PACKAGE INSERT

Paragon Z CRT

Manufactured in
Menicon Z® (tisilfocon A)

RIGID GAS PERMEABLE CONTACT LENSES FOR CONTACT LENS CORNEAL REFRACTIVE THERAPY

OVERNIGHT WEAR

IMPORTANT
Please read carefully and keep this information for future use.

This package insert is intended for the eye care practitioner, but should be made available to patients upon request. The eye care practitioner should provide the patient with the patient instructions that pertain to the patient's prescribed lens.

CAUTIONS: Federal (US) law restricts this device to sale by, or on the order of a licensed eye care practitioner.

Contact lenses for Corneal Refractive Therapy should be fitted only by a contact lens fitter trained and certified in the fitting of conventional and sigmoid geometry contact lenses.

Nonsterile. Clean and condition lenses prior to use.

WARNING: The eye care practitioner should provide this warning to the patient.

PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE. It is essential that you follow your eye care practitioner's directions and all labeling instructions for proper use of your contact lenses and lens care products, including the lens case.

Patients should follow the complete recommended lens rubbing and rinsing times in the product labeling to adequately disinfect their lenses and reduce the risk of contact lens contamination. Reduced rubbing or rinsing times may not adequately clean their lenses.

Patients should fill their lens case with fresh solution every time they store their lenses, and never re-use solution. They should discard their solution immediately after their lenses have been removed from the lens case. They should not store their lenses in or rinse their lens case with tap water, bottled water or any non-sterile solution.

Patients should clean and rinse their lens case between uses as recommended by their eye care practitioner.

EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION; THEREFORE, IF YOU EXPERIENCE EYE DISCOMFORT, EXCESSIVE TEARING, VISION CHANGES, REDNESS OF THE EYE, OR OTHER PROBLEMS WITH YOUR EYES, IMMEDIATELY REMOVE YOUR LENSES, AND PROMPTLY CONTACT YOUR EYE CARE PRACTITIONER OR ATTENDING HOSPITAL EMERGENCY ROOM PHYSICIAN.

Paragon Z CRT
CONTACT LENSES FOR
CORNEAL REFRACTIVE THERAPY OVERNIGHT WEAR

DESCRIPTION

Paragon Z CRT contact lenses are manufactured from Menicon Z® (tisilfocon A). The lenses are designed to have congruent anterior and posterior surfaces each consisting of three zones:

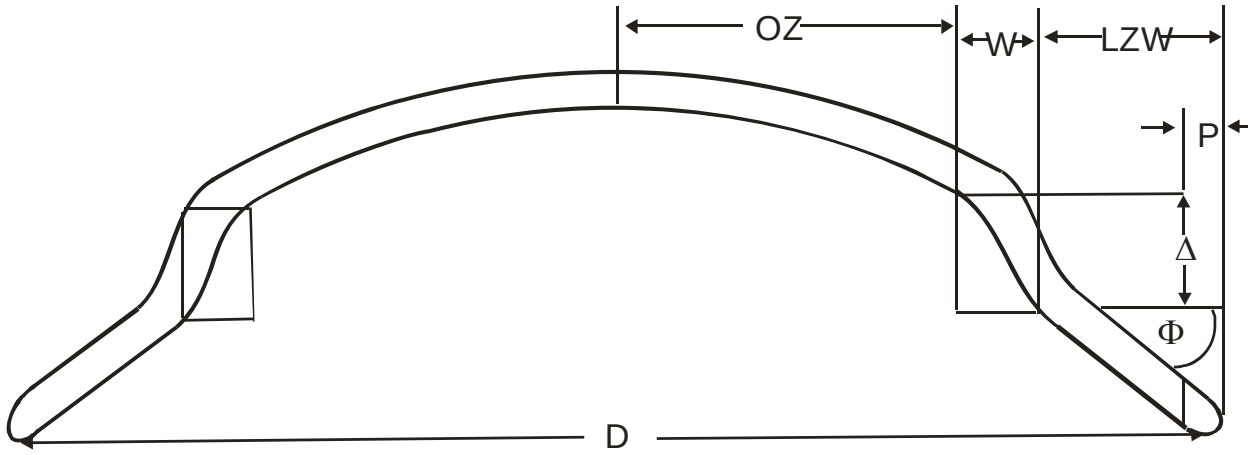
1. The central spherical zone.
2. A mathematically designed sigmoidal corneal proximity "Return Zone".
3. A non-curving "Landing Zone".

The lens design also includes a convex elliptical edge terminus smoothly joining the anterior and posterior surfaces.

