**Bausch & Lomb Vision Shaping Treatment™**

**CAUTION:** Federal law restricts this device to sale by, or on the order of a licensed practitioner.

Boston Orthokeratology (oprifocon A) Shaping Lenses should be fitted only by contact lens fitter trained and certified in the fitting of conventional (non-reverse geometry) and reverse geometry contact lenses.

Nonsterile. Clean and condition lenses prior to use.

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### ORTHO-K PROBLEM SOLVING:

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- **Loose Lens**
- **High Reading Lens**
- **Radial Lens**
- **Vializing**
- **Under-responders**
- **Central Islands**
- **Central Staining**
- **Air Bubbles**
- **Reduced Holding Time**
- **Grafting at Night**

**Follow-Up Care**

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- **Follow-Up Time**
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- **Topographic Data**
- **Corneal Topography**

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- **Radius and Position**

**Alignment Zone**

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- **At the edge of the lens.**

**Peripheral Curve**

- **Radius and Position**
- **Peripheral Curves**

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- **Radius Only**
- **Peripheral Radius**

**Select Base Curve**

- **Position Only**
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- **Radius and Position**

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3. **Initial Lens Diameter Selection:**
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- **Trial Lens Set:**
- **Trial Lens Procedure:**
- **Centering Movement**

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**INTRODUCTION**

Boston Orthokeratology (oprifocon A) Shaping Lenses produce a temporary reduction of myopia by reversibly altering the curvature of the cornea. 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 it is the objective of the Boston Orthokeratology Shaping Lens design, it is possible to bring the eye into correct focus and completely compensate for myopia. The lens is designed to be worn overnight with removal during the following day. The Boston Orthokeratology Shaping Lenses must be worn night on a regular schedule to maintain the corneal reshaping, or the pre-treatment myopia will return.

**PRODUCT DESCRIPTION**

Boston Orthokeratology (oprifocon A) Shaping Lenses are latex contact lenses with spherical posterior surfaces in blue, green, red and yellow tinted versions. The posterior curve is selected to properly fit an individual eye for orthokeratology and the anterior curve is selected to provide the necessary optical power for a temporary reduction of myopia. A peripheral curve system on the posterior surface allows tear exchange between the lens and the cornea.

Boston Orthokeratology (oprifocon A) Shaping Lenses are made from Boston® Equalens®II (oprifocon A) polymer with water content of less than 1 percent. The material contains an ultraviolet absorber, Uvinul D-29. The blue tinted lenses contain D&C Green #6 and D&C Yellow #18 as a color additive. The green tinted lenses contain D&C Green #6 and D&C Yellow #18 as a color additive. The red tinted lenses contain D&C Red #17 as a color additive. The yellow tinted lenses contain D&C Yellow #18 as a color additive. The red tinted lenses contain D&C Red #17 as a color additive. The yellow tinted lenses contain D&C Yellow #18 as a color additive.

**Detailed Description**

The Boston Orthokeratology (oprifocon A) Shaping Lenses have a design known as reverse geometry. This means that the secondary curve on the posterior surface, next to the base curve, has a radius of curvature that is steeper (shorter radius) than the base curve.

**PHYSICAL PROPERTIES**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water Content</td>
<td>less than 1%</td>
</tr>
<tr>
<td>Hardness</td>
<td>114 Rockwell</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>1.24</td>
</tr>
<tr>
<td>Wetting Angle</td>
<td>30 degrees by Captive Bubble</td>
</tr>
<tr>
<td>Refractive Index</td>
<td>1.423</td>
</tr>
<tr>
<td>Light Absorbance (absorbance units/m²)</td>
<td>10.0</td>
</tr>
<tr>
<td>Blue(460nm)</td>
<td>10.0</td>
</tr>
<tr>
<td>Green(460nm)</td>
<td>4.8</td>
</tr>
<tr>
<td>Yellow(470nm)</td>
<td>10.3</td>
</tr>
<tr>
<td>Red(525nm)</td>
<td>2.5</td>
</tr>
<tr>
<td>Oxygen Permeability</td>
<td>127* (85)**</td>
</tr>
<tr>
<td></td>
<td>* Primarily, Oxygen Gas to Gas Method (x 10⁻¹¹ [cm³ / sec] (mL O₂ x mmHg) @ 35° C) <strong>Polarographic Method (ISO-Fatt)</strong></td>
</tr>
</tbody>
</table>

**ACTIONS**

The Boston Orthokeratology (oprifocon A) Shaping Lenses produce a temporary reduction of myopia by changing the shape (flattening) of the cornea, which is elastic in nature. Flattening the cornea reduces the focusing power of the 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.
The peripheral surface of regular contact lenses generally aligns with the central cornea and rests directly on the corneal layer. Regular contact lenses are designed to cause little or no effect on the cornea but Boston Orthokeratology (opkonic A) Shaping Lenses are designed to properly flatten the shape of the cornea by applying slight pressure to the center of the cornea when the patient is asleep.

