Introduction to Fitting Paragon CRT & CRT Dual Axis Certification Training

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US FDA Approval – 2002

First to receive FDA market approval for orthokeratology overnight wear – June 2002

Approval includes myopia correction:
- up to −6.00D
- with or without astigmatism
- up to −1.75D of astigmatism
- NO AGE RESTRICTIONS

This is the **highest** range of approval for any ortho-k lens
How Does OrthoK work?

Hydraulic Forces in Closed Eyelid Environment
- Positive (Push) Force applied to BC
- Negative (Pull) Force in the Return Zone
Normal Human Cornea

<table>
<thead>
<tr>
<th>Layer</th>
<th>Average Thickness of Central Cornea</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epithelium</td>
<td>50 Microns</td>
</tr>
<tr>
<td>Bowmans Layer</td>
<td>10 Microns</td>
</tr>
<tr>
<td>Stroma</td>
<td>465 Microns</td>
</tr>
<tr>
<td>Descemets Membrane</td>
<td>10 Microns</td>
</tr>
<tr>
<td>Endothelium</td>
<td>5 Microns</td>
</tr>
</tbody>
</table>

Approximate Total Thickness
540 Microns (.54 mm)
Compression versus Redistribution

Images courtesy of Pat Caroline
Redistribution of Cellular Fluid

Images courtesy of Pat Caroline
How Does OrthoK work?

Forces work together in a semi-closed environment to allow for appropriate epithelial changes.
Paragon CRT®

RETURN ZONE 1MM (FIXED)

OPTIC ZONE 6 MM (FIXED)

LANDING ZONE (NOT FIXED)
BASED ON DIAMETER SIZE
1. Base Curve (BC) – millimeters (ex: 8.9mm)
2. Return Zone Depth (RZD) - sagittal depth, microns (ex: 550um)
3. Landing Zone Angle (LZA) – degrees (ex: -33°)
Base Curve (Treatment Curve) Selection

- Provides the mold for the treatment
- Measured in mm of radius (ex: 8.9mm)

- Calculated from the Initial Lens Selector (slide rule or electronic format)
- Jessen Factor set at +0.50 in all lenses for regression
Calculating BC Selection

• Jessen Factor set at +0.50D in all lenses for regression, fit 0.50D flatter than K

• Patient Manifest Rx: -3.00  
  Target Rx: -3.00-0.50 = -3.50

• Patient K Values: 42.00/42.40

BC Selection: 42.00 - 3.50 = 38.5 (8.76 → 8.8)

8.8mm
Base Curve (Treatment Curve) Selection

• The Base Curve is *never* adjusted to change the fit.
• When to change the Base Curve?

• CHECK REFRACTION OVER LENS (ROL) to ensure BC is accurate
  • Typically, ROL should be plano to +0.50

• The corneal shape does not fully conform to the back surface of the lens
  • Young adults, +0.50 to +1.00
  • Pre-presbyopes, plano
Return Zone Depth (RZD)

Measured in Sagittal depth (um)
25um increments

DEEPER
600 um
575 um
550 um
525 um
500 um

SHALLOOWER
Return Zone Depth (RZD)

When to change Return Zone Depth?

Centration!
Return Zone Depth (RZD) – Too Flat

Sagittal Depth Changes (changes in 25um steps)

500 RZD

525 RZD

Precise Control of Applied Treatment through Proximity Control Technology™
Return Zone Depth (RZD) – Too High

Sagittal Depth Changes (changes in 25um steps)

600 RZD

550 RZD

Precise Control of Applied Treatment through Proximity Control Technology™
Return Zone Depth (RZD)

Spherical CRT on eye with corneal cylinder and enough elevation difference = incomplete peripheral alignment

550 RZD

550/600
RZD1/
RZD2
Paragon CRT Dual Axis Design
Dual Axis Candidates

Corneal Toricity \( \geq 0.75 \text{D} \)

Incomplete Treatment or “Bull’s Eye” Pattern

Stubborn Decentered CRT Lens
Using Corneal Cylinder to help determine initial Dual Axis depth difference