Paragon Z CRT Contact Lenses for Corneal Refractive Therapy are to be worn overnight with removal during all or part of each following day. The lens material (tisilfocon A) is a thermoset copolymer derived from fluoro-methacrylate and siloxanylstyrene bound by crosslinking agents. The lenses for Corneal Refractive Therapy are available as lathe cut firm contact lenses with a light blue tint. The blue tinted lens contains D&C Green No. 6. A UV absorber (Benzotriazol) is added as an additive during the manufacturing process.

LENS PARAMETERS AVAILABLE (See drawing)

Overall Diameter (D)	9.5 to 12.0 mm
Central Base Curve Radius	6.50 to 10.50 mm
Optical Zone Semi Chord (OZ)	2.50 to 3.50 mm
Return Zone Width (w)	0.75 to 1.5 mm
Return Zone Depth (Δ)	to 1.0 mm
Landing Zone Radius	to infinity
Landing Zone Angle (Φ)	-25° to -50°
Landing Zone Width (LZW)	0.5 to 2.75 mm
Peripheral Edge Curve Width (P)	0.04 mm to LZW
Dioptric Powers	-2.00 to +2.00 Diopters



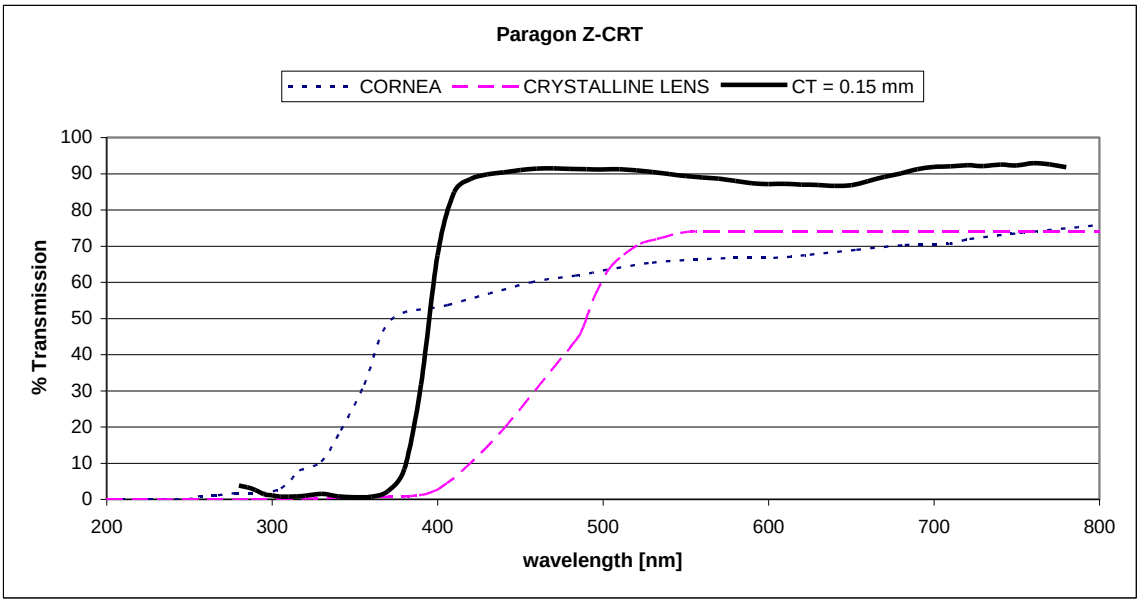
ATTRIBUTES OF THE PARAGON Z CRT LENS (tisilfocon A)

Refractive Index	1.436 (Nd at 25°C)
Light Transmittance	
Visible Region	>95% (380nm – 780nm)
Ultraviolet Region (sample thickness 0.08mm)	<6% (210nm – 380nm)
Wetting Angle (after plasma)	≤40°
Specific Gravity	1.20
Water Absorption	<0.5% by weight
Oxygen Permeability[+]	163 Dk x 10^{-11}

[+] (cm^2/sec) (mL O_2)/ (mL x mm Hg) ISO/ANSI Method, ISO 9913-1

OXYGEN PERMEABILITY - CRT® LENS DESIGN					
Material	Power	Oxygen Permeability (ISO Method*) Dk x 10^{-11}	Center Thickness (mm)	Harmonic Mean Thickness** (mm)	Oxygen Transmissibility (ISO) Dk/l x10^{-9}
Menicon Z®	-2.00	163	0.145	0.163	99
Menicon Z®	Plano	163	0.163	0.166	98
Menicon Z®	+2.00	163	0.180	0.168	98

* (cm^2/sec) (mL O_2)/ (mL x mm Hg) ISO/ANSI Method, ISO 9913-1
** Sammons, W.A., "Contact Lens Thickness and All That", The Optician, 12/05/80.



