PROFESSIONAL FITTING AND INFORMATION GUIDE

Boston® Orthokeratology (oprifocon A) Shaping Lenses

FOR OVERNIGHT WEAR FOR

BAUSCH + LOMB

Vision Shaping Treatment VST®

B+L

℞ ONLY **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 a contact lens fitter trained and certified in the fitting of conventional (non-reverse geometry) and reverse geometry contact lenses.

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

TABLE OF CONTENTS

INTRODUCTION
PRODUCT DESCRIPTION
LENS PARAMETERS AVAILABLE
PHYSICAL PROPERTIES
ACTIONS
INDICATIONS
CONTRAINDICATIONS
WARNINGS
ADVERSE EFFECTS
PRECAUTIONS
SELECTION OF PATIENTS
FITTING CONCEPT
PREDICTING LENS RESULTS
CLINICAL STUDY DATA
FITTING PROCEDURES
TRIAL LENSES
ORTHO-K PROBLEM SOLVING
FOLLOW-UP CARE
RECOMMENDED WEARING SCHEDULE
HANDLING OF LENSES
PATIENT LENS CARE RECOMMENDATIONS
VERTEX DISTANCE & KERATOMETRY CONVERSION CHARTS
HOW SUPPLIED
REPORTING OF ADVERSE REACTIONS

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 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 at 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 lathe cut 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 is available with or without an ultraviolet absorber, Uvinul D-49. The blue tinted lenses contain D&C Green #6 as a color additive. The green tinted lenses contain D&C Green #6 and C.I. Solvent #18 as a color additive. The red tinted lenses contain D&C Red #17 as a color additive. The yellow tinted lenses contain C.I. Solvent #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 (central curve). This curve is referred to as the "Fitting Curve" or the "Reverse Curve" (Figure 1).

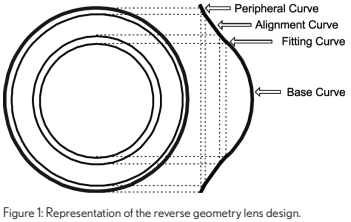


Figure 1: Representation of the reverse geometry lens design.

The Fitting Curve is surrounded by a flatter intermediate zone that is approximately equal in radius to the flat keratometer reading of the central cornea. This zone is referred to as the "Alignment Zone" or the "Alignment Curve". In this way the geometry of the secondary curves are in the opposite relationship to the base curve, as occurs with standard GP contact lenses. Outside the Alignment Zone, at the edge of the lens, is a peripheral curve that allows for tear exchange under the lens to take place.

The function of the steep Fitting Curve, on the Boston Orthokeratology (oprifocon A) Shaping Lenses, is to allow the base curve to be fit in a flat relationship to the central cornea and still maintain lens stability on the cornea. With a regular GP 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 de-center on the cornea. With the Boston Orthokeratology (oprifocon A) Shaping Lenses, there is support for the lens at both the central cornea and in the area of the Alignment Zone. This will reduce lens rocking and aid in centering.

There is no fixed diopter relationship between the Base Curve and the Fitting curve for the Boston Orthokeratology (oprifocon A) Shaping Lenses. The Fitting Curve is calculated to control the sagittal depth of the optical zone, and control the amount of bearing the Base Curve will have on the central Cornea.

A lens design with an overall diameter of 10.2 or less will generally have one Alignment Curve. A larger diameter lens will generally have two alignment curves with the innermost curve approximately equal in radius to the flat keratometer reading, and the outermost Alignment Curve 1.0 diopters flatter than the first Alignment Curve.

