FRONT PANEL VISIBLE UPON FOLDING

FRONT SIDE

PROFESSIONAL FITTING AND INFORMATION GUIDE

BOSTON® XO (hexafocon A) RIGID GAS PERMEABLE CONTACT LENSES FOR ORTHOKERATOLOGY

Daily Wear

CAUTION: Federal (U.S.A.) law restricts this device to be sold by or on the order of a licensed practitioner.

TABLE OF CONTENTS

Product Description
Lens Parameters Available
Actions
Indications
Contraindications, Warnings, and Adverse Reactions
Precautions
Selection of Patients
Fitting Procedure
- Orthokeratology Lens Description
- Predicting Lens Results
- Clinical Study Results
- Myopic Reduction Maintenance Lens or Retainer Lens Wear
- Risk Analysis

Fitting BOSTON XO Contact Lenses for Orthokeratology
- Pre-fitting Examination
- Initial Lens Power Selection
- Initial Lens Diameter Selection
- Initial Lens Base Curve Selection
- Initial Lens Evaluation

Trial Lenses
Follow-Up Care
Ortho-K Problem Solving
Recommended Initial Wearing Schedule
Handling of Lenses
Patient Lens Care Directions
Vertex Distance and Keratometry Conversion Charts
Reporting of Adverse Reactions
How Supplied

DESCRIPTION - BOSTON XO

BOSTON® XO (hexafocon A) Rigid Gas Permeable (RGP) contact lenses for daily wear orthokeratology are lathe cut contact lenses with spherical or aspherical anterior or posterior surfaces in tinted versions. The posterior curve is selected so as to properly fit an individual eye for orthokeratology for a temporary reduction of myopia and the anterior curve selected to provide the necessary optical power. A peripheral curve system on the posterior surface allows tear exchange between the lens and the cornea.

BOSTON XO contact lenses for orthokeratology are made from a fluoro silicone acrylate polymer, hexafocon A, with a water content of less than 1%. The tinted lens contains D&C Green #6 for blue, ice blue lenses; D&C #6 Green and D&C Yellow #18 for green lenses, D&C Violet #2 for violet lenses, D&C Red #17 for red lenses and D&C Yellow #18 for yellow lenses. BOSTON XO contact lenses for orthokeratology are to be worn for daily wear only and should not be worn overnight.

LENS PARAMETERS AVAILABLE:

Chord Diameter Approx 6.5 to 11.5

Center Thickness for
Low Minus Lens: 0.10 to 0.30 mm
for Plus Lens: 0.20 to 0.70 mm

Base Curve	6.5 to 11.0 mm
Secondary Curves (Flatter or steeper than Base Curve)	0.10 to 2.00 mm
Peripheral Curves (Flatter or steeper than Base Curve)	0.10 to 2.0 mm
Powers	-10.00 to +3.00 Dioptors
Aspheric Lens Eccentricity (Oblate, Prolate or Tangent Conic)	-1.5 to 1.5

The physical properties of BOSTON XO are:

Refractive Index	1.415
Light Absorbance (absorbance units/inch)	
Blue (640 nm)	8.1
Ice Blue (640 nm)	5.4
Green (640 nm)	4.9
Violet (585 nm)	5.4
Yellow (420 nm)	5.6
Red (525 nm)	4.5
Wetting Angle (Contact Receding Angle)	49°
Specific Gravity	1.27
Hardness (Rockwell)	112
Water Content	<1 %
Oxygen Permeability	140* (100**)

* gas to gas method
**polarographic method (ISO/Fatt)

ACTIONS:

BOSTON XO contact lenses for orthokeratology 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 compensate for myopia. Contact lenses rest directly on the corneal tear layer and can influence the corneal shape. Regular contact lenses are designed to cause little or no effect on the shape of the cornea, but BOSTON XO contact lenses for orthokeratology are designed to flatten the shape of the cornea by applying slight pressure to the center of the cornea. If the cornea is flattened, this reduces the focusing power of the eye, and if the amount of corneal flattening is sufficient, it is possible to bring the eye into correct focus and compensate for myopia. After the contact lens is removed, the cornea generally retains its altered shape for part or all of the remainder of the day. A Myopic Reduction Maintenance Lens also referred to as a Retainer Lens (see Wearing Schedule Section) must be worn each day to maintain the corneal flattening, or the myopia will revert back to the pre-treatment level.