Menicon Z® (tisilfocon A) Contact Lens - Spectral transmittance curve for Menicon Z® (tisilfocon A) Contact Lens - D&C Green No. 6 and UV absorbing agent (sample thickness Menicon Z® (tisilfocon A) lens polymer plate = 0.08mm, representing the thinnest marketed version of the lens).
CORNEA - Human cornea from a 24-year-old person as described in Lerrnan, S., Radiant Enerqv and the Eve, MacMillan, New York, 1980, P. 58, figure 2-21.
CRYSTALLINE LENS - Human crystalline lens from a 25-year-old person as described in Waxier, M., Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p. 19, figure 5.

WARNING: UV-absorbing contact lenses are not substitutes for protective UV-absorbing eyewear such as UV-absorbing goggles or sunglasses. Persons should continue to use their protective UV-absorbing eyewear as directed.

NOTE: The effectiveness of wearing UV-absorbing contact lenses in preventing or reducing the incidence of ocular disorders associated with exposure to UV-light has not been established at this time.

ACTIONS

Paragon Z CRT Contact Lenses for Corneal Refractive Therapy produce a temporary reduction of myopia by changing the shape (flattening) of the cornea, which is elastic in nature. Slightly reducing the curvature of the cornea reduces the excessive focusing power of the myopic 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.

Contact lenses rest directly on the corneal tear layer and can gently influence the corneal shape. Regular contact lenses are designed to cause little or no effect, but Paragon Z CRT Contact Lenses for Corneal Refractive Therapy are designed to purposely flatten the shape of the cornea by applying gentle pressure to the center of the cornea during sleep.

After the contact 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 Paragon Z CRT lens design must be worn at night on a regular schedule to maintain the corneal reshaping, or the myopia will revert to the pretreatment level.

INDICATIONS (USES)

Paragon Z CRT (tisilfocon A) Rigid Gas Permeable Contact Lenses for Corneal Refractive Therapy are indicated for use in the reduction of myopic refractive error in nondiseased eyes. The lenses are indicated for overnight wear in a Corneal Refractive Therapy fitting program for the temporary reduction of myopia up to 6.00 diopters in eyes with astigmatism up to 1.75 diopters. The lenses may be disinfected using only a chemical disinfection system.

> Note: To maintain the Corneal Refractive Therapy 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 (REASONS NOT TO USE)

DO NOT USE Paragon Z CRT Contact Lenses for Corneal Refractive Therapy 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)
- If eyes become red or irritated

WARNINGS

Paragon Z CRT Contact Lenses for Corneal Refractive Therapy are shipped to the practitioner nonsterile. Clean and condition lenses prior to use.

Incorrect use of contact lenses and lens care products can result in serious injury to the eye. It is essential for the patient to 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 the patient experiences eye discomfort, excessive tearing, vision changes, or redness of the eye, instruct the patient to 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.

Paragon Z CRT Contact Lenses for Contact Lens Corneal Refractive Therapy are to be worn overnight 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 overnight Contact Lens Corneal Refractive Therapy prescribes only overnight wear with removal during the waking hours, and although the safety risks of intermittent overnight wear may not be as great as with sustained overnight 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 of the lens 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.

Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.

ADVERSE EFFECTS (PROBLEMS AND WHAT TO DO)

Patients should be informed that the following problems may occur.

- Eyes stinging, burning, itching (irritation), or other eye pain
- 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 the patient notices any of these conditions, the patient should IMMEDIATELY REMOVE THE LENSES. The patient should follow these instructions.

- 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.
- If the problem continues, you should IMMEDIATELY remove the contact lenses and consult your eye care practitioner.

When any of the above problems occurs, a serious condition such as infection, corneal ulcer, neovascularization, iritis, persistent stromal edema or GPC (giant papillary conjunctivitis) may be present. Instruct the patient to keep the lens off the eye and seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage, including corneal scarring, opacification, blindness or loss of eye.

PRECAUTIONS

Eye Care Practitioner

Clinical studies have demonstrated that Paragon Z CRT contact lenses manufactured from Menicon Z® material are safe and effective for their intended use. However, due to the small number of patients enrolled in the clinical investigation of lenses, all refractive powers, design configurations, and lens parameters available in the lens materials were not evaluated in significant numbers. This is especially true for adolescent subjects in this investigation. 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 the patient's 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. Corneal edema is more prevalent when the lens is used in high altitudes.

