Paragon NormalEyes®
Guidelines for Successful Fitting

RIGID GAS PERMEABLE SCLERAL
CONTACT LENSES

Manufactured in
Paragon HDS® 100 (paflufocon D)

FOR DAILY WEAR

PARAGON
VISION SCIENCES
We don’t just change vision, we change lives.™
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INTRODUCTION

Paragon NormalEyes® has been developed to meet the need for an easy to fit scleral lens for the purpose of optimizing the comfort, vision and health of the wearer’s eyes. The fitting system uses a diagnostic set made of lenses having a rational difference in the three independent and variable fitting parameters of the lenses. The fitting concept uses Proximity Control Technology® to enable the fitter to control the separation of the lens from the eye where clearance is desired. The lenses are intended to completely clear the cornea and have the point of greatest contact with the eye at a chord of approximately 13.0 mm.

Paragon CRT® for overnight Corneal Refractive Therapy was the first proximity control design to gain FDA approval. The design incorporates a third order polynomial shape in the proximity control zone and an uncurved landing zone that is controlled by an angle. Lenses having this geometry have been manufactured and successfully distributed worldwide since 2002 and are worn by tens of thousands of patients. The polish free processes are well managed through a quality system and produce highly consistent lenses.

Bioshape data of a large sample of eyes were evaluated to determine the distribution of the ocular contours over a chord diameter of approximately 15.5 mm. This analysis was conducted to determine the required shape (geometry) of lenses to meet a set of fitting criteria. The criteria included:

- 30 microns of clearance over the central cornea
- 50 microns of clearance at the peripheral aspect of an optic zone having a diameter of 8 mm
- 80 microns of clearance at a chord diameter of 10.5 mm
- A point of maximum contact at a chord of 13.0 mm and an edge lift of 50 microns before conjunctival compression at a chord diameter of 15.5 mm

The analysis revealed the need to have a convex curvature to the landing zone that is otherwise controlled by an angle in a manner similar to the Paragon CRT design. Since there is limited clinical metrology for the sclera to determine the proper angle for each eye, a diagnostic set of lenses having a series of base curve radii, return zone depths and landing zone angles was designed and manufactured. This set has the potential to determine the proper parameters for a respective eye through the observation of a fluorescein pattern when diagnostic lenses are placed on the eye.

- An optimum pattern will demonstrate total corneal clearance under the optic zone and return zone
- Clearance at the medial portion of the landing zone
- Clearance at the edge of the landing zone

PRODUCT DESCRIPTION

Paragon NormalEyes® paflufocon D (Trade name: Paragon HDS® 100) Rigid Gas Permeable scleral contact lenses are available as lathe cut firm contact lenses with spherical or aspherical surfaces in clear and tinted versions.

The lenses have a posterior surface consisting of three elements. The three elements are the central base curve zone (optic zone), a corneal proximity control zone (return zone), and a scleral contact zone (landing zone) that allows tear exchange between the lens and the sclera and cornea. Each of the zones may be spherical or aspherical. Generally the central base curve is chosen to align the curvature of the central cornea so as to be relatively parallel to it when suspended in front of it. The return zone, the first zone peripheral to the optic zone, will generally be designed to return the posterior lens surface to a position that is approximately 80 microns in front of the cornea.

The third element (landing zone) is concentric to and peripheral to the return zone. This element is intended to be tangential to and/or approximately harmonic to the sclera. The landing zone is curved
convex to the eye such that the zone will make its maximum point of contact with the sclera midway from
the origination of the zone and the lens edge. The landing zone has a Paragon CRT Dual Axis® feature
with a deep meridian and a shallow meridian. The landing zone angle of the deep meridian is a standard
4° greater than the shallow meridian to account for a near universal elevation difference found in the
sclera at a chord of approximately 13.0 mm. This feature produces a lens which is rotationally stable.

The landing zone provides edge lift and the termination of the landing zone is shaped to provide the
posterior portion of the edge shape.

The anterior central curve, a ¼ independent variable, is selected to provide the necessary optical power to
correct any residual refractive error not corrected by the optical and mechanical effect of the posterior
base curve and the tear lens forming between it and the cornea.

Paragon NormalEyes® paflufocon D (Trade name: Paragon HDS® 100) rigid gas permeable scleral
contact lenses provide a correction for hyperopia, myopia with and without regular or irregular
astigmatism by the combination of a tear lens formed between the lens and cornea and the refractive
power of the anterior lens surface. Paragon NormalEyes® are intended to vault the cornea and limbus
while making contact with the sclera outside the limbus. In some cases the fitter may choose to select
parameters which result in a light “feather” touch on the cornea.

