

PROFESSIONAL FITTING AND INFORMATION GUIDE

Paragon CRT®

Manufactured in
Paragon HDS® (paflufocon B)

or

Paragon CRT® 100

Manufactured in
Paragon HDS® 100 (paflufocon D)

**RIGID GAS PERMEABLE
CONTACT LENSES
FOR
CONTACT LENS CORNEAL REFRACTIVE THERAPY**

OVERNIGHT WEAR



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INTRODUCTION

Paragon CRT® and Paragon CRT® 100 Contact Lenses for Corneal Refractive Therapy produce a temporary reduction of myopia by reversibly altering the curvature of the cornea. The Paragon CRT® and CRT® 100 contact lenses are manufactured from Paragon HDS® and Paragon HDS® 100 respectively. A slight reduction of the curvature of the cornea can reduce the excessive focusing power of the myopic eye. If the amount of corneal reshaping is precisely controlled as is the objective of the CRT® lens design, it is possible to bring the eye into correct focus and completely compensate for myopia. After the contact lens is removed, the cornea retains its altered shape for all or most of one's waking hours. The lens is designed to be worn overnight with removal during following day. The Paragon CRT® and Paragon CRT® 100 lenses must be worn at night on a regular schedule to maintain the corneal reshaping, or the pre-treatment myopia will return.

PRODUCT DESCRIPTION

Paragon CRT® contact lenses are manufactured from Paragon HDS® (paflufocon B) and Paragon CRT® 100 contact lenses are manufactured from Paragon HDS® 100 (paflufocon D). The lenses are designed to have congruent anterior and posterior surfaces each consisting of three zones:

1. The central spherical zone.
2. A mathematically designed sigmoidal corneal proximity "Return Zone".
3. A non-curving "Landing Zone".

The lens design also includes a convex elliptical edge terminus smoothly joining the anterior and posterior surfaces.

Paragon CRT® and Paragon CRT® 100 Contact Lenses for Corneal Refractive Therapy are to be worn overnight with removal during all or part of each following day. Both materials are thermoset fluorosilicone acrylate copolymer derived primarily from siloxane acrylate, trifluoroethyl methacrylate and methylmethacrylate with a water content of less than 1%. These contact lenses for Corneal Refractive Therapy are available as lathe cut firm contact lenses with blue and green tints. The blue tinted lens contains D&C Green No. 6. The green lens contains D&C Green No. 6 and Perox Yellow No. 9 (4-[(2,4-dimethylphenyl)azo]-2,4-dihydro-5-methyl-2-phenyl-3H-pyrazol-3-one). These products may be plasma treated.

Detailed Description

Generally the central base curve is chosen to be flatter than the curvature of the central cornea by an amount such that if the cornea were to take on this lens curvature a significant reduction in myopia would be expected. The lens is fitted to allow this zone to contact the central corneal apex. Until such time as the cornea has taken on the curvature of this zone of the lens, it is expected that this zone will gradually diverge from the corneal curvature, thus rising away from it with a maximum deviation at the edge of the zone.

The first zone peripheral to the central base curve, the Return Zone, has a sigmoidal shape that smoothly joins this zone to the central zone and the third element. The sigmoid will be mathematically designed to return the posterior lens surface to closer proximity to the cornea than it would have had if the geometry of the central base curve were continued through this zone. This zone is conveniently described by referring to the width and depth of a rectangle which would enclose a cross section through the Return Zone (see drawing page 4). The width of the zone is fixed at 1 mm while the fitter determines the Return Zone Depth (RZD).

The third element, referred to as the Landing Zone, has the form of a truncated cone and is concentric to the Return Zone. This element is intended to be tangential to the cornea at a specified diameter but not initially in contact with it. Since the Landing Zone naturally deviates from the cornea peripheral to the point of tangential correspondence, there is no need for an additional peripheral curve to give "edge lift". Fluid forces arising from the approximation of Landing Zone and cornea participate with other factors in stabilizing the lens orientation on the eye. The Landing Zone is characterized by the angle that its cross section makes with the horizontal and by its chord diameter; both parameters are selected by the fitter.

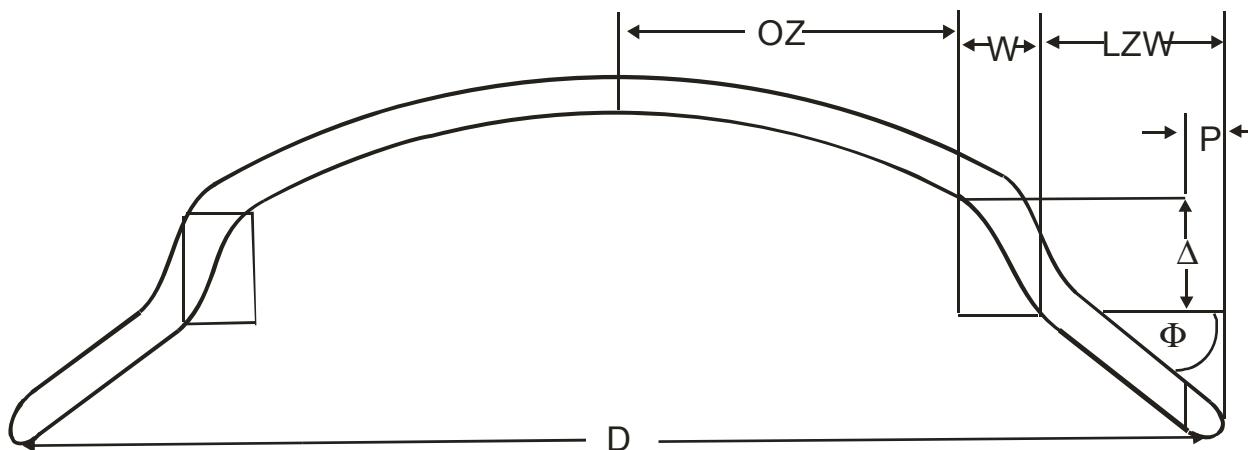
The last and most peripheral element, the edge terminus, deviates from the uncurved Landing Zone and curves away from the underlying cornea to merge with the anterior surface thereby forming the edge of the lens. This zone follows the prescribed shape of a convex ellipse thereby “rolling” the lens surface away from the cornea promoting comfort. This terminus is not to be confused with a “peripheral curve” frequently found in RGP designs. Such peripheral curves are concave toward the cornea with a radius specified to maintain nearly parallel alignment with it. Such lenses also have a separate edge contour, which is created by grinding and polishing the edge but its shape is typically arbitrarily derived by the nature of the processes and lens edge thickness. The CRT® edge is pre-specified and equivalent in all lenses regardless of their other parameters.

Paragon CRT® and Paragon CRT® 100 contact lenses are used to temporarily reshape the cornea to change its refractive power with a resultant reduction in the pretreatment refractive error. Corneal tissue is redistributed without significant alteration of its physiology. The change in shape is the result of gentle mechanical pressure from the flattened central zone of the lens augmented by the availability of unoccupied volume beneath the Return and Landing Zones of the lens. After wearing of the lens, the cornea typically demonstrates an increased radius of curvature in the central area and a decreased radius of curvature in the paracentral area allowed by the clearance within the outer portion of the optic zone and the Return Zone of the lens.

Although rarely required, the anterior central curve is selected to provide any necessary optical power to correct residual refractive error not corrected by the optical and mechanical effect of the posterior base curve and the tear lens formed between it and the cornea. Typically this surface and the other anterior surfaces exactly parallel their posterior counterparts. Lens thicknesses in the three zones are not dependent on lens parameters but have been selected to maximize oxygen transmission, stability and comfort.

LENS PARAMETERS AVAILABLE (See drawing)

Overall Diameter (D)	9.5 to 12.0 mm
Central Base Curve Radius	6.50 to 10.50 mm
Optical Zone Semi Chord (OZ)	2.50 to 3.50 mm
Return Zone Width (w)	0.75 to 1.5 mm
Return Zone Depth (Δ)	to 1.0 mm
Landing Zone Radius	to infinity
Landing Zone Angle (ϕ)	-25° to -50°
Landing Zone Width (LZW)	0.5 to 2.75 mm
Edge Terminus Width (P)	0.04 mm to LZW
Dioptic Powers	-2.00 to +2.00 Diopters



ATTRIBUTES OF THE PARAGON CRT® LENS (paflufocon B)

Refractive Index	1.449 (Nd at 25°C)
Luminous Transmittance ⁺ (Blue)	95%
Wetting Angle (Receding Angle) ⁺⁺	14.7°
Wetting Angle (Contact Angle) ⁺⁺⁺	62°
Specific Gravity	1.16
Hardness (Shore D)	84
Water Content	<1%

ATTRIBUTES OF THE PARAGON CRT® 100 LENS (paflufocon D)

Refractive Index	1.442 (Nd at 25°C)
Luminous Transmittance ⁺ (Green)	95%
Wetting Angle (Receding Angle) ⁺⁺	42°
Wetting Angle (Contact Angle) ⁺⁺⁺	70°
Specific Gravity	1.10
Hardness (Shore D)	79
Water Content	<1%

+ Determination of the Spectral and Luminous Transmittance, ISO 8599:1994

++ Adapted from: A New Method for Wetting Angle Measurement; Madigan, et. al., International Eyecare, 01/1998. vol. 2, no.1, p.45

+++ Sessile Drip Technique per ANSI Z80.20, 8:11

OXYGEN PERMEABILITY - CRT® LENS DESIGN					
Material	Power	Oxygen Permeability (ISO Method*) Dk x 10 ⁻¹¹	Center Thickness (mm)	Harmonic Mean Thickness** (mm)	Oxygen Transmissibility (ISO Dk/l x 10 ⁻⁹)
HDS 100	-2.00	100	0.145	0.163	61
HDS 100	Plano	100	0.163	0.166	60
HDS 100	+2.00	100	0.180	0.168	60
HDS	-2.00	40	0.124	0.148	27
HDS	Plano	40	0.147	0.149	27
HDS	+2.00	40	0.169	0.161	25

* (cm²/sec) (mL O₂)/(mL x mm Hg) ISO/ANSI Method, ISO 9913-1

** Sammons, W.A., "Contact Lens Thickness and All That", The Optician, 12/05/80.

ACTIONS

Paragon CRT® and Paragon CRT® 100 Contact Lenses for Corneal Refractive Therapy produce a temporary reduction of myopia by changing the shape (flattening) of the cornea, which is elastic in nature. Slightly reducing the curvature of the cornea reduces the excessive focusing power of the myopic eye, and if the amount of corneal flattening is properly controlled, it is possible to bring the eye into correct focus and completely compensate for myopia.