INDICATIONS (USES):

The BOSTON XO (hexafocon A) RGP Contact Lens for orthokeratology is indicated for daily wear in an orthokeratology fitting program for the temporary reduction of myopia of up to 3.00 diopters in non-diseased eyes. The lens may be disinfected using a chemical disinfection system only.

Note: To maintain the orthokeratology effect of myopia reduction, lens wear must be continued on a prescribed wearing schedule.

CONTRAINDICATIONS (REASONS NOT TO USE) WARNINGS AND ADVERSE REACTIONS:

DO NOT USE BOSTON XO Contact Lenses when any of the following conditions exist:

- Acute and subacute inflammations or infection of the anterior segment of the eye.
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva or eyelids.
- Severe insufficiency of tears (dry eyes).
- Corneal hypoesthesia (reduced corneal sensitivity).
- Any systemic disease which may affect the eye or be exacerbated by wearing contact lenses.
- Allergic reactions of ocular surfaces or adnexa which may be induced or exaggerated by wearing contact lenses or use of contact lens solutions.
- Allergy to any ingredient, such as mercury or Thimerosal, in a solution which is to be used to care for contact lenses.
- Any active corneal infection (bacterial, fungal, or viral)
- Red or irritated eyes

Caution: BOSTON XO contact lenses for orthokeratology are shipped to the practitioner non-sterile. Clean and condition lenses prior to use.

Safety and effectiveness of this device when worn overnight in an orthokeratology fitting and maintenance program have not been established. BOSTON XO contact lenses for orthokeratology should be prescribed for daily wear only.

PRECAUTIONS:

Clinical studies have demonstrated that contact lenses manufactured from the BOSTON XO contact lens for orthokeratology materials are effective for their intended use. However, due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the lens material were not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the eye care practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.

The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive reduction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eye care practitioner.

SELECTION OF PATIENTS:

Patients are selected who have a demonstrated need and desire for a refractive reduction by orthokeratology with rigid gas permeable contact lenses and who do not have any of the contraindications for contact lenses described above. BOSTON XO contact lenses for orthokeratology 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 want to be able to see clearly. This might include such activities as swimming and other sports. BOSTON XO contact lenses for orthokeratology may be useful in occupations that require exposure to smoke, noxious gases or conditions of low humidity if the lenses can be worn before exposure to such substances and removed during their presence. In addition, some patients may be content to wear their contact lenses for normal activities during part of the day and remove them for evening activities.

BOSTON XO contact lenses for orthokeratology are primarily intended for patients who are within the following parameters.

Refractive error:	-1.00 to –3.00 diopters
Keratometry:	39 to 48 diopters
Visual Acuity:	20/30 to 20/400

FITTING PROCEDURE:

BOSTON XO contact lenses for orthokeratology are designed to be fitted so as to flatten the central cornea and thereby reduce myopia. The lens design and the manner in which the lens is fitted are intended to work together to accomplish this goal.

BOSTON XO Lens Descripton

The BOSTON XO contact lens for orthokeratology has a design known as reverse geometry. This means that the secondary curve on the posterior surface has a radius of curvature that is steeper (shorter radius) than the base curve (central curve). The secondary curve is surrounded by a flatter peripheral curve near the edge. In this way the geometry of the secondary curve is in the opposite relationship to the base curve making the design different from that of standard rigid gas permeable contact lenses.

The function of the steep secondary curve in the BOSTON XO contact lens for orthokeratology is to allow the base curve to be fitted flat in relation to the central cornea and still maintain lens stability on the cornea. With a regular contact lens design that is fitted flat on the cornea, the only support point for the contact lens occurs at the center of the lens. Thus, a regular lens will tend to rock and decenter on the cornea. With the BOSTON XO contact lens for orthokeratology, there is support for the lens at both the central cornea and also in the area of the secondary curve. This design tends to reduce lens rocking and aids in centering.