Paragon NormalEyes® paflufocon D (Trade name: Paragon HDS® 100) rigid gas permeable scleral
contact lenses for refractive error correction contact lens material is a thermoset copolymer derived
primarily from siloxane acrylate, trifluoroethyl methacrylate, and methylmethacrylate.

Paragon NormalEyes® paflufocon D (Trade name: Paragon HDS® 100) rigid gas permeable scleral
contact lenses for refractive error correction contact lens material offer a handling aid for locating the
lens. The lens materials, paflufocon D, is a fluorosilicone acrylate Polymer which contains D & C Green
No. 6 and Peroxide 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 as color additives.

LENS PARAMETERS AVAILABLE:

Chord Diameter(D)…………………..15.5 mm
Center Thickness………………….0.08 to 0.7 mm
Base Curve Radii……………….5.80 to 10.50 mm
Optical Zone Semi Chord (OZ) ……2.50 to 4.50 mm
Return Zone Width(w)………………up to 2.5 mm wide from J1
Return Zone Depth (Δ)……………to 2.0 mm translation posteriorly @ J2 from base curve @ J1
Landing Zone Radii………………..- 100 mm to +100 MM
Landing Zone Angle @J2 (Φ)…………35° to 75° (from apical tangent to zone 3 tangent @ J2
Peripheral Zone (edge lift width P)……0.1 to 0.5 mm
Powers……………………………-30.00 to +30.00 Diopeters
Aspheric Lens Eccentricity…………..-1.5 to 1.5 (Oblate, Prolate or Tangent Conic)
The Paragon NormalEyes® paflufocon D (Trade name: HDS 100) rigid gas permeable scleral contact lenses have the following physical properties:

**THE PHYSICAL PROPERTIES OF THE LENS ARE:**

- Refractive Index... ...1.442(Nd at 25°C)
- Light Transmittance ...90-94%
- Wetting Angle (Receding Angle) . . 42°
- Specific Gravity .................1.100
- Hardness (Shore D) .................79
- Water Content .....................< 1%
- Oxygen Permeability .............151 x 10^{-11} Dk* at 35°C
  *(cm²/sec)(mL O₂/mL x mm Hg) Revised method of Irving Fatt, Ph.D.

**SELECTION OF PATIENTS**

Patients are selected who have a demonstrated need and desire for a refractive correction with rigid gas permeable contact lenses and who do not have any of the contraindications for contact lenses previously described. Paragon NormalEyes® contact lenses for daily wear are indicated for patients with myopia and hyperopia with and without regular and irregular astigmatism, and with and without presbyopia, who desire to wear contact lenses during their waking hours.

Paragon NormalEyes® contact lenses for daily wear are primarily intended for patients who are within the following parameters.

- Refractive Error -30.00 to +30.00 diopters with up to 20.00 diopters of astigmatism
- Keratometry 35 to 70 diopters
- Visual Acuity 20/20 to 20/1000

**FITTING CONCEPT**

Paragon NormalEyes® contact lenses for daily wear are intended to be fitted to substantially avoid touch of the cornea and come to rest on the bulbar conjunctiva outside of the limbus. 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 approximately 0.50 to 2.00 Diopters. 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 and avoid heavy impingement of the bulbar conjunctiva at the
periphery of the lens. The lens will demonstrate central corneal clearance, paracentral lens-cornea and limbal clearance and landing zone-scleral tangential correspondence.

The Paragon NormalEyes® contact lens fitting system utilizes the following fixed parameters.

- Spherical Optic Zone = 8.0 mm
- Return Zone Width = 1.25 mm
- Harmonic optic zone area thickness = 0.22 mm ± 0.02
- Convex to the eye radius in landing zone
- Dual Axis landing zone with 4° difference between shallow and deep meridian
- Overall Diameter = 15.5 mm

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. For corneal diameters greater than 10.8 mm, the standard parameters are recommended. For corneal diameters larger than 12.8, a larger overall diameter is recommended while holding all other fixed variables the same.

There are four primary fitting objectives:

1. Provide a base curve radius that is greater than the apical radius that aligns the underlying cornea to provide a resultant clearance at the corneal apex and the 8.0 mm optic zone junction.

