



Perspectives on Fitting Paragon CRT® Dual Axis™

Collected Fitting Suggestions from Experienced Paragon CRT® Dual Axis™ Users

Having collected feedback from CRT® fitting practitioners, Paragon created a document for our valued CRT practitioners; "*Perspectives on Fitting Paragon CRT® Dual Axis™*". The following information provides valuable insights on how CRT fitters utilize Paragon's CRT Dual Axis lenses to fit corneas with irregular peripheries by modifying the Return Zone Depth (RZD) and Landing Zone Angle (LZA) at 90 degree intervals around the lens.

We hope this information on the expanded use of the existing Paragon CRT parameters provides useful guidance in fitting Paragon CRT Dual Axis.

We would like to thank the following practitioners for their insight, guidance and input into the enclosed document.

Armin Duddek, dipl. Augenoptiker SBAO, ISCLS, VDC (Switzerland)
Bruce Williams, OD
Cesar Villa Collar BOptom, MSc, FAAO
Dianne Anderson, OD, FAAO
Michael Lipson, OD, FAAO
Jerry Legerton, OD, FAAO, MS, MBA
Jose M Gonzalez Meijome, OD, PhD
Kevin Reeder, OD
Nick Despotidis, OD
Pat Caroline, FAAO, FCLSA
Russell Lowe, BScOptom, FAAO



PARAGON CRT® DUAL AXIS™ OPTIONS TO COMPENSATE FOR PERIPHERAL CORNEAL ELEVATION DIFFERENCES

Most eyes with corneal astigmatism manifest a significant difference in elevation between the steep and the flat corneal meridians (Image A). Some corneas that appear spherical may also manifest a peripheral corneal elevation difference. The Paragon CRT® lens design has a fixed chord length of 8 mm (6mm treatment zone surrounded by a 1 mm return zone width). When the elevation difference exceeds approximately 13 microns at a chord diameter of 8 mm, it may not be possible for the lens to reach the cornea circumferentially in the landing zone (Image B). This creates a weakened compressive force in the steep meridian and results in poor centration, lens flexure, and/or under treatment. An example of an elevation map with elevation values at 4 mm from reference center in each meridian is shown in Image C.

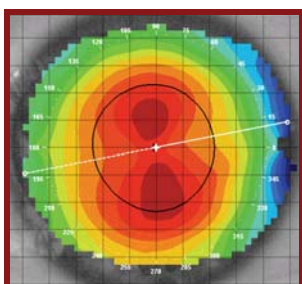


Image A: Apical Astigmatism

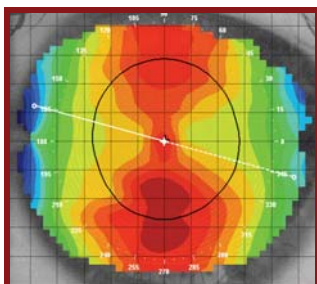


Image B: Limbus-to-Limbus Astigmatism

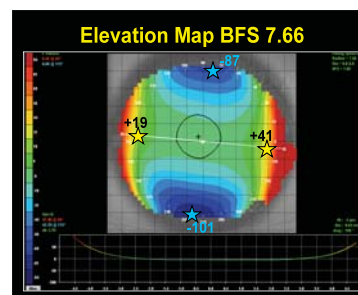


Image C: Annotated Elevation Map

A common rule in contact lens fitting holds that spherical lenses will always move freely along the steep meridian and exhibit restricted movement along the flat meridian. The clinician will observe that spherical lenses will touch first in the flattest meridian peripherally and rock, flex or tilt over the steepest meridian. In conventional corneal reshaping designs, the lens can only reach the peripheral steep meridian by compressing or applanating the flat meridian or by way of lens flexure. Oval treatment zones are commonly observed with peripheral corneal elevation differences.