After the 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 Boston Orthokeratology (opkonic A) Shaping Lenses must be worn at night on a regular schedule to maintain the orthokeratology effect, or the myopia will revert to the pre-treatment level.

INDICATIONS
Boston Orthokeratology (opkonic A) Shaping Lenses are indicated for use in the reduction of myopic refractive error in non-diseased eyes. The lenses are indicated for overnight wear for the temporary reduction of myopia up to 5.00 diopters in eyes with astigmatism up to 1.50 diopters. The lenses may only be disininfected using a chemical disinfection system. Note: To maintain the Orthokeratology effect of myopia reduction, overnight lens wear must be continued on a prescribed schedule. Failure to do so can effect daily activities (e.g., night driving), visual fluctuations and changes in intended correction.

CONTRAINDICATIONS (REASONS NOT TO USE)
Reference “Contraindications” found in the enclosed Package Insert.

WARNINGS
Reference “Warnings” found in the enclosed Package Insert.

ADVERSE EFFECTS (PROBLEMS AND WHAT TO DO)
Reference “Adverse Effects (Problems and what to do)” found in the enclosed Package Insert.

PRECAUTIONS
Reference “Precautions” found in the enclosed Package Insert.

SELECTION OF PATIENTS
Patients are selected who have a demonstrated need and desire for a refractive reduction by orthokeratology with gas permeable contact lenses and who do not have any of the contraindications for contact lenses described above.

Boston Orthokeratology (opkonic A) Shaping Lenses are indicated for myopic patients who desire to have time periods during the day in which they do not need to wear their contact lenses, but still need to see clearly.

Boston Orthokeratology (opkonic A) Shaping Lenses are primarily intended for patients who are within the following parameters.

Refractive error: -1.00 to –5.00 diopters with up to 1.50 diopters of astigmatism
Keratometry - 40.00 to 46.00 diopters

FITTING CONCEPT
Boston Orthokeratology (opkonic A) Shaping Lenses are designed to be fit so that they flatten the central cornea and thereby reduce myopia. The 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-fitted lens will have the proper sagittal depth to prevent movement off the central corneal apex and prevent excessive bearing in the alignment zone(s). There should be adequate edge lift to allow for proper tear exchange.

KERATOMETRY FITTING METHOD:
Fitting of ortho-k lenses is generally accomplished using data obtained from keratometry readings and spectacle (manifest) refraction.

Keratometry findings are derived by averaging the corneal curvature at two points horizontally and two points vertically in an area of the corneal apex measuring 3 to 4 millimeters in diameter. These readings are then averaged to arrive at the horizontal and vertical “K” findings used to fit a lens on the total corneal diameter of approximately 12.0 millimeters.

Keratometry Fitting System

Step 1: Patient obtains refraction examination (to determine Target Correction) and keratometry measurements. A lens diameter of 10.2mm to 11.0mm is chosen depending on corneal size. These data are forwarded to the lens finishing laboratory.

Step 2: At the lens finishing laboratory, PAR (Posterior Alcician Radius) is calculated using a computer software program that calculates as follows:

PAR = 337.5 / (Flat K + Target Correction - Correction Constant of -0.750).

Step 3: The lens finishing laboratory derives the lens base curve, reverse, alignment, and peripheral zones from these calculations. The base curve, reverse zone and alignment zones that comprise the correct sagittal height required to effect the desired myopic reduction plus the Correction Constant of -0.750.

TOPOGRAPHY FITTING METHOD:
There may be different types of topography-based fitting methods. Each method requires adequate training of the eye care professional and appropriate instrumentation. Below is an example of one type of topography-based fitting method. Fitting ortho-k lenses is accomplished using data obtained from topography and spectacle refraction.

A typical topographer provides corneal height and curvature data derived from 7,000 to 300,000 points* on the cornea in an area between 10mm and the full area of the cornea.*

* Depending on brand of topographer.