2. Provide clearance after conjunctival-compression has concluded at approximately 80 microns at the junction of the return zone and landing zone (10.5 mm chord) to allow for complete clearance of the cornea and limbus.

3. Provide a landing zone that has the proper angle to provide a point of greatest contact with the underlying sclera near the midpoint of the zone itself (approximate chord of 13.0 mm).

4. Provide a lens diameter that, in conjunction with the landing zone angle, provides minimal conjunctival compression.

Paragon NormalEyes® 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 full wearing time and all day comfort.

Paragon NormalEyes® contact lenses for daily wear may produce a full correction of the patient’s refractive error. The amount of correction and resultant visual acuity will depend on many factors, including the amount of refractive error, the difference between the refractive cylinder and the corneal cylinder, the centration of the lens and lens flexure. Average amounts of refractive correction have been established by clinical studies but the correction for an individual patient may vary significantly from the averages.
RISK ANALYSIS

There is a small risk involved when any contact lens is worn. It is not expected that Paragon NormalEyes® for daily wear 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 NormalEyes® contact lenses for daily wear. 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 the lenses are not fitted for corneal clearance, it is possible that corneal shape changes may occur with a resultant distortion of vision. The duration of distorted vision would rarely persist to the next day after removal before sleep and a regular night sleep.

In rare instances, there may occur permanent corneal scarring, decreased vision, infection 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. (See Patient Insert for more information).

FITTING PARAGON NORMALEYES® FOR DAILY WEAR

Diagnostic Lens Selection

The starting lens is determined from the flat keratometry value with a secondary consideration for corneal diameter (Horizontal Visible Iris Diameter (HVID)). The general rule of always having a base curve radius that is flatter than the flat keratometry measurement is recommended. While lenses may be ordered in 0.1 mm steps, base curve radius is usually prescribed in 0.4 mm increments. Unlike corneal GP lenses, the base curve radius can depart from a mathematical match. The return zone depth (RZD) is based on the suggested base curve radius and corneal elevation in the shallow meridian. The landing zone angle (LZA) for the diagnostic lenses is a mean value based on biometric corneal contour measurement distribution statistics. The prescribed LZA will be determined from diagnostic lens observations.

The diagnostic lens may be selected by using the Paragon NormalEyes® Fitting Set Look-up Table below:

<table>
<thead>
<tr>
<th>Flat K of Regular Cornea</th>
<th>Suggested BCR</th>
<th>Suggested Dx RZD</th>
<th>Suggested Dx LZA</th>
</tr>
</thead>
<tbody>
<tr>
<td>47.50 to 48.37</td>
<td>7.40</td>
<td>1.050</td>
<td>60-64</td>
</tr>
<tr>
<td>46.50 to 47.37</td>
<td>7.40</td>
<td>0.950</td>
<td>60-64</td>
</tr>
<tr>
<td>45.00 to 46.37</td>
<td>7.80</td>
<td>0.900</td>
<td>60-64</td>
</tr>
<tr>
<td>44.25 to 44.87</td>
<td>7.80</td>
<td>0.900</td>
<td>60-64</td>
</tr>
<tr>
<td>42.75 to 44.12</td>
<td>8.20</td>
<td>0.900</td>
<td>60-64</td>
</tr>
<tr>
<td>41.75 to 42.62</td>
<td>8.20</td>
<td>0.850</td>
<td>60-64</td>
</tr>
<tr>
<td>40.50 to 41.62</td>
<td>8.60</td>
<td>0.900</td>
<td>60-64</td>
</tr>
<tr>
<td>Flatter than 40.37</td>
<td>8.60</td>
<td>0.800</td>
<td>60-64</td>
</tr>
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</table>

Corneal Diameter > 12.2 increase LZA 2°
In most cases, the suggested diagnostic lens base curve radius will be the final base curve radius for the prescribed lens for the respective eye.

**Choose Diagnostic Lens**

Example: Flat Keratometry = 43.75 and HVID = 11.8; the diagnostic lens suggested in the look up table is:

**BCR:** 8.20  **RZD:** 0.950  **LZA:** -60 / 64

Look for this lens in the Diagnostic Set and evaluate for meeting the fitting criteria.