The Paragon CRT proximity control technology and manufacturing system was designed to allow for independent modulation of the three zones of the lens: Base Curve (BC), Return Zone Depth (RZD) and Landing Zone Angle (LZA). The Base Curve radius controls treatment of the refractive error and remains

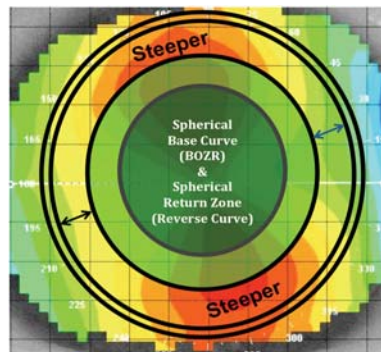
spherical and unchanged. In the new Dual Axis version, the Return Zone Depth (RZD) can be varied in selected meridians to compensate for the peripheral corneal elevation differences of an eye. Correspondingly, the Landing Zone Angle, by itself, may be varied in a second axis while the base curve and return zone depths are unchanged or both RZD and LZA may be varied in the second meridian to compensate for the peripheral corneal slope meridional differences of an eye.

In other words, when fitting a CRT Dual Axis™ design, the BC remains constant throughout the treatment process, unless there is a need to correct untreated or residual power.

Using this standard CRT lens example: BC 8.7 RZD 550 LZA -33

The possible parameter alternatives for the Dual Axis product are;

1. The RZD could have a second value and the LZA would remain a single parameter: 8.7/550 & 600/ -33
2. The LZA could have a second value and the RZD remains a single parameter: 8.7/550/ -33 & -34.
3. The RZD and LZA could both have second values: 8.7/550 & 600/-33 & -34



Corneal Topography and CRT Dual Axis Prescribing

It is common for Placido-based corneal topographers to directly measure curvature data out to about 9 – 10 mm. This curvature data can be reconstructed into height data and represented as an ELEVATION MAP. Elevation maps illustrate relative height deviations from the best fit reference sphere for a particular cornea in MICRONS. On a cornea with asymmetric peripheral saggital depth, a relative deviation from a reference sphere (RED shaded areas) can be observed between the meridian having the greatest elevation above the reference sphere and the meridian having the lowest elevation below the reference sphere (BLUE shaded areas). By placing the cursor at a point 4 mm from the center of the plot, the local elevation may be observed along the CRT lens chord length. If the total difference is greater than 13 microns on the two meridians at the 4 mm radius, a CRT Dual Axis option may be indicated.

When to consider Paragon CRT, or Paragon CRT Dual Axis:

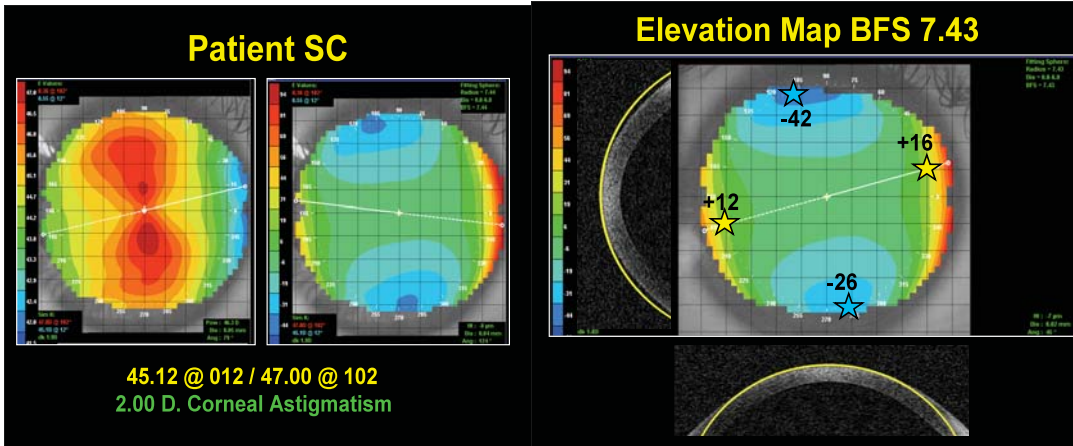
Difference In Flat & Steep Meridians at 4 mm reference points	Suggest Using This Design
< 13 Microns	Paragon CRT
> 13 Microns	Paragon CRT Dual Axis

