger when in doubt.

The SMARTLENS™ diagnostic lenses are labelled according to their sagittal depth (Sag). The initial lens is best chosen based on the eye condition rather than the radius of the eye. Is the eye essentially normal in shape? If so, choose the **"Normal Depth"** diagnostic. If the patient has a corneal thinning disorder then choose the **"Keratoconus Depth"** sag. If the patient has had a graft, then choose **"High Depth".** Simply determine the condition and find the sag of lens in this category from the fitting chart below. (See Image 1.0)

1.0

FIT BY HORIZONTAL VISIBLE IRIS DIAMETER AND CONDITION		
HVID	≤11.5	≥11.6
TRIAL SET DIAMETER	15.5mm	16.5mm
NORMAL DEPTH Post refractive surgery, normal shape	3400µm	4000µm
MEDIAN DEPTH Keratoconus, PMD	3800µm	4400µm
HIGH DEPTH Corneal transplant, keratoglobus, bulging	4200µm	4800µm
For unusually small visible iris diameters or narrow fissures, the 15.0mm diagnostics can be useful. For normal shape eyes, choose the 3400µm and for median depth eyes, choose the 3800µm		



DIAGNOSTIC LENSES:

The SMARTLENS™ is available in 3 standard trial diameters, 15.0mm, 15.5mm and 16.5mm.
It's SMART design allows you to fit small and large corneas, as well as low and high asymmetries.

NOTE:

Initial trial lenses are selected by patient condition, as opposed to K-reading. The depth of the eye determines the depth of the initial trial lens. Lenses are labeled, selected and ordered according to their sagittal depth as opposed to base curve. See chart above.

SMARTLENS™ FITTING TECHNIQUE

15.0mm

• Symmetric landing because they align closer to the limbus where the scleral elevation is more uniform 360 degrees around.
• Unique Zone 3 (Limbal Lift Zone) scribes that help practitioners determine if the diameter is appropriate to clear and protect the sensitive limbal stem cell region of the eye.
• These markers run the width of Zone 3 and end where Zone 4 begins. Zone 3 scribes that appear outside the border of the horizontal visible iris indicate the appropriate lens diameter. Zone 3 scribes 100% inside the horizontal visible iris diameter would suggest a larger diameter is required. The width of the Zone 3 is 0.6mm which provides a measuring tool to indicate how much larger in diameter the custom lens should be ordered.

15.5mm and 16.5mm

• The larger 15.5mm and 16.5mm diagnostic lenses come standard as a toric landing because they touch down farther out on the sclera where the surface shape is increasingly toric or asymmetric.
• In cases where a front toric is required, the toric 15.5mm and 16.5mm diagnostic lenses can be evaluated for rotational stability. Two scribe marks are placed on the anterior surface of the lens 180 degrees apart and denote the flat meridian of the back surface.
• If the scribes are rotationally stable, then front surface cylinder can be added to lens with the confidence it will stay on the correct axis.
• The 15.5mm and 16.5mm diameters use toricity in the landing to distribute the force evenly across the asymmetric scleral. This produces better comfort, less blanching (tight edge) and less fogging. It also means that the lens should be rotationally stable in case we need a bitoric scleral lens due to residual astigmatism. Smart and super-efficient!

STEP 2

APPLICATION AND INITIAL EVALUATION:

• APPLICATION: WITH PRESERVATIVE FREE SALINE AND FLUORESCEIN IN THE BOWL
• BUBBLES: CHECK FOR THE ABSENCE OF APPLICATION BUBBLES. RE-APPLY IF PRESENT
• CORNEAL BEARING: APPLY A HIGHER SAG DIAGNOSTIC IF TOUCH OR NEAR BEARING IS APPARENT

- After washing and drying your hands, remove the lens from the case and clean with an approved GP lens surfactant cleaning solution.
- Rinse the cleaner off with an approved contact lens rinsing solution.
- Place the lens in the large suction cup (bowl side up) and fill with preservative free saline.
- Then with the fluorescein strip, place a generous amount of dye in the bowl and top up the fluid so it is overfilling the lens.