Fitting Guide

*just a guide to start - may still need to adjust/increase RZD difference based on NaFl pattern of lens and topography

**0.75D – 1.50D of cyl ~ 50μm RZD1/2**

**1.50D – 1.75D of cyl ~ 75μm RZD1/2**

Customize RZD1/RZD2 in 25 μm steps,

Lens has been made up to 175 μm difference in dual depth
“Safe” Landing Zone Angle (LZA)

Landing Zone can only be tangent to the underlying corneal surface
Landing Zone Angle (LZA)

Angle (degrees)
1° increment

Higher degree number (34°) = Steeper
• 1° increase = increase sagittal depth (+15um)

Lower degree number (31°) = Flatter
• 1° decrease = decrease sagittal depth (-15um)

Controls:
• Edge lift
• Overall sagittal depth
Landing Zone Angle (Too flat)

Excessive edge = tangent point too far

180°

-32°
Landing Zone Angle $-32^\circ \rightarrow 33^\circ$

1-2 mm of tear reservoir is the desired amount of edge lift.
Landing Zone Angle -33° → -34°
Landing Zone Angle (Too Steep)

Tangent point too close

Problems with lens adhering to eye with overnight wear
CRT Dual Axis

+ Proximity Control Technology – CRT is the ONLY lens able to change lens parameters independently of each other

+ Allows for independent manipulation of a second RZD and LZA (if needed) to mimic elevation difference
  - RZD1 (500um) and RZD2 (550um)
  - LZA1 (32°) and LZA2 (33°)

+ Base curve remains the same
Questions?
Calculate Initial Lens Parameters

<table>
<thead>
<tr>
<th>Flat K /Steep K</th>
<th>Manifest Refraction Sphere</th>
<th>Corneal Diameter Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>42.00/43.00</td>
<td>-2.50 -0.50 x 180</td>
<td>11.6mm</td>
</tr>
</tbody>
</table>

1) Slide tab until arrow appears at correct Flat K
### Initial Lens Selection – Numbered Ruler

<table>
<thead>
<tr>
<th>Lens #</th>
<th>Parameters</th>
<th>BC</th>
<th>RZD</th>
<th>LZA</th>
</tr>
</thead>
<tbody>
<tr>
<td>92</td>
<td>88-525-33</td>
<td>-3.50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>96</td>
<td>88-550-33</td>
<td>-3.75</td>
<td></td>
<td></td>
</tr>
<tr>
<td>109</td>
<td>89-550-33</td>
<td>-4.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>109</td>
<td>89-550-33</td>
<td>-4.25</td>
<td></td>
<td></td>
</tr>
<tr>
<td>118</td>
<td>90-550-33</td>
<td>-4.50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>118</td>
<td>90-550-33</td>
<td>-4.75</td>
<td></td>
<td></td>
</tr>
<tr>
<td>127</td>
<td>91-550-33</td>
<td>-5.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>127</td>
<td>91-550-33</td>
<td>-5.25</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2) Manifest refraction sphere
3) Initial diagnostic lens parameters appear in the window to the left

**Lens #96**
- Parameters: 88-550-33
- BC = 8.8mm
- RZD = 550um
- LZA = 33 degrees
## Initial Lens Selector

### Electronic Version

<table>
<thead>
<tr>
<th></th>
<th>OD</th>
<th>OS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flat K</td>
<td>42.00</td>
<td>42.50</td>
</tr>
<tr>
<td>Steep K</td>
<td>42.50</td>
<td>44.00</td>
</tr>
</tbody>
</table>

**MR Sphere**

<table>
<thead>
<tr>
<th></th>
<th>3.25</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.00</td>
<td></td>
</tr>
</tbody>
</table>

**CRT**

<table>
<thead>
<tr>
<th></th>
<th>88-525-32</th>
</tr>
</thead>
<tbody>
<tr>
<td>89-575-625-33</td>
<td></td>
</tr>
</tbody>
</table>

**Lens #**

91

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**Note:**
- Do not insert a minus symbol (-) for Manifest Refraction Sphere.
- All calculations include Vertex Power Adjustment.