LENS PARAMETERS AVAILABLE

Chord Diameter	9.6mm to 11.6mm
Center Thickness	
For Low Minus Lens	0.20mm to 0.32mm
For Plus Lenses	0.20mm to 0.32mm
Base Curve	7.30mm to 10.15mm
Reverse Curve	5.0mm to 9.0mm Steeper than the base curve in proportion to the amount of correction
Alignment Curve 1	7.0mm to 9.0mm Steeper than the base curve but flatter than the reverse curve. Generally equal to the Flat K of the cornea being fit.
Alignment Curve 2	7.25mm to 9.25mm Steeper than the base curve but flatter than AC1 and reverse curve
Peripheral Curves	9.00mm to 15.00mm
Back Vertex Power	+1.50 Diopters to -5.00 Diopters

PHYSICAL PROPERTIES

The physical properties of oprifocon A	
Refractive index	1.423
Light Absorbance (absorbance units/inch)	
Blue (640nm)	10.0
Green (640nm)	4.8
Yellow (420nm)	10.3
Red (525nm)	2.5
Wetting Angle	30 degrees by Captive Bubble
Specific Gravity	1.24
Hardness	114 Rockwell
Water Content	less than 1%
Oxygen Permeability	127* (85**)

*Gas to Gas Method

{ x 10^{-11} (cm^2/sec) [mL O_2/(mL x mmHg)] @ 35°C)
**Polarographic Method (ISO/Fatt)

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 posterior surface of regular contact lenses generally aligns with the central cornea and rests directly on the corneal tear layer. Regular contact lenses are designed to cause little or no effect on the cornea but Boston Orthokeratology (oprifocon A) Shaping Lenses are designed to purposely 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 (oprifocon A) Shaping Lenses must be worn at night on a regular schedule to maintain the orthokeratology effect, or the myopia will revert to the pretreatment level.

INDICATIONS

Boston Orthokeratology (oprifocon 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 disinfected 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 affect daily activities (e.g., night driving), visual fluctuations and changes in intended correction.

CONTRAINDICATIONS

Reference ***"CONTRAINDICATIONS (REASONS NOT TO USE)"*** found in the enclosed Package Insert.

WARNINGS

Reference ***"WARNINGS"*** found in the enclosed Package Insert.

ADVERSE EFFECTS

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 in the Package Insert.

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

Refractive error: -1.00 diopters to -5.00 diopters with up to 1.50 diopters of astigmatism.

Keratometry: 40.00 diopters to 46.00 diopters.

FITTING CONCEPT

Boston Orthokeratology (oprifocon A) Shaping Lenses are designed to be fit so that they flatten the central cornea and thereby reduce myopia. This goal is accomplished by the lens design and the manner in which the lens is fitted. The goal in fitting is a well-centered lens having a base curve that is flatter than the flattest meridian of the cornea by at least the attempted treatment power in that meridian. A well-fit lens will have the proper sagittal depth to prevent vaulting 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: Practitioner obtains spectacle refraction (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 Apical Radius) is calculated using a computer software program that calculates as follows: PAR = 337.5 / (Flat K + Target Correction - Correction Constant of -0.75D).

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 affect the desired myopic reduction plus the Correction Constant of -0.75D.

TOPOGRAPHY FITTING METHOD

There may be different types of topography-based fitting methods. Each method requires adequate training of the eye care practitioner 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: Practitioner 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 (Ro), corneal sagittal height, horizontal visible iris diameter (HVID), and Target Correction into a computer software calculation program in the office.

Step 3: The in-office software program derives the base curve, reverse, alignment and peripheral zones that comprise the correct lens sagittal height required to affect the desired myopic reduction plus the Correction Constant of -0.75D. In the case of the proposed design, the base curve, lens diameter, and lens power along with sagittal height data coded as "TRF" number, is sent to the lens finishing laboratory.

Define All Curve Widths & Zone Diameters

Defaults for the Curve Widths

The Boston Orthokeratology (oprifocon A) Shaping Lenses have four zones: A Base Curve Zone for optical properties, a Reverse Curve Zone (sometimes called 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:

Base Curve Optical Zone	POZ	6.2mm
Reverse Curve Width (Fitting Curve)	FC	0.6mm
Alignment Curve Width	AC	1.0mm
Peripheral Curve Width	PC	0.4mm
Overall Diameter	OAD	10.2mm

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:

Base Curve Optical Zone	POZ	6.2mm
Reverse Curve Width (Fitting curve)	FC	0.6mm
Alignment Curve One	AC_1	0.7mm
Alignment Curve Two	AC_2	0.5mm
Peripheral Curve	PC	0.4mm
Overall Diameter	OAD	10.6mm