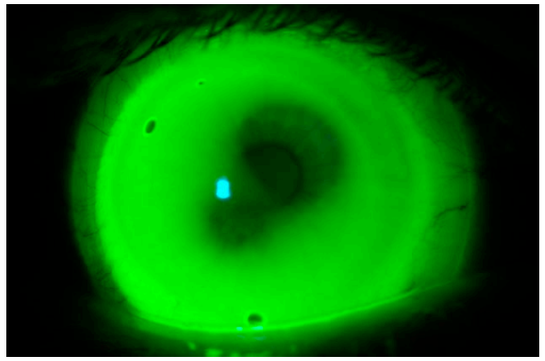
SMARTLENS™ FITTING TECHNIQUE

APPLICATION:

- Patient position: Have the patient stand with their back at a 45 degree angle and their face flat to the plane of the floor.
- Lids: Have the patient pull down on their cheek to move the lower lid out of the way. The practitioner can lift the upper lid to open the fissure completely.
- Application: With the patient looking into the bowl bring the lens to the eye and gently apply the lens, squeezing the access fluid out during the process.

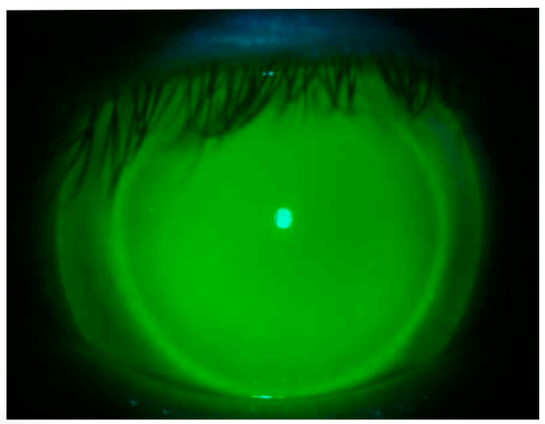
INITIAL EVALUATION:
CHECK FOR BUBBLES

With a blue penlight, check for obvious bubbles trapped in the fluid reservoir.
If bubbles are present, remove the lens and re-apply without any air pockets trapped behind the lens.



CORNEAL BEARING:

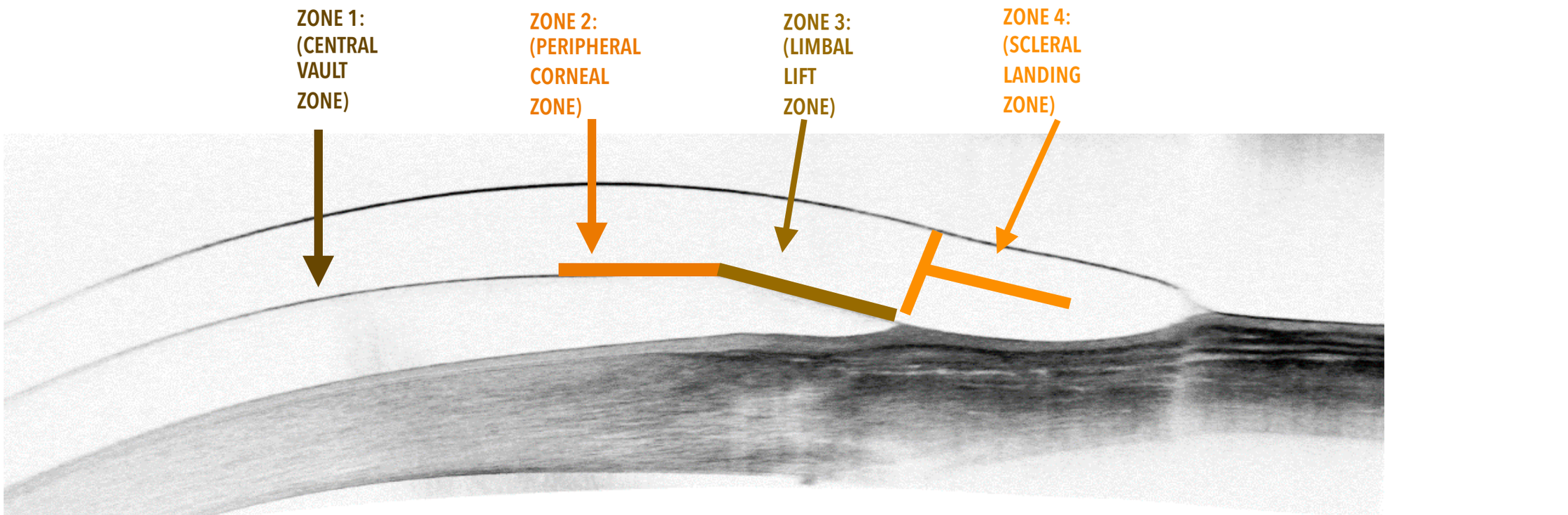
If a diagnostic lens exhibits obvious bearing or is very near to the corneal surface, then it should be removed and a higher depth diagnostic applied.