Topography Fitting Method

Step 1: Patient obtains spectacle (manifest) refraction (to determine Target Correction) and topography data. A lens diameter of 10.2mm to 11.0mm is chosen depending on corneal size.

Step 2: From the topography data, the practitioner then enters: apical radius (Rv), corneal sagittal height, horizontal visible iris diameter (HVID), and TargetCorrection into a computer software calculation program in the office.

Step 3: The software program derives the base curve, reverse, alignment and peripheral zones that comprise the correct lens sagittal height required to effect the desired myopic reduction plus the Correction Constant of -0.750. In the case of the proposed design, the base curve, lens diameter, and lens power along with sagittal height data is coded as “IRF” number, is sent to the lens finishing laboratory.

Define All Curve Widths & Zone Diameters

Data tables for the curve widths

The Boston Orthokeratology (opkonic A) Shaping Lenses have four zones: A Base Curve Zone for optical properties, a Reverse Curve Zone (sometimes referred to the Fitting Curve) which provides the proper positioning of the Base Curve to the apex of the eye, an Alignment Curve Zone which allows the lens to properly center on the eye, and a Peripheral Curve Zone that provides edge lift and tear exchange.

See Figure 1 (PRODUCT DESCRIPTION Section)

The default parameters for a lens with a single curve in the Alignment Zone would be:

<table>
<thead>
<tr>
<th>Curve Width</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Base Curve Optical Zone</td>
<td>PZD</td>
</tr>
<tr>
<td>Reverse Curve Width</td>
<td>FC</td>
</tr>
<tr>
<td>Alignment Curve Width</td>
<td>AC</td>
</tr>
<tr>
<td>Peripheral Curve Width</td>
<td>PC</td>
</tr>
<tr>
<td>Overall Diameter</td>
<td>OAD</td>
</tr>
</tbody>
</table>

For a lens with an overall diameter greater than 10.2mm it is typical to split the alignment zone into two or more spherical curves. The default parameters for a larger lens would be:

<table>
<thead>
<tr>
<th>Curve Width</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Base Curve Optical Zone</td>
<td>PZD</td>
</tr>
<tr>
<td>Reverse Curve Width</td>
<td>FC</td>
</tr>
<tr>
<td>Alignment Curve One</td>
<td>AC_1</td>
</tr>
<tr>
<td>Alignment Curve Two</td>
<td>AC_2</td>
</tr>
<tr>
<td>Peripheral Curve</td>
<td>PC</td>
</tr>
<tr>
<td>Overall Diameter</td>
<td>OAD</td>
</tr>
</tbody>
</table>

The fitter will be able to adjust any or all of the default widths and zone diameters.

Defaults for the curve transitions - Fittings

In addition to the widths, each zone will be smoothly transitioned to its neighbor by use of a fillet curve. The default values are specified in the table below:

<table>
<thead>
<tr>
<th>Curve Width</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Base Curve to Fitting Curve</td>
<td>FCAC</td>
</tr>
<tr>
<td>Fitting Curve to Alignment Curve</td>
<td>FCAC</td>
</tr>
<tr>
<td>Alignment Curve to Peripheral Curve</td>
<td>ACPC</td>
</tr>
</tbody>
</table>

The fillet curve is calculated by scribing a circle, which is tangent to each of the adjoining curves at the point described by traversing the distance given in this table along each of the curves. The fitter will be able to adjust any or all of these default fillet widths.

Measure the cornea

Topographic Data

- A topographic map that yields apical radius, sagittal depth and/or eccentricity data from the apex out to a distance no less than the outermost diameter of the Alignment Curve Zone is desirable. Smaller samplings could be used, but the alignment curve would then be based on extrapolated data, similar to the K reading assumption below.

- *Eccentricity values for the flat corneal meridian may be substituted for sagittal values

Keratometry Reading

- A standard K reading can be used to approximate the curvature of the eye.

- Fitter is allowed to enter any Keratometry value.

Select Alignment Curve - Radius and position

The Alignment Curve should match to the corneal surface

Topographic Data

- The Alignment Curve is determined by sampling the topographic values of the eye in the region where the curve will fit, and applying a common contact lens fitting algorithm (e.g., least squares, linear) to determine the relationship of the corneal curvature at the midpoint of the AC. This path is used to determine the Alignment Curve Radius.