Each Paragon Z CRT lens is supplied nonsterile in an individual plastic case. The lens is shipped wet in Boston SIMPLUS® solution. This solution contains poloxamine, hydroxyalklphosphonate, boric acid, sodium borate, sodium chloride, hydroxypropylmethyl cellulose, Glucam and preserved with chlorhexidine gluconate (0.003%), polyaminopropyl biguanide (0.0005%).The case, packing slip or invoice is marked with the central base curve radius, dioptric power, overall diameter, Return Zone Depth, Landing Zone Angle, center thickness, serial number, ship date and the color of the lens. If the patient has experienced a prior history of allergy to any of these ingredients; remove the lens from the solution and soak the lens 24 hours in sterile unpreserved saline prior to cleaning, disinfecting and dispensing.
*Boston SIMPLUS® is a registered trademark of Bausch & Lomb

Never reuse the solution. You may store the lens in the unopened container until ready to dispense, up to a maximum of twenty-five (25) days from the Ship Date (see Packing Slip). When a lens has been stored for 25 days in its original packaging solution, it should be cleaned and disinfected with an FDA approved product, and placed into inventory as you presently do with any other RGP lens held in your office. Follow the directions on the selected disinfecting solution regarding prolonged storage.

Patients should be informed 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 contact lens solutions used.
- Use only a chemical lens care system. Use of a heat (thermal) lens care system can cause damage by warping your contact lenses.
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- Do not use saliva, tap water 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 and hands are free of foreign material before touching your contact lenses, as 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 eye care 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. Patients should follow the complete recommended lens rubbing and rinsing times in the product labeling to adequately disinfect their lenses and reduce the risk of contact lens contamination. Reduced rubbing or rinsing times may not adequately clean their lenses.

Lens Wearing Precautions

- CAUTION: Clean and condition lenses prior to use. Lenses come non-sterile.
- 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 nonmovement of the lens continues, you should immediately consult your eye care practitioner or attending hospital emergency room physician.
- 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, Patients should fill their lens case with fresh solution every time they store their lenses, and never re-use solution. They should discard their solution immediately after their lenses have been removed from the lens case. They should not store their lenses in or rinse their lens case with tap water, bottled water or any non-sterile solution.
- Patients should clean and rinse their lens case between uses as recommended by their eye care practitioner.
- Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or eye care practitioner.

Discuss these topics with each patient:

- Wear of contact lenses during sporting activities.
- Use of any medication in his or her eyes
- Importance of adhering to the recommended follow-up schedule to assure the continuing health of his or her eyes
- Inform your doctor (health care practitioner) about being a contact lens wearer.
- Inform 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.

SUMMARY OF CLINICAL STUDY

INTRODUCTION

Two-hundred four eyes of 102 patients are presented in this report of a study of myopia and myopia astigmatism treatment with overnight wear of contact-lens corneal refractive therapy lenses in tisilfocon A material in a protocol controlled investigation at nine U.S. sites. The objective of this investigation was to determine the safety and effectiveness of the lenses in the population defined in the protocol. The corneal refractive therapy design used in this clinical trial gained FDA market approval on June 13, 2002 when manufactured in paflufocon B and paflufocon D.

DEMOGRAPHIC INFORMATION

The data presented in this report were collected and analyzed from the 204 eyes of 102 enrolled subjects of which 196 eyes of 98 subjects were treated at nine U.S. centers. The mean age of the full cohort of patients was 34.56 ± 11.6 years (range 11-57). There were 67 female and 31 male subjects enrolled and treated. The data for 72 patients (144 [1] eyes) were analyzed for effectiveness following 6 months of treatment. The mean age of these patients was 34.97 ± 12.0 years (range 11 to 57). A waiver was granted for one subject that was age 11 years 8 months at the baseline visit. There were 10 adolescent subjects enrolled, 2 withdrew prior to treatment. There were 48 female and 24 male subjects of these 47 were classified Caucasian, 3 were African American, 14 were Asian/Pacific Islander, 1 was American Indian/Aleut Eskimo, and 5 were classified Hispanic.

EFFECTIVENESS OUTCOMES

The average amount of myopia that can be expected to be corrected is shown in the following table. These values assessed on 137 eyes on which full correction was attempted are only averages and some patients can be expected to achieve more or less than these averages. Seven patients were given a monovision treatment in which one eye was targeted for emmetropia and one targeted to remain myopic, in order to provide near vision.