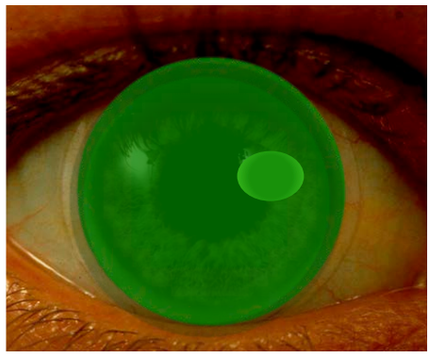
TIP:

The principle function of the diagnostic lens is to determine which height of lens (Sag) will optimally vault the cornea. Once the correct height of lens has been determined, then the other zones of the lens can be assessed.
Reminder: the first step is to fit the lens with the optimal apical clearance.

SMARTLENS™ FLUORESCEIN

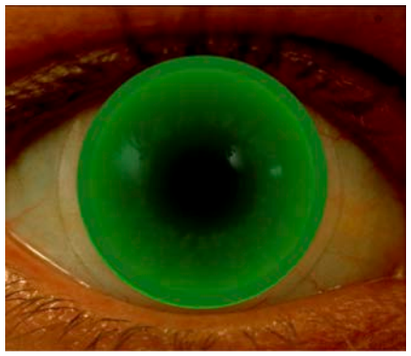


BUBBLE IN RESERVOIR



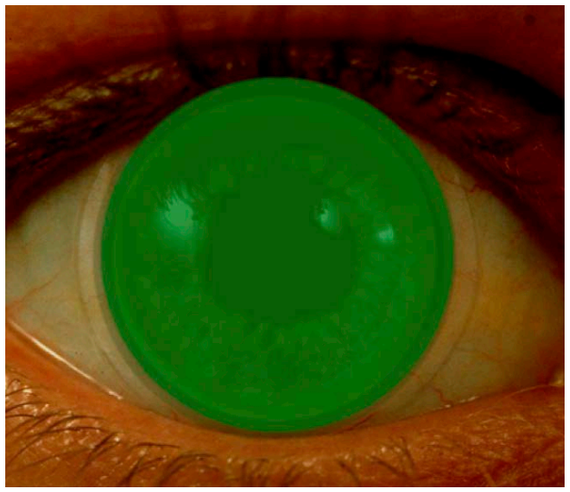
Re-apply lens with plenty of solution

CORNEAL TOUCH INADEQUATE SAG.