Calculating for CRT Dual Axis from Elevation Differences

1. Select the elevation plot feature on the corneal topographer. Look at the elevation plot and observe the presence of significant elevation difference (**BLUE** vs. **RED**) in the periphery of the plot.
2. Place the cursor on the shallow area (**BLUE** in color), 4 mm from the center of the plot and record the number of microns below the reference sphere
3. Repeat the measure 180 degrees away in the shallow area opposite to the first measurement
4. Place the cursor on the elevated area (**RED** in color), 4 mm from the center of the plot and approximately 90 degrees from the shallow area and record the number of microns above the reference sphere
5. Repeat the measure 180 degrees away in the elevated area opposite the first elevated measurement
6. Calculate the average difference from the elevated areas to the shallow areas
7. If the average difference is:

- less than 13 microns, a Dual Axis lens may not be indicated.
- between 13 to 30 microns, consider prescribing a one-step (25 micron) increase in RZD.
- between 31 to 60 microns, consider prescribing a two-step (50 micron) RZD difference.
- is greater than 61 microns, consider prescribing a three-step (75 micron) RZD difference.

The average elevation differences are calculated using this best fit sphere example:

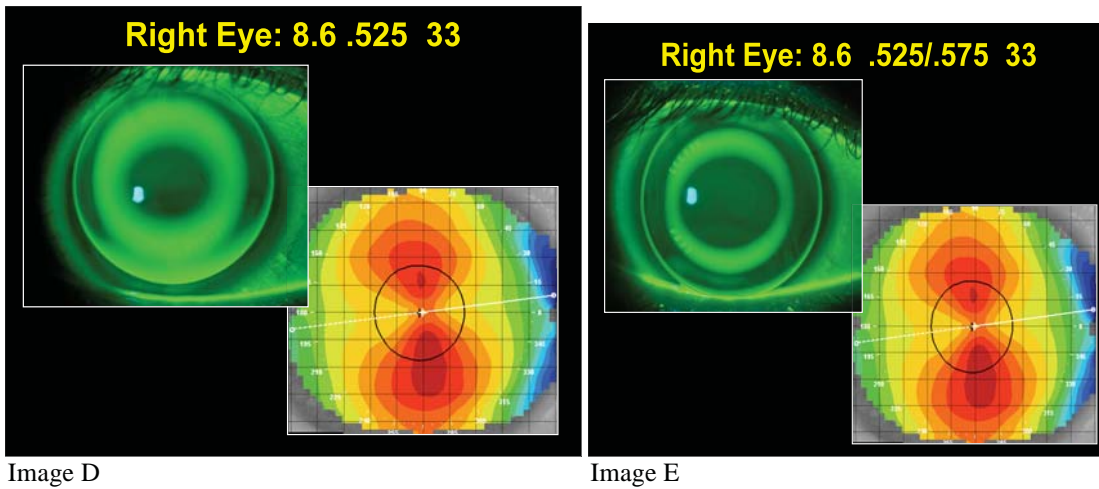


Elevation Map

<p><u>Horizontal Meridian</u></p> <p>Nasal = +12 microns</p> <p>Temporal = +16 microns</p> <p>Total = +28 microns</p> <p><i>Divided by 2 = +14</i></p>	<p><u>Vertical Meridian</u></p> <p>Superior = -42 microns</p> <p>Inferior = -26 microns</p> <p>Total = -68 microns</p> <p><i>Divided by 2 = -34</i></p>
<p>Difference between Horizontal and Vertical Meridians</p> <p>+14 - (-34) = 48 microns</p>	

Image C

A standard two 25 micron step (50 micron) difference in the RZD, 90 degrees apart is offered to compensate for differences in peripheral corneal elevation. The recommended method of fitting is to continue the use of the RZD suggested by the Initial Lens Selector (ex: 550) and observed to provide the recommended fluorescein pattern. (Image C) This RZD continues to be recommended for the flat meridian with the respective higher peripheral elevation. An RZD increase of 50 microns (two 25 micron steps) is recommended for the steep meridian with the lower or shallower peripheral elevation. (Image D) In this case, no change is recommended in the LZA. The LZA will remain constant circumferentially. Some eyes may manifest more than 50 microns of meridional difference in elevation at the 8 mm chord diameter. In such cases, a three-step, 75 micron meridional difference in the RZD may be indicated.