**Lens Evaluation**

The lens should present with:

- Freedom from contact over the entire cornea
- Relatively centered, in relation to pupil
- Contact with the sclera outside the limbus
- Proper edge lift and freedom from impingement of the conjunctival vessels

The lens does *NOT* meet the criteria when any of these problems exist:

- Contact with central cornea greater than feather touch
- Central bubble
- Black arc of touch inside the limbus
- Impingement of conjunctival vessels indicating no edge lift
Touch within the optic zone; sagittal depth too shallow

Touch within the optic zone, but clearance at the edge of the optic zone. Base curve is too flat.

Central bubble; sagittal depth too great

Clearance good at the optic zone junction but there is too much clearance in the center of the optic zone. Base curve is too steep.

If base curve is flattened and bubble persists, then study LZA and then RZD for being too deep. In this case LZA is too shallow and RZD is too deep.
Black arc of touch inside the limbus; LZA too shallow

Black arc or full circle of touch inside the limbus. Landing zone angle is too shallow. An arc of touch usually requires two degrees of increase while a full circle of touch requires at least four degrees of increase.

If clearance inside the black arc is good, decrease the RZD while increasing the LZA. Decrease the RZD 50 microns for every 1 degree of LZA increase.

Impingement of conjunctival vessels indicating no edge lift; LZA too great

Impingement of conjunctival vessels. Landing zone angle is too great. Usually requires two degrees of decrease.

If clearance inside the limbus and over the cornea is good, increase the RZD while decreasing the LZA. Increase the RZD 50 microns for every one degree of LZA decrease.
How To Fix Fitting Problems

Touch within the optic zone; sagittal depth too shallow

First option
Second option
Third option

Increase RZD
Steepen base curve radius
Increase LZA

Central bubble; sagittal depth too deep

First option
Second option
Third option

Decrease RZD
Flatten base curve radius
Decrease LZA

Black arc of touch inside the limbus; LZA too shallow

First option

Increase LZA

Impingement of conjunctival vessels indicating no edge lift; LZA too deep

First option

Decrease LZA

Landing Zone Angle Assessment

Excessive edge lift

Black arc touch pattern

Significant edge lift may be seen when the LZA has too low an angle and will present visible fluorescein under the edge and a black arc touch inside the limbus.

Excessive edge lift

LZA too shallow demonstrating excessive edge lift
Ideal LZA after conjunctival compression:

Other Fitting & Problem Solving Concepts

What to do for poor visual acuity:

If,

Corneal and refractive cylinder are near equal
Centered lenses
No bubbles
Surfaces clean

but have unexpected **UNCORRECTED residual cylinder power**, then

Conduct keratometry or corneal topography over the lens to determine if there is flexure.

- if flexure is present, indicate on lens order to increase thickness.
- if flexure is not present:

  Call your Paragon Clinical Specialist; the LZA, RZD, or BCR may need to be reduced/flattened or a combination of these to reduce the overall sag.

What to do for poor comfort:

If,

Centered
No bubbles
No touch within the optic zone
Surfaces clean

**but have black arc or excessive edge lift,** then

Increase the LZA and decrease the RZD.
What to do for poor comfort:

If,

Centered
No bubbles
No touch inside the limbus
Surfaces clean

but have excessive conjunctival compression

then

Decrease the LZA and increase the RZD.

Lens-Eye Appearance

If,

The lens sag is too great (deep) the lens will:

- have too much clearance
- have post lens tear thickness greater than 100μ
- be difficult to remove
- cause reduced comfort
- cause reduced vision

If,

The lens sag is too little (shallow) the lens will:

- show touch inside the limbus
- cause reduced comfort
- cause reduced vision
- create secondary corneal staining
- have significant edge lift

Approximate Adjustments in “Sag”

The RZD is adjustable in 25 micron steps. Lenses are usually ordered in 50 micron steps.

Base curve changes of 0.1 mm are available. Lenses are usually ordered in 0.4 mm steps (approximately 2.00 D). A 0.4 mm increment represents approximately a 75 micron change in sag over the 8.0 mm optic zone diameter.

An LZA reduction of 1 degree results in approximately 40 microns of increased edge lift and a concurrent decrease in sag at the RZD-LZA junction. An increase in RZD of 50 microns is needed to maintain the same overall sag when the LZA is decreased 1 degree. Therefore, changes in RZD of 50 microns and LZA of 1 degree in opposite directions are approximately a 10 micron difference in resultant sag.