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**Paragon Vision Sciences**

We don't just change vision. We change lives™.
Customization of Lens

Tint: Green, Blue, Red, Yellow, Clear

G indicates green tint
ALL lenses are laser marked in the RZD to identify exact parameters

BC = 7.9
RZD = 525 (53), 575 (58), 625 (63)
LZA = 33
1 - Determine Initial Diagnostic Lens

2 – Centration

   Appropriate Treatment Zone (3-4mm)
   Moderate tear-film touch in the mid-periphery
   Adjust Edge Lift, if necessary

   *Be aware of lid interaction*

3 – Check Refraction over lens (ROL) to determine BC/myopia treatment → +0.50

Centration is the key to success
# Ordering Paragon CRT Lenses

## Empirical Lens Order
- **Flat K/Steep K (for CRT Dual Axis)**
- **Manifest Refraction**
- Standard Power: +0.50, Can Customize Power
  - (-2.00 to +2.00)
- **Corneal Diameter Size, 10.5mm**
  >12.0mm, order 11.0mm, 11.5mm
- **Material:** Paragon HDS 100, Menicon Z
- **Tint:** Green, Blue, Red, Yellow

## Diagnostic Dispensing System
- **100/136 CRT Lenses**
- **16/80 CRT Dual Axis**
  - 10/14 different Base Curves
  - Combination of RZD & LZA
- **Power:** +0.50
- **Diameter:** 10.5mm
- **Material:** Paragon HDS 100
- **Tint:** Green
Questions?
What if the suggested lens is not the DDS set?

• The lens you need has been previously dispensed = 8.6  550  -33

• Fit 0.10mm Flatter in Base Curve = 8.7  550 -33

• BC is the least important parameter for evaluating centration.

• RZD/LZA combination is the most important for centering and tear pattern evaluation.

• ROL will determine which BC is necessary (+0.50D)
A subjective refraction over the lens (ROL) determines:

- Accuracy of the treatment Base Curve calculation
- Check residual astigmatism (lenticular cylinder)!!

For best distance vision for children and young adults, ROL should be +0.50 to +1.00
Adjusting BC from Refraction OVER Lens

GP laws
- 0.50D change = 0.1mm
- Steeper ADD Minus, Flatter ADD Plus
- Cylinder present in the ROL will remain untreated as with any spherical gas permeable lens design

Plus Power (+) ROL = Steepen BC to Adjust
Example, BC 8.8, ROL= +1.50 sphere

Want ROL = +0.50 (add -1.00 MINUS/0.2mm), change BC 8.8 → 8.6

Minus Power (-) ROL = Flatten BC to Adjust
Example, BC 9.0, ROL = -1.00 sphere

Want ROL = +0.50 (add +1.50 PLUS/0.3mm), change BC 9.0 → 9.3
Initial Lens Dispense Overview

- Schedule appointment for following morning (AM) after sleeping in lenses
- Patient returns with their lenses in eye
<table>
<thead>
<tr>
<th>Day 1 Follow Up</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Refraction OVER Lens (ROL)</strong></td>
</tr>
<tr>
<td>• Still +0.50 to +1.00?</td>
</tr>
<tr>
<td>• Residual cyl? (unable to correct if through lens)</td>
</tr>
<tr>
<td><strong>Centration (&amp; Edge Lift)</strong></td>
</tr>
<tr>
<td>• Is the lens moving?</td>
</tr>
<tr>
<td>• Instill NaFl to observe pattern (Use wratten filter)</td>
</tr>
<tr>
<td><strong>Remove Lens</strong></td>
</tr>
<tr>
<td>• Visual Acuity? Check Refraction</td>
</tr>
<tr>
<td>• Slit Lamp Examination – any staining? edema?</td>
</tr>
<tr>
<td><strong>Topography</strong></td>
</tr>
<tr>
<td>• Day 1 – Baseline</td>
</tr>
<tr>
<td>• Any lens decentration?</td>
</tr>
</tbody>
</table>
The rate of treatment is not predictable