When fitting Paragon CRT Dual Axis, use this chart, in conjunction with the average elevation differences, to determine the variation of RZD or LZA

If the Average Meridional Elevation difference is:	Use This RZD in the Elevated/RED Meridian	Use This RZD in the Shallow/BLUE Meridian	Use This LZA in the Elevated/RED Meridian	Use This LZA in the Shallow/BLUE Meridian
> 13 - 30 Microns	RZD suggested by CRT Lens Selector (550)	Increase the RZD used in Flat Meridian by 25 Microns (550 & 575)	LZA suggested by CRT Lens Selector (-33)	Add one degree if edge lift is excessive (-33 & -34)
30 - 60 Microns	RZD suggested by CRT Lens Selector (550)	Increase the RZD used in Flat Meridian by 50 Microns (550 & 600)	LZA suggested by CRT Lens Selector (-33)	Add one degree if edge lift is excessive (-33 & -34)
> 60 Microns	RZD suggested by CRT Lens Selector (550)	Increase the RZD used in Flat meridian by 75 Microns (550 & 625)	LZA suggested by CRT Lens Selector (-33)	Add one degree if edge lift is excessive (-33 & -34)

When to Change the LZA?

One may observe a cornea that does not manifest a meridional elevation difference at the 8 mm chord diameter but does manifest significant differences in the edge clearance circumferentially. In such cases, the Landing Zone Angle should be varied in a second axis to provide a more uniform circumferential edge clearance. The recommended method of fitting is to continue to use the LZA that appears to be correct in the meridian having proper edge clearance and increase the LZA for the alternate meridian where there is

excessive edge clearance. A difference of one degree in the second meridian will be clinically significant and a difference of two degrees may be needed when there is a marked difference in the edge clearance observed in the fluorescein pattern.

The example below (Image F) with a single LZA shows adequate edge lift in the more elevated, horizontal meridian but excessive edge lift in the shallow, inferior meridian. The pattern shown with the two-step LZA (Image G) displays the appropriate edge lift in both meridians as a result of increasing the LZA by one degree in the shallow meridian.

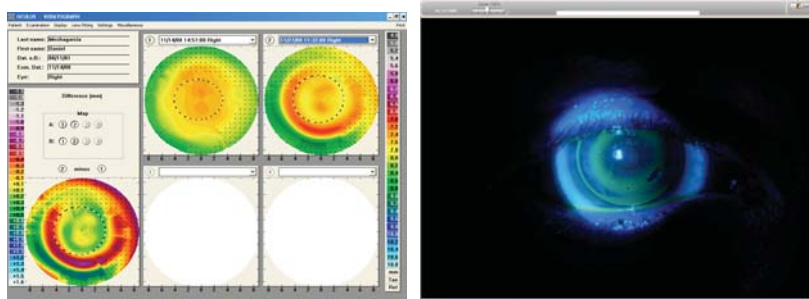


Image F – 8.30/550/-34

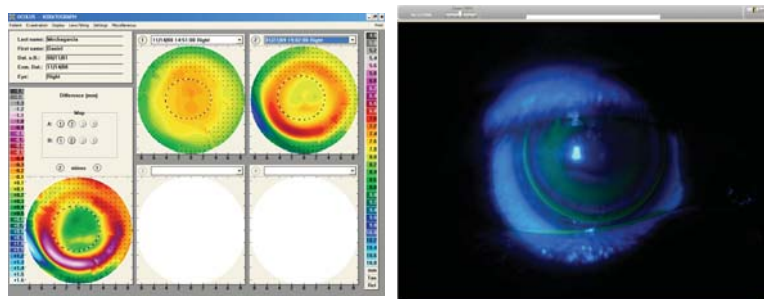


Image G – 8.30/550/-34 & -35

Consider using a one-degree difference in LZA for every 0.2 mm difference in fluorescein width inward from the edge of the lens. The increased angle will cause the edge clearance to decrease by about 0.2 mm for every one-degree increase in angle in the meridian having the excessive clearance.

