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PATIENT INFORMATION BOOKLET

FOR POTENTIAL USERS OF

Boston® Orthokeratology (oprifocon A) Shaping Lenses

FOR OVERNIGHT WEAR FOR

BAUSCH + LOMB

Vision Shaping Treatment VST®

B+L

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.

Nonsterile. Clean and condition lenses prior to use.

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INTRODUCTION

The information in this booklet is to help you decide whether or not to be fitted with the Boston® Orthokeratology Shaping lenses for Overnight Wear, as part of the Bausch + Lomb Vision Shaping Treatment VST® process. Orthokeratology is a fitting procedure that temporarily corrects or greatly reduces nearsightedness (known by the medical name, myopia) with or without astigmatism after shaping lenses have been removed. By temporary, it is meant that the shaping lenses are worn while sleeping (overnight) and then removed upon awakening; whereupon the nearsightedness remains corrected or greatly reduced for all or most of your waking hours. The exact time period over which the myopia remains corrected varies with each patient. Generally, Boston Orthokeratology (oprifocon A) Shaping Lenses must be worn each night to maintain the effect.

Note: Boston Orthokeratology (oprifocon A) Shaping Lenses should be fitted only by a contact lens fitter trained and certified in the fitting of reverse geometry shaping lenses.

HOW THE EYE FUNCTIONS

The eye is very much like a camera and must be in good focus to see objects clearly. The focusing power of the eye comes from two eye structures, the cornea and the lens.

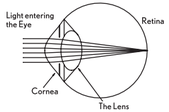

Figure 1: Normal Eye

The cornea is the clear, bubble-like structure on the front of the eye, where light first enters the eye. It provides about two thirds of the eye's focusing power, and the lens inside the eye provides the other third. In a normal eye, light focuses at the retina, at the back of the eye, which acts like the film in a camera. Some eyes focus, or refract, the light too much, so that the images of distant objects are formed in front of the retina, and the image on the retina is blurred, producing myopia.

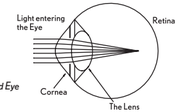

Figure 2: Nearsighted Eye

Myopia usually starts in childhood and gets progressively worse through adolescence. It normally stops increasing by the late teens, but it can sometimes continue to get worse into the mid-twenties.

HOW THE BOSTON ORTHOKERATOLOGY (OPRIFOCON A) SHAPING LENS FUNCTIONS

The Boston Orthokeratology (oprifocon A) Shaping Lens produces a temporary reduction of myopia by changing the shape (flattening) of the cornea, which is elastic in nature. Contact lenses rest directly on the cornea, separated only by a layer of tears, and can influence the corneal shape. Regular contact lenses are designed to nearly match the shape of the cornea and thereby cause little or no flattening effect.

Boston Orthokeratology (oprifocon A) Shaping Lenses are designed to purposely not match the shape of the cornea but instead apply slight pressure to the center of the cornea, in a design known as reverse geometry.

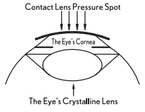

Figure 3: Eye Fitted with Boston Orthokeratology (oprifocon A) Shaping Lens

Pressure is produced when the lens is less curved than the cornea, which places more of the lens weight on 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.

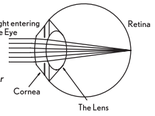

Figure 4: Nearsighted Eye after Orthokeratology

After the lens is removed, the cornea retains its altered shape for all or part of the remainder of the day.

Boston Orthokeratology (oprifocon A) Shaping Lenses are indicated for patients who desire to have time periods during the day in which they do not need to wear their lenses, but still be able to see clearly. Some patients are content to wear their lenses for normal activities during part of the day and remove them for evening activities.

These shaping lenses for Orthokeratology produce a temporary reduction of all or part of your myopia. The amount of reduction will depend on many factors, including the amount of your initial myopia, the elastic characteristics of your eye and the way that the shaping lens fits your eye.

