PROFESSIONAL FITTING AND

INFORMATION GUIDE

PARAGON RG-4™

Manufactured in Paragon HDS® 100 (paflufocon D)

RIGID GAS PERMEABLE CONTACT LENSES FOR CORNEAL RESHAPING

OVERNIGHT WEAR

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INTRODUCTION

Paragon RG-4™ Contact Lenses for Corneal Reshaping produce a temporary reduction of myopia by reversibly altering the curvature of the cornea. The Paragon RG-4™ contact lenses are manufactured from Paragon HDS® 100. 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 Paragon RG-4™ 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 RG-4™ lenses must be worn at night on a regular schedule to maintain the corneal reshaping, or the pretreatment myopia will return.

PRODUCT DESCRIPTION

The Paragon RG-4™ four zone reverse geometry design is manufactured in Paragon HDS® 100 (paflufocon D) rigid gas permeable contact lens material. The design has a posterior surface consisting of four zones:

1. The central spherical or aspheric zone.
2. An annular "Reverse Zone(s)"surrounding the central zone with a curvature steeper (shorter radius) than the central zone.
3. An "Alignment Zone(s)" generally paralleling the underlying corneal surface.
4. Peripheral curve(s) with a radius selected to create "edge lift" to promote tear flow under the lens and avoid impingement of the peripheral curve on the cornea.

The lens design also includes a "rounded" edge terminus extending from the anterior to the posterior surfaces to promote comfort.

Paragon RG-4™ Contact Lenses for Corneal Reshaping are to be worn overnight with removal during all or part of each following day. The material is a 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 reshaping are available as lathe cut firm contact lenses with blue, green, red and yellow tints, containing 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) and D&C Red No. 17. 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 zone is characterized by its diameter, radius and eccentricity.

The first zone peripheral to the central base curve, the Reverse Zone, has a spherical or slightly aspherical shape with a curvature steeper than the central base curve. This is the "reverse" of the arrangement found in lenses not designed to alter corneal curvature. This zone is characterized by the increased diopteric power it possesses relative to the central zone and the width of the zone.

The third element, generally referred to as an Alignment Zone, can be described as spherical, aspheric or as a conic section with a curvature nearly that of the underlying cornea. It is concentric to the Reverse Zone. This element is intended to parallel the cornea, initiating contact on fitting and maintaining nearly constant contact during treatment over the width of the zone. The contact with the peripheral cornea is intended to exert compressive force on and to move the peripheral corneal epithelium fluid centrally to enhance the effects of the central zone in changing corneal shape. Since the Alignment Zone parallels the underlying cornea, which is typically flattening in this region a continuation of the curve would likely ultimately impinge on the cornea creating a region of excessive bearing. This factor leads to the need for an additional peripheral curve to give "edge lift". With aspheric Alignment Curve, the Alignment Zone may parallel the peripheral cornea all the way outward and less likely to impinge on the cornea. Fluid forces arising from the approximation of Alignment Zone and cornea participate with other factors in stabilizing the lens orientation on the eye. The Alignment Zone is characterized by its radius of curvature and by its chord diameter; both parameters are selected by the fitter.

The fourth zone is the peripheral curve, this zone is common to nearly all historic RGP designs regardless of their intended mode of action is still concave toward the cornea but generally significantly flatter than the curvature of all zones it surrounds and the underlying cornea. It is designed to lift the lens surface away from the cornea and create a region of tear pooling promoting tear flow upon lens movement. This zone is characterized typically by its radius and width.

The last and most peripheral element, the edge terminus, deviates from the Alignment Zone and curves away from the underlying cornea to merge with the anterior surface thereby forming the edge of the lens. The edge has a separate contour which is created by grinding and polishing the edge but its shape is typically dictated by the nature of the processes and lens edge thickness. When the shape is characterized it is done by attempting to describe the intended location of the apex of the edge contour relative to the midline between the anterior and posterior surfaces.