Contact lenses rest directly on the corneal tear layer and can gently influence the corneal shape. Regular contact lenses are designed to cause little or no effect but Paragon CRT® and Paragon CRT® 100 Contact Lenses for Corneal Refractive Therapy are designed to purposely flatten the shape of the cornea by applying gentle pressure to the center of the cornea during sleep.

After the contact lens is removed, the cornea retains its altered shape for all or most of one's waking hours. The lenses are designed to be worn overnight with removal during the following day. The CRT® lens design must be worn at night on a regular schedule to maintain the corneal reshaping, or the myopia will revert to the pretreatment level.

INDICATIONS (USES)

Paragon CRT® (paflufocon B) and Paragon CRT® 100 (paflufocon D) Rigid Gas Permeable contact lenses for Corneal Refractive Therapy are indicated for use in the reduction of myopic refractive error in nondiseased eyes. The lenses are indicated for overnight wear in a Corneal Refractive Therapy fitting program for the temporary reduction of myopia up to 6.00 diopters in eyes with astigmatism up to 1.75 diopters. The lenses may be disinfected using only a chemical disinfection system.

Note: To maintain the Corneal Refractive Therapy effect of myopia reduction lens wear must be continued on a prescribed wearing schedule. Failure to do so can affect daily activities (e.g., night driving), visual fluctuations and changes in intended correction.

CONTRAINDICATIONS (REASONS NOT TO USE)

Reference the so entitled section found in the enclosed Package Insert.

WARNINGS

Reference the so entitled section found in the enclosed Package Insert.

ADVERSE EFFECTS (PROBLEMS AND WHAT TO DO)

Reference the so entitled section found in the enclosed Package Insert.

PRECAUTIONS

Reference the so entitled section found in the enclosed Package Insert.

SELECTION OF PATIENTS

Patients are selected who have a demonstrated need and desire for a refractive reduction by Contact Lens Corneal Refractive Therapy with rigid gas permeable contact lenses and who do not have any of the contraindications for contact lenses previously described. Paragon CRT® and Paragon CRT® 100 Contact Lenses for Corneal Refractive Therapy are indicated for myopic patients who desire not to wear vision correction devices during the daytime hours, but still require the ability to see clearly during that time.

Paragon CRT® and Paragon CRT® 100 contact lenses for overnight Contact Lens Corneal Refractive Therapy are primarily intended for patients who are within the following parameters.

Refractive Error	-0.5 to -5.50 diopters with up to -1.75 diopters of astigmatism
Keratometry	37 to 52 diopters
Visual Acuity	20/20 to 20/1000

FITTING CONCEPT

Paragon CRT® and Paragon CRT® 100 Contact Lenses for Corneal Refractive Therapy are intended to be fitted so as to flatten the central cornea and thereby reduce myopia. This goal is accomplished by the lens design and the manner in which the lens is fitted. The goal in fitting is a well-centered lens having a base curve that is flatter than the flattest meridian of the cornea by at least the attempted treatment power in that meridian. A well-fit lens will have proper sagittal depth to prevent z-axis tilt and achieve centration over the corneal apex. A well-fit lens will also have a proper sagittal depth profile to prevent bearing at the Return Zone – Landing Zone junction or heavy bearing in the periphery of the lens. The lens will demonstrate central corneal appplanation, paracentral lens-cornea clearance and Landing Zone-cornea tangential correspondence.

The Paragon CRT® and Paragon CRT® 100 Contact Lens Corneal Refractive Therapy fitting system utilizes the following fixed parameters.

- Optic Zone = 6.0 mm
- Return Zone Width = 1.0 mm
- Center thickness = 0.15 mm + 0.01

The optic zone and Return Zone Width may be changed in rare circumstances by means of a special order. Smaller optic zones may be appropriate in unusually small corneal diameters and in the case of target reductions greater than 5.00 diopters. For corneal diameters greater than 10.8 mm and target improvements less than 5.00 diopters, the standard parameters are recommended.

There are four primary fitting objectives:

- Provide a base curve that will reshape the underlying cornea to a resultant curvature that produces emmetropia or low hyperopia.
- Provide an initial clearance at the point of tangential correspondence of the Landing Zone and peripheral cornea that will allow the corneal apex to retreat approximately 6 microns per diopter of treatment.
- Provide a Landing Zone that has the proper angle to provide a midpoint of tangency to the underlying cornea near the midpoint of the zone itself.
- Provide a lens diameter that, in conjunction with the Landing Zone Angle, provides optimum centration.

The Paragon CRT® and Paragon CRT® 100 contact lenses in conjunction with the following fitting procedure can fulfill these objectives.

Predicting Lens Results

Clinical studies have not established reliable methods to predict which patients will achieve the greatest corneal flattening with these contact lenses for Corneal Refractive Therapy.

Paragon CRT® and Paragon CRT® 100 Contact Lenses for Corneal Refractive Therapy may produce a temporary reduction of all or part of a patient's myopia. The amount of reduction will depend on many factors including the amount of myopia, the elastic characteristics of the eye and the way that the contact lenses are fitted. Average amounts of reduction have been established by clinical studies but the reduction for an individual patient may vary significantly from the averages.

CLINICAL STUDY DATA

Reference the so entitled section found in the enclosed Package Insert.

RISK ANALYSIS

There is a small risk involved when any contact lens is worn. It is not expected that Paragon CRT® or Paragon CRT® 100 Contact Lenses for Corneal Refractive Therapy will provide a risk that is greater than other rigid gas permeable contact lenses.

The two most common side effects, which occur in rigid contact lens wearers are corneal edema and corneal staining. It is anticipated that these two side effects will also occur in some wearers of Paragon CRT® or Paragon CRT® 100 Contact Lenses for Corneal Refractive Therapy. Other side effects, which sometimes occur in all rigid contact lens wearers are pain, redness, tearing, irritation, discharge, abrasion of the eye or distortion of vision.

These are usually temporary conditions if the contact lenses are removed promptly and professional care is obtained. When overnight Corneal Refractive Therapy lenses dislocate during sleep, transient distorted vision may occur the following morning after removal of the lenses. This distortion may not be immediately corrected with spectacle lenses. The duration of distorted vision would rarely be greater than the duration of the daily visual improvement normally achieved with the lenses.

In rare instances, there may occur permanent corneal scarring, decreased vision, infections of the eye, corneal ulcer, iritis, or neovascularization. The occurrence of these side effects should be minimized or completely eliminated if proper patient control is exercised. Patients should be instructed to remove the contact lenses if any abnormal signs are present. Patients should be instructed never to wear their contact lenses while in the presence of noxious substances. Patients should be instructed in the importance and necessity of returning for all follow-up visits required by the eye care practitioner.

To assure proper communication of the need for compliance with all instructions for use, Paragon Vision Sciences strongly recommends the use of informed consent documents by all practitioners fitting Paragon CRT® lenses. Examples of an adult informed consent, a child informed assent and an “informed consent quiz” are appended to this Professional Fitting and Information Guide.

FITTING PARAGON CRT® AND PARAGON CRT® 100 CONTACT LENSES FOR CORNEAL REFRACTIVE THERAPY

Note: Contact lenses for Corneal Refractive Therapy should be fitted only by a contact lens fitter trained and certified in the fitting of conventional and sigmoid geometry contact lenses.

Slide Rule Calculator

Utilizing a provided slide rule calculator, practitioners will cross-reference a patient's flat Keratometric value and their vertexed Manifest Refraction Sphere (MRS) and thereby will determine a suggested diagnostic lens from an in-office diagnostic/dispensing lens system.

The slide rule will suggest a specific lens including the parameters of Base Curve, Return Zone Depth (RZD) and Landing Zone Angle (LZA) for initial evaluation by the practitioner. Based on the results of fluorescein pattern evaluation of the suggested lens, the practitioner may move to other lenses in the dispensing system to determine the best fit lens for dispensing to the patient.

The slide rule will calculate the Base Curve for 0.00 Target as follows:

Calculation Treatment Base Curve

<u>Calculated Base Curve</u>	
43.75	FK
<u>+ 0.00</u>	TGT
43.75	
<u>- 4.00</u>	MRS (Vertexed)
39.75	
<u>- 0.50</u>	Rx = +0.50
39.25	Base Curve

In the above example, the slide rule will suggest the following lens from the diagnostic/dispensing set for initial evaluation.

Choose Trial Lens

Look for this lens in the Trial Set and evaluate for “Dispensability”.

39.25 BC 0.550 RZD - 33 LZA

39.25 (8.60)B.C.

Deeper ↑	Increased sag depth Decreased angle	Increased sag depth Same angle	Increased sag depth Increased angle
Sagittal Depth	Same RZD Decreased angle	<u>Initial Lens</u> 39.25 .550 RZD -33 angle	Same RZD Increased angle
Shallower ↓	Decreased sag depth Decreased angle	Decreased sag depth Same Angle	Increased sag depth Increased angle

← - Angle Degree + →

39.25 (8.60)B.C.