ALTERNATIVE WAYS TO CORRECT MYOPIA

Myopia can be corrected by any method that reduces the focusing power of the eye. The most common methods of reduction are by glasses or regular daily wear or extended wear contact lenses. These represent a means of correcting myopia only during the time that the glasses or regular contact lenses are worn, with no lasting effect on the myopia. Other methods of correcting myopia involve various surgical procedures such as LASIK.

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 lens will provide a risk that is greater than other overnight wear rigid gas permeable contact lenses. The most common patient symptoms concerned poor distance vision and flare/ghosting (visual disturbances). The incidence of these symptoms tends to decrease over time in orthokeratology treatment, and they will go away if lens wear is discontinued.

The two most common side effects which occur in general 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, or abrasion of the eye. These are usually temporary conditions if the contact lenses are removed promptly and professional care is obtained. When overnight orthokeratology shaping 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. You should carefully discuss the benefits and risks of overnight wear lenses with your eye care professional. You should remove your lenses if any abnormal signs are present.

INDICATIONS

Boston Orthokeratology (oprifocon A) Shaping Lenses for Overnight Wear, as part of the VST® process, 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 with eyes having 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.

PRECAUTIONS

General

Clinical studies have demonstrated that Boston Orthokeratology (oprifocon A) Shaping Lenses are safe and effective for their intended use. However, the clinical studies may not have included all design configurations or lens parameters that are presently available in the material. Consequently, when selecting an appropriate lens design and parameters, the eye care practitioner should consider all factors that affect lens performance and the patient's ocular health; including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.

> The safety and effectiveness of the Boston Orthokeratology (oprifocon A) Shaping Lenses **have not** been clinically studied in adolescent and pediatric subjects.

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

Boston Orthokeratology (oprifocon A) Shaping Lenses are supplied non-sterile in an individual plastic case. The lens is shipped dry and must be cleaned and conditioned prior to use.

Patient

You should be aware of the following precautions.

Solution Precautions
- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions with the contact lenses.
- Do not heat the wetting/soaking solution and lenses.
- Always use fresh unexpired lens care solutions.
- Always follow directions in the package inserts of the lens care products used.
- Use only a chemical lens care system. Use of a heat (thermal) lens care system can cause damage by warping Boston Orthokeratology (oprifocon A) Shaping Lenses.
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored).

Handling Precautions
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-base cosmetics are less likely to damage lenses than oil-base products.
- Be certain that your fingers or hands are free of foreign material before touching your contact lenses. Microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in this booklet and those prescribed by your eyecare practitioner.
- Always handle your lenses carefully and avoid dropping them.
- Never use tweezers or other tools to remove your lenses from the lens container unless specifically indicated for that use. Pour your lens into your hand.
- Do not touch the lens with your fingernails.
- To minimize lens warpage during cleaning, the lenses should be cleaned in the palm of the hand rather than between the thumb and fingers.

Lens Wearing Precautions
- CAUTION: Nonsterile. Clean and condition lenses prior to use.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens in the ***Instructions for Wearers Booklet.*** The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, you should immediately consult your eye care practitioner.
- Never wear your contact lenses beyond the period recommended by your eye care practitioner.
- Avoid, if possible, all harmful or irritating vapors and fumes when wearing lenses.
- If aerosol products such as sprays are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

Lens Case Precautions
- Contact lens cases can be a source of bacterial growth. To prevent contamination and to help avoid serious eye injury, always empty and rinse the lens case with fresh, sterile rinsing solution and allow to air dry.
- Lens cases should be replaced monthly.