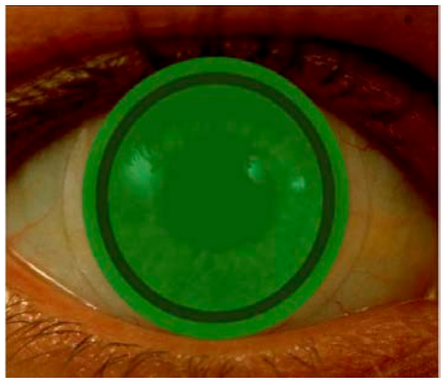


Choose a higher sag lens, steepen the base curve or increase Zone 2 (Peripheral Corneal Zone)

IDEAL APPLICATION AND CORNEAL CLEARANCE

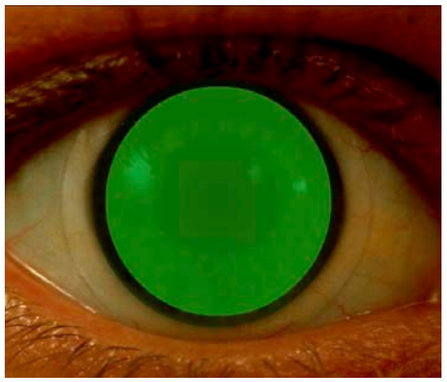


PCZ BEARING



Increase Zone 2 (Peripheral Corneal Zone) +4 or Zone 3 (Limbal Lift Zone) +4

LCZ BEARING



Increase Zone 3 (Limbal Lift Zone)+5

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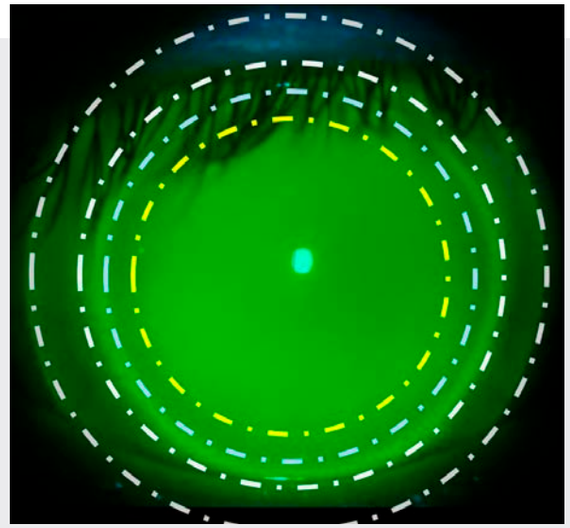
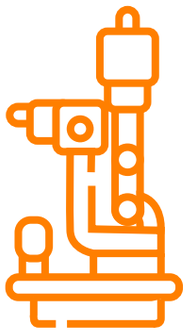
SMARTLENS™ FITTING TECHNIQUE

STEP 3

POST SETTLING EVALUATION

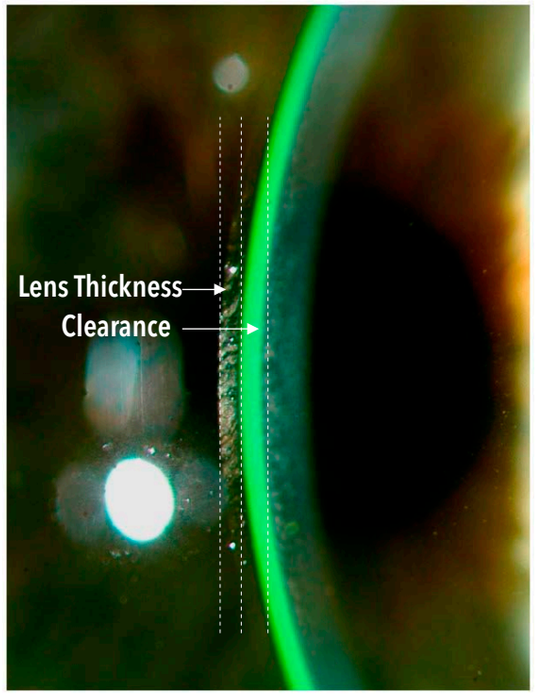
- ZONE 1 (CENTRAL VAULT ZONE): MEASURE THE APICAL CLEARANCE WITH OPTIC SECTION AND CHECK FOR ANY CORNEAL BEARING
- ZONE 2 (PERIPHERAL CORNEAL ZONE): CHECK FOR ANY PERIPHERAL CORNEAL BEARING
- ZONE 3 (LIMBAL LIFT ZONE): CHECK FOR ANY LIMBAL BEARING
- ZONE 4 (SCLERAL LANDING ZONE): CHECK FOR BLANCHING OR A TIGHT EDGE
- OVER-REFRACTION: SPHERE OR SPHERO-CYLINDRICAL
- CHECK SCRIBE MARKS
- 15.0MM: DETERMINE IF THE ZONE 3 (LLZ) SCRIBES ARE INSIDE, OVER OR BEYOND THE HVID