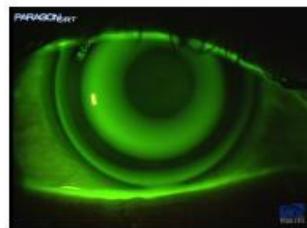
Deeper ↑	39.25 .575 RZD -32 angle	39.25 .575 RZD -33 angle	39.25 .575 RZD -34 angle
Sagittal Depth	39.25 .550 RZD -32 angle	<u>Initial Lens</u> 39.25 .550 RZD -33 angle	39.25 .550 RZD -34 angle
Shallower ↓	39.25 .525 RZD -32 angle	39.25 .525 RZD -33 angle	39.25 .525 RZD -34 angle

← - Angle Degree + →

39.25 (8.60)B.C.

With shallower
Lens in place:

1. Does it still center?
2. If Yes....
3. Evaluate Edge Lift



39.25 .575 RZD -32 angle	39.25 .575 RZD -33 angle	39.25 .575 RZD -34 angle
39.25 .550 RZD -32 angle	<u>Initial Lens</u> 39.25 .550 RZD -33 angle	39.25 .550 RZD -34 angle
39.25 .525 RZD -32 angle	39.25 .525 RZD -33 angle	39.25 .525 RZD -34 angle

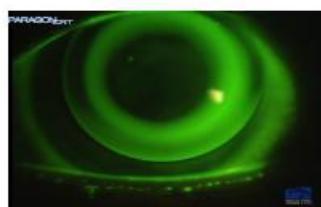
- Angle Degree +

Sagittal
Depth

39.25 (8.60)B.C.

With Indicated
Lens in place:

1. If No....
2. Return to Initial lens
and evaluate edge
lift



39.25 .575 RZD -32 angle	39.25 .575 RZD -33 angle	39.25 .575 RZD -34 angle
39.25 .550 RZD -32 angle	<u>Initial Lens</u> 39.25 .550 RZD -33 angle	39.25 .550 RZD -34 angle
39.25 .525 RZD -32 angle	39.25 ↑ .525 RZD -33 angle	39.25 .525 RZD -34 angle

- Angle Degree +

Sagittal
Depth

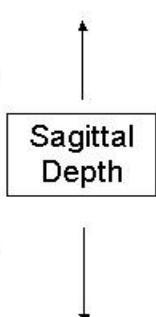
39.25 (8.60)B.C.

With Initial Lens
in place:
Evaluate Edge lift



39.25 .575 RZD -32 angle	39.25 .575 RZD -33 angle	39.25 .575 RZD -34 angle
<u>Initial Lens</u> 39.25 .550 RZD -32 angle	39.25 .550 RZD -33 angle	39.25 .550 RZD -34 angle
39.25 .525 RZD -32 angle	39.25 .525 RZD -33 angle	39.25 .525 RZD -34 angle

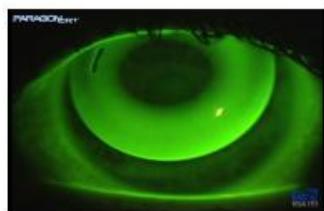
- Angle Degree +



39.25 (8.60)B.C.

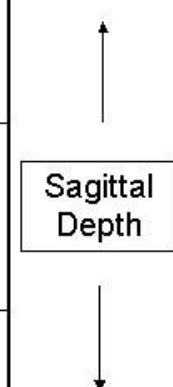
With Initial Lens
Lens in place:

1. Does it center?
2. If No....
3. Increase RZD



39.25 .575 RZD -32 angle	39.25 .575 RZD -33 angle	39.25 .575 RZD -34 angle
<u>Initial Lens</u> 39.25 .550 RZD -32 angle	39.25 .550 RZD -33 angle	39.25 .550 RZD -34 angle
39.25 .525 RZD -32 angle	39.25 .525 RZD -33 angle	39.25 .525 RZD -34 angle

- Angle Degree +

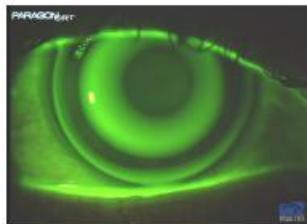


CRT Dispensing Set

39.25 (8.60)B.C.

With Lens in place:

1. Does it center?
2. If Yes....
3. Evaluate Edge Lift



39.25 .575 RZD -32 angle	39.25 .575 RZD -33 angle	39.25 .575 RZD -34 angle
39.25 .550 RZD -32 angle	<u>Initial Lens</u> 39.25 .550 RZD -33 angle	39.25 .550 RZD -34 angle
39.25 .525 RZD -32 angle	39.25 .525 RZD -33 angle	39.25 .525 RZD -34 angle

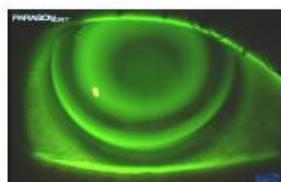
- Angle Degree +



39.25 (8.60)B.C.

With Increased RZD
Lens in place:

1. Does it center?
2. If No....
3. Increase Angle



39.25 .575 RZD -32 angle	39.25 .575 RZD -33 angle	39.25 .575 RZD -34 angle
39.25 .550 RZD -32 angle	<u>Initial Lens</u> 39.25 .550 RZD -33 angle	39.25 .550 RZD -34 angle
39.25 .525 RZD -32 angle	39.25 .525 RZD -33 angle	39.25 .525 RZD -34 angle

- Angle Degree +

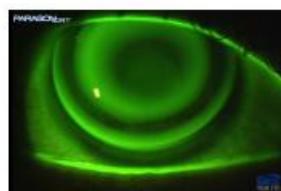


CRT Dispensing Set

39.25 (8.60)B.C.

With Increased angle lens in place:

1. Does it center?
2. Yes
3. Dispense



39.25 .575 RZD -32 angle	39.25 .575 RZD -33 angle	39.25 .575 RZD -34 angle
	<u>Initial Lens</u>	
39.25 .550 RZD -32 angle	39.25 .550 RZD -33 angle	39.25 .550 RZD -34 angle

39.25 .525 RZD -32 angle	39.25 .525 RZD -33 angle	39.25 .525 RZD -34 angle

- Angle Degree +



CRT Dispensing Set

39.25 (8.60)B.C.

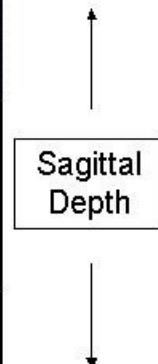
With Lens in place:

1. Does it center?
2. If No....
3. Custom Lens

39.25 .575 RZD -32 angle	39.25 .575 RZD -33 angle	39.25 .575 RZD -34 angle
	<u>Initial Lens</u>	
39.25 .550 RZD -32 angle	39.25 .550 RZD -33 angle	39.25 .550 RZD -34 angle

39.25 .525 RZD -32 angle	39.25 .525 RZD -33 angle	39.25 .525 RZD -34 angle

- Angle Degree +



Evaluate Edge Lift

When you have found the shallowest lens that centers- evaluate edge lift.

With shallowest RZD lens that centers-
Evaluate Edge Lift



Excessive Edge Lift-
Increase angle



Good Edge Lift
Dispense



Insufficient Edge Lift
Decrease edge lift

39.25 (8.60)B.C.

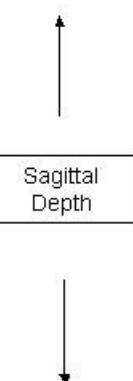


1. Excessive Edge Lift?
2. If Yes....
3. Increase Angle

39.25 .575 RZD -32 angle	39.25 .575 RZD -33 angle	39.25 .575 RZD -34 angle
39.25 .550 RZD -32 angle	<u>Initial Lens</u> 39.25 .550 RZD -33 angle	39.25 .550 RZD -34 angle
39.25 .525 RZD -32 angle	39.25 .525 RZD -33 angle	39.25 .525 RZD -34 angle

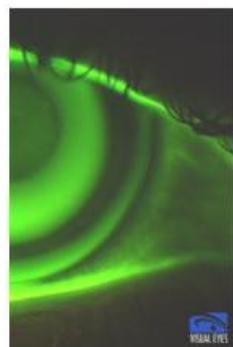
- Angle Degree +

Shallowest RZD with centration



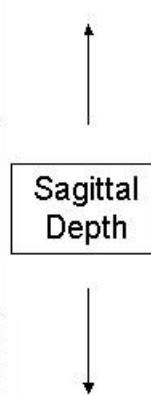
39.25 (8.60)B.C.

1. Good Edge Lift?
2. If Yes...
3. Dispense



39.25 .575 RZD -32 angle	39.25 .575 RZD -33 angle	39.25 .575 RZD -34 angle
39.25 .550 RZD -32 angle	<u>Initial Lens</u> 39.25 .550 RZD -33 angle	39.25 .550 RZD -34 angle
39.25 .525 RZD -32 angle	39.25 .525 RZD -33 angle	39.25 .525 RZD -34 angle

- Angle Degree +



39.25 (8.60)B.C.