Discuss these topics with your eye care practitioner:
- During initial weeks of treatment, some patients may experience changes in vision that may require temporary alternate corrective eyewear. This should be discussed with your eye care practitioner.
- Wear of contact lenses during sporting activities
- Use of any medication in your eye(s).
- Importance of adhering to the recommended follow-up schedule to assure the continuing health of your eyes.
- Informing your doctor (health care practitioner) about being a contact lens wearer
- Informing your employer of being a contact lens wearer. Some jobs may require the use of eye protection equipment or may require that you not wear contact lenses during work hours.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE your Boston Orthokeratology (oprifocon A) Shaping Lenses for the Bausch + Lomb Vision Shaping Treatment VST® process when any of the following conditions exist:
- Acute and sub-acute inflammations or infection of the anterior chamber 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 your Boston Orthokeratology (oprifocon A) Shaping Lens.
- Any active corneal infection (bacterial, fungal or viral).
- If eyes become red or irritated

WARNINGS

Incorrect use of contact lenses and lens care products can result in serious injury to the eye. It is essential that you follow the eye care practitioner's directions and all labeling instructions for proper use of contact lenses and lens care products. Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision. If you experience eye discomfort, excessive tearing, vision changes, or redness of the eye, immediately remove the lenses and do not wear them until instructed to do so by the eye care practitioner.

All contact lens wearers must see their eye care practitioner according to the schedule given to them.

Boston Orthokeratology (oprifocon A) Shaping lenses are to be worn overnight, as part of the VST® process, with removal during all or part of each following day. Wearing the lenses continuously (extended wear) presents increased risk, which increases with the number of consecutive days that the lenses are worn between removals. Although the VST® process prescribes only overnight wear with removal during waking hours, and although the safety risks of overnight wear with removal upon awakening may not be as great as with uninterrupted extended wear, there is still increased risk beginning with the first overnight period.

WARNING

The risk of ulcerative keratitis has been shown to be greater among wearers of extended wear lenses than among wearers of daily wear lenses. The risk among extended wear lens wearers increases with the number of consecutive days that lenses are worn between removals, beginning with the first overnight use. This risk can be reduced by carefully following directions for routine lens care, including cleaning the storage case. Additionally, smoking increases the risk of ulcerative keratitis for contact lens wearers. It is recommended that contact lens wearers see their eye care practitioners twice each year or, if directed, more frequently.

ADVERSE EFFECTS

You should be informed that the following problems might occur:

- Eyes stinging, burning, itching (irritation), or other eye pains.
- Comfort is less than when lens was first placed on eye.
- Feeling of something in the eye, such as a foreign body or scratched area.
- Excessive watering (tearing) of the eyes
- Unusual eye secretions
- Redness of the eyes
- Reduced sharpness of vision (poor visual acuity)
- Blurred vision, rainbows, or halos around objects
- Sensitivity to light (photophobia)
- Dry eyes

If you notice any of the above, **IMMEDIATELY REMOVE YOUR LENSES.**

- If the discomfort or problem stops, then look closely at the lens.
- If the lens is in any way damaged, DO NOT put the lens back on your eye. Place the lens in the storage case and contact your eye care practitioner.
- If the lens has dirt, an eyelash, or other foreign objects on it, or the problem stops and the lens appears undamaged, you should thoroughly clean, rinse and disinfect the lens; then reinsert it. Do not use a tap water rinse, use the approved conditioning solution as a rinsing agent.
- If the problem continues, you should **IMMEDIATELY** remove the contact lenses and consult your eye care practitioner.

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, iritis, persistent stromal edema or GPC (giant papillary conjunctivitis) may be present. You should be instructed to keep the lens off the eye and seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

CLINICAL STUDY DATA

Introduction

Boston® Orthokeratology (oprifocon A) Shaping Lenses may produce a temporary reduction of all or part of your myopia. The amount of reduction will depend on many factors, including the amount of your initial myopia, the elastic characteristics of your eye and the way that your shaping lens fits on your eye.

Demographic Information

A total of 378 eyes (191 patients) were enrolled in the clinical study with 264 eyes (134 patients) completing a minimum of 9 months of contact lens wear. Data on 210 eyes (eyes with more complete effectiveness data) were analyzed for safety and effectiveness after 9 months of wear (the "core" group). In addition to this core group, 54 eyes were analyzed for safety data (the "adjunct" group). The entire population consisted of 128 females and 63 males, ranging in age from 17 to 64.