In all cases the lenses will “seek” the respective meridian in a relatively short period of time after application. The concept is very much like a saddle fitting a horse. The lens will best position over the cornea with the deepest axis of the lens seeking the deepest axis of the cornea.

Using the 16 lens trial set of CRT Dual Axis lenses, follow these procedures:

1. After evaluating the suggested lens from the CRT Initial Lens Selector, (example: 8.60/550/-33) place the dual axis lens having the next flatter BCR, but same RZD, and LZA. The RZD for the deeper meridian will be 50 microns greater. (8.90/550 & 600/-33)
2. Observe the lens on eye for the criteria for an ideal fit
 - a. A minimum of 4 mm treatment zone that is round in appearance
 - b. Lens centered within 0.5 mm of pupil center
 - c. Circumferential bearing under the landing zone (complete/uniform “bulls eye” pattern)
 - d. Edge clearance between 0.2 and 0.5 mm
3. If the edge clearance is significantly different 90 degrees apart, consider trialing a dual axis LZA difference where the angle is increased by one degree for every 0.2 mm required decrease in the edge clearance in the respective meridian. (8.90/550 & 600/-33 & -34)
4. Over-refract for the appropriate BCR and order the final Dual Axis lens

It is of critical importance that the desired meridian is identified relative to the shallow and deep RZD meridians. In some cases you may need to deepen the LZA in the same meridian that is already made deeper by the RZD increase. In other cases you may need to reverse the LZA difference provided by the deeper RZD increase.

General Rule for LZA Options

If excessive edge clearance is in the steepest corneal meridian, an increase in angle will be in the same meridian as the increase in the RZD. An LZA decrease may be required in the same meridian that you have the increase in RZD, if the increased RZD results in minimal edge lift.

Example: If the selected lens is an 8.90/550 & 600/-33 and the edge lift in the meridian with the 550 RZD is adequate but the edge lift in the meridian with the 600 RZD is minimal or “sealed off”, then order the lens as such – 8.90/550 & 600 /-33 & -32

Prescribing Paragon CRT Dual Axis Lenses in the Absence of Topographic Elevation Map Options

The Dual Axis feature can be successfully used in the absence of elevation data by careful identification of corneal astigmatism on the AXIAL topography map as well as careful observation of the fluorescein pattern of the initial CRT lens parameter suggested from the flat K and spherical refraction. The following are the indicators for a dual axis design:

- ✓ Limbus-to-limbus corneal astigmatism greater than 1.00 D
- ✓ Oval versus the round treatment zone observation in a best fit CRT diagnostic lens
- ✓ Significant difference in edge clearance 90 degrees apart with a best fit CRT diagnostic lens
- ✓ Flexure as measured by keratometry or topography over a best fit CRT lens
- ✓ Failure to center or complete treatment with a spherical CRT lens using suggested parameter changes
- ✓ Decentered treatment zone on follow up with an otherwise best fit CRT lens

All of the above indicate the potential for a peripheral meridional corneal elevation difference. Peripheral differences are expected with limbus-to-limbus astigmatism and can result in:

- Oval treatment zone
- Edge lift differences
- Lens Flexure
- Lens decentration
- Under treatment

Differences of 13 microns are sufficient to cause flexure, decentration, and under treatment due to weakened circumferential attraction between the landing zone of the lens and the peripheral cornea. Consider use of the two RZD difference (50 micron) design when these indicators are present.

The indication of the CRT Dual Axis design is confirmed if the treatment zone becomes more circular, flexure is eliminated, lens centration is improved, circumferential landing is observed, and the targeted treatment is achieved.

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For additional information on Paragon CRT® Dual Axis™, please call your Authorized CRT Laboratory Consultant, or Paragon Consultation at: 800-528-8279.



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