The secondary and alignment curve relationships are altered to achieve an optimal lens design for each patient's individual cornea.

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. There is some evidence that patients with corneas of higher eccentricities are more likely to undergo greater amounts of corneal flattening than do patients with more spherical corneas. Corneal eccentricity can be measured by video keratography or by comparing central and peripheral keratometry readings. 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 BOSTON XO contact lenses for orthokeratology.

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

Clinical Study Results:*

A total of 138 eyes were enrolled in the clinical study with 110 eyes completing a minimum of 3 months of contact lens wear. Of the completed eyes, a total of 106 eyes showed some reduction in myopic refractive error during the 3-month time period that the RGP contact lenses for orthokeratology were worn. The average reduction was 1.69 diopters with a range from 0.25 to 4.25 diopters.

35 eyes (32%) had a reduction of between 0.25 and 1.00 D,
35 eyes (32%) between 1.25 and 2.00 D,
25 eyes (23%) between 2.25 and 3.00 D,
10 eyes (9%) between 3.25 and 4.00 D and,
1 eye (1 %) reduced by 4.25 D

Other clinical refractive outcomes:

- 1 eyes had no change and 3 eyes increased in minus power by 0.25D.
- The reduction in myopia was greater for eyes with a higher initial refractive error.
- 0 eyes over -3.50D were able to achieve a full reduction in myopia.
- For eyes with an initial myopia of greater than 3.75D, the average final exam reduction in myopia was 2.75D.
- The limit in initial myopia that could be reduced to emmetropia in was -3.50D.

The average amount of myopia that can be expected to be corrected is shown in the following table. These values are only averages and some patients can be expected to achieve more or less than these averages.

AVERAGE REDUCTION IN MYOPIA (Diopters)

INITIAL Myopia	REDUCTION Myopia
-1.00	0.80
-2.00	1.50
-3.00	2.00
-4.00	2.40

The average reduction was 1.69 diopters with a range from 0.25 to 4.25 diopters. The amount of myopia

© Polymer Technology (USA) Corporation

1400 North Goodman Street
Rochester, New York 14609
1-800-333-4730

BOSTON XO is a trademark of Polymer Technology (USA) Corporation

Print Date: 03/02 LB6298/01

BACK SIDE

reduced varied between patients and could not be predicted prior to treatment. There was an insignificant difference between the patients who wore contact lenses prior to the study and those with no previous contact lens experience.

RGP contact lenses for orthokeratology provided a temporary full reduction in some patients with up to 3.00 diopters of myopia. For patients with greater than 3.00 diopters of myopia only a partial reduction of myopia can be expected. The percentage of patients that can be expected to achieve full or partial temporary refractive reduction is shown in the following table:

PERCENT OF EYES THAT ACHIEVED FULL OR PARTIAL TEMPORARY REDUCTION OF MYOPIA

INITIAL MYOPIA	FULL TEMP. REDUCTION	UP TO 0.50 D UNDER FULL REDUCTION	FINAL V.A. 20.20 OR BETTER	FINAL V.A. 20/40 OR BETTER
<1.00 D	52%	84%	78%	100%
-1.25 TO – 2.00 D	36%	55%	74%	96%
-2.25 TO –3.00 D	18%	35%	48%	72%
-3.25 TO –4.00 D	4%	13%	16%	64%

For the 110 eyes that completed this study, the initial visual acuity by best refraction was 20/20 or better for 104 eyes and 20/40 or better for all 110 eyes. At the final visit, visual acuity with contact lenses was equal to or better than 20/20 for 99 eyes, 20/40 for 109 eyes and one eye had a visual acuity of 20/70. Nine eyes had a one line drop in visual acuity for contact lenses compared to best refraction, one eye had a two-line drop and three eyes had a three-line drop. In each case, the reduced visual acuity was attributed to residual astigmatism when wearing contact lenses.

The percentage of eyes that achieved uncorrected visual acuity of 20/20 or better and 20/40 or better in relation to the initial myopia is given in the above table. A total of 43 (39%) eyes achieved a visual acuity of 20/20 or better and 78 (71 %) eyes achieved 20/40 or better.