Effectiveness Outcomes

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) (210 Core Eyes)

Initial Myopia	Mean Reduction (D)	Mean Residual (D)
0 to -1.00	1.15	0.21
>-1.00 to -2.00	1.52	-0.15
>-2.00 to -3.00	2.39	-0.13
>-3.00 to -4.00	3.29	-0.22
>-4.00 to -5.00	3.85	-0.57
>-5.00 to -6.00	4.67	-0.68
>-6.00	4.88	-1.25

Uncorrected Visual Acuity (UCVA)

Post-treatment visual acuity was assessed on the 210 analyzed eyes. 73% achieved 20/20 or better and 95% achieved 20/40 or better. 110 out of 374 enrolled eyes were discontinued, primarily due to unacceptable vision, loss-to-follow-up, or unacceptable comfort (in decreasing order).

Accuracy

At 9 months, 80% of the core eyes achieved a reduction of myopia to within 0.50 D of target and 93% achieved a reduction to within 1.00D of target. The accuracy of the temporary reduction in myopia is given in the following table, which also shows the final acuity without lenses. However, accuracy of correction is less with correction higher than 4.00D than with those less than 4.00D.

VISUAL OUTCOME ACCURACY OF THE TEMPORARY REDUCTION OF MYOPIA, FINAL ACUITY WITHOUT CONTACT LENSES (Core Eyes at 9-Months)

Initial Myopia**	% Within 0.50D of Target	% Within 1.00 D of Target	Final VA 20/20 or Better	Final VA 20/40 or Better
<0 to -1.00D	100%*	100%	100%	100%
-1.25 to -2.00D	81%	93%	82%	94%
-2.25 to -3.00D	87%	96%	77%	94%
-3.25 to -4.00D	79%	94%	71%	100%
-4.25 to -5.00D	60%	88%	64%	95%

* 100s# reported/# in category.

** Manifest Refraction Spherical Equivalent.

Wearing Time

The lenses were intended for overnight wear only. The average wear time was reported to be between 8 and 10 hours per night, and there was no apparent relationship between the number of hours of wear and the visual outcome, for any amount of pretreatment myopia.

Effects on Astigmatism

Either increases or decreases in astigmatism may occur following orthokeratology. Of the 210 analyzed eyes, 35% showed no change in refractive astigmatism, 41% showed a decrease of one diopter or less, 2% showed a decrease greater than one diopter, 20% showed an increase of one diopter or less, and 2% showed an increase greater than one diopter.

OVERNIGHT WEAR SAFETY SUMMARY

In this trial all eyes were evaluated for safety and effectiveness of overnight wear for orthokeratology to treat myopia and myopia with astigmatism. There were 264 eyes of 134 subjects followed for 9 months and the data on best corrected acuity, adverse events, slit lamp findings and symptoms provide reliable indications of the safety of oprifocon A in this treatment modality.

Best Spectacle Corrected Visual Acuity (BSCVA)

The majority of core eyes, 73% had no change in BSCVA from baseline. Concurrently, 8% had a loss of >1 line as compared to baseline. No core eyes had a loss of ≥2lines of BSCVA.

41% of the 54 completed adjunct eyes had no change in BSCVA from baseline to the 9-month post-treatment interval and 4% of eyes had a loss of 1 line of BSCVA. Data were not reported for 29 eyes.

When considering all eyes entered into the study, there were a total of 42 incidents (in 34 eyes) of at least a temporary reduction of ≥2 lines of BSCVA during the course of the study. Only 12 of the 42 incidents occurred after 3 months. Duration of the vision loss was not accurately determined in all cases, but for incidents in which there is some documentation and recovery was demonstrated, length of time to documented recovery varied from 1 day to 9 months. Thirty-three eyes had a duration of reduced vision of >7 days.