Paragon RG-4™ contact lenses are used to temporarily reshape the cornea to change its refractive power with a resultant reduction in the pre-treatment 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 Reverse and Alignment Zones of the lens and concomitant peripheral pressure from the Alignment Zone. After wearing of the lens, the cornea typically demonstrates a decreased radius of curvature in the central area and an increased radius of curvature in the paracentral area allowed by the clearance within the outer portion of the optic zone and the Reverse 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 the anterior and posterior surfaces deviate from one another as is dictated the need to maintain lens minimal and maximal thicknesses. Lens thicknesses in the four zones are dependent on lens parameters but attempts are made to maximize oxygen transmission, stability and comfort.

LENS PARAMETERS AVAILABLE (See Figure 1 on next page)

Chord Diameter (D)	7.0 to 12.0 mm
Optical Zone Diameter (OZ)	5.0 to 7.0 mm
Base Curve Radius (BCOR)	6.50 to 10.50 mm
Reverse Zone Width (R)	0.5 to 2 mm radius
Reverse Curve(s) Radius (RCR)	up to 2.0 mm steeper than Base Curve
Alignment Curve Width (A)	0.5 to 2.5 mm
Alignment Curve(s) Radius (ACR)	2.0 mm flatter to 2.0 mm steeper than Base Curve
Peripheral Curve Width (P)	0.5 to 1.5 mm
Peripheral Curve(s) Radius (PCR)	2.0 mm to 10.0 mm flatter than Base Curve
Powers	-2.00 to +2.00 Diopters
Aspheric Lens Eccentricity	-1.5 to 1.5 (Oblate, Prolate or Tangent Conic)

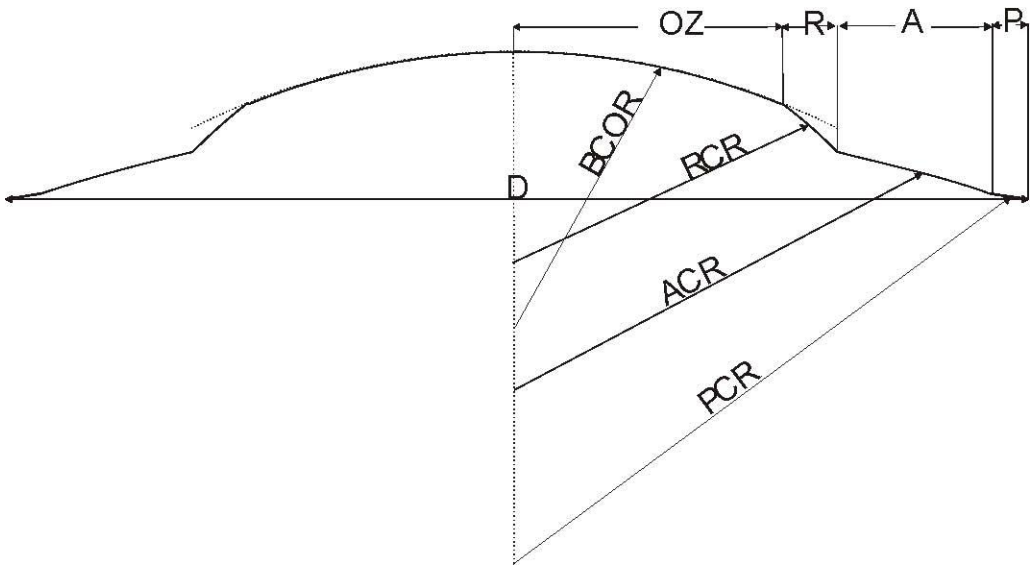

Figure 1

ATTRIBUTES OF THE PARAGON RG-4™ LENS (paflufocon D)