1. Insufficient Edge Lift?
2. If Yes....
3. Decrease Angle

39.25 .575 RZD -32 angle	39.25 .575 RZD -33 angle	39.25 .575 RZD -34 angle
	<u>Initial Lens</u>	
39.25 .550 RZD -32 angle	39.25 .550 RZD -33 angle	39.25 .550 RZD -34 angle

- Angle Degree +

↑
Sagittal
Depth

↓

Dispensability

The lens should present with:

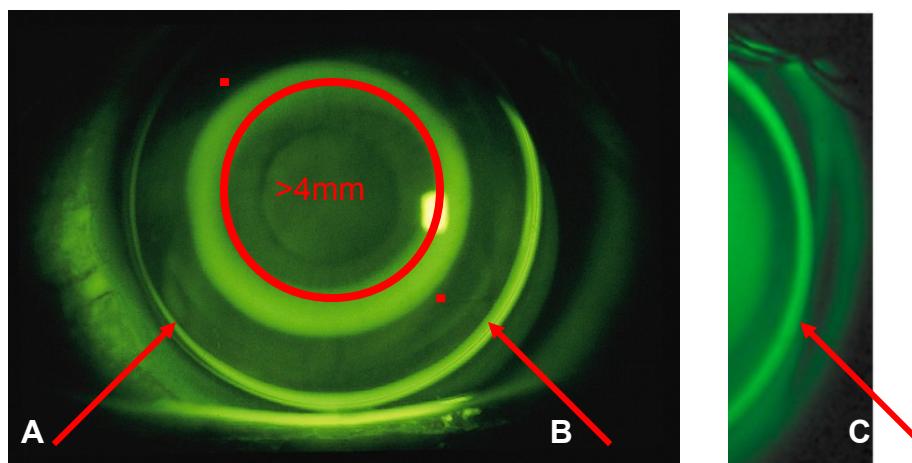
4+ mm Treatment Zone (*see below illustration*)

Centered, limbus-to-limbus and in relation to pupil (*see below illustration*)

Acceptable Edge Lift (note A, B, C arrows in below illustration)

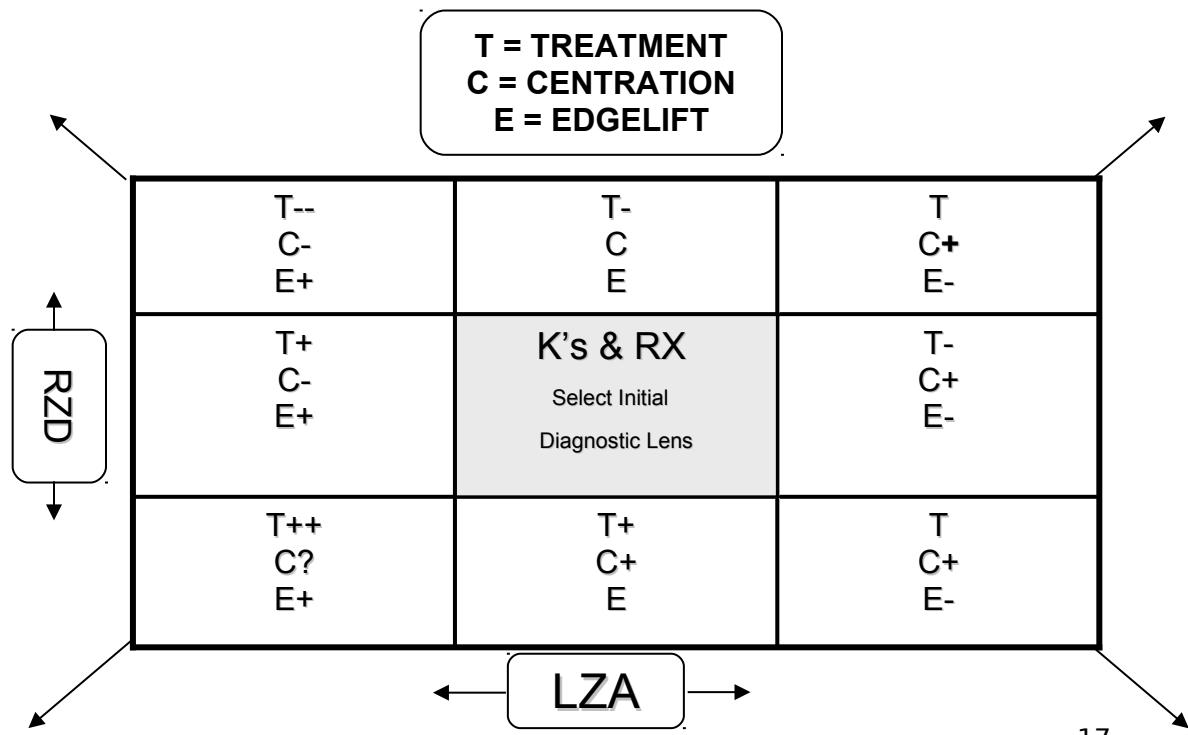
More than "Just Landed" Appearance: "IL" to moderately heavy landing is acceptable.

Fluorescein reveals a “Black, Green, Black, Green” pooling pattern



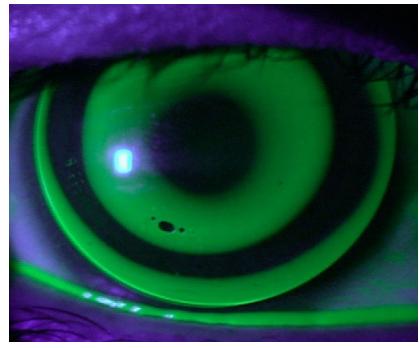
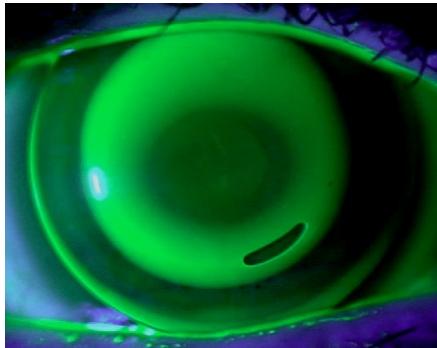
- A: minimal edge lift, however, acceptable
- B: more edge lift than necessary, but OK as is
- C: optimum edge lift appearance

The Diagnostic/Dispensing system suggested an initial lens and based on observation, the clinician moves to centration, additional treatment and appropriate edge lift by moving to other lenses, if necessary, within the same Base Curve range, based on the following parameter options.

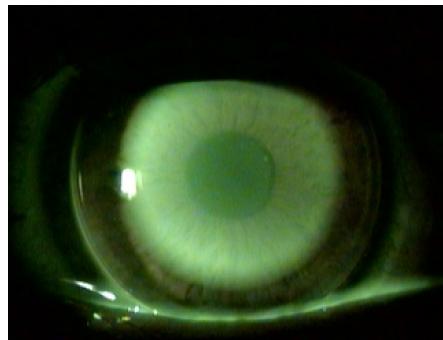


The lens is NOT dispensable when any of these problems exist:

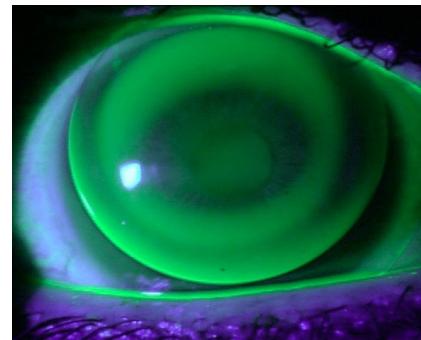
- Small or NO treatment zone
- Decentered lens
- Minimal edge lift or seemingly tight periphery (LZA is excessive)



Small Treatment Zone resulting from sag too deep.



No Treatment Zone; Excessive pooling of Fluorescein centrally resulting from sag too deep.



Oval Treatment Zone with “Just Landed” appearance resulting from sag too deep; if zone is circular, both major meridians are “treated” equally.

How To Fix Fitting Problems

Small or No Treatment Zone

First option
Second option
Third option

decrease LZA
flatten Base Curve
decrease RZD

Decentered Lens

If inferior & nasal
If inferior & centered (or slightly temporal)
If superior & nasal
If superior & centered laterally **

decrease LZA
decrease LZA
and if remains decentered, decrease RZD
increase RZD
and if remains decentered, increase LZA
increase RZD

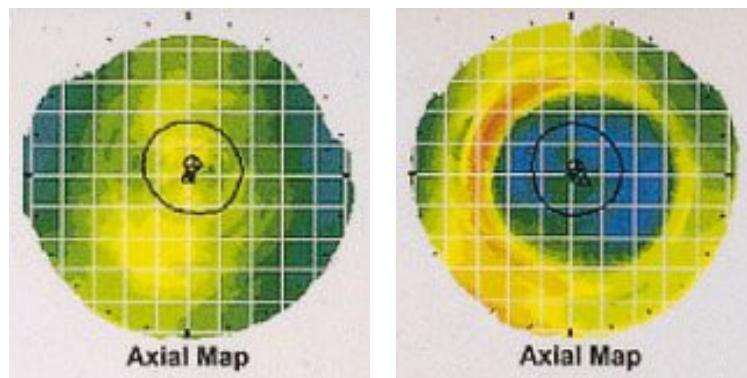
Minimal edge lift or seemingly tight periphery (LZA is excessive.) **

First option

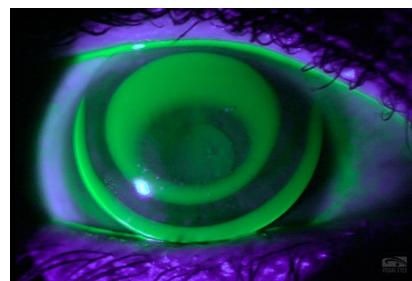
decrease LZA

** "Z" Axis tilt may occur if the LZA is 2 degrees too great. Sometimes this will cause a superiorly decentered lens showing excessive fluorescein pooling from the RZD all the way to the edge of the lens. Decrease the LZA by 2 degrees and increase the RZD (25 to 50 microns) if this occurs.