The default parameters for a 11.0mm diameter lens would be:

Base Curve Optical Zone	POZ	6.2mm
Reverse Curve Width (Fitting curve)	FC	0.6mm
Alignment Curve One	AC_1	0.7mm
Alignment Curve Two	AC_2	0.7mm
Peripheral Curve	PC	0.4mm
Overall Diameter	OAD	11.0mm

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

Defaults for the Curve Transitions - Fillets

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:

Base Curve to Fitting Curve	BC-FC	0.05mm
Fitting Curve to Alignment Curve	FC-AC	0.10mm
Alignment Curve to Peripheral Curve	AC-PC	0.20mm

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

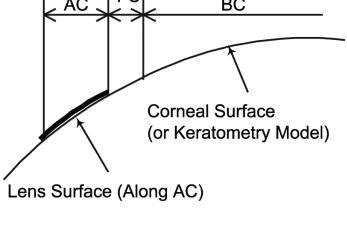
The Alignment Curve should match to the corneal surface

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 Flat 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 curves radius is 0.50 diopters flatter.



Fitter May Be Allowed to Adjust the Alignment Curve

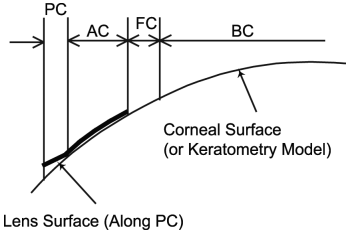
- Curve may be adjusted by steepening or flattening (e.g., based on clinical results showing too much movement).

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 (e.g., AC + 2.5mm).

Peripheral Curve	PC	11.0mm to 12.0mm



Select Base Curve - Radius Only

"End Result" implies that the back surface of the Base Curve of the lens should be of the same curvature as required by the eye to give good vision. The lens should be constructed in a way that is close to the desired end result, but with a small additional flattening beyond the exact result desired.

If the cornea was somehow elasticized to attain the exact shape of the lens, then this additional flattening would not be required.

Topographic Data

- Central curvature is estimated based on topographic data in the method that generates the Sim-K value. Then this value for central curvature is used as if it were a K value. (see next: Keratometry Reading).

Keratometry Reading

- The Base Curve Radius is determined by starting with the keratometry reading, then subtracting the desired power correction (in Diopters) and finally flattening further by a fixed increment (default=0.75D).
- The Fitter can adjust the additional flattening increment if desired.

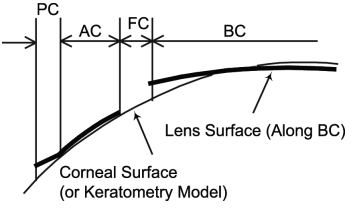
Select Base Curve - Position Only

Calculate Maximum Displacement of the Corneal Surface

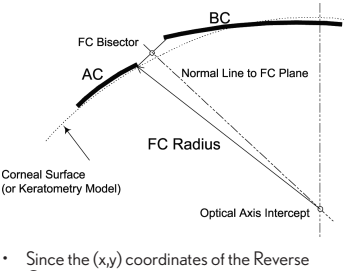
- The defined Base Curve is mathematically calculated to compress the tear film and to compress and displace corneal surface.
- The exact amount that the base curve compresses and displaces the corneal surface varies based on the design method.
- The amount that the base curve compresses and displaces the corneal surface is related to Munnerlyn's Formula used by excimer lasers for refractive surgery to determine the amount of tissue to be ablated to achieve the desired post-operative correction. In no case will a displacement of the cornea exceed the displacement estimated by Munnerlyn's Formula.

Position the Base Curve

- From the position of maximum displacement, the Base Curve is then mathematically lifted up (or backed off) towards the apex of the cornea by a proprietary adjustable amount.
- The Fitter can adjust the amount of compression on the apex of the cornea.
- Once the Base Curve is placed in this position relative to the corneal surface, the sagittal depth values at the endpoints of the Base Curve Zone and the Alignment Curve Zone are known.