EFFECTS ON ASTIGMATISM

Either increases or decreases in astigmatism may occur following orthokeratology. Of the 110 eyes (55 patients) which completed the three month clinical, 8% showed no change in corneal astigmatism, 32% showed a decrease less than one diopter, while 41% showed an increase less than one diopter and 16% showed an increase greater than one diopter.

The following changes were noted:

Decrease

- From 0.12 to 1.00D was observed for 36 eyes (32%)
- From 1.12 to 1.50D for 3 eyes (3%)
- No eyes decreased more than 1.50D.

Increase

- From 0.12 to 1.00D was observed for 45 eyes (41%)
- From 1.12 to 2.00D for 15 eyes (14%)
- From 2.12 to 3.00D for 1 eye (1%)
- From 3.12 to 3.50D for 1 eye (1%)
- No eyes increased more than 3.50D

WEARING TIME

The average wearing time required for patients who wore RGP contact lenses for orthokeratology for various time periods was as follows:

One week	7.7 hours
Two weeks	7.8 hours
One month	8.0 hours
Three months	8.4 hours

There was considerable variability, however, as many patients required several hours more or less than the averages as shown for the three month time period as follows:

Daily Wear

Time Worn	Percent of patients
0 to 4 hours	25.0%
4.1 to 8 hours	21.8%
8.1 to 12 hours	23.7%
12.1 to 16 hours	27.2%

*Data based on CONTEX (siflufocon A) 3-month Clinical Study.

Myopic Reduction Maintenance Lens or Retainer Lens Wear

Studies have shown that the long-term wear of BOSTON XO contact lenses for orthokeratology does not eliminate the need to continue wearing contact lenses in order to maintain the orthokeratology effect. After the cornea has been flattened by wearing BOSTON XO contact lenses for orthokeratology, the patient will need to continue wearing Myopic Reduction Maintenance Lenses also referred to as a Retainer Lenses for a portion of each day. A Retainer Lens may be either the last BOSTON XO contact lens for orthokeratology design or a modification of this design in which the central portion of the lens applies just enough pressure to the cornea to maintain the corneal flattening achieved but with no additional corneal flattening. The last pair of lenses in the fitting program is usually used as the first Retainer Lens. If it is found that this lens has a secondary curve that is too tight for the lens to be worn on a long-term basis, a new Retainer Lens should be prescribed which has the same base curve but a flatter secondary curve, usually by one or two diopters. The Retainer Lenses are generally worn for the same daily schedule as the BOSTON XO contact lenses for orthokeratology and must be worn each day to maintain the orthokeratology effect.

One of the most common and effective schedules is to wear the Retainer Lens for several hours in the morning and a few hours before bedtime. Higher lens powers may require additional wearing time.

It is important to make certain that the retainer lenses center well on the cornea, as the same lens will be worn for a prolonged period. Check the patient's lenses every 3 to 4 months.

Risk Analysis

There is a small risk involved when any contact lens is worn. It is not expected that, when used for daily wear, the BOSTON XO contact lens for orthokeratology will provide a risk that is greater than other rigid gas permeable contact lenses.

The two most common side effects that occur in rigid contact lens wearers are corneal edema and corneal staining. It is anticipated that the same side effects will also occur in some wearers of BOSTON XO contact lenses for orthokeratology. Other side effects that sometimes occur in all 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.

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

Studies have not been conducted to support the safety and effectiveness of wearing BOSTON XO contact lenses for orthokeratology for overnight wear. The lenses should not be prescribed for overnight wear.

FITTING OF BOSTON XO CONTACT LENSES:

BOSTON XO contact lenses for orthokeratology may be fitted using a modification of the standard techniques for rigid gas permeable contact lenses.

1. Prefitting 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 BOSTON XO contact lenses for orthokeratology (consider patient hygiene and mental and physical states).
     - * Collect and record baseline clinical information to which post-fitting examination results can be compared.
2. Initial Lens Power Selection:

   Standard procedures for determining power of rigid gas permeable contact lenses may be used, including compensation for vertex distance.
3. Initial Lens Diameter Selection:

   Usually, lens diameters between 9.8 mm to 11.5 mm are chosen to maximize centering to the cornea and to minimize lens movement. Lens diameters outside of this range are occasionally used for some eyes. This guide is only a general recommendation and the specification for an individual patient will depend on the eye care practitioner's professional judgment.