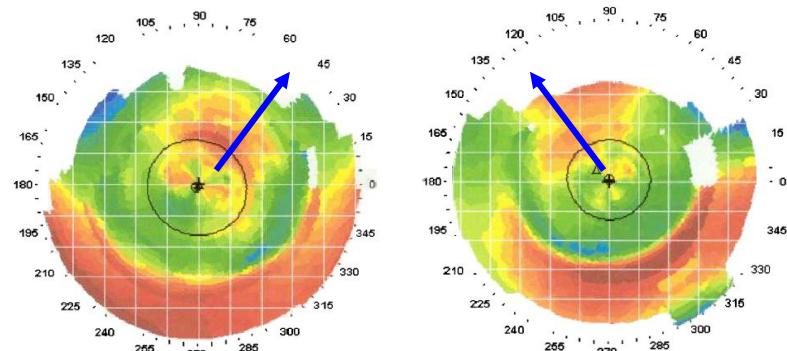
WELL-CENTERED LENS BEFORE & AFTER



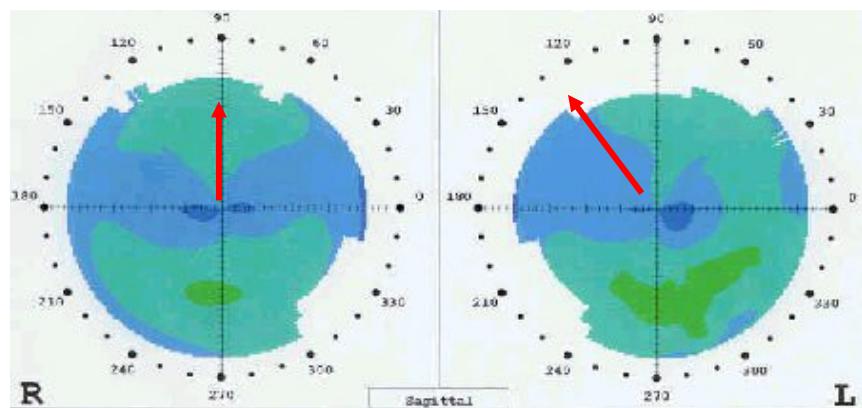
DECENTERED LENS EXAMPLES



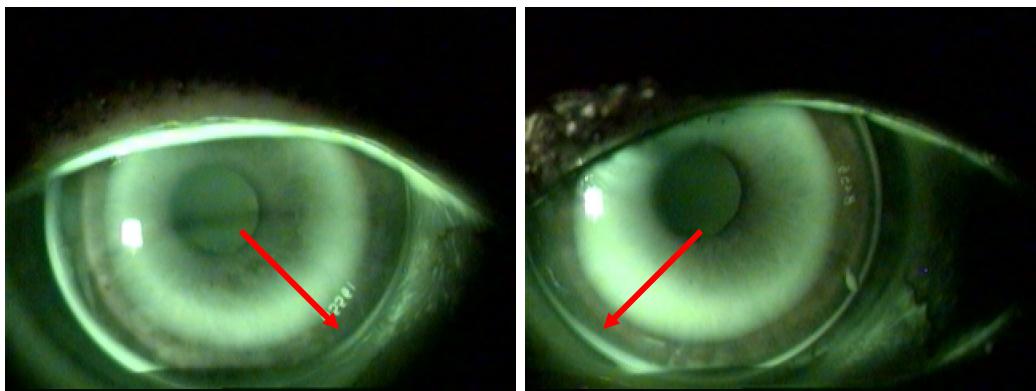
Superiorly Riding (with oval treatment zone)



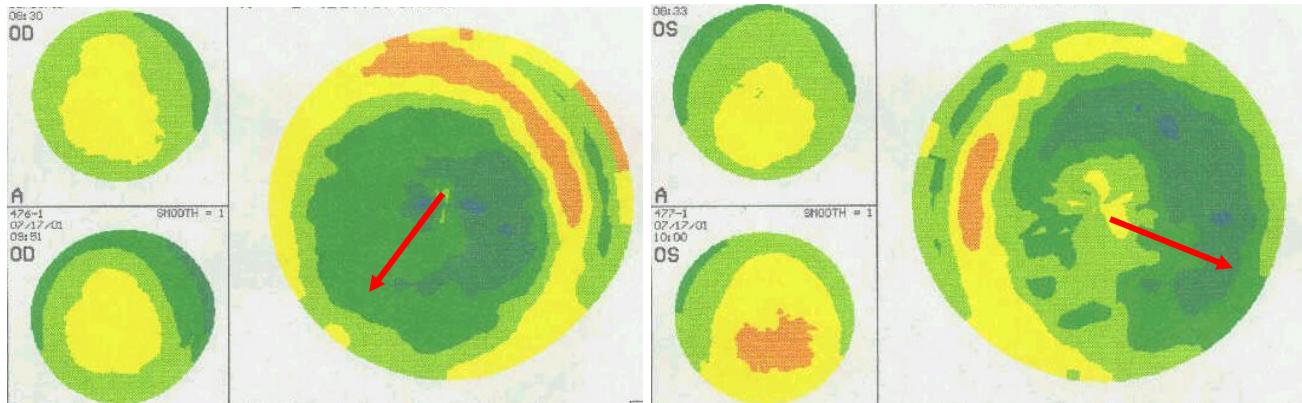
Both lenses are riding superiorly and slightly nasal, confirmed by topography. Note the inferior and steep “smile” (epithelium being pushed inferiorly from the high riding lens) and the “up and in” displacement of the steeper central zone (central island).



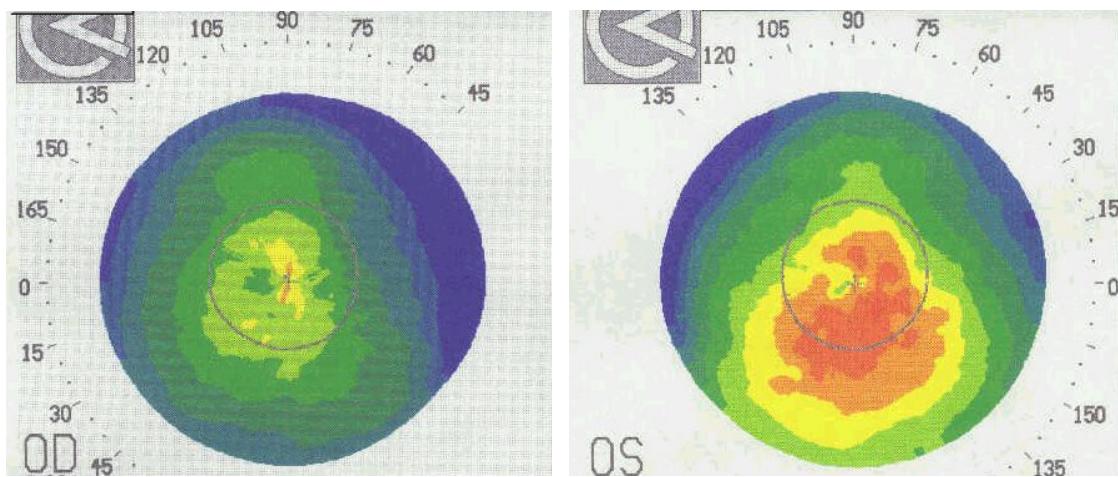
The lens in the right eye is decentered slightly superiorly, whereas the left lens not only rides high, but slightly nasally.



The lenses are riding low and nasally decentered.

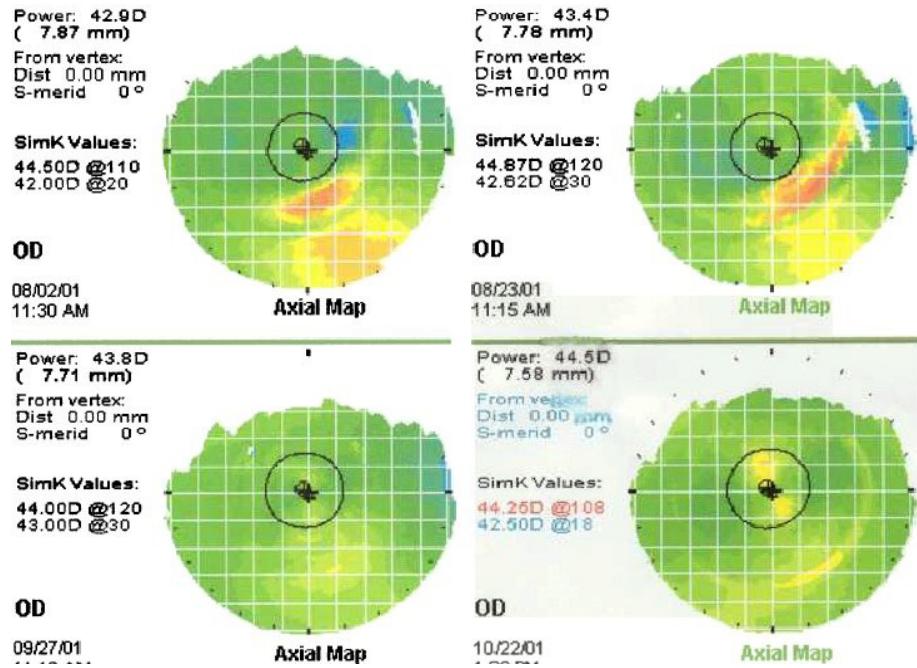


These topography “difference maps” confirm that lenses are riding infero-temporally or “down & out”.