Four eyes in 3 patients showed a reduction of ≥2lines of best corrected acuity from initial visit to last study visit. One of these eyes was subsequently documented to return to normal acuity. No significant ocular abnormalities were observed in these eyes with biomicroscopy at the time of study exit.

Biomicroscope Exam

For 2,907 eye exams, there were 14 exams showing slit lamp findings greater than grade 2 (moderate or severe) which were reported as follows:

- moderate staining (3 incidents);
- severe staining (2 incidents);
- moderate injection (2 incidents);
- "other" (4 incidents); and,
- ungraded (3 incidents: 2 staining and 1 tarsal abnormality).

All findings greater than grade 2 resolved without further complications. There were 5 moderate, severe or ungraded findings, in the Core, and 9 in the adjunct. The most significant findings were 3 moderate Corneal Staining cases, 2 severe Corneal Staining cases, 1 moderate Corneal Infiltrates case and 2 cases (2 eyes of 1 subject) of trace Iritis. The overall incidents of biomicroscope examination findings of subject's eyes reported moderate or severe findings for <1% of exams.

Symptoms, Problems and Complaints

Subjects were asked to report symptoms and complaints at each follow-up visit. For core and completed adjunct eyes, poor distance vision was reported at 17 %, flare or ghosting were reported for 10%, and all other symptoms (poor near vision, red eye, excessive lens awareness/pain, excessive discharge, burning/itching, and photophobia) were reported for 8% throughout the study. It appears that the eyes with initial myopia above 3.00D had a higher incidence of these visual disturbances.

Discontinuations

Of the 90 adjunct subjects, 55 subjects (110 eyes) discontinued before completing 9 months of wear, for reasons as listed in the following table.

REASONS FOR DISCONTINUATION

Clinical Reason*	#eyes	% of all eyes
Unacceptable vision	52	14%
Lack of comfort	28	8%
Unacceptable physiology	12	3%
Non-clinical Reasons		
Lost-to-follow-up	38	10%
Other**	10	3%

* Several subjects reported more than 1 reason for discontinuation, without giving any priority to the reasons.

** "Other" included returned to spectacles (2 eyes), night vision bothered (2 eyes), wanted prior uncorrected near vision (2 eyes), financial (2 eyes), and could not maintain visit schedule (2 eyes).

Adverse Events and Complications

There were 12 significant lens-related adverse events reported in 10 subjects. Two eyes had bilateral staining; one eye had corneal staining and a dislodged lens; one eye had corneal distortion and rippling on the cornea; two eyes had iritis and flare; one eye had corneal infiltrates; two eyes had an abrasion; one eye had reduction of vision to 20/50 due to a decentered lens; one eye had reduction of vision to 20/60 due to central staining; and one eye had reduction of vision to 20/60 with no reason given.

All of these eyes that showed acuity reductions were documented as returning to normal vision, except two eyes of one subject with severe corneal staining that showed >2 lines loss of BSCVA. The return to pretreatment VA was not recorded on the case report form of this subject although the subject returned to soft contact lens wear and verbally reported that vision was normal. Of the 10 subjects for which adverse events were reported, 4 subjects discontinued the study. All adverse events resolved without further complications.

Summary of Key Safety and Efficacy Variables

A summary of key safety variables is presented in the following table.

SUMMARY OF KEY SAFETY VARIABLES

Criteria	All Treated Eyes (364)	
	n	%
Significant Adverse Events	12*	3
Loss of ≥ 2 lines BSCVA†‡	4	1
BSCVA worse than 20/40†	1	<1
Increase of > 1 D Refractive Cylinder†	12	3
Increase of > 1 D Corneal Cylinder†	50	14

* Includes 4 discontinued subjects (6 eyes).

† From baseline to exit visit.

‡ There were 42 incidents (in 34 eyes) of at least a temporary reduction of ≥2 lines of BSCVA during the course of the study. All except 4 discontinued eyes were documented as returning to normal during the study; one eye was documented to return to normal acuity after the study. No significant ocular abnormalities were observed in these eyes with biomicroscopy at the time of study exit.