SLIT LAMP EVALUATION:

Check that the lens Zone 1 (Central Vault Zone) is completely clearing the central cornea. Using the optic section of your slit lamp at 45 degrees, estimate the posterior fluid thickness in relationship to the known thickness of the diagnostic (0.3mm or 300 microns). Prior to settling, an apical clearance of 300-400 microns is desirable and allows the lens ample vault to sink into the soft conjunctival tissue. Choose a higher or lower depth diagnostic if inadequate or excessive apical clearance exists.



COMFORT:

The SMARTLENS™ should have minimal discomfort on application and should feel very similar to soft contact lens wear. A lens that is uncomfortable is a sign that something needs modification in the fit.

SETTLING:

Scleral lenses slowly sink into the soft, spongy conjunctival tissue over time. Research shows these lenses sink over the entire course of the day with the vast majority of settling in the initial four hours of wear. Before making a final lens assessment, allow approximately 1-Hour of settling time or more where possible. This will help observe any signs of inadequate clearance over high points in the cornea. It will also make apparent whether any of the zones require adjustments.

SMARTLENS™ FITTING TECHNIQUE

POST SETTLING EVALUATION:

After the settling period, each zone of the SMARTLENS™ can be assessed and a determination of the final lens parameters can be made. Observations are best made from the center towards the periphery with the outer zones requiring the most detailed assessment.

STEP 4

POST SETTLING EVALUATION:

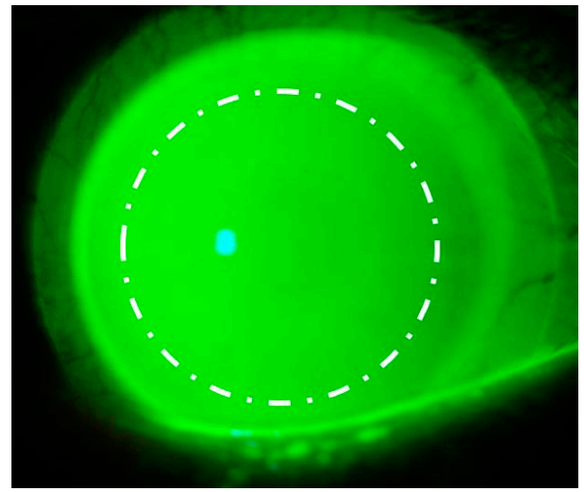
Zone1: (Central Vault Zone) The lens should clear the central corneal tissue and exhibit approximately 200-300 microns of post settling vault.
Zone 1 Tips: There are three ways to alter the apical clearance when required in the custom SMARTLENS™ .