Refractive Index	1.442 (Nd at 25°C)
Luminous Transmittance+ (Green)	95%
Luminous Transmittance+ (Yellow)	99%
Luminous Transmittance+ (Blue)	93%
Luminous Transmittance+ (Red)	89%
Wetting Angle (Contact)++	70°
Specific Gravity	1.10
Hardness (Shore D)	79
Water Content	<1%

+ Determination of the Spectral and Luminous Transmittance, ISO 18369-3
++ Sessile Drop Technique per ANSI Z80.20, 8.11

OXYGEN PERMEABILITY - PARAGON RG-4™ 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	+1.25	100	0.20 - 0.22	0.157 - 0.199	64 - 50

* (cm^2/sec) (mL O_2)/ (mL x mm Hg) ISO/ANSI Method, ISO 18369-4
** Sammons, W.A., "Contact Lens Thickness and All That", The Optician, 12/05/80.

ACTIONS

Paragon RG-4™ Contact Lenses for Corneal Reshaping 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 RG-4™ Contact Lenses for Corneal Reshaping 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. These contact lenses 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 RG-4™ (paflufocon D) rigid gas permeable contact lenses for corneal reshaping are indicated for use in the reduction of myopic refractive error in nondiseased eyes. The lenses are indicated for overnight wear in a corneal reshaping fitting program for the temporary reduction of up to 3.00 diopters of myopia in eyes with astigmatism up to 1.50 diopters. The lenses may be disinfected using only a chemical disinfection system.

Note: To maintain the Contact Lens Corneal Reshaping 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 Reshaping with rigid gas permeable contact lenses and who do not have any of the contraindications for contact lenses previously described. Paragon RG-4™ Contact Lenses for Corneal Reshaping 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 RG-4™ contact lenses for overnight corneal reshaping are primarily intended for patients who are within the following parameters.

Refractive Error	-0.5 to – 3.00 diopters with up to –1.50 diopters of astigmatism
Keratometry	37 to 52 diopters
Visual Acuity	20/20 to 20/1000

FITTING CONCEPT

Paragon RG-4™ Contact Lenses for Corneal Reshaping are designed 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.

These contact lenses for corneal reshaping have a design known as reverse geometry. This means that the secondary curve on the posterior surface has a radius of curvature that is steeper (shorter radius) than the base curve (central curve). The secondary curve is surrounded by a flatter peripheral curve near the edge (Figure 1). In this way the geometry of the secondary curve is in the opposite relationship to the base curve, as occurs with standard rigid gas permeable contact lenses.

The function of the steep secondary curve in these contact lenses for corneal reshaping is to allow the base curve to be fitted flat in relation to the central cornea and still maintain lens stability on the cornea. With a regular contact lens design that is fitted flat on the cornea, there is only one support point for the contact lens, which occurs at the center of the lens. This lens will tend to rock and decenter on the cornea. With the Paragon RG-4™ Contact Lenses for Corneal Reshaping there is support for the lens at both the central cornea and in the area of the Alignment Curve. This tends to reduce lens rocking and aid in centering.

The most commonly used configuration for the Paragon RG-4™ contact lenses has a secondary curve that is 3.00 diopters steeper (shorter radius) than the base curve. The Alignment Curve is created aspheric and equal to the radius of the contacted mid-peripheral cornea, of which the curvature is derived from the mean central cornea curvature measured by keratometry. The peripheral curve is a standard flatter curve. The secondary curve relationship can be altered to achieve an optimal lens design for each patient. Normally the secondary curve is between 2.00 and 12.00 diopters steeper than the base curve. In some lenses the secondary curve is divided into two curves of nearly equal width. The inner portion of the secondary curve is equivalent to the usual radius value of the Paragon RG-4™ lens and the outer portioned is flattened to provide a smooth transition to the peripheral curve, in the manner of a blend.

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 reshaping.

Paragon RG-4™ Contact Lenses for Corneal Reshaping 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 RG-4™ contact lenses for 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 RG-4™ Contact Lenses for Corneal Reshaping. Other side effects, which sometimes occur in all hard 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 reshaping 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.