AVERAGE REDUCTION IN MYOPIA (DIOPTERS) N=137*

Refractive Range and Count	Average Subjective Refraction (MRSE)	Average Myopia Reduction (MRSE)	Average Residual Subjective Refraction (MRSE)
-0.25>-1.00 N=8	-0.89	0.81+/ -0.48	-0.08+/ -0.38
-1.25>-2.00 N=40	-1.63	1.49+/ -0.45	-0.13+/ -0.40
-2.25>-3.00 N=46	-2.57	2.37+/ -0.62	-0.20+/ -0.57
-3.25>-4.00 N=25	-3.67	3.23+/ -0.67	-0.44+/ -0.62
-4.25>-5.00 N=13	-4.40	3.88+/ -0.67	-0.52+/ -0.60
-5.25>-6.00 N=5	-5.50	5.65+/ -0.55	0.15+/ -0.55

*All completed eyes targeted for emmetropia.

Uncorrected Visual Acuity (UCVA)

Post treatment visual acuity was assessed on 137 eyes on whom full correction was attempted. Of these eyes 41.5% obtained 20/20 or better uncorrected visual acuity and 94.8% obtained 20/40 or better visual acuity at 6 months. See the following table.

Paragon Z CRT Contact Lenses for Corneal Refractive Therapy provided a temporary full reduction in some patients with up to -5.5 diopters of myopia. For patients with greater than -5.5 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 based on 144 [2] treated eyes is shown in the following table.

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

INITIAL MYOPIA	FULL REDUCTION ± 0.50 D from Target*	PARTIAL REDUCTION ± 1.00 D from Target*	FINAL V.A. 20/20 or better**	FINAL V.A 20/40 or better**
1.00 D or less	88%	N/A	50%	100%
-1.25 to - 2.00 D	83%	100%	60%	95%
-2.25 to - 3.00 D	81%	95%	39%	93%
-3.25 to - 4.00 D	70%	93%	24%	92%
-4.25 to - 5.00 D	79%	86%	23%	100%
-5.25 to -6.00 D	33%	83%	33%	100%

[1] At 1 month one subject converted to, and completed wearing only one lens.
[2] At 1 month one subject converted to, and completed wearing only one lens.

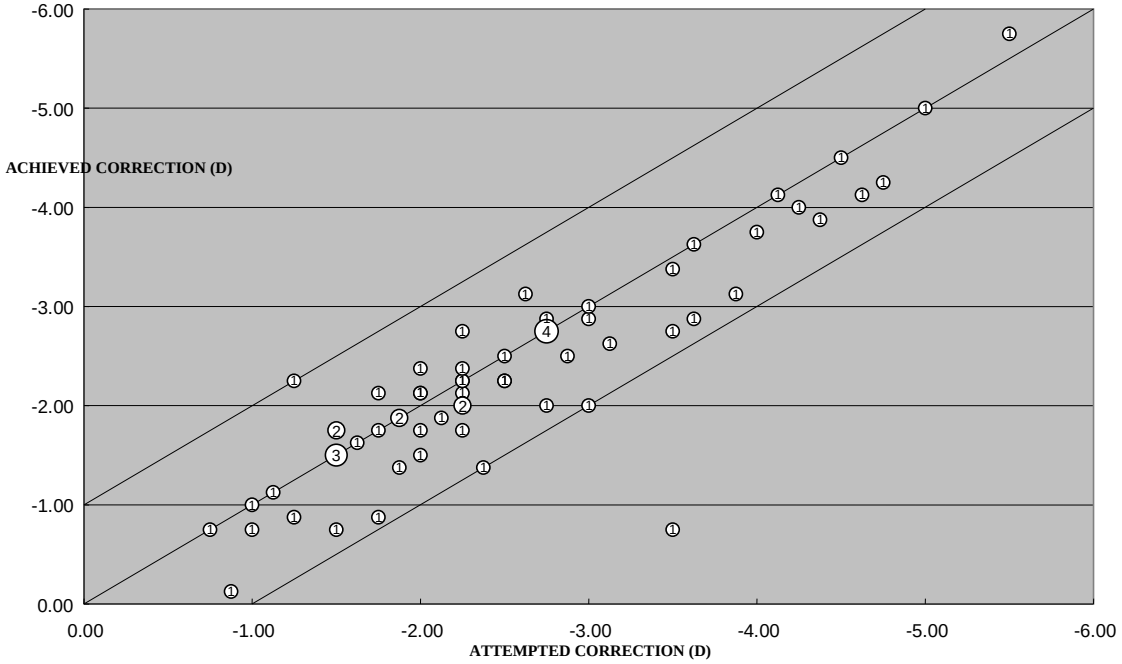
* N=144 for reduction (all efficacy qualified eyes)
** N=137 for Final VA (only eyes targeted for emmetropia)

Accuracy

Accuracy of outcome was evaluated by analysis of attempted versus achieved manifest refraction spherical equivalent. At the 6 month visit, 77.6% (111/144 [3]) of 6-month completed eyes were within 0.50 D attempted spherical equivalent correction, and 95.1% (136/144) of eyes were within 1.00 D of attempted correction. In this clinical study the higher the initial myopia the lower the percentage of patients achieved full correction and/or 20/20 vision. The preceding table demonstrates the relationship of initial myopia with treatment success.