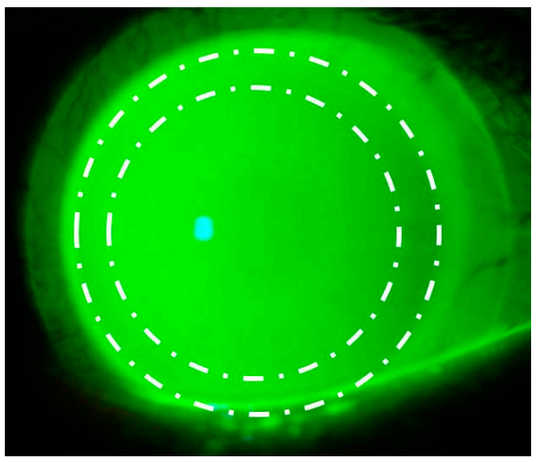
BASE CURVE:

A 1.00 diopter change in base curve creates an approximately 50 micron sagittal height change. Flatten the custom lens base curve 1.00 diopter and there will be 50 microns less sagittal height and apical clearance. Steepen the base curve 1.00 diopter and there will be 50 microns more apical clearance.

CHANGE THE SAG:

When large adjustments of approximately 200 microns are required, switch to a different sag of lens. For instance, if the 4400 micron trial had 500 microns of apical clearance and 300 microns was desired, custom order the 4200 micron sag. Conversely, if an additional 200 microns was required then switch from a 4400 micron lens to a 4600 sag.



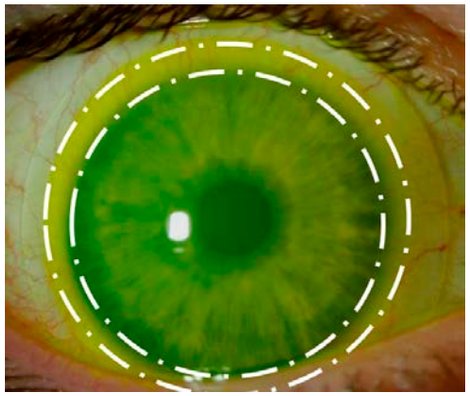


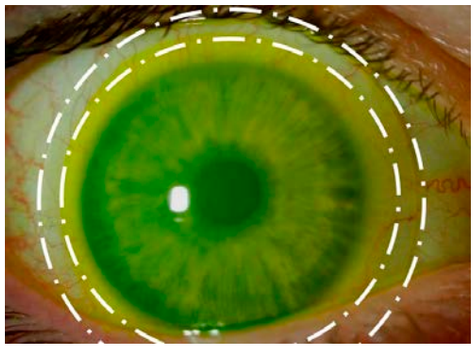
Zone 2: (Peripheral Corneal Zone): The lens should clear the peripheral corneal tissue and protect the epithelium from any mechanical agitation. The lens does not need to clear the peripheral corneal by a specific micron vault but there should be enough to allow for the settling that occurs throughout the daily wearing time.

Zone 2: (Peripheral Corneal Zone) Tips: If the lens is bearing on the peripheral corneal, then order Zone 2 (Peripheral Corneal Zone) **:** +4 (4 x 25 = +100 microns) which creates a significant change in the vault. This adjustment is often required on kerato-globus and bulging transplant eyes. Conversely, in post refractive surgery and oblate corneal shapes, it may be necessary to reduce the Zone 2 (Peripheral Corneal Zone) to decrease the central vault in which case you can order an adjustment based on the required change in apical clearance.

Modifying the Zone 2 (PCZ) lifts or drops Zone 1 (CVZ) and apical clearance. Zone 2 (PCZ)+1 would increase the vault +25 microns. Zone 2 (PCZ) -1 would decrease the vault -25 microns. Use multiple steps when necessary to create larger sagittal height changes.

SMARTLENS™ FITTING TECHNIQUE





Zone 3 (Limbal Lift Zone): The lens should clear the visible iris and the area immediately adjacent to ensure we are protecting the sensitive limbal stem cell region.

Zone 3 Tips: In patients with high scleral angles, it is common to require an increased Zone 3 vault. If the diagnostic lens is landing or bearing at the limbus, increase the Zone 3+5 (5 x 25 = 125 microns). A +5 step adjustment in the Zone 3 is typically enough to create clearance when the diagnostic lens is in touch.