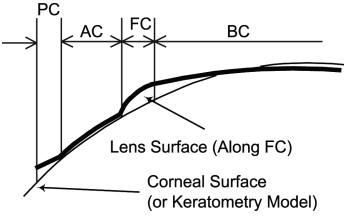


Determine Required Fitting Curve - Radius and Position



- Since the (x,y) coordinates of the Reverse Curve are determined by the inner diameter of the Alignment Curve Zone, and the outer diameter of the Base Curve Zone (POZ), these can be used to create a line between the two points.

- This line is bisected (a midpoint is found). And the slope is determined.
- Negating and Inverting the slope yields a line perpendicular to the Fitting Curve line.
- This perpendicular line is extended from the bisection point until it crosses the optical axis, this intersection point is noted.
- The radius from this intersection point to either endpoint of the Fitting Curve is determined, and this value becomes the Fitting Curve Radius.



This describes the back surface of the lens.

PREDICTING 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 are 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

Reference the ***"Clinical Study Data"*** 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 the Boston Orthokeratology (oprifocon A) Shaping Lenses will provide a significant risk that is greater than other overnight wear gas permeable contact lenses. Additionally, orthokeratology patients may experience episodes of blurry distance vision or visual flare and/or ghosting.

The two most common side effects that occur in contact lens wearers are corneal edema and corneal staining. It is anticipated that these two side effects will also occur in some wearers of Boston Orthokeratology (oprifocon A) Shaping Lenses. Other side effects, which sometimes occur in all hard 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 orthokeratology 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 the 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, and resulting permanent decreases in vision may occur. The risk of serious problems (such as corneal ulcers and vision loss) is greater when lenses are worn overnight. In addition, studies have shown that smoking increases the risk of corneal ulcers, for those who wear lenses overnight. The benefits and risks of overnight wear lenses should be carefully discussed with your patient. Your patient should be instructed to remove the contact lenses if any abnormal signs are present.

FITTING PROCEDURES

The Boston Orthokeratology (oprifocon A) Shaping Lenses may be fit using a modification of the standard techniques for gas permeable contact lenses. A normal GP contact lens is fit with the Base Curve in alignment with the central cornea. The Boston Orthokeratology (oprifocon A) Shaping Lenses are fit with the Alignment Curve in alignment with the peripheral cornea.

The specifications of the Boston Orthokeratology (oprifocon A) Shaping Lenses are determined by using measurements (e.g., keratometry, topography, eccentricity, and sagittal height), the refractive power you are trying to correct, and the diameter.

1. *Pre-fitting Examination:*
   A. Complete refraction and visual health examination should be performed.
   B. Pre-fitting patient history and examination are necessary to:
      - Determine whether a patient is a suitable candidate for the Boston Orthokeratology (oprifocon A) Shaping Lenses (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:*
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

Desired correction is the full -3.75 diopters

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

The additional 0.75 diopters compensate 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 10.2mm if the flat keratometer 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 Base Curve of the Lens is expected to be flatter than the corneal keratometer readings and the alignment curves. PAR refers to posterior apical radius measured in mm. The correction constant is an additional amount of flattening that is figured into the Base Curve to overcome a slight amount of initial rebound of the cornea when the lens is first removed. The correction constant is typically 0.75 diopters.

The PAR is calculated by:

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

For a Flat K of 41.25 and a Target Correction of -3.75

PAR = (337.5 / (41.25 + (-3.75) - 0.75)= 337.5 / 36.75 = 9.184mm

5. *Initial Lens Evaluation*

Movement:
Blink induced lens movement should show downward lens movement with the lid motion and then upward with the lid motion as with a regular GP contact lens. During the interblink period, the lens should have little or no motion (average less than one millimeter).

Positioning:
The lens should position centrally on the cornea when the eyelids are closed. To achieve this, in an open eye state, the lens should not ride more than 1.0mm below center nor 1.0mm above center. A slightly low position of the lens is preferred. A slightly low riding lens will center when the eyelids are closed.