Keratometric Data

- The Alignment Curve is equal to the radius derived from the Flit K reading.

- If more than one curve is used in the alignment curve zone, the radius of curvature will get progressively flatter from the inside to the outside of the zone. Typically the first alignment curve radius is equal to the radius derived for the Flat K reading and the second alignment curve radius is 0.5 diopters flatter.

Fitter may be allowed to adjust the Alignment Curve

- Curve may be adjusted by steepening or flattening (e.g. based on clinical results showing too much movement)

Select Peripheral Curve - Radius and position

Peripheral Curve

The default radius of the Peripheral Curve is shown in the table below. It is also possible to apply a simple calculation to determine the peripheral curve radius (e.g. AC + 2.5 mm).

<table>
<thead>
<tr>
<th>Curve Width</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peripheral Curve</td>
<td>PC</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Curve Width</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lens Surface (Along AC)</td>
<td>PC</td>
</tr>
</tbody>
</table>

Lens Surface (Along PC)
When overnight orthokeratology lenses dislocate during sleep, transient distorted vision may occur the following morning. These are usually temporary conditions if the contact lenses are removed promptly and professional care is obtained. The Back Vertex Power of the Boston Orthokeratology (oprifocon A) Shaping Lenses is calculated by subtracting the amount of myopia you want to correct from the spectacle refraction and adding a correction constant of 0.75 diopters.

RX = -3.75 diopters

BVP = 3.75 - (-3.75) + 0.75 = +0.75 diopters

The additional 0.75 diopters compensates for a small regression in the unaided visual acuity when the lens is first removed. No compensation is made for vertex distance.

3. Initial Lens Diameter Selection:

Initial diameters of 10.6mm to 11.0mm are suggested, varying slightly depending on fitting approach. Standard lens diameters for the Boston Orthokeratology (oprifocon A) Shaping Lenses are 10.2mm to 11.0mm. Lens diameters outside of this range are occasionally used for some eyes. Select an initial diameter of 10.0mm if the flattest keratometry readings are steeper than 45.00 diopters or if the corneal diameter is smaller than 11.5mm Select an initial diameter of 10.6mm to 11.0mm if the cornea is spherical. This guide is only a general recommendation and the specification for an individual patient will depend on the eye care practitioner’s professional judgment.

4. Initial Lens Base Curve Selection:

The Boston Orthokeratology (oprifocon A) Shaping Lenses are fit with the Alignment Curve in alignment with the peripheral cornea. The Boston Orthokeratology (oprifocon A) Shaping Lenses may be fit using a modification of the standard techniques for gas permeable contact lenses. Various methods have been proposed for predicting the amount of corneal flattening that may be achieved for a given patient by orthokeratology. Other studies have not supported these conclusions, however, and further research is needed. It is not possible at this time to predict which patients will achieve the greatest corneal flattening with other orthokeratology designs. The clinical results for the Boston Orthokeratology (oprifocon A) Shaping Lenses Study show that the lens design is effective and predictable for correcting myopia between the range of -1.00 to -5.00 diopters.

The Boston Orthokeratology (oprifocon A) Shaping Lenses will 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 lenses fit. Average amounts of reduction have been established by clinical studies but the reduction for an individual patient may vary from the averages.

CLINICAL STUDY DATA

Refer to the “Clinical Study Data” found in the enclosed Package Insert.

TRIAL LENSES:

Trial Lens Fitting:

Trial lens fitting may be helpful in determining lens selection. Trial lens fitting may also allow a more accurate determination of lens specification for the lens fit and power. Choose the first lens according to the procedure given for lens selection. Trial lenses are very helpful in fitting patients whose corneal topography has been distorted by previous contact lens wear. In some fitting scenarios, the trial lens may be worn overnight to allow a better assessment of lens fit.

Trial Lens Set:

To evaluate just the fitting characteristics of the lens, a trial lens set would consist of ten (10) to fifty (50) lenses. The lenses should be labeled according to the flat keratometer reading or individual base curves. A trial lens set will allow evaluation of the lens centration on the cornea. This is a valuable tool and is particularly useful for fitting the astigmatic cornea.

CAUTION: Non-sterile lenses. Clean and condition lenses prior to use.

Eye care practitioners should educate contact lens technicians regarding proper care of trial lenses. Each contact lens is shipped non-sterile in a case with no solution (dry). Therefore in order to ensure 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 a trial lens or before dispensing to a patient, lenses should be surface cleaned and disinfected, following the manufacturer’s instruction.