POST LENS REMOVAL (REGRESSION STUDY) UNCORRECTED VISUAL ACUITY (UCVA)

The effects of wearing your lenses at night are not permanent and slowly diminish after you remove your lenses. While this does not present a problem for most wearers, it is important to realize for some patients their vision at the end of the day may not be fully satisfactory for highly demanding visual tasks. Although this may not be an issue for most wearers, the eye care practitioner should consider each patient's "late in the day" circumstance to discuss what steps the patient should take if this is a concern. The objective of this study was to evaluate the post-lens removal regression in subjects who had achieved refractive stability* following overnight orthokeratology treatment using Boston Orthokeratology (oprifocon A) Shaping Lenses.

Regression of Visual Acuity

To help you assess the change in vision over time following lens removal, subjects that achieved refractive stability in this clinical study were evaluated at 5-Hour, 24-Hour, 3-Day, and 1-Week Visits after removing their lenses. One hundred eighty four eyes (105 subjects) achieved refractive stability* and completed the Regression Phase.

The following table presents a summary of uncorrected distance visual acuity (UCVA) through the Regression Phase.

At the beginning of the regression phase, 100% of the eyes that achieved refractive stability had UCVA of 20/40 or better**. At the 5-Hour visit of the Regression Phase, 98.9% of the eyes had 20/40 or better. By the 24-Hour visit, 66.5% of the eyes still had UCVA of 20/40 or better.

Summary of uncorrected distance visual acuity (UCVA) through the Regression Phase

	At Lens Removal		5-Hour Visit		24-Hour Visit		3-Day Visit		1-Week Visit	
	#	%	#	%	#	%	#	%	#	%
20/15	8	4.3	10	5.4	4	2.2	0	0	0	0
20/20	136	73.9	131	71.2	48	26.4	20	11.3	3	1.7
20/25	26	14.1	22	12.0	25	13.7	14	7.9	7	3.9
20/30	10	5.4	16	8.7	21	11.5	23	13.0	8	4.4
20/40	4	2.2	3	1.6	23	12.6	20	11.3	20	11.0
Worse than 20/40	0	0	2	1.1	61	33.5	100	56.5	143	79.0
Total	184	100.0	184	100.0	182	100.0	177	100.0	181	100.0

* Refractive stability was considered to be achieve when on two visits, separated by a minimum of 27 days in the same lens, the refraction (defined as the MRSE) varied not more than ± 0.50D.

** Most states require 20/40 in better eye for an unrestricted driver's license.

At the start of the Regression Phase, there were 101 (54.9%) eyes that had a Manifest Refractive Spherical Equivalent (MRSE) between ± 0.25D and 134 (72.8%) between ± 0.50D. For these eyes, the mean time (in hours) following lens removal until MRSE regression to –1.00D or worse is summarized in the following table for completed eyes achieving stability. The eyes with greater pretreatment myopia had less time (in hours) until MRSE regression to –1.00D. Similarly, there was tendency for the eyes with greater pretreatment myopia to have less time until they regressed to 20/40 or worse as time progressed.

Average number of hours until Manifest Refractive Spherical Equivalent (MRSE) regressed to –1.00D following lens removal

	Pretreatment Myopia (MRSE)				
Refraction (MRSE at Lens Removal	-1.00D to -2.00D	-2.12 to -3.00D	-3.12 to -4.00D	-4.12 to -5.00D	-5.12 to -5.75D
+0.37 to +0.50D	156.3	62.2	32.0	–	–
+0.12 to +0.25D	136.9	56.2	28.7	24.0	–
Plano	92.0	63.3	25.2	58.0	–
-0.12 to -0.25D	101.8	56.1	28.5	29.0	25.0
-0.37 to -0.50D	75.7	24.7	44.6	7.0	5.0

POSTMARKET SURVEILLANCE STUDY INCIDENCE RATE OF MICROBIAL KERATITIS IN CHILDREN COMPARED TO ADULTS

A study was conducted looking back at past medical records of children and adult patients wearing Paragon CRT®, Paragon CRT® 100, or Boston Orthokeratology (oprifocon A) Shaping Lenses. The purpose was to compare the chance of developing a rare and severe infection of the cornea called microbial keratitis. Please speak to your eye care professional for information on this study.