FITTING PARAGON RG-4™ CONTACT LENSES FOR CORNEAL RESHAPING

Note: Contact lenses for corneal reshaping should be fitted only by a trained and certified contact lens fitter.

Paragon RG-4™ contact lenses for Contact Lens Corneal Reshaping may be fitted using a modification of the standard techniques for rigid gas permeable contact lenses.

1. Pre-fitting Examination

   A complete refraction and visual health examination should be performed. Pre-fitting patient history and examination are necessary to determine whether a patient is a suitable candidate for Paragon RG-4™ contact lenses for Contact Lens Corneal Reshaping. Consider patient hygiene and mental and physical state. Collect and record baseline clinical information to which post-fitting examination results can be compared.

2. Initial Lens Power Selection Standard procedures for determining power of rigid gas permeable contact lenses may be used, including compensation for vertex distance. The standard power of the Paragon RG-4 lens is +1.25D.

3. Initial Lens Diameter Selection

   Usually, lens diameters between 10.0 mm to 11.2 mm are chosen to maximize centering to the cornea and to minimize lens movement. Lens diameters outside of this range are occasionally used for some eyes. This guide is only a general recommendation and the specification for an individual patient will depend on the eye care practitioner's professional judgment.

   Determining Starting Lens Diameter: The lens diameter is a function of the corneal diameter (horizontal visible iris diameter). The lens diameter should be between 0.5 to 2.0 mm less than the HVID. Lens centration is critical to the success of the treatment. Larger lens diameters may be needed to optimize centration.

4. Initial Lens Base Curve Selection The base curve of the first lens fitted is generally fitted flatter than the mean keratometric finding in an amount equal to the attempted reduction in myopia.

5. Initial Lens Evaluation

   Movement: Blink induced lens movement should show minimal downward lens movement with the lid motion (average 1.0 mm.) and then upward with the lid motion (average 1.0 mm.) to a lesser degree than regular RGP contact lens. During the inter-blink period the lens should have little or no motion (average less than one millimeter).

   Positioning: The lens should position centrally to minimize both lens movement and lid sensation. The lens should not ride more than 0.5 mm. below center nor 0.5mm above center.

6. Characteristics of a Tight (too steep) Lens

A lens that is too tight will show reduced movement upon blinking. The lens will be centered or decentered inferiorly and exhibit little or no movement. Bubbles may be detected behind the lens.

7. Characteristics of a Loose (too flat) Lens

A lens that is too loose will move excessively on the cornea following each blink. The lens may ride in either a position that is too high or too low or in an eccentric position. A loose lens is usually uncomfortable for the patient.

DIAGNOSTIC LENSES & EMPIRICAL FITTING

Diagnostic Lens Fitting: Diagnostic lens fitting is recommended whenever possible. Diagnostic lens fitting allows a more accurate determination of lens specifications for the lens fit and power. To choose the first lens for the patient (either a diagnostic lens or empirical fitting with the intention to order), refer to Reference Table A on page 13 for the patient data of mean keratometry value and spherical equivalent. This will refer to an ID code.

For example, Reference Table ID Code 108L04 refers to:

- 108 = 10.8 Diameter
- L = Mean K in the range of 42.60D-42.85D
- 04= -3.00D (calculated corneal spherical equivalent indicate the desired amount of flattening for myopia correction on the cornea)

K-Code listed in text represents the alphabetized letter from the mean K in Reference Table A, page 13. Diagnostic lenses are essential in fitting patients whose corneal topography has been distorted by previous contact lens wear.

Diagnostic Lens Set: A basic diagnostic lens set consists of an appropriate number of targeted corneal curves with one total diameter for each K-Code. All diagnostic lenses have the same Power-Code.