There is reference in a published study [4] regarding visual acuity in the "better seeing eye" of a subject as a useful method of estimating functional vision when using both eyes. Of course, very few patients need to rely on the vision from a single eye. When the study subjects were analyzed for only their "better seeing eye", 86% had 20/20 or better vision, and 100% had 20/40 or better. The accuracy calculation also changes slightly. 80% Are estimated to be within 0.5 D of target; 96% are estimated to be within 1.0 D of target in keeping with the method of better eye analysis. The scatter plot below graphically depicts the accuracy of the treatment based on the better seeing eye.

ATTEMPTED versus ACHIEVED Correction of Refractive Error
Estimated From The Residual Error Of the Better Seeing Eye, N=65*
(multiple identical results indicated by number in circle)



* Excludes 7 subjects not targeted for emmetropia in both eyes.

Wearing Time

The lenses were used for overnight wear only. They were applied within 30 minutes of sleep and removed within 30 minutes of awakening. The average wearing time was 6 to 8 hours and reflected the expected distribution of night-sleep time. There was no apparent relationship between the number of hours of wear during sleep and the visual acuity outcome for any amount of pretreatment myopia.

Regression Of Visual Acuity

To help you assess the change over time following lens removal, subjects in the clinical study were evaluated at 8, 24, 48, and 72 hours after removal of their lenses following either the six or nine month scheduled visit.
Remember that the times given are averages, many patients will do better, many will not fare as well. The 1 Diopter regression point was chosen because it approximately corresponds to 20/40 unaided vision, the legal requirement for driving in many states.

[3] At 1 month one subject converted to, and completed wearing only one lens.
[4] Monocular Versus Binocular Visual Acuity as Measures of Vision Impairment and Predictors of Visual Disability, Rubin, et al, Invest Ophthalmol Vis Sci 2000; 41:3327-3334

The following guidance table is intended for counseling patients regarding the stability of their vision throughout the day. Values in the table represent the number of hours from the time of lens removal before the average patient's vision will have regressed to the point that his refraction is -1.0 Diopter (roughly corresponding to 20/40).

To use the chart, find the patient's original pretreatment manifest refractive spherical equivalent (MSRE) in the 3rd horizontal row then move down that column to the row where the refraction (in column 2) matches the refraction your patient achieves immediately on lens removal after a night's wear. The bold value found in the cell identified in this way represents the average number of hours that similar patients have experienced before their refractive error has regressed to approximately -1.0 Diopter. Beneath that value is the minimum projected time for any subject in the study. This is only a guideline; every patient should test his/her vision as it relates to the requirements of their own daily schedules.

BE SURE TO MAKE YOUR PATIENTS AWARE OF THESE LIMITATIONS OF CORNEAL REFRACTIVE THERAPY AND THE OPTIONS AVAILABLE TO THEM WHEN A PROBLEM ARISES.

AVERAGE AND MINIMUM HOURS UNTIL REGRESSION TO -1.0 DIOPTER OR WORSE

(estimated for all subjects with pretreatment MRSE > -1.0 D targeted for emmetropia and corrected to better than -1.0 D MRSE N=79)