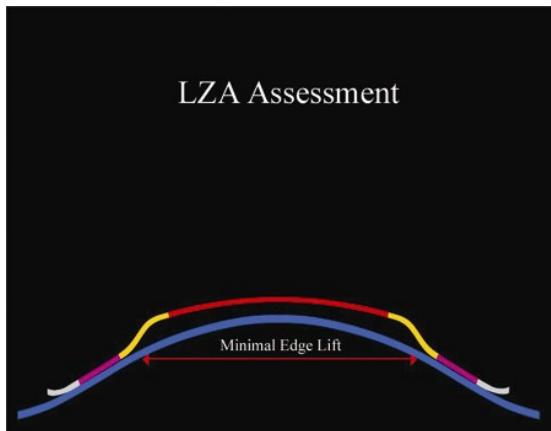


The right topography map confirms a low riding lens that is slightly temporal or “down & out”. The left map appearance shows this lens is primarily low riding. Both topographies show “central islands” or untreated areas beneath the retainer lenses. Central islands often result from the lens sag been too deep; they may also occur in a well-centered lens or a high riding lens (with the steep zones centered or superiorly located, respectively).

A decentered lens only makes the corneal topography more misshapen if lens parameters remain unchanged (top photos). After increasing the RZD to achieve better centration, it may take months for the cornea to right itself (bottom photos). It is prudent to change lens parameters immediately to eliminate this form of corneal distortion. Do not expect a decentered lens to get better on its own accord.



LZA Assessment



Significant edge lift may be seen when the LZA has too low an angle and will present with a "sealed off" periphery when the LZA is too steep.

Other Fitting & Problem Solving Concepts

What to do for "Under Treatment"

1) If,

Centered (confirmed with topography, if available)
 Treatment zone is round and 5+mm in diameter
 Adequate edge lift
 PLANO over-refract on the lenses
 No induced astigmatism in the MR

and

Have - 0.50 residual myopia

Have - 1.00 residual myopia

Have - 1.50 residual myopia

then

flatten base curve by 0.50D to 0.75 D

flatten base curve by 0.75D to 1.00D

reduce LZA 1 degree

2) If,

Centered (confirmed with topography, if available)
 Treatment zone is round and 5+mm in diameter
Lack edge lift
 PLANO over-refract on the lenses
 No induced astigmatism in the MR

and

Have - 1.00 or less residual myopia

Have - 1.50 residual myopia

then

reduce LZA 1 degree, and
 increase BC by no more than 0.50D

reduce LZA by 1 degree

3) If,

Centered (confirmed with topography, if available)
 Treatment zone is round and 5+mm in diameter
 Adequate Edge Lift

PLANO over-refract on the lenses
No induced astigmatism in the MR,
but have UNCORRECTED residual cylinder power

and

Myopia is fully treated

-or-

Have - 1.00 or less residual myopia

-or-

Have - 1.50 residual myopia

then

Call your Paragon Clinical Specialist; either the LZA, RZD, BC will need to be reduced/flattened or a combination of these processes to reduce sag will be necessary.

What to do for “Over Treatment”

If,

Centered (confirmed with topography, if available)
Treatment zone is round and 5+mm in diameter
Adequate edge lift
PLANO over-refract on the lenses
No induced astigmatism in the MR

and

Spherical power is over-corrected

then

increase the sag by steepening BC or the RZD using a 1:1 relationship per diopter in BC, or approximately 25 microns in RZD per 1.50 diopters

What to do if “Cylinder over-refraction” on the lenses

1) First, ascertain if lens base curve is warped

2) **If,**

No warpage present
Lenses are centered (confirmed with topography, if available)

then

source is lenticular astigmatism

Concerning Lens Appearance

If,

The Lens **Sag Is Too Great** (deep)

the lens will

ride low
undertreat
seal off peripherally
be difficult to remove
ride nasally (if significantly too great/deep)
have Z-axis tilt (if significantly too great/deep)

If,

The Lens **Sag Is Too Little** (shallow)

the lens will

ride high
ride temporally
have Z-axis tilt (if significantly too great/deep)
create secondary corneal SPK
have significant edge lift

Approximate Adjustments in "Sag"

The RZD is adjustable in 25 micron steps.

Base curve changes of 0.50 D represent approximately 7 micron changes.

An LZA reduction of 1 degree (15 microns) and an increase in RZD by 25 microns represent approximate "Relative Sag," and vice versa. Therefore, changes in RZD and LZA in opposite directions are approximately a 10 micro difference in sag.

Evaluation Of Lenses

The use of the lens prescribing system should result in a lens having a base curve that provides the desired post treatment keratometry target. This lens will also have a Return Zone Depth that will return the lens toward the cornea with enough clearance to allow the corneal apex to retreat posteriorly. The Return Zone clearance will allow for displacement of corneal volume and continued flattening through the optic zone region.

Initially the fluorescein pattern should demonstrate apical bearing over 3 to 5 mm surrounded by pooling under the return curve and initial portion of the Landing Zone. This should be surrounded by an area of tangency without heavy touch or bearing.

1. The absence of apical touch is problematic. This may be the result of the following:

- Error in calculating the base curve.
- Diagnostic lens error [lens not to package specification].
- Return Zone too deep resulting in Return Zone junction bridging [outer Return Zone bearing that lifts the optic zone off the cornea].
- Landing Zone angle too large resulting in Landing Zone bridging [Landing Zone bearing that lifts the optic zone off the cornea].

In the case of Return Zone or Landing Zone bridging, the fluorescein pattern will demonstrate a black circle of touch. For Return Zone junction bridging, the black circle will be at the outer junction of the Return Zone. For Landing Zone bridging, the black circle will be further out toward the lens edge. If the Return Zone is too deep AND the Landing Zone Angle is also too deep, the pattern will appear like Landing Zone bridging. To differentiate, first place a diagnostic lens having a Return Zone that is less deep. If the pattern still appears like Landing Zone bridging, the Landing Zone Angle must be decreased

Keep in mind that cases of low target myopia reduction and moderate myopia reduction with high eccentricity may NOT require Paragon CRT® contact lenses. In these cases, even the shallowest Return Zone may cause Return Zone bridging. In this event, consider a conventional large diameter tricurve RGP lens design.

2. Return Zone too shallow

If the Return Zone depth is too shallow, the lens will fail to approach the cornea outside the optic zone. The result will be a lens that teeters or tilts on the apex or decenters. When nudged to center, the lens pattern will demonstrate excessive clearance under the Return Zone and much of the Landing Zone. Bubbles may form under the lens and the lens may easily move off the cornea.

3. Decentration and excessive clearance

Remove the lens and recheck the following:

- Base curve and Return Zone depth determination.
- Diagnostic lens error [lens not to package specification].

Note: All Paragon CRT® and Paragon CRT® 100 lenses are laser-marked in the Return Zone with a six-place designation. The first two numbers correspond to the base curve, the second two denote the RZD; and, the fifth and sixth numbers indicate the LZA.

The laser mark should be inspected when lenses do not demonstrate expected patterns.

If the determination and lens measurements are correct, select a lens with a greater Return Zone Depth. After placing the lens, the clearance and decentration should be reduced. If the Return Zone clearance is appropriate but the lens continues to gain in clearance toward the edge, the Landing Zone Angle is too small and the final lens order should reflect the need for a larger angle.

When initially placed and allowed to equilibrate, the well-fit lens will center and provide for a fluorescein pattern that demonstrates central bearing, paracentral clearance and peripheral alignment. After treatment, the fluorescein pattern will appear to be aligned through all zones of the lens with a low degree of paracentral clearance.

The initial pattern of a poorly fit lens may demonstrate any of the following characteristics.

- Poor centration
- Absence of central bearing
- Absence of paracentral clearance
- Excessive paracentral clearance with bubbles in the Return Zone
- Heavy bearing [black arc] at junction of the Return Zone and peripheral Landing Zone
- Heavy bearing through the peripheral Landing Zone
- Excessive clearance in the peripheral Landing Zone

The presence of any of the poorly fit patterns is followed by failure to obtain optimum treatment. A well-fit lens pattern must be achieved through diagnostic lens fitting prior to lens ordering.

UNDERSTANDING POOR FIT DYNAMICS

1. Poor Centration

Poor centration can result from insufficient fluid forces relative to lid interaction or gravity. If the lens is nudged to center and it demonstrates ideal central bearing, paracentral clearance, and peripheral tangency, the overall diameter is too small and centration should be achieved by increasing overall diameter only.

If the pattern is ideal in the central and paracentral zones but the landing zone exhibits clearance, the angle of the peripheral zone must be increased along with a possible diameter increase.

Poor centration can result from too much sagittal depth in the lens as well. If the poor centration is accompanied by either lack of central bearing, excessive return zone depth [bubble formation] or excessive bearing at the Return Zone – Landing Zone junction (junction two), the Return Zone Depth should be reduced first to see if centration is achieved.

2. Absence Of Central Bearing

A lens may fail to demonstrate central bearing for two reasons. First, the base curve selected may simply be wrong. Recheck the keratometry or corneal topography to be sure the lens selected is flatter than the corneal apex. If the base curve has been properly selected, the cause is most always excessive sagittal depth with resultant “bridging”. If the Return Zone Depth is too great, the lens will gain in sagittal depth relative to the same chord diameter of the cornea. Even a lens that has a base curve that is significantly flatter than K may vault the cornea. In this case, the fluorescein pattern should demonstrate an arc bearing outside the Return Zone.

This arc bearing is the foundation of the “Lens Bridge”. The lens designed as flatter than K with a Return Zone that is too deep or too wide will span over the corneal apex instead of bearing on it.

The solution for this problem is to decrease the RZD. The lens will then be free to touch first in the central bearing zone instead of at the outside of the Return Zone.

In cases of high pre treatment corneal eccentricity it is possible for the Landing Zone Angle to also be too large in combination with the Return Zone Depth. In this case, the “bridging” starts with bearing toward the edge of the lens or the most peripheral portion of the Landing Zone. Decreasing the angle of the Landing Zone will allow the lens to increase its central bearing.