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

Eye care practitioners should educate contact lens technicians concerning proper care of diagnostic lenses. Each contact lens is shipped nonsterile in a case with no solution (dry). Therefore, in order to insure disinfection, clean and condition lenses prior to use. Hands should be thoroughly washed, rinsed and dried with a lint free towel prior to handling a lens.

Prior to reusing in a diagnostic procedure or before dispensing to a patient, lenses should be surface cleaned and disinfected, following the manufacturer's instruction.

Diagnostic Lens Procedure

1. Determine the Manifest Refraction for the patient’s distance vision.
2. Determine the Mean K by averaging the flat and steep K measurements.
3. If corneal cylinder is present, calculate the corneal spherical equivalent. Corneal spherical equivalent is determined by calculating one-half of the difference between the steep and flat keratometric readings and adding that value to the sphere power. Always subtract the flat K reading from the steep K reading. No vertex correction of the power is required.
    - Calculated corneal spherical equivalent indicate the desired amount of flattening for myopia correction on the cornea
4. Select the initial diagnostic lens by selecting the diagnostic lens with the patient’s corresponding Mean K. Refer to the lens Reference Table A (see page 13)
5. Select a diagnostic lens and place the lens on the eye. Evaluate the lens using white light for the following:
    1. Centering: The lens should center as well or better than a regular RGP lens. The lens should be fitted according to the interpalpebral fitting philosophy. Lenses fitted according to the "lid attachment"

philosophy, in which the lens purposely rides in a high position should be avoided.

2. Movement: Lens movement should be equivalent to or slightly less than a regular RGP lens, fitted according to the interpalpebral philosophy.

3. Evaluate the Fluorescein Pattern: The fluorescein pattern should show a lens with definite central touch, approximately 3 to 5 mm diameter with a surrounding area of pooling. In the periphery there should be another area of lighter touch and near the edge a thin band of pooling.

If the fitting criteria (centration, bull's eye pattern, minimal movement and acceptable comfort) are achieved, then complete an over-refraction to determine the optimal prescription lens to order. The desired over-refraction is plano.

The Over-Refraction Is Completed As Follows:
1. If the over-refraction of the -3.00D diagnostic lens yields -1.00D, then order a lens with a target sphere of -4.00D with the Mean-K by providing this data or by providing the lens identification code from the Reference Table A.

2. If the over-refraction yields +0.50D or less, make no lens change. Simply order a lens with the same parameters as the diagnostic lens.

3. If the over-refraction is +1.00D or more, select the appropriate power. For example, if the over-refraction is +1.00D (over the -3.00D diagnostic lens), the lens ordered should have a target sphere power of -2.00D with the patient's Mean K.

<u>Empirical Fitting (no diagnostic set):</u>

1. Determine the Manifest Refraction for the patient's distance vision.
2. Determine the Mean K by averaging the flat and steep K measurements.
3. If corneal cylinder is present, calculate the corneal spherical equivalent. Corneal spherical equivalent is determined by calculating one-half of the difference between the steep and flat keratometric readings and adding that value to the sphere power. Always subtract the flat K reading from the steep K reading. No vertex correction of the power is required.
    - Calculated corneal spherical equivalent indicate the desired amount of flattening for myopia correction on the cornea
4. Order the lens providing the corneal spherical equivalent and the Mean K or by providing the lens identification code noted in the Reference Table.

For example:

IF:
- Manifest refraction: -2.50 – 0.75 x 180º
- Keratometric Readings: 42.50D / 43.50D (K Reading presents 1.00D of corneal cylinder)

THEN:
- Corneal Spherical Equivalent: -3.00D (-2.50 + ½ of difference in K readings)
- Mean K: 43.00D (43.50D - 42.50D divided by 2 = 0.50D) (Add 0.50D to 42.50D = 43.00D)

Therefore, the prescription lens order would be:
- -3.00D with a Mean K of 43.00D OR Provide the Lens Code, 108M04.