			-1.12 to -2.00	-2.12 to -3.00	-3.12 to -4.00	-4.12 to -5.00	-5.12 to -6.00
REFRACTION AT LENS REMOVAL	+0.50	**Mean**	**163.7 Hrs**	**52.6 Hrs**	**19.8 Hrs**	**12.1 Hrs**	**16.9 Hrs**
		Minimum	9.3 Hrs	3.7 Hrs	4.3 Hrs	5.3 Hrs	5.5 Hrs
	+0.25	**Mean**	**162.3 Hrs**	**51.6 Hrs**	**18.9 Hrs**	**11.4 Hrs**	**15.9 Hrs**
		Minimum	9.3 Hrs	3.5 Hrs	4.1 Hrs	4.9 Hrs	5.1 Hrs
	0.00	**Mean**	**159.4 Hrs**	**49.9 Hrs**	**17.5 Hrs**	**10.5 Hrs**	**14.4 Hrs**
		Minimum	9.2 Hrs	3.2 Hrs	3.9 Hrs	4.4 Hrs	4.7 Hrs
	-0.25	**Mean**	**153.5 Hrs**	**46.9 Hrs**	**15.5 Hrs**	**9.1 Hrs**	**12.3 Hrs**
		Minimum	9.1 Hrs	2.8 Hrs	3.4 Hrs	3.8 Hrs	4.1 Hrs
	-0.50	**Mean**	**139.7 Hrs**	**41.1 Hrs**	**12.3 Hrs**	**7.1 Hrs**	**9.5 Hrs**
		Minimum	8.5 Hrs	2.2 Hrs	2.8 Hrs	2.9 Hrs	3.1 Hrs
	-0.75	**Mean**	**103.9 Hrs**	**28.8 Hrs**	**7.5 Hrs**	**4.3 Hrs**	**5.5 Hrs**
		Minimum	5.1 Hrs	1.2 Hrs	1.6 Hrs	1.6 Hrs	1.8 Hrs

Effects On Astigmatism

Corneal Refractive Therapy does not predictably affect the magnitude of pretreatment astigmatism.
Either increases or decreases in astigmatism may occur following Contact Lens Corneal Refractive Therapy. Of the eyes that completed the nine-month clinical study, 27% showed no change in refractive astigmatism, 49% showed a decrease of one diopter or less and 1% showed a decrease more than one diopter, while 23% showed an increase of one diopter or less and 1% showed an increase greater than one diopter of refractive astigmatism.

OVERNIGHT WEAR SAFETY SUMMARY

In this trial, 196 eyes from 98 patients were evaluated for safety during six months overnight wear corneal refractive therapy when treating myopia and myopia with astigmatism. In this study analysis of safety outcomes was performed for BSCVA losses, adverse events, complications, intraocular pressure, slit lamp findings and symptoms problems and complaints. The analysis was completed for all eyes that reported at all visits.
Best Spectacle-Corrected Visual Acuity (BSCVA)

The BSCVA change analyzed in this trial is the difference between the baseline acuity with best subjective refraction and the acuity with the subjective refraction at the specified visit.

Seventy percent of completed eyes (101/144 [5]) experienced no change in BSCVA at 6 months, while 15 % (22/144) experienced one line of improved BSCVA and 10% (14/144) eyes experienced on line of diminished BSCVA. Five completed eyes, 3.5% (5/144) manifested a transient loss of two or more lines of BSCVA at the six-month visit. All losses except one were found to be transient as they were not found to be present at the post-removal visits. In one case recovery was not documented before the eye was lost to follow-up. There was one eye with BSCVA worse than 20/40 at the six month visit. At prior visits, with the exception of 3 cases, eyes measuring worse than 20/40 BSCVA were re-tested with a contact lens in place. In those cases retested with a lens, the acuity improved to within one line of vision, indicating that the loss was due to higher order aberration in the anterior corneal plane. In the cases when the test was

[5] At 1 month one subject converted to, and completed wearing only one lens.

mistakenly omitted the BSCVA loss improved to within one line of vision by the next scheduled visit. There is a pattern of transient BSCVA loss at each visit and a trend toward a decreasing percentage with time.

After passing the dispensing and a successful day one visit, of the 204 eyes originally enrolled in the study, 35 were found, at one point or another, to have temporarily lost 2 lines or more of BSCVA from baseline. In one case recovery was not documented before the eye was lost to follow-up. Additionally, eight subjects were observed to temporarily have BSCVA's of 20/40 or worse.

Absence of Persistent Corneal Change

The protocol stipulates that all treated eyes of subjects who discontinued the clinical trial must be followed one month post discontinuation and every one month thereafter until there was no difference greater than 0.50 D in either of the keratometric meridians from the baseline measures. Of the 58 discontinued eyes of the 29 discontinued subjects, 39 eyes of 20 subjects were within 0.50 D of the baseline measurements at the discontinuation visit. One of the discontinued subjects (2 eyes) was lost to follow-up during the investigation. Eleven eyes of 6 subjects were measured to be within 0.50 D of their baseline visit at a post discontinuation visit. Two enrolled subjects were not dispensed.

Slit Lamp Findings

There were no grade 2 or 3 observations at baseline. There were 1578 observations for all scheduled and unscheduled follow up visits. There were 61 grade 2 (mild) observations (3.9%) during treatment and 7 grade 3 (moderate) observations (< 0.5%) reported. There were no grade 4 (severe) observations reported that would constitute adverse events.