3. Absence Of Paracentral Clearance

The use of a yellow Wrattan filter is recommended to assist in detecting tear film thickness variances under the lens with fluorescein.

If a lens exhibits a uniform tear film when initially placed and the paracentral clearance zone is not apparent, you must first recheck the lens to determine that it has a proper design. Naked eye inspection of the ocular surface using the reflection of a single fluorescent lamp tube should facilitate determination of sigmoid geometry in the paracentral zone that is steeper than the base curve. This general inspection should reveal breaks in the lamp that correspond to the changes in geometry. You may also use the corneal topographer to capture and process an image of the base curve of the lens. Note: All Paragon CRT® and Paragon CRT® 100 lenses have a six-place laser mark in the Return Zone.

A lens having too much overall sagittal depth may seal off and prevent fluorescein from migrating under the lens. The result is a pattern that is uniform and without color. The lens can be nudged or partially lifted to allow the fluorescein containing tear film to travel under the lens. In this case, the pattern will significantly change and demonstrate excessive “bridging”.

Experience will result in increased judgment of the proper ratio of central bearing and paracentral clearance for a given amount of refractive change. The greater the attempted dioptic change, the greater the central bearing and the greater the paracentral clearance. For that reason, a one diopter-attempted change will not demonstrate deep or wide paracentral clearance.

4. Excessive Paracentral Clearance With Bubbles In The Return Zone

A lens with too much clearance at junction one before returning to the cornea may contain air bubbles in the optic zone and Return Zone. Check the base curve to determine it is correct for the attempted treatment. If the base curve is correct and the proper Return Zone Depth is in place and the peripheral tangency and edge lift appear good, the optic zone should be reduced to decrease the junction one elevation from the cornea. This is expected in some cases above 5.00 diopters of target treatment. In some cases, bubbles are reduced by reducing the RZD by 25 microns or the LZA by 1 degree.

5. Heavy Bearing [Black Arc] At Junction Of Return Zone And Landing Zone

If the optic zone bearing and Landing Zone tangency are good, the Return Zone is too deep and must either be reduced in width or decreased in depth. An increase in the Landing Zone Angle will also move the midpoint of the tangency out from the junction and toward the lens edge.

6. Heavy Bearing Through The Landing Zone

Once again, verify that the base curve is correct and the Return Zone is proper for the attempted treatment. If the bearing is less than full seal off but the fluorescein pattern demonstrates a uniform dark bearing instead of a light tear film clearance decrease the Landing Zone Angle one level. If the Landing Zone actually approaches seal off, decrease the RZD in conjunction with the LZA.

7. Excessive Clearance In Landing Zone

This problem is often associated with poor centration. To study the fluorescein pattern, always nudge the lens to center, while minimizing any tilting of the lens. If the lens demonstrates proper central bearing and junction two clearance but the Landing Zone progresses to too much edge lift or excessive clearance, increase the Landing Zone Angle.

PROBLEM SOLVING TABLE

Problem	Possible Cause	Solution
Apical clearance	<ul style="list-style-type: none"> • bridging due to excessive sagittal depth 	<ul style="list-style-type: none"> • Decrease Return Zone Depth • Decrease Landing Zone Angle
Excess central bearing, lack of good centration	<ul style="list-style-type: none"> • base curve too flat • shallow Return Zone Depth • Landing Zone Angle too small 	<ul style="list-style-type: none"> • Increase Return Zone Depth • Increase Landing Zone Angle
Poor lateral centration	<ul style="list-style-type: none"> • inadequate sagittal depth • inadequate lens diameter 	<ul style="list-style-type: none"> • Increase depth of Return Zone • Increase Landing Zone Angle • Increase overall diameter*
Superficial punctate staining	<ul style="list-style-type: none"> • sag of lens inadequate • ocular lens surface has become soiled 	<ul style="list-style-type: none"> • Increase depth of Return Zone • Decrease Landing Zone Angle • Clean or replace lens
Lack of movement	<ul style="list-style-type: none"> • sag of lens excessive 	<ul style="list-style-type: none"> • Decrease Return Zone Depth • Decrease Landing Zone Angle • Decrease overall diameter*
Excessive LZ clearance	<ul style="list-style-type: none"> • junction two clearance is excessive • low corneal eccentricity 	<ul style="list-style-type: none"> • Increase Return Zone Depth • Increase Landing Zone Angle
Over-treatment	<ul style="list-style-type: none"> • excessive corneal reshaping 	<ul style="list-style-type: none"> • Steepen base curve of optic zone
Under-treatment without apical pooling	<ul style="list-style-type: none"> • base curve too steep • poor lens centration 	<ul style="list-style-type: none"> • Flatten base curve of optic zone and increase the Return Zone Depth as needed • Improve centration increase Landing Zone Angle
Under-treatment with apical pooling	<ul style="list-style-type: none"> • bridging 	<ul style="list-style-type: none"> • RZ bridging-decrease Return Zone Depth • LZ bridging -decrease the Landing Zone Angle
Tight lens or no movement	<ul style="list-style-type: none"> • Return Zone too deep • diameter too large 	<ul style="list-style-type: none"> • Decrease Return Zone Depth • Reduce diameter
Loose lens	<ul style="list-style-type: none"> • Return Zone too shallow • Landing Zone too small • diameter too small 	<ul style="list-style-type: none"> • Increase Return Zone Depth • Increase Landing Zone Angle • Increase diameter
High-riding lens	<ul style="list-style-type: none"> • Return Zone Depth too shallow • diameter too small 	<ul style="list-style-type: none"> • Increase Return Zone Depth • Increase diameter
Low-riding lens (without bridging)	<ul style="list-style-type: none"> • Landing Zone too deep • diameter too small 	<ul style="list-style-type: none"> • Decrease Landing Zone Angle • Increase diameter*
Flare, glare or ghosts	<ul style="list-style-type: none"> • Return Zone bridging • poor centration 	<ul style="list-style-type: none"> • Decrease Return Zone Depth • Increase diameter*
Fogging and scratchy lens	<ul style="list-style-type: none"> • dirty lens • improper care & handling of lenses • oily eye make-up removers 	<ul style="list-style-type: none"> • See "Lens Care"
Increase in corneal astigmatism	<ul style="list-style-type: none"> • poor centration • diameter too small • Return Zone too shallow 	<ul style="list-style-type: none"> • Improve centration • Increase diameter* • Increase Return Zone Depth
Poor VA with lenses	<ul style="list-style-type: none"> • poor centration • power error 	<ul style="list-style-type: none"> • Improve centration • Check over-refraction/lens power
Poor VA without lenses	<ul style="list-style-type: none"> • poor centration • irregular corneal astigmatism • bridging 	<ul style="list-style-type: none"> • Increase LZA and/or OAD • Improve centration • See under-treatment solutions

*common adjustment, increase 0.5 mm in diameter up to 12.0 or 0.5 mm less than corneal diameter

FOLLOW-UP CARE

1. Follow-up examinations, as recommended by the eye care practitioner, are necessary to ensure continued successful contact lens wear. Follow-up examinations should include an evaluation of lens movement, centration, comfort and fluorescein pattern. Lens movement will decrease as tear volume is diminishing during adaptation. The patient should also begin to feel more comfortable. An assessment of vision and eye health, including inspection of the cornea for edema and/or staining should be performed.
2. On the first morning following overnight wear, with lenses in place on the eyes, evaluate fitting performance to assure that the criteria of a well-fitted lens continue to be satisfied. The fluorescein pattern provides a guide to lens adaptation. If the cornea flattens rapidly there will be a larger area of central touch and the pooling at the lens transition will be reduced. The lens will usually show reduced movement.
3. A lens with excessive movement should be replaced with another that is larger in diameter and approaches the corneal diameter less 0.5 to 1.0 mm. Landing Zone Angle should be reevaluated to determine possible need for larger LZA.
4. If the cornea shows no flattening, this may be due to a base curve that is not flat enough or a Return Zone that is too deep, resulting in “bridging”. Bridging is caused by the outer junction of the Return Zone having a heavy touch. The result of the touch is the lifting of the base curve off the cornea. When the base curve is lifted off the central cornea, it will not flatten the cornea, even if the base curve is significantly flatter than the cornea it is covering. If the base curve has been selected to be flatter than the cornea equivalent to the attempted reduction in myopia, the failure to flatten most often resides in a Return Zone that is too deep. In this case, the Return Zone Depth should be decreased until the fluorescein pattern demonstrates a proper central bearing of 3.0 to 5.0 mm.
5. After lens removal, conduct a thorough biomicroscopy examination to detect the following:
 - The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization is indicative of excessive corneal edema.
 - The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of a reaction to solution preservatives, excessive lens wear, and/or a poorly fitted lens.

RECOMMENDED INITIAL WEARING SCHEDULE

Although many practitioners have developed their own initial wearing schedules, the following sequence is recommended as a guideline. Patients should be cautioned to limit the wearing schedule recommended by the eye care practitioner regardless of how comfortable the lenses feel.

It is ideal for the patient to start with overnight wear the first night. A well fit lens provides for centration with the closed eye. The effects of lid interaction on blinking and gravity may result in lens decentration during open eye wear. Patients should be instructed to place the lens in the eye 15 to 20 minutes before going to sleep.

Patients must be cautioned; “when in doubt, take it out”. It is important that the new wearer not sleep in a lens that has a significant foreign body sensation. In the event of foreign body sensation, the patient should be instructed to remove the lens, clean and rewet it and replace the lens. If the sensation continues, the lens should not be worn.

The patient should report for follow-up evaluation the morning after the first overnight wear. The visit is best scheduled within a few hours of awakening and the patient should report with the lens in place. This visit provides an excellent opportunity to evaluate lens centration and potential lens adherence.