Trial Lens Procedure:

Select a trial lens and place the lens upon the eye. Evaluate the lens using white light for the following:

Centering:

Lenses should center as well or better than regular GP lenses. The lenses should be fitted according to the interpalpebral fitting philosophy. Lenses fitted according to the “bead attachment” philosophy, in which the lens purposely rides in a high position, should be avoided.

Movement:

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

PREVENTING LENS RESULTS:

Various methods have been proposed for predicting the amount of corneal flattening that may be achieved for a given patient by orthokeratology. Other studies have not supported these conclusions, however, and further research is needed. It is not possible at this time to predict which patients will achieve the greatest corneal flattening with other orthokeratology designs.

The clinical results for the Boston Orthokeratology (oprifocon A) Shaping Lenses Study show that the lens design is effective and predictable for correcting myopia between the range of -1.00 to -5.00 diopters. The Boston Orthokeratology (oprifocon A) Shaping Lenses will 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 lenses fit. Average amounts of reduction have been established by clinical studies but the reduction for an individual patient may vary from the averages.

CLINICAL STUDY DATA

Refer to the “Clinical Study Data” found in the enclosed Package Insert.
Solution: Follow the same solutions for vaulting. If no vaulting is present, recheck the original exam figures. If the air bubbles are a common occurrence and typically disappear after wear. Only when staining occurs under a persistent air bubble does the lens need to be changed. Cause: Air bubbles form when not enough solution is under the fitting curve. Usually the upper lids will compress the lens to the cornea and the bubbles will disappear in the morning. The fitting curve has a steep configuration, which is sometimes difficult to fill with tears. Occasionally, the resultant air bubble can encompass 270 degrees around the FC. Any staining present is due to the air bubble where the cornea is not getting the lubrication or oxygen that it needs. If the air bubble is less than 45 degrees in length upon inspection, just monitor the next day to see if any stains occur. If the air bubble is greater than 45 degrees, have the patient remove the lens and fill the concave surface with solution and have the patient reinsert while looking down. If a large air bubble persists, monitor the next day to see if still present and if staining is present. If staining is present, monitor for three days to see if the bubble and staining recede. If the bubble and staining persists then flatten the fitting curve 0.10mm. This will reduce the steepness of the fitting curve and reduce the air bubble. Air bubbles look bad but are usually a self-limiting condition, which require no change.

Reduced Holding Time: This is when the unaided visual acuity does not hold an acceptable amount of time.

Cause: Generally caused by a lens that is not centered, with the steep area almost touching the visual axis. When the cornea normally regresses, the visual axis is impacted sooner because there is less distance between the visual axis and the edge of the peripheral steep ring. If some vaulting has occurred, there will be a smaller central visual zone with a corresponding wider concentric steep ring. The cornea will then undergo a limited amount of change. Usually, the more induced change, the faster the cornea will regress. Therefore, if you have reduced 0.50 diopters of myopia, you should not expect the unaided visual acuity to hold all day. As a general rule, the lower the starting amount of myopia, the greater the chance of holding all waking hours. The Boston Orthokeratology (apropicon A) Shaping Lenses are not recommended for reducing myopia greater than −5.00 diopters.

Solution: If the lens is de-centered, make the appropriate modifications to the design to center the lens better. If vaulting is present, do what is required to reduce the vaulting. Flattening the BC by 0.50 diopters can also prolong the holding time by making the cornea change more before a decrease in UCA is noticed. Flattening the base curve will only be effective for a patient that is able to accommodate the additional correction early in the day.

Night Gasping At Night: Night gasping is a normal observation. This usually recedes with time but may always be present to some extent.

Cause: The main cause of gasping is when the reduced illumination at night causes the pupil to become larger than the central correction area of the cornea. This might occur even with a well-centered lens. Patients with smaller pupils will not experience this to the extent of patients with very large pupils. Another cause is a decentered lens. This can also cause gasping during the day. Central islands can also give the same subjective complaints as gasping.

Solution: Increase light intensity and filter settings. The cornea becomes flatter from the apex to the periphery. This degree of corneal flattening is different for everyone, with some corneas having a greater or lesser degree of flattening. If the flattening is too great, the central region will be too steep.

Solution: Flatten the alignment curves by 0.10mm or reduce the diameter by 0.50mm.