- Average treatment the first night = 2.00 D

- 7-14 days is the average treatment/transition period
  - Lower myopes – within a few days
  - Higher myopes – up to a week

- Vision will regress some during the first day until “corneal mold” is set

- Manage options for VA - temporary soft daily disposable lenses through the day
  - If BC is correct, vision through CRT will be habitual VA
Recommended Follow Up

Have patient always return with lenses to check:
- optimal treatment
- ensure the lenses are clean
- patient is following the proper cleaning and disinfecting procedures
Optimal Fitting Guide Overview

Lens decentered SUPERIOR
- Increase RZD by 25um
  - 525 → 550

Lens decentered INFERIOR
- Flatten/Decrease LZA by 1
  - 33 → 32

Lens decentered LATERAL
- Increase diameter size (adjust LZA accordingly)
  - 10.5mm → 11mm

Treatment Zone TOO SMALL
- Decrease RZD
  - 525 → 500

NaFl bleeding (6 o’clock)
- Use 2 RZD
  - CRT Dual Axis 525 → 525/575
Optimal Fitting Guide Overview

Lens Edge THIN
- Flatten/Reduce LZA
- 33 → 32

Lens Edge THICK
- Steepen/Increase LZA
- 33 → 34

Refraction OVER Lens not +0.50/+1.00
- MINUS (-) ROL, flatten BC
- PLUS (+) ROL, steepen BC

Refraction without lens other than plano
- Check Topography – Incomplete Mid-Peripheral Ring?
- Use CRT Dual Axis 525 → 525/575
Questions?
Don’t Make Changes Too Quickly

• Lens centration!

• Parameter adjustments to improve lens centration should be done during the one-day follow up.

• Wait to adjust for under-treatment until 1-week follow up visit
  • Lenses centered
  • ROL +0.50 to +1.00
Making First Follow Up Changes

• Decentration – verified by topography

• Unacceptable VA with lenses
  • Lens power/Base Curve
  • Surface/wetting issues

• Discomfort/Slit Lamp Findings
  • Excessive/inadequate edge lift
  • Abnormal staining, edema, etc.
  • Lens adhesion

Make appropriate parameter changes and dispense appropriate diagnostic lens for follow up evaluation
When Not to Make Changes

Do Not Make Changes When:

- Treatment zones are centered
- ROL is acceptable (no minus)
- SLE is unremarkable
- Patient is content & happy
- Under-treatment is apparent at day 1

Proceed to next scheduled appointment with no changes. Order final lenses with warranty.
Great First Few Patients

Ideal Initial 5 patients should be:

- Children progressing in myopia
- Current soft contact lens wearers that complain of dryness or discomfort.
- Spectacle wearers (often contact lens drop-outs).
- In the low to moderate myopia range

- < -4.00D
- Flat K’s: 42.00D to 45.00D
Proceed with Caution

• Current GP or Ortho-K wearers
• Over 1.50 D of ATR Astigmatism
• Cylinder is Greater than Sphere
  Example: -0.75 –1.75 X180

Final treatment takes Cornea Curves below 38.00D
Example:
  • Flat K= 41.00
  • MRS = -4.00D
  • Target treatment= 37.00 Flat K
Higher myopes (>4.00 D) require centration first, treatment second

• Always sacrifice initial applanation for centration

• Choose an RZD that is 25 microns higher/deeper than the suggested RZD to ensure proper centering for the initial overnight wear. Find the lens number suggested from the slide ruler and select the lens vial in the same BC row to select the deeper RZD.