Evaluation of Lenses

The use of the lens prescribing system should result in a lens having a base curve that provides the desired alignment with the underlying cornea. This lens will also have a return zone depth that will join the landing zone approximately 80 microns anterior to the cornea and maintain the optic zone clearance. The landing zone angle is the only parameter which can provide clearance over the limbus and proper edge lift. The proper landing zone angle will place the junction with the return zone anterior to the cornea.
Initially the fluorescein pattern should demonstrate apical clearance, clearance at the optic zone junction, clearance at the junction of the return zone and landing zone and freedom from conjunctival impingement.

Lenses may be evaluated within a few minutes of lens application. **There is no need for a prolonged equilibration period** as a lens that is too shallow will not change with time and a lens which is too deep can be immediately evaluated and the post lens tear thickness can be estimated using the method described below. An adjustment in the final lens order can be made to compensate for average conjunctival compression.

**Conjunctival compression must be anticipated** in the selection of the proper return zone depth. There is a relationship between corneal diameter and the amount of conjunctival compression that will be demonstrated after wearing Paragon NormalEyes® lenses for 7 to 10 days or longer. The smaller the cornea, the less the compression observed and the larger the cornea the greater the compression. This is due to the increased thickness of the conjunctiva nearer to the limbus and the standard touch point of 13.0 mm. The lenses have the midpoint of the landing closer to the limbus when the cornea is larger and rest on thicker conjunctiva which compresses more.

As a rule, add 50 microns to the optimum RZD observed in diagnostic fitting for conjunctival compression for small corneas and 100 microns for conjunctival compression for large corneas.

The use of a yellow Wratten filter and an optic section or parallel pipette illumination with the biomicroscope is recommended to assist in detecting tear film thickness variances under the lens with fluorescein. The diagnostic lenses must be applied with fluorescein in the bowl of the lens. Experience will result in increased judgment of the proper proportion of central and paracentral clearance.

Optic Section: The post lens tear film is approximately equal to the lens thickness (200+µ). This is ideal upon first lens application. It is too much clearance after conjunctival compression.
**Undesired Lens-Eye Patterns:**

1. The presence of frank corneal touch is problematic. This may be the result of the following:
   - Error in selecting the base curve
   - Diagnostic lens error [lens not to package specification]
   - Return zone too shallow resulting in the optic zone not being elevated from the cornea
   - Landing zone angle too shallow resulting in a black arc or circle of touch inside the limbus

2. Return zone too shallow

   If the return zone depth is too shallow, the lens will touch the cornea inside 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 touch in the optic zone. Bubbles may form under the landing zone or lens edge.

3. Excessive clearance or bubbles on application

   Remove the lens and recheck the following:
   - Base curve and return zone depth determination
   - Diagnostic lens error [lens not to package specification]
   - Lens applied with the bowl filled with solution

   **Note:** All Paragon NormalEyes™ 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 reduced return zone depth. After placing the lens, the clearance should be reduced. If the return zone clearance is appropriate but the lens continues to gain in clearance toward the lens center, the base curve radius is too steep and the final lens order should reflect the need for a flatter base curve.

   When initially placed, the well-fit lens will center and provide for a fluorescein pattern that demonstrates central clearance, paracentral clearance, and alignment over the sclera without impingement of the conjunctival vessels.

   The initial pattern of a poorly fit lens may demonstrate any of the following characteristics.
   - Bubbles larger than 1.0 mm
   - Touch inside the optic zone
   - Excessive paracentral clearance with bubbles in the return zone
   - Heavy bearing [black arc] at junction of the return zone and landing zone
   - Conjunctival impingement
   - Excessive clearance at the lens edge

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

**UNDERSTANDING POOR FIT DYNAMICS**

- Contact with central cornea greater than feather touch
- Central bubble
- Black arc of touch inside the limbus
- Impingement of conjunctival vessels indicating no edge lift
1. Contact with central cornea greater than feather touch

A lens may 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 slightly flatter than the corneal apex. If the base curve is more than 0.3 mm flatter than the flat K, the cause is most always more sagittal depth at the edge of the optic zone than in the center relative to the cornea. If the return zone depth is too shallow, the lens will lack the sagittal depth relative to the same chord diameter of the cornea even when the base curve radius is correct. Even a lens that has a base curve that is significantly flatter than K may fail to vault the cornea if the RZD is too shallow.

In this event, the solution for corneal touch is to increase the RZD. The lens clearance will be increased inside the landing zone and return zone junction.