Characteristics of a Tight (too steep) Lens:
A lens that is too tight will show reduced movement upon blinking and will show too much pooling of fluorescein in the center. The lens will be centered or decentered inferiorly and exhibit little or no movement. Bubbles may be detected behind the lens in the Fitting curve area.

Characteristics of a Loose (too flat) Lens:
A loose lens 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. The fluorescein pattern will show too much clearance in the mid-periphery under the alignment curve. A loose lens is usually uncomfortable for the patient.

TRIAL LENSES

Trial Lens Fitting:
Trial lens fitting may be helpful in determining lens selection. Trial lens fitting may 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 would 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 concerning 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 as 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

Lens should center as well or better than regular GP 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.

Movement

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

Fluorescein Pattern Interpretation

Evaluate the fluorescein pattern. The fluorescein pattern should show a lens with definite central touch, approximately 4.0mm to 6.0mm in diameter with a surrounding area of pooling. The pattern should show alignment in the mid-periphery and there should be normal clearance at the edge.

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 orthokeratology. The cornea adapts by flattening in the central area, which reduces the space near the transition reservoir. 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 a good method for monitoring the fit of the contact lens over time. As the cornea flattens, the area of pooling at the transition becomes less.

The presence of the UV-absorber in the Boston Orthokeratology (oprifocon A) Shaping Lenses may require equipment enhancement to visualize fluorescein patterns adequately. A simple, inexpensive approach is the use of an auxiliary yellow Kodak Wratten #12 filter in conjunction with the cobalt blue filter of the biomicroscope.

Slit Lamp Application (if desired):

1. All customary light intensities and filter settings (Cobalt Blue) are left in place.
2. The Kodak Wratten Filter #12* (yellow) is secured on the patient side of the slit lamp microscope with a small piece of adhesive tape.

Burton Lamp Application (necessary):

1. Replace blue bulbs with ordinary white bulbs.
2. Place Kodak Wratten Filter #47* (blue) over white bulb area.
3. Place Kodak Wratten Filter #12 (yellow) over patient side of viewing lens.
4. Use system in usual manner.

Important Note: Use of the Wratten filters will also enhance the view of non-UV rigid lenses and corneal fluorescein evaluation.

*Wratten #47 and #12 filters are available from Authorized Boston Manufacturers in the following kits: #7503 Slit Lamp Filter Kit, #7502 Burton Lamp Modification Kit.

ORTHO-K PROBLEM SOLVING

Low Riding Lens:

A slight low riding lens is the ideal position upon dispensing. The lens will then center with the eye closed. Do not make a change unless the lens is chronically low riding with eyelid closed (as demonstrated by topography) or if unacceptable ghosting persists.

Cause: 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 alignment curves will be too steep.

Solution: Loosen (flatten) the alignment curves by 0.10mm or reduce the Diameter by 0.50mm.

Loose Lens:

Cause: Generally caused by a low amount of flattening of the peripheral cornea or from an asymmetrical corneal shape.

Solution: If the lens is too loose, tighten (steepen) the alignment curves by 0.10mm.

High Riding Lens:

Cause: The high riding lens is usually caused either from the lens being too loose or from an asymmetrical corneal shape.

Solution: If the lens is too loose, tighten (steepen) the alignment curves by 0.10mm.

Lateral Riding Lens:

Cause: Generally caused by a very spherical cornea or a cornea with against the rule cylinder.

Solution: Increase the diameter of the lens by at least 0.40mm. The recommended diameter would be 11.0mm.

Vaulting:
Vaulting occurs when excessive bearing is present in the peripheral regions causing reduced central bearing. This will be seen as central pooling or increased fluorescein under the center of the lens.

Cause: The major cause of central vaulting is an alignment curve that is too steep. The more peripheral one goes from the corneal apex, the more difficult it is to predict the rate of corneal flattening. When the alignment curve is too steep, the central portion of the lens will rise up, preventing it from applying compression to the center of the cornea. A fitting curve that is too steep can also cause central vaulting but is much less common.

Solution: Flatten the alignment curves by at least 0.10mm. The risk is that by loosening the alignment curves too much, centering problems can develop. If the lens is well centered, and does not appear tight in the alignment curve area, flatten the fitting curve by 0.10mm.