This lens will be a 10.8 mm Diameter, -3.00D Target Sphere Power and a base curve to accommodate the 43.00D Mean K-reading. (Reference Table Lens ID Code, 108M04) 5. Upon receipt, place the lens on the eye and instill fluorescein.

5. Upon receipt, place the lens on the eye and instill fluorescein.
6. Evaluate the following:
    a. Centration: A well centered lens is most important.
    b. Does the fit present a bull's eye pattern? The bull's eye pattern should present: • No less than 4 mm of central applanation. • 1 - 2 mm of pooling in the reverse zone. • 360º of peripheral dark

band in the alignment zone. • Present sufficient edge lift providing a combination of tear pumping and acceptable comfort.

c. Movement: Generally, about .05 mm of movement is sufficient.

If the fitting criteria (centration, bull's eye pattern, minimal movement and acceptable comfort) are achieved, then complete an over-refraction to determine if you have a dispensable lens. The desired over-refraction is plano.

The over-refraction (over lens -3.00D, Mean K 43.00D) is completed as follows:
1. If the over-refraction of the initial lens ordered yields plano, then you have the dispensable lens. If the over-refraction yields a -1.00D, then you must add this to the sphere power and order the lens. (Reference Table Lens ID Code, 108M06)
2. If the over-refraction yields +0.50D or less, make no lens change.
3. If the over-refraction is +1.00D or more, decrease the sphere power by +1.00D in your order. (Reference Table Lens ID Code, 108M02)

The area of pooling near the transition between the base curve and secondary curve serves as a reservoir for tears and as a potential space for corneal shifting during the flattening process of Contact Lens Corneal Reshaping. The cornea molds by flattening the central cornea, which reduces the space near the transition reservoir. Hence, the size of the transition reservoir, as observed from the fluorescein pattern, is a good indicator not only of the initial fit of the lens but also of the progress of corneal flattening over time as the lens is worn.

The fluorescein pattern provides the best method for monitoring the fit of the contact lens over time. As the cornea flattens, the area of pooling at the transition becomes less and less. When this occurs the lens begins to tighten and at some point barely moves on the cornea. The lack of pooling at the transition area indicates that the lens should be changed for another that has a flatter base curve. Or the optimum treatment has been reached for the appropriate lens design.

When the cornea has flattened enough for the desired reduction of the patient's myopia (even though the fluorescein pattern indicates that further flattening is possible) it is time to switch to a Retainer Lens or modulate the wearing time for an optimum Contact Lens Corneal Reshaping effect. A Retainer Lens is a contact lens that is designed to maintain the current level of corneal flattening without additional flattening. It is usually made with the same reverse geometry design as the last lens used for corneal flattening but with a different secondary curve.

Limits of Flattening

In some cases the corneal flattening stops before a full reduction of the refractive error has been accomplished. If no further corneal flattening occurs, it is an indication that the cornea has reached a point of maximum change and the patient may require a design change for a retainer lens.

CORNEAL RESHAPING PROBLEM SOLVING

Fitting too flat may decenter the lens, cause vision problems and increase corneal astigmatism. The most important points to remember are:

1. CENTERING
2. 1.0 mm MOVEMENT
3. MODERATE APICAL TOUCH
4. PATIENT COMFORT

	Possible Cause	Solution
Tight lens or no movement	Secondary Curve too steep Alignment Curve too steep Diameter too large	flatten Secondary Curve flatten Alignment Curve reduce Diameter
Loose lens	Secondary Curve too flat Alignment Curve too flat Diameter too small	steepen Secondary Curve steepen Alignment Curve increase Diameter
High-riding lens	Secondary Curve too flat Alignment Curve too flat Diameter too small	steepen Secondary Curve steepen Alignment Curve increase Diameter
Low-riding lens	Secondary Curve too flat or steep Diameter too small Lower lid margin too loose or too inferior	steepen or flatten Secondary Curve increase Diameter wear lenses only for bedtime
Fogging and scratchy lens	dirty lens improper care & handling of lenses improper blinking oily eye make-up removers	see "Lens Care"
Increase in corneal astigmatism	lens de-centered Diameter too small Secondary Curve or Alignment Curve too flat	improve centration increase Diameter steepen Secondary Curve or Alignment Curve
Poor VA with lenses	de-centered lens power error	improve centration check over-refraction
Poor VA w/out lenses	poor centration irregular corneal astigmatism lens overwear	steepen Secondary Curve or increase Diameter improve centration decrease wearing time and recheck