2. Central bubble

A lens may demonstrate a central bubble for two reasons: First, the base curve selected may have too steep causing the lens to have more clearance in the center than at the edge of the optic zone. This may occur in cases of high corneal eccentricity. In this case, select the lens having the next flattest base curve radius. The second reason is too much sag from the RZD or LZA. If the edge lift appears appropriate, decrease the RZD. This will lower the entire optic zone to eliminate the bubble. If the edge lift is inadequate and conjunctival compression is observed, decrease the LZA instead of the RZD. This action will lower the lens everywhere from the RZD-LZA junction and inward.

3. Touch within the limbus with clearance inside of the touch (black arc of touch inside the limbus)

The touch within the limbus with clearance inside the touch is always caused by a landing zone angle which is too shallow. The solution is to increase the LZA. Consider increasing 2 degrees if an arc is observed and 4 degrees if a full circle of touch is observed. If the clearance within the touch appeared ideal, the RZD must be adjusted in the opposite direction. Consider 50 microns of change in the RZD for every 1 degree of LZA change.

4. Excessive paracentral clearance with bubbles in the return zone

Bubbles in the return zone occur when the volume of the lens in the paracentral region exceeds the volume of the eye. This can occur when a combination of a flat base curve radius and a slightly excessive LZA are selected. The volume will decrease if a shallower LZA is selected. Consider a 1 degree shallower LZA. Usually no concurrent change in RZD is required.

If the edge lift appears ideal when the bubbles are observed and there appears to be some excess central clearance, a 25 or 50 micron decrease in RZD may eliminate the paracentral bubbles with no change in LZA or BCR.

5. Impingement of conjunctival vessels indicating no edge lift

This most often occurs in conjunction with bubbles or excessive paracentral clearance. Since the landing zone is a convex to the eye curve, an LZA that is too great or excessive will have too much clearance inside the limbus at the same time it has impingement at the lens edge. A decrease in the LZA will increase edge lift and decrease clearance inside the limbus. Conversely, an increase in the LZA will decrease the edge lift while increasing the limbal clearance. A 1 degree change in the LZA will have approximately 40 micron change in the edge lift and clearance at the junction of the LZA and RZD.

6. Excessive edge lift

This problem is often seen in conjunction with the black arc touch within the limbus. It can also occur when a lens is far too shallow due to a shallow RZD. Study the fluorescein pattern by nudging the lens to center, while minimizing any tilting of the lens. If the lens demonstrates central bearing, the RZD is too shallow to evaluate the LZA properly. Remove the lens and apply a lens with a deeper RZD. If the lens then demonstrates central clearance with excessive edge lift, the LZA is too shallow. Most often, the black arc touch will be observed with this combination of parameters. A lens with a greater LZA is required to reduce the edge lift and increase the clearance inside the limbus at the junction of the LZA and RZD. A final adjustment may be required in the RZD.
when the proper LZA is in place that demonstrates clearance inside the limbus and freedom from conjunctival impingement.