Determining Starting Lens Diameter:

If K is 41.00 and flatter use 10.6 mm diameter
41.25 to 45.25 use 10.0 mm diameter
45.50 and steeper use 9.8 mm diameter

Lens diameter is primarily a function of the base curve but may be influenced by power (plus lenses require a larger diameter to compensate for weight) and anatomical considerations (small palpebral opening, excessively large pupil, etc.)

4. Initial Lens Base Curve Selection:

   The base curve of the first lens fitted is generally as flat as the number of diopters as the refractive error plus 0.75 diopters flatter than the flattest keratometric finding but may vary according to the following table, which takes into account the corneal astigmatism.

Corneal Astigmatism	9.5	10.0	10.5
0 to .75	2.25 flatter	2.50 flatter	2.75 flatter
1.00 to 1.50	2.00 flatter	2.25 flatter	2.50 flatter
> 1.50	2.00 flatter	2.00 flatter	2.25 flatter

As shown in the above table, the base curve determination is a function of corneal cylinder and lens diameter. This guide is only a general recommendation and the specification for an individual patient will depend on the eyecare practitioner's professional judgment of such factors as the lens movement, riding position, and the fluorescein pattern analysis.

5. Initial Lens Evaluation

Movement:

Blink induced lens movement should show downward lens movement with the lid motion (average 1 mm.) and then upward with the lid motion (average 1 mm.) as with a regular RGP contact lens. During the interblink period the lens should have little or no motion (average less than 1 mm).

Positioning:

The lens should position centrally or slightly superiorly to minimize both lens movement and lid sensation. The lens should not ride more than 2 mm below center nor 3 mm above center.

Characteristics of a Tight (too steep) Lens:

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

Characteristics of a Loose (too flat) Lens:

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

TRIAL LENSES:

Trial Lens Fitting

Trial lens fitting is recommended whenever possible. Trial lens fitting allows a more accurate determination of lens specifications for the lens fit and power. Choose the first lens according to the table given for base curve selection. Trial lenses are essential in fitting patients whose corneal topography has been distorted by previous contact lens wear.

Dispensable Inventory Set

A dispensable inventory set consists of a series of lenses for any given target power of 10.0 to 10.6 diameter to cover K range of 40.50 to 46.00 in half diopter increments. The power of all lenses is +0.75. Standard sets are available covering –1.50 to –6.00 target powers.

CAUTION: The lenses are non-sterile. 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 insure disinfection, clean and condition lenses prior to use. Hands should be thoroughly washed and rinsed and dried with a lint free towel prior to handling a lens.

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

Trial Lens Procedure

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

1. Centering

   Lens should center as well or better than a regular RGP lens. The lens should be fitted according to the interpalpebral fitting philosophy. Lenses fitted according to the "lid attachment" philosophy, in which the lens purposely rides in a high position, should be avoided.
2. Movement

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

   Evaluate the fluorescein pattern. The fluorescein pattern should show a lens with definite central touch, approximately 3 to 4 mm. diameter with a surrounding area of pooling. In the periphery there should be another area of touch and near the edge a thin band of pooling.

   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 molds by flattening the central cornea, which reduces the space near the transition reservoir. Hence, the size of the transition reservoir, as observed from the fluorescein pattern, is a good indicator not only of the initial fit of the lens but also of the progress of corneal flattening over time as the lens is worn.

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

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

Limits of Flattening

In some cases, the corneal flattening stops before a full reduction of the refractive error has been accomplished. Additional flattening may be possible by using a lens with a steeper secondary curve. If no further corneal flattening occurs, it is an indication that the patient should be fitted with a Retainer Lens.