After moderate treatment (7-14 days), subsequent lenses with reduced sagittal depth (RZD and/or LZA) will center and provide full treatment.
3 Quick Steps to fitting CRT/CRT Dual Axis

1) Total Diameter: HVID – 1mm
   • >11.8mm, customize with 11.0mm diameter lens
   • Steepen LZA to keep edge lift relationship the same

2) Corneal toricity > 0.75D → CRT Dual Axis
   • Especially limbal to limbal astigmatism

3) Jessen factor set at +0.50 for all lenses
   • faster treatment, especially for children = flatten BC an additional 0.1mm for a total ROL:+1.00D
Questions?
1) What is the approximate thickness of the corneal epithelium?
   a. 130 microns   b. 50 microns   c. 80 microns
2) What is the fixed optic zone diameter of the Base Curve?
   a. 5.0mm  
   b. 7.0mm  
   c. 6.0mm
3) Which parameter is never adjusted to change the fit or centration of a lens?
   a. LZA   b. BC   c. RZD
4) What is the target refraction over the CRT lens? (ROL)
   a. -0.50  
   b. +0.50  
   c. +2.00
5) If the refraction over the lens (ROL) is -1.00D, what adjustment should be made in the Base Curve to achieve a +0.50D ROL?

a. Steepen 0.3mm
b. Flatten 0.1mm
c. Flatten 0.3mm
6) Which of the following would indicate the lens with the greatest sagittal depth?

a. 8.5 / 550 / -33

b. 8.6 / 550 / -32

c. 8.6 / 575 / -33
7) Of the following, which is the best option to improve centration of a superiorly positioned lens?

a. Increase RZD  

b. Decrease RZD  
c. Steepen BC
8) Of the following, which is the best option to improve centration of an inferiorly positioned lens?

a. Increase LZA  
   b. Decrease LZA  
   c. Flatten BC
9) Return Zone Depths are available in micron increments of:

a. 15 microns  
b. 7 microns  
c. 25 microns
10) A one-degree change in LZA affects overall sagittal depth by

a. 15 microns  
b. 25 microns  
c. 7 microns
11) At dispensing, there is an excessive amount of edge lift. What adjustment is needed?

a. Increase the BC (8.8 → 8.9)
b. Decrease LZA (32 → 31)
c. Increase LZA (32 → 33)
12) At dispensing, there is an insufficient amount of edge lift. What adjustment is needed?

a. Decrease LZA (33 → 32)

b. Increase LZA (33 → 34)

c. Change RZD (525 → 550)
13) What is the age restriction for wearing the Paragon CRT® Contact Lens?

a. No age restriction

b. Must be over 18

c. Must be over 21
14) How long is the average treatment period for a new Paragon CRT® Contact Lens wearer?

a. 7 to 14 days  
b. 1 Month  
c. 2 Months
15) When using the Lens Selector Slide Rule, what two components are absolutely needed to determine the correct lens?

a. Steep K / Manifest Refraction Sphere
b. Steep K / Spherical Equivalent
c. Flat K / Manifest Refraction Sphere
16) What patient would be considered a proper candidate based on the FDA approval?

a. Up to -8.00D myopia, with or without up to -2.50D astigmatism

b. Up to -5.00D myopia, with or without up to -2.25D astigmatism

c. Up to -6.00D myopia, with or without up to -1.75D astigmatism
17) When should CRT Dual Axis be considered?

a. Patient’s who display corneal elevation differences  
b. Patient’s who display corneal astigmatism  
c. Patient’s who display incomplete treatment on topography  
d. All of the above
18) Which of the following statements is true?
CRT Dual Axis enables you to choose:

a. 2 BC or 2 RZDs to align the cornea displaying corneal astigmatism
b. 2 LZAs to align the cornea displaying differences in corneal elevation
c. 2 RZDs or 2 LZAs to align eyes displaying differences in corneal elevation
d. 2 BC to align the cornea displaying refractive astigmatism
19) A patient presents to your clinic to be fitted with OrthoK.
• The right eye’s subjective refraction of -3.25DS
• Flat/Steep K 44.00/45.00
• Corneal diameter size 11.5mm

What would be the best initial lens selection for this patient?

a) 84/550/600/33
b) 84/550/33
c) 84/575/33
d) 84/550/32/34
Thank You For Participating in Paragon CRT Contact Lens Certification & Training Presentation

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