**PROBLEM SOLVING TABLE**

<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible Cause</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excess corneal touch</td>
<td>• Base curve radius too flat&lt;br&gt;• Return zone depth to shallow&lt;br&gt;• Landing zone angle too shallow</td>
<td>• Increase return zone depth&lt;br&gt;• Increase landing zone angle</td>
</tr>
<tr>
<td>Central bubble</td>
<td>• Base curve too steep&lt;br&gt;• Overall sag too great</td>
<td>• Flatten base curve radius</td>
</tr>
<tr>
<td>Poor lateral centration</td>
<td>• Inadequate sagittal depth&lt;br&gt;• Inadequate lens diameter</td>
<td>• Increase return zone depth&lt;br&gt;• Increase landing zone angle&lt;br&gt;• Increase overall diameter*</td>
</tr>
<tr>
<td>Superficial punctate staining</td>
<td>• Sag of lens inadequate&lt;br&gt;• Ocular lens surface has become soiled&lt;br&gt;• Care product toxicity</td>
<td>• Increase return zone depth&lt;br&gt;• Increase landing zone angle&lt;br&gt;• Clean or replace lens</td>
</tr>
<tr>
<td>Conjunctival impingement</td>
<td>• Landing zone angle too great&lt;br&gt;• Too much overall sag (clearance)&lt;br&gt;• Corneal diameter too large for 15.5 mm lens</td>
<td>• Decrease landing zone angle&lt;br&gt;• Decrease return zone depth&lt;br&gt;• Increase overall diameter*</td>
</tr>
<tr>
<td>Excessive edge lift</td>
<td>• Low overall sag&lt;br&gt;• Landing zone angle too shallow</td>
<td>• Increase return zone depth if apical bearing&lt;br&gt;• Increase landing zone angle if no apical bearing</td>
</tr>
<tr>
<td>Difficult lens removal</td>
<td>• Return zone depth too great&lt;br&gt;• Landing zone angle too great</td>
<td>• Decrease return zone depth&lt;br&gt;• Decrease landing zone angle</td>
</tr>
<tr>
<td>Loose lens</td>
<td>• Return zone depth too shallow&lt;br&gt;• Landing zone angle too shallow&lt;br&gt;• Diameter too small</td>
<td>• Increase return zone depth&lt;br&gt;• Increase landing zone angle&lt;br&gt;• Increase diameter</td>
</tr>
<tr>
<td>High-riding lens</td>
<td>• Return zone depth too shallow&lt;br&gt;• Diameter too small</td>
<td>• Increase return zone depth&lt;br&gt;• Increase overall diameter*</td>
</tr>
<tr>
<td>Flare, glare or ghost images</td>
<td>• Flexure&lt;br&gt;• Residual astigmatism</td>
<td>• Increase center thickness&lt;br&gt;• Call Paragon consultant for availability of front surface toric</td>
</tr>
<tr>
<td>Fogging</td>
<td>• Dirty lens&lt;br&gt;• Improper care &amp; handling of lenses&lt;br&gt;• Oily eye make-up removers</td>
<td>• See “Lens Care”</td>
</tr>
<tr>
<td>Poor VA with lenses</td>
<td>• Poor centration&lt;br&gt;• Power error&lt;br&gt;• Flexure or residual astigmatism&lt;br&gt;• Dirty lens</td>
<td>• See poor centration&lt;br&gt;• Check over-refraction/lens power&lt;br&gt;• See flare, glare or ghost images&lt;br&gt;• See fogging</td>
</tr>
</tbody>
</table>

*common adjustment, increase 2.0 mm in diameter up to 17.5 mm
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 experience reduced lens awareness. An assessment of vision and eye health, including inspection of the cornea for edema and/or staining should be performed.

2. Visual acuity with the lenses and a sphero-cylindrical over-refraction are recommended to confirm lens power and visual performance.

3. Care product regimen should be reviewed and the lenses should be inspected to confirm the cleaning methods are adequate to assure maintenance of the surface integrity of the lenses.

4. After lens removal, conduct a thorough biomicroscopy examination of the cornea, limbus, bulbar conjunctiva and palpebral conjunctiva.

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.

Patients must be cautioned “when in doubt, take it out.” It is important that the new wearer remove 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 in the event of persistent lens awareness. The visit is best scheduled within a few hours of applying the lens and the patient should report with the lens in place. This visit provides an excellent opportunity to evaluate the lens eye relationship and the pre and post lens tear film with the lens in place.

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

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

<table>
<thead>
<tr>
<th>Day</th>
<th>Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 1</td>
<td>3</td>
</tr>
<tr>
<td>Day 2</td>
<td>6</td>
</tr>
<tr>
<td>Day 3 - Day 5</td>
<td>9 hours</td>
</tr>
<tr>
<td>Day 6 - Day 8</td>
<td>12 hours</td>
</tr>
<tr>
<td>Day 9</td>
<td>Full waking hours</td>
</tr>
</tbody>
</table>

HANDLING OF LENSES

Standard procedures for cleaning and storage of rigid gas permeable lenses may be used. The standard of care for scleral lenses includes rinsing of the storage care product from the lenses with non-preserved saline and application of the lenses with the bowl of the lens filled with non-preserved saline.

Patients should be instructed to position their heads horizontally (parallel with the floor) to allow the lens to approach the eye from below. In this manner, the lens will remain filled with the non-preserved saline. The lens can be placed on a device to assist in application.

A suction device is required for lens removal for most all patients.

CAUTION: Paragon NormalEyes® contact lenses for daily wear are shipped to the practitioner non-sterile. Clean and condition lenses prior to use.
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 NormalEyes™ 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.

Caution patient to 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 more than 25 days clean and disinfect prior to dispensing. When returning a lens to inventory, treat it 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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NormalEyes® 15.5 is protected by patent numbers US 8,113,652 and 8,813,653.
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