FOLLOW UP CARE:

a. Follow-up examinations, as recommended by the eye care practitioner, are necessary to ensure continued successful contact lens wear. Follow-up examinations should include an evaluation of lens movement, centration, comfort and fluorescein pattern. Lens movement will decrease as tear volume is diminishing during adaptation. The patient should also begin to feel more comfortable. An assessment of vision and eye health, including inspection of the cornea for edema and/or staining, should be performed.

b. Prior to a follow-up examination, the contact lenses should be worn for at least 4 continuous hours, and the patient should be asked to identify any problems which occur that are related to contact lens wear.

c. 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. These are indications that the lens can be exchanged for another of flatter base curve. Usually, a lens with a 0.50 diopters flatter base curve should be the next choice with variations from this up to the judgment of the eye care practitioner.

A lens with excessive movement should be replaced with another that is 0.2 to 0.5 mm larger in diameter.

If the cornea shows no flattening, assess the lens position, fluorescein pattern and Corneal Topography, if available. Call your Authorized BOSTON Manufacturer or contact Polymer Technology for assistance.

d. After the lens removal, conduct a thorough bio microscopy examination to detect the following:

1. The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization. The presence of these conditions may be indicative of excessive corneal edema.
2. The presence of corneal staining and/or limbal-conjunctival hyperemia, which can be indicative of a reaction to solution preservatives, excessive lens wear, and/or a poorly fit ted lens.

Potential solutions to various lens-wearing problems are given in the following table:

ORTHO-K PROBLEM SOLVING

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

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

Problem	Possible Cause	Solution
Tight lens or no movement	BC too steep Diameter too large diameter	Flatten BC Reduce
Loose lens	BC too flat Diameter too small	Steepen BC Increase diameter
High-riding lens	BC too flat Diameter too small High myopia or high amount of corneal astigmatism weight	Steepen BC Increase diameter Use looser fits because of extra
Low-riding lens	CK & TK may be similar	Use trial lenses to determine better centration
Flare, Glare or Ghosts	BC too flat Poor centration OZD too small	Steepen BC Increase size Use larger OZD
Instability of Ortho-k changes	Quick, large corneal changes induces quicker & larger regression Rigidity of the cornea	Smaller BC changes Good concentration at all times Longer retainer wear Increase center thickness
Fogging and scratchy lens	Dirty lens Improper care & handling of lenses Improper blinking Oily eye make-up removers	See "lens care"
Increase in corneal astigmatism	Lens de-centered Spherical lens being used	Improve centration Smaller BC changes
Poor VA with lenses	De-centered lens; displacement of corneal & visual axis	Improve centration Check over-refraction
Poor VA w/out lenses	Displacement of corneal & visual axis irregular corneal astigmatism	Steepen BC diameter; improve centration

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.

The following schedule depends upon the professional judgment of the eye care practitioner and should be modified according to the response to the initial lenses.

Daily Wear
Maximum wearing time:

Day	Wearing Time (Hours)
1	3
2	6
3	7
4	8
5	9
6	10
7	15
8 and after	All hours awake

Myopic Reduction Maintenance Lens (Retainer Lens) Schedule

The Retainer Lens schedule must be customized for each patient. The Retainer Lens wearing time begins with the same wearing time required for the last fitted BOSTON XO contact lenses for orthokeratology. There is considerable variability, however, as many patients require several hours more or less than the averages.

After a period of several days, or when the eye care practitioner is satisfied that the patient has adapted to the first Retainer Lenses, the Retainer Lens wearing time can be reduced daily by intervals of one hour. This may continue for as long as the patient can see clearly for the remainder of the day following lens removal. When it is found that the patient experiences a visual decrement following lens removal, the previous wearing time is then followed on a constant basis.

HANDLING OF LENSES:

Standard procedures for rigid gas permeable lenses may be used.

Caution: BOSTON XO contact lenses for orthokeratology are shipped to the practitioner non-sterile. Clean and condition lenses prior to use.

PATIENT LENS CARE DIRECTIONS:

Please see package insert and patient information booklet.

VERTEX DISTANCE AND KERATOMETRY CONVERSION CHARTS:

Standard charts may be used.

REPORTING OF ADVERSE REACTIONS:

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

Polymer Technology (USA) Corporation
1400 North Goodman Street
Rochester, New York 14609
800-333-4730

HOW SUPPLIED

Each lens is supplied non-sterile in an individual flat pack case containing one or two lenses. The container is marked with the base curve, distance power, diameter, center thickness, color, and lot number.