Upon the absence of clinical signs and complications, the patient may be instructed to continue overnight wear of the lens until the next scheduled follow-up visit.

An alternate initial daytime wear schedule may be offered at the practitioner's discretion.

Day 1	two periods of wear not to exceed 6 hours total
Day 2	6 hours
Day 3 - Day 5	8 hours
Day 6	overnight wear with follow up visit within 24 hours

The cornea normally changes within five to eight hours of wear. The wearing schedule should be modulated to determine the MINIMUM wear required for myopic reduction. The average wearing time is between 8 and 10 hours. Determine the wearing time at which lens movement appears to stop. Attempt to maintain wearing time at this level.

MYOPIC REDUCTION MAINTENANCE LENS (RETAINER LENS) WEARING SCHEDULE

With the Paragon CRT® and Paragon CRT® 100 contact lenses, the lens used to achieve refractive therapy is usually the lens used to maintain achieved correction. The Retainer Lens wearing time begins with the same wearing time required for the last fitted Paragon CRT® or Paragon CRT® 100 contact lenses for overnight Contact Lens Corneal Refractive Therapy. After a period of several days, or when the eye care practitioner is satisfied that the patient has adapted to the first Retainer Lenses, the patient may attempt to skip a night of wear to monitor the duration of visual improvement. This may continue for as long as the patient can see clearly. When it is found that the patient experiences a visual decrement following lens removal, the schedule of overnight wear must be modulated to maintain visual performance.

Note: To maintain the Contact Lens Corneal Refractive Therapy effect of myopia reduction overnight lens wear must be continued on a prescribed schedule. Failure to do so can affect daily activities (e.g., night driving), visual fluctuations and changes in intended correction.

HANDLING OF LENSES

Standard procedures for rigid gas permeable lenses may be used.

CAUTION: Paragon CRT® and Paragon CRT® 100 Contact Lenses for Corneal Refractive Therapy are shipped to the practitioner nonsterile. Clean and condition lenses prior to use.

LENS CARE DIRECTIONS

Reference the so entitled section found in the enclosed Package Insert.

VERTEX DISTANCE AND KERATOMETRY CONVERSION CHARTS

Standard charts may be used.

HOW SUPPLIED

CAUTION: Nonsterile lenses. Clean and condition lenses prior to use.

Each Paragon CRT® and Paragon CRT® 100 lens is supplied nonsterile in an individual plastic case. The lens is shipped dry; or, wet shipped in Boston SIMPLUS®* solution. This solution contains poloxamine, hydroxyalkylphosphonate, boric acid, sodium borate, sodium chloride, hydroxypropylmethyl cellulose, Glucam and preserved with chlorhexidine gluconate (0.003%), polyaminopropyl biguanide (0.0005%). The case, packing slip or invoice is marked with the central base curve radius, dioptric power, overall diameter, Return Zone Depth, Landing Zone Angle, center thickness, serial number, ship date and the color of the lens. If the patient has experienced a prior history of allergy to any of these ingredients, remove the lens from the solution and soak the lens 24 hours in sterile unpreserved saline prior to cleaning, disinfecting and dispensing.

*Boston SIMPLUS® is a registered trademark of Bausch & Lomb.

Never reuse the solution. You may store the lens in the unopened container until ready to dispense, up to a maximum of twenty-five (25) days from the Ship Date (see Packing Slip). When a lens has been stored for 25 days in its original packaging solution, it should be cleaned and disinfected with an FDA approved product, and placed into inventory as you presently do with any other RGP lens held in your office. Follow the directions on the selected disinfecting solution regarding prolonged storage.

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing or experienced with the lenses should be reported to the manufacturer.

Paragon Vision Sciences, Inc.
947 E. Impala Avenue
Mesa, Arizona 85204-6619

www.paragoncrt.com

1-800-528-8279
1-480-892-7602
1-480-926-7369 FAX

(Package Insert enclosed)

ZQF100001E-12/10

Appendix A – Informed Consent Document

You are being fitted with rigid gas permeable (RGP) contact lenses used for Corneal Refractive Therapy. Corneal Refractive Therapy refers to the use of specially designed RGP contact lenses to temporarily reshape the cornea (the clear layer on the front of the eye), allowing you to see clearly without the use of glasses or contact lenses during waking hours. The Corneal Refractive Therapy contact lenses must be worn on a regular basis during sleep in order to reduce the need for glasses or contact lenses during the day.

Complications and Side Effects

Corneal Refractive Therapy carries the same risks as other types of contact lenses, such as swelling of the cornea, scratching of the eye, irritation, infection, unusual eye discharge, excessive tearing, dry eyes, sensitivity to light, pain, redness, and distorted vision. These risks are usually temporary if the contact lenses are removed promptly and if appropriate professional care is received. In some instances permanent corneal scarring, infection, or blood vessel growth on the cornea may occur, which can lead to reduced sight in rare cases. Although uncommon, infection of the cornea can develop rapidly and lead to loss of vision. The risk of infection of the cornea has been shown to be greater among patients who wear their lenses overnight than among those who do not sleep in their lenses.

Corneal Refractive Therapy also has risks that are not typically associated with other types of contact lenses, such as blurry or variable vision, especially late in the day. The blurry vision and how long it lasts each day should decrease with time. You may also experience distortions or ghost images, particularly outside at night which may affect night driving. The risk may be increased in patients with a high degree of correction or large pupils. You may also develop a pigmented ring in the cornea. This is not noticeable, it does not change your vision, and it does not require treatment.

All risks are minimized if you follow the correct contact lens wearing schedules and care procedures. If problems occur, remove your contact lenses and report to your primary eye care practitioner as soon as possible. With any procedure, there may be unforeseeable risks. If you experience any of the symptoms listed above, remove your lenses immediately. If the condition continues after lens removal, you should immediately call for an appointment or consultation with your eye care practitioner who will provide the necessary treatment.

Lens Wear Schedule

Your doctor will recommend a wearing schedule for you to follow. The wearing time necessary for Corneal Refractive Therapy is typically 7 to 8 hours per night. Your doctor will also recommend a follow-up schedule to check your vision and contact lenses. **It is important that you attend every visit that your eye care practitioner recommends in order to maintain the health of your eyes.**

Alternative to Corneal Refractive Therapy

Alternatives to Corneal Refractive Therapy include, among others, eyeglasses, traditional contact lenses, and refractive surgical procedures.

Pregnancy

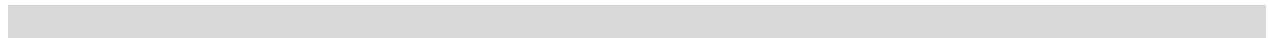
Pregnancy could adversely affect my treatment results with Corneal Refractive Therapy. If problems exist during pregnancy, you may need to temporarily discontinue Corneal Refractive Therapy contact lens wear.

I have read and fully understand the above information. I agree to adhere to the wearing and follow-up schedules as prescribed. If I fail to return for my scheduled follow-up visits, I may forfeit my chance to continue overnight wear of Corneal Refractive Therapy contact lenses. All of my questions concerning my eyes and contact lenses have been answered to my satisfaction.

Patient Name: _____

Signature: _____

Attending Doctor/Witness Signature: _____ Date: _____



Appendix B – Child Assent Document

I am being fitted with rigid gas permeable (RGP) contact lenses used for Corneal Refractive Therapy. These contact lenses reshape the cornea (the clear layer on the front of the eye) for a short time, which allows me to see clearly without the use of glasses or contact lenses while I am awake. The Corneal Refractive Therapy contact lenses must be worn on a regular basis during sleep so that I can see clearly during the day without glasses or contact lenses.

It is important that I agree to the following guidelines to keep my eyes healthy and allow me to wear contact lenses. Place a checkmark in each box if you agree.

- I agree to wear my lenses no more than _____ hours per night.
- I agree to wash my hands before inserting or removing my contact lenses.
- I agree to clean my lenses according to my doctor's instructions each time I remove them.
- I agree not to rinse my contact lenses in water from the sink. I will only use contact lens solutions to rinse my contact lenses.
- I agree to tell my parents or my doctor immediately if my contact lenses irritate my eyes.
- I agree to tell my parents or my doctor immediately if my eyes appear red or are painful.
- I understand that if I do not do the things listed above, my eyes may get hurt or I may not be able to wear my contact lenses.

Child's Name

Child's Age

Child's Signature

Date

Appendix C – Informed Consent Quiz

Please choose the single best answer for each question.

- 1.) If I experience red eyes, irritated eyes, excessive tearing, or light sensitivity, I should:
 - A.) go to the emergency room.
 - B.) remove your contact lenses immediately.
 - C.) wait for three days to see if it goes away.
 - D.) put a drop of artificial tears in your eyes.

- 2.) After wearing corneal reshaping contact lenses for approximately three months, the cornea will be permanently reshaped so contact lenses will never need to be worn again.
 - A.) True
 - B.) False

- 3.) To minimize risks associated with corneal reshaping contact lens wear, I should:
 - A.) follow the correct contact lens wearing schedules and procedures.
 - B.) remove all contact lenses if problems occur.
 - C.) report to an eye care practitioner if I have problems with my eyes or contact lenses.
 - D.) all of the above.

- 4.) If I am not experiencing problems with my eyes or contact lenses, I do not need to attend a regularly scheduled appointment with my eye care practitioner.
 - A.) True
 - B.) False

- 5.) The risk of infection is _____ for patients who wear contact lenses overnight than for patients who do not sleep in their contact lenses.
 - A.) greater
 - B.) lower

Patient Name: _____

Signature: _____

Attending Doctor/Witness Signature: _____ Date: _____

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