Under-Responders:
An under-responder is a patient whose myopia does not reduce as anticipated. An example is a -3.00, which was reduced to -1.00 after one month of wear and has not changed for 3 weeks. You will be able to refract the patient, without the lenses in, to 20/20 or better.

Cause: Typically, the under-responder will have vaulting in the center. Some patients will, however, respond slower than others perhaps due to different cell structure of the cornea. You do not want to rush into making a change if the exam figures are correct.

Solution: Follow the same solutions for vaulting. If no vaulting is present, recheck the original exam figures. If the fluorescein pattern looks good, wait a while longer, at least two to three weeks to allow for slow responders. If there is still no further reduction on the unaided visual acuity, increase the target power by 0.50D to 0.75D.

Central Islands:
Central islands are areas of distortion in the visual axis that are observed with corneal topography. If you do not use a corneal topographer in the follow-up exams, you will observe slightly distorted mires on the keratometer. This condition differs from the under-responder in that you will not be able to refract the patient, without the lenses in, to 20/20.

Cause: Generally caused by the fitting curve being too steep, causing the Base curve to lift off too much from the central cornea. Another cause is excessive astigmatism. With corneal astigmatism present, there are unequal bearing areas where the fitting curve comes into contact with the cornea.

Solution: Flatten the fitting curve by 0.05mm to 0.10mm. This will apply pressure that is more central and smooth out the central region. If the central disturbance is from astigmatism, then flattening the BC will help to correct this. Target the spherical equivalent of the original refraction to be Plano to +1.00 assuming the patient will not have any accommodative symptoms.

Central Staining:
This is a complication due to either mechanical irritation or physiological problems.

Cause: One major cause of central staining is a coated lens. Because of the steep Fitting Curve, it is difficult to clean the central posterior surface of the lens. This will create an irritating surface, which in turn causes the staining and a tendency for lens adherence. If the BC is too flat, the reduced mechanical pressure can also cause irritation. Reduced oxygen availability can also cause central staining, but this is a rare occurrence.

Solution: The first thing is to make sure the posterior surface of the lens is clean. Review the cleaning solution used. Make sure there are no dry spots. If the staining remains, steepen the BC by 0.5D.

Air Bubbles:
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.

Solution: If the air bubble is less than 45 degrees in length upon insertion, just monitor the next day to see if any staining occurs. 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 recedes. If the bubble and staining persist 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 can only undergo a limited amount of change. Usually, the more induced change, the faster the cornea will regress. Therefore, if you have reduced -5.00 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 chance of holding all waking hours. The Boston Orthokeratology (oprifocon 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 UCVA 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.

Ghosting at Night:
Night ghosting is a normal observation. This usually recedes with time but may always be present to some extent.

Cause: The main cause of ghosting 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 ghosting during the day. Central islands can also give the same subjective complaints as ghosting.

Solution: Time is the answer for normal ghosting. If the lens is not centered, then follow the methods used to center the lens. The optical zone of the lens can also be enlarged to 6.2mm to 6.5mm. However, this might lead to a decrease in the holding time. It is recommended that you wait 1 month before increasing the size of the optical zone.

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:
With lenses in place on the eyes, evaluate fitting performance to assure that the criteria of a well-fitted lens continue to be satisfied. The fluorescein pattern provides a guide to lens adaptation. If the cornea flattens rapidly there will be a larger area of central touch and the pooling at the lens transition will be reduced. The lens will usually show reduced movement. After the lens is removed, conduct a thorough slit-lamp examination to detect the following:

1. The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization. These conditions are indicative of excessive corneal edema.
2. The presence of corneal staining and/or limbal-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 the Boston Orthokeratology (oprifocon A) 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.

Corneal Topography:
A corneal topographer is a valuable tool to use for evaluating any fitting of overnight wear lenses and particularly the Boston Orthokeratology (oprifocon 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(es) 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 re-wet 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 awakening 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 reduction. 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 affect 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 (oprifocon A) Shaping Lenses are shipped to the practitioner non-sterile. 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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