All Paragon RG-4™ lenses are laser-marked with a six- or seven-place designation. The first three (3) numbers correspond to the lens diameter (OAD); the 4th place, [and 5th, if seven (7) places], denote the K-Code; the 5th and 6th places, [or 6th and 7th, if seven (7) places], indicate the Power-Code. Reference the table found below, for the values represented by each code. If the first three (3) places are "104", the lens diameter is 10.4 mm.

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

Table A: Reference Table for Initial Lens Selection with Mean K in Diopters (D) on the left-hand column and the desired spherical equivalent (S.E.) of myopia correction in Diopters (D) on the top row. Standard lens power is +1.25D.

Reference Code 108L04 refers to:

- 108 = 10.8 Diameter
- L = Mean K in the range of 42.60D-42.85D, letter denotes the K-Code
- 04= -3.00D (calculated corneal spherical equivalent indicate the desired amount of flattening for myopia correction on the cornea)

Mean k/S.E	-1.50	-2.00	-2.50	-3.00	-3.50	-4.00	-4.50	-5.00
39.74 - 40.00	112A01	112A02	112A03	112A04	112A05	112A06	112A07	112A08
40.01 - 40.26	112B01	112B02	112B03	112B04	112B05	112B06	112B07	112B08
40.27 - 40.52	112C01	112C02	112C03	112C04	112C05	112C06	112C07	112C08
40.53 - 40.78	112D01	112D02	112D03	112D04	112D05	112D06	112D07	112D08
40.79 - 41.04	112E01	112E02	112E03	112E04	112E05	112E06	112E07	112E08
41.05 - 41.30	112F01	112F02	112F03	112F04	112F05	112F06	112F07	112F08
41.31 - 41.56	112G01	112G02	112G03	112G04	112G05	112G06	112G07	112G08
41.57 - 41.82	112H01	112H02	112H03	112H04	112H05	112H06	112H07	112H08
41.83 - 42.08	112I01	112I02	112I03	112I04	112I05	112I06	112I07	112I08
42.09 - 42.33	112J01	112J02	112J03	112J04	112J05	112J06	112J07	112J08
42.34 - 42.59	108K01	108K02	108K03	108K04	108K05	108K06	108K07	108K08
42.60 - 42.85	108L01	108L02	108L03	108L04	108L05	108L06	108L07	108L08
42.86 - 43.09	108M01	108M02	108M03	108M04	108M05	108M06	108M07	108M08
43.10 - 43.35	108N01	108N02	108N03	108N04	108N05	108N06	108N07	108N08
43.36 - 43.61	108O01	108O02	108O03	108O04	108O05	108O06	108O07	108O08
43.62 - 43.86	104P01	104P02	104P03	104P04	104P05	104P06	104P07	104P08
43.87 - 44.11	104Q01	104Q02	104Q03	104Q04	104Q05	104Q06	104Q07	104Q08
44.12 - 44.36	104R01	104R02	104R03	104R04	104R05	104R06	104R07	104R08
44.37 - 44.61	104S01	104S02	104S03	104S04	104S05	104S06	104S07	104S08
44.62 - 44.86	104T01	104T02	104T03	104T04	104T05	104T06	104T07	104T08
44.87 - 45.10	104U01	104U02	104U03	104U04	104U05	104U06	104U07	104U08
45.11 - 45.35	104V01	104V02	104V03	104V04	104V05	104V06	104V07	104V08
45.36 - 45.60	104W01	104W02	104W03	104W04	104W05	104W06	104W07	104W08
45.61 - 45.84	104X01	104X02	104X03	104X04	104X05	104X06	104X07	104X08
45.85 - 46.09	104Y01	104Y02	104Y03	104Y04	104Y05	104Y06	104Y07	104Y08
46.10 - 46.33	104Z01	104Z02	104Z03	104Z04	104Z05	104Z06	104Z07	104Z08
46.34 - 46.57	104ZA1	104ZA2	104ZA3	104ZA4	104ZA5	104ZA6	104ZA7	104ZA8
46.58 - 46.81	104ZB1	104ZB2	104ZB3	104ZB4	104ZB5	104ZB6	104ZB7	104ZB8
46.82 - 47.05	104ZC1	104ZC2	104ZC3	104ZC4	104ZC5	104ZC6	104ZC7	104ZC8
47.06 - 47.29	104ZD1	104ZD2	104ZD3	104ZD4	104ZD5	104ZD6	104ZD7	104ZD8
47.30 - 47.53	104ZE1	104ZE2	104ZE3	104ZE4	104ZE5	104ZE6	104ZE7	104ZE8
Over 47.53								