MAINTAINING EFFECTS OF BOSTON ORTHOKERATOLOGY (OPRIFOCON A) SHAPING LENSES FOR OVERNIGHT ORTHOKERATOLOGY

The long-term wear of Boston Orthokeratology (oprifocon A) Shaping Lenses, as part of the VST® process, does not eliminate the need to continue wearing shaping lenses to produce the reduction in myopia. After the cornea has been changed by wearing these shaping lenses, you must continue overnight wear of the lenses to maintain the results. Usually the treatment lenses will continue to be the lenses worn after successful treatment. In unusual circumstances, new lenses may be prescribed that are Myopic Reduction Maintenance Lenses or Retainer Lenses. Such Retainer Lenses would be only a slight modification of the patient's Boston Orthokeratology (oprifocon A) Shaping Lens prescription.

The wearing schedule for Boston Orthokeratology (oprifocon A) Shaping Lenses or Retainer Lenses may vary from the schedule prescribed during treatment. In cases of low pretreatment myopia, the effect may last for more than one day.

Note: To maintain the Bausch + Lomb Vision Shaping Treatment VST® 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.

GLOSSARY

Adnexa:	Tissues near the eye
Adverse effects:	Undesirable effects
Aphakia:	Eye that does not have a lens structure
Astigmatism:	Eye condition in which one or more surfaces of the cornea or lens has a shape that is not round but more like that of a football
Best Spectacle Corrected Visual Acuity:	Best vision you can achieve wearing glasses in your exact prescription under optimum viewing conditions
Contact Lens Sticking:	Lack of movement of a contact lens on the cornea
Cornea:	The clear, bubble-like structure on the front of the eye, where light first enters the eye.
Corneal abrasion:	Loss of cells on the corneal surface due to mechanical trauma
Corneal edema:	Accumulation of fluid in the cornea
Corneal hypoesthesia:	Partial loss of sensitivity to touch in the cornea
Corneal staining:	Bright areas on the cornea where dye collects. Indicates an abrasion or other disturbance of the cornea
Corneal ulcer:	Small area of tissue loss in the cornea
Disinfection:	Destruction of bacteria and viruses but not some spores
Diopter:	Unit of power for glasses or contact lenses
Enzyming contact lenses:	Placing contact lenses in a solution that contains an enzyme that dissolves proteins on the surface of the lens
Hypoesthesia:	Reduced corneal sensitivity to touch
Iritis:	Infection of the iris or colored portion of the eye
Lacrimal secretion:	Generation of tears
Manifest Refraction Spherical Equivalent:	A measure of vision correction requirements (in diopters), which combines your myopia and your astigmatism
Myopia:	Medical term for nearsightedness
Myopic Reduction Maintenance Lens:	A modification of the orthokeratology contact lens 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
Neovascularization:	New vessel growth in the cornea
Orthokeratology:	Contact lens fitting procedure that temporarily reduces myopia after contact lenses have been removed
Refract:	Bending of light in order to make it focus
Refractive anomalies:	Eye conditions leading to blurred vision including myopia (nearsightedness), hyperopia (farsightedness) and astigmatism
Retainer Lenses:	Another name for the Myopic Reduction Maintenance Lens
Retina:	Structure at the back of the eye that receives the light image
Rewetting contact lenses:	Placing a solution in the eye while contact lenses are worn that acts as an artificial tear to wet the lens
Sticking lens: does not move	Lens on the cornea that

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