Zone 4 (Scleral Landing Zone): This zone should bear the weight of the lens across the bulbar conjunctiva. A well fit lens should show 360 degrees of alignment with the absence of any bubble ingress. Additionally, there should be an absence of any restriction of the blood vessels at the tip of the edge or throughout Zone 4.

Zone 4 Tips: If the lens exhibits any blanching of the conjunctiva due to a tight edge, then increase the edge lift. For one acute point of restriction, order Zone 4 -1. If the lens is tight on opposing sides, order Zone 4 -2. If greater than 180 degrees appears tight, order Zone 4 -3. Each step is equal to a sag adjustment of 25 microns. An increase in edge lift, is a negative step because this will result in a lower sag. To tighten the lens would be a positive step which would increase the overall lens sag.

Lens Power: Determine the spherical over-refraction and the overall quality of vision. If cylinder is required to achieve acceptable vision, then determine if the lens is flexing or if the astigmatism is internal. To do this, perform keratometry readings or topography over the lens on eye. If the anterior surface of the lens is astigmatic, the lens should be made thicker to reduce flexing and eliminate the cylindrical over-refraction. If the anterior surface is spherical, then the astigmatism must be internal and a front toric is required (See "Front Toric" fitting below). Your SMARTLENS™ consultant can assist with these cases.

Front Toric:

When lenticular astigmatism is present, the standard 15.5mm or 16.5mm trials are required with their toric back surface alignment. The toric landing of the 15.5mm or 16.5mm diagnostics should be rotationally stable on most eyes. Observe and record the axis of the flat meridian scribes. Then rotate the lens 90 degrees off axis and determine if the scribes return to the same axis within a few minutes. The lab would need to know the exact axis the flat meridian scribes are positioned at. It is not important for the scribes to be at 0/180 or 90/270, but it is important that they are rotationally stable and the axis is provided to the lab. Do not record that there is 10 degrees of clockwise rotation or 20 degrees of counter-clockwise rotation. What the lab needs is the axis the flat meridian scribes rest along. Then the front surface cylinder is placed at its measured axis which is usually independent of the flat.

SMARTLENS™ FITTING TECHNIQUE

TROUBLE SHOOTING

FIT OBSERVATION	RESOLUTION
Excessive apical clearance:	Choose a lower sag lens, flatten the base curve or reduce the Zone 2 (Peripheral Corneal Zone)
Inadequate apical clearance:	Choose a higher sag lens, steepen the base curve or increase the Zone 2 (PCZ)
Peripheral corneal bearing:	Increase the Zone 2:(PCZ) +4 or Zone 3 (LLZ) +4
Limbal bearing:	Increase the Zone 3 (LLZ) +5
Excessive edge lift:	Order Zone 4: (SLZ) +1 for mild lift, +2 for moderate or +3 if the edge lift is extreme
Tight edge:	Order Zone 4: (SLZ) -1 if mildly tight, -2 if moderate or -3 if excessively tight
Bubbles entering through the SLZ:	Determine if a symmetric, toric or asymmetric is required Contact your SMARTLENS Consultant at anytime for assistance
Cylindrical over-refraction:	If lens warping or flexing is inducing cylinder, order a thicker lens if lenticular, fit a front toric
Anterior surface non-wetting:	Perform a thorough cleaning and conditioning of the lens
Fogging or Clouding of the fluid reservoir:	Check for excessive central vault and/or apply with preservative free artificial tear
Pinguecula/Pterygium:	Reduce or increase diameter, order an asymmetric or notch the edge
Oblate cornea:	Decrease Zone 2 (PCZ) accordingly or flatten the base curve

SMARTLENS™

Thank you for making the Smart choice.
Our team will be happy to guide you in fitting
the next generation of scleral lens!

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