Color Coding	11.2 Diameter	10.8 Diameter	10.4 Diameter

FOLLOW-UP CARE

1. Follow-up examinations, as recommended by the eye care practitioner, are necessary to ensure continued successful contact lens wear. The wearer should be instructed to remove their overnight lenses at home and carry the cleaned-up lenses for follow-up. Follow-up examinations could include an evaluation of lens movement, centration, comfort and fluorescein pattern, whenever addressing a lens problem or replacing lens is required. 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. Prior to a follow-up examination, the contact lenses should be worn overnight and the patient should be asked to identify any problems which occur that are related to contact lens wear. When evaluation is required, lenses can be placed on the eyes, and 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, the lens may have a "bridging" phenomenon and there will be a smaller area of central touch and the pooling at the lens transition will be fluffy and extended toward the center portion of the lens. The lens will usually show reduced movement. These are indications that the lens can be exchanged for another flatter lens when residual refractive error persists. The overall tightness or K-Code of the new lens can be flatter by the extent of "bridging". Trial fitting for the second lens may be required to avoid a loose lens-cornea relationship.

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 1.5 mm OR with another that has a steeper or wider secondary (Reverse Zone) radius or width, OR with another that has a steeper Alignment Curve radius. For the purpose of steepening a Paragon RG-4™ lens with a steeper K-Code can be selected as a second pair. If the cornea shows no flattening, this may be due to a base curve that is not flat enough or a secondary curve that is too steep, resulting in "bridging". Bridging is caused by the outer junction of the secondary curve or the Alignment Curve 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 it 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 the secondary curve or Alignment Curve being too steep. In this case, the secondary curve and/or Alignment Curve should be made flatter until the fluorescein pattern demonstrates a proper central bearing of 3.0 to 5.0 mm. For the purpose of flattening, a Paragon RG-4™ lens with a flatter K-Code can be selected as a second pair.

4. For regular cases, 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. Daytime wear is prohibited to prevent possible lens binding and corneal erosion.
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

The Retainer Lens schedule must be customized for each patient. The Retainer Lens wearing time begins with the same wearing time required for the last fitted Paragon RG-4™ contact lenses for overnight Contact Lens Corneal Reshaping. 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 Reshaping 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 RG-4™ Contact Lenses for Corneal Reshaping are shipped to the practitioner nonsterile. Clean and condition lenses prior to use.

PATIENT LENS CARE DIRECTIONS

Please see Package Insert of lens care product.

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 RG-4™ 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, hydroxyalklphosphonate, 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 base curve radius, dioptric power, diameter, center thickness, serial number, fill date and the color of the lens.

*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.

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