Central Staining: On night one lenses should be inserted at a time early enough to achieve 8 to 10 hours of closed eye 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.

Follow-Up Time: Follow-up examinations should be conducted at different times during the day to get a proper evaluation of unaided visual acuity throughout the day. The patient should be asked to identify any problems, which occur that are related to shaping lens wear.

Evaluation: When 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 adoption. 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.

After the lens is removed, conduct a thorough slit-lamp examination to detect the following:

1. Presence of vertical central striae in the posterior central cornea and/or central neovascularization.

Ortho-K Problem Solving:

Low Riding Lens:

Lateral Riding Lens:

Lateral Riding Lens:

Under-responders:

Evaluation:

Follow-Up Care:

General Information:

Follow-up examinations, as recommended by the eye care practitioner, are necessary to ensure continued successful lens wear. Follow-up examinations should include an evaluation of lens movement, centering, 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.

Follow-Up Time:

Follow-up examinations should be conducted at different times during the day to get a proper evaluation of unaided visual acuity throughout the day. The patient should be asked to identify any problems, which occur that are related to shaping lens wear.

Evaluation:

When 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 adoption. 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.

After the lens is removed, conduct a thorough slit-lamp examination to detect the following:

1. Presence of vertical central striae in the posterior central cornea and/or central neovascularization.

2. Presence of central corneal striae or limbic conjunctival hyperemia can be indicative of a reaction to solution preservatives, excessive lens wear, and/or an improperly fitted lens.

Follow-Up Frequency:

You need to get a good evaluation of the patient early on in the process to see how they are reacting to overnight wear of GP shaping lenses and to optimize the improvement in their unaided visual acuity. After vision has stabilized, the patient should probably be recalled every 6 months to check on progress. The follow-up schedule is determined by the eye care practitioner for each patient.

Corenel Topography:

A corneal topographer is a valuable tool to use for evaluating any fitting of overnight wear lenses and particularly the Boston Orthokeratology (apropicon A) Shaping Lenses. Since you are not able to evaluate the fit of the lenses when they are being worn at night, a corneal topographer can give you a picture of the resulting changes that have taken place.

A corneal topographer will give you an accurate view of how the lens centered on the eye the previous night.

Recommended 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 as recommended by their eye care practitioner regardless of how comfortable the lenses feel.

Wearing Schedule: On night one lenses should be inserted at a time early enough to achieve 8 to 10 hours of closed eye wearing time (sleep). A well fit lens provides for centration with the eye closed. The effects of lid interaction on blinking and gravity may result in lens decentration during open eye wear. The patient should place the lens(s) in their eye 15 to 20 minutes before going to sleep. Your eye care practitioner will advise you if the wearing schedule needs to be changed. Be aware “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, remove the lens, clean and rewet it; and again place the lens on your eye. If the sensation continues, remove the lens. The lens should not be worn. 

Appointment Schedule: 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 awaking and you should report with your lenses in place. This visit provides an excellent opportunity to evaluate lens centration and potential lens adherence.

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

The cornea normally changes within five to eight hours of wear. The practitioner should modulate the wearing time to determine the MINIMUM wear required for myopic correction. The average wearing time is between 8 and 10 hours. The patient should attempt to maintain wearing time at this minimal level.
Myopic Reduction Maintenance Lens (Retainer Lens) Schedule

After a period of several days, or when the eye care practitioner is satisfied that the patient has adapted to the Boston Orthokeratology (oprifocon A) Shaping Lenses, the patient may attempt to skip a night of wear to monitor the duration of visual improvement. This may continue 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 Orthokeratology effect of myopia reduction, overnight lens wear must be continued on a prescribed schedule. Failure to do so can effect daily activities (e.g., night driving), visual fluctuations and changes in intended correction.

HANDLING OF LENSES

Standard procedures for gas permeable lenses may be used.

CAUTION: Boston Orthokeratology (oprifoconA) Shaping Lenses are shipped to the practitioner nonsterile. Clean and condition lenses prior to use.

PATIENT LENS CARE RECOMMENDATIONS

Please see list of lens care products in Package Insert

VERTEX DISTANCE & KERATOMETRY CONVERSION CHARTS

Standard charts may be used.

HOW SUPPLIED

Each lens is supplied non-sterile in an individual plastic case. The case, packing slip or invoice is marked with the base curve, power in diopters, diameter, center thickness, [color] and Lot #.

REPORTING OF ADVERSE REACTIONS:

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

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