Of the 8 grade 3 reports five were for staining, one for injection and two were for other and described as corneal infiltrates. All 8 cases resolved without further complication. These occurred in 4 subjects. In each case lens wear was discontinued. Two subjects discontinued the study and 2 completed. All cases resolved without further complication.

Symptoms, Complaints and Discontinuations

One hundred two subjects underwent baseline evaluation in the study. Of these, 98 subjects (196 eyes) had lenses dispensed and wore them for at least one night of treatment. The safety analysis was conducted on all 196 treated eyes of the 98 subjects. Seventy-two subjects, 73.5% (144 [6]/196 eyes), completed six months of treatment. The efficacy analysis was conducted on all 72 subjects (144 eyes) that completed six months of treatment. Of the 98 subjects, 29 were discontinued prior to the six-month visit. The table below reports the tabulation of subjects that were discontinued prior to the six-month visit and the reason for discontinuation.

Reason for Discontinuation (N=102 enrolled subjects)	
Reason for Discontinuation	Number of Patients
Unacceptable Visual Acuity	13
Other	6
Lack of Comfort	3
Lack of Interest	5
Protocol Violation	2
Missed Visits	0
Pathology	0

The reasons given for "other" include two subjects who reported lens adherence, one that reported "lens slipping" at night, one who had back surgery and could not attend visits, and two not dispensed. The protocol violation listing includes two subjects who stopped wear of the lenses for long periods during the study.

[6] At 1 month one subject converted to, and completed wearing only one lens.

The clinical reasons for discontinuation are unacceptable vision, lack of comfort, lens adherence and lens slipping that account for 13% (13/98), 3% (3/98), 2% (2/98) and 1% (1/98) respectively. The total discontinuation rate for clinical reasons was 19%.

PERCENT OF EYES EXHIBITING COMPLAINT OR SYMPTOM AT VISIT						
Visit	Unscheduled	2-Week	1-Month	2-Month	3-Month	6-Month
Total Eyes at Visit	260	168	158	164	160	144
None	39%	44%	63%	68%	69%	81%
Discomfort	24%	20%	15%	14%	15%	8%
Itching/Burning	6%	4%	0%	4%	1%	0%
Blurred Vision	26%	20%	8%	4%	4%	5%
Dryness/Scratch	6%	3%	6%	7%	3%	5%
Redness	5%	2%	1%	0%	0%	0%
Variable Vision	12%	15%	4%	2%	4%	3%
Photophobia	3%	1%	0%	0%	1%	0%
Halos	4%	11%	8%	5%	3%	1%
Ghost Images	0%	1%	1%	1%	0%	1%
Lens Adhesion	5%	2%	1%	0%	1%	1%
Lens Need Cleaning	2%	5%	1%	3%	0%	1%
Other	6%	3%	1%	1%	0%	2%

Adverse Events and Complications

Study related complications were reported, along with other clinical findings throughout the course of the study. Investigators were encouraged to report all clinical findings, regardless of severity or frequency. As these events were brought to the attention of the study monitors, appropriate information was examined regarding the treatment and post-treatment course of each individual eye. Often this information included but was not limited to BSCVA, UCVA, refraction, slit lamp findings and videokeratography.

These reports were followed up, where necessary, with a phone call to the investigator. One subject was found to have suffered a loss of greater than 2 lines of acuity from his baseline BSCVA and it was lost to follow-up. Although recovery was not documented, this subject had no significant ocular pathology observed at any visit. Another subject was found to have similar a loss and was not documented to have recovered for 216 days. One subject experienced a loss of acuity in one eye to worse than 20/40 whose recovery was not documented for 89 days.

There were three events reported on Adverse Event Forms. Two were rated as moderate and one as mild. No serious adverse events were reported.

The following is the description of the adverse events. One subject experienced a peripheral corneal infiltrate, discontinued lens wear, administered medication, and the infiltrate resolved in 7 days. A second subject experienced two incidents of corneal infiltrates, discontinued lens wear, administered medication, and each occurrence resolved in 6 days. Lens adherence was reported in two subjects who discontinued and was listed as a study related complication. It was also reported as a symptom, problem or complaint. There were twenty one positive reports of lens adherence in thirteen eyes of nine subjects. The right eye of one subject was the only eye to report persistent lens adherence (at multiple sequential visits). It is noteworthy that this eye was also reported to have a moderate adverse event.

There were no slit lamp findings graded at level 4 (severe). All grade 2 or greater measures resolved without complication. The remaining study related complications were restricted to the transient losses of two or more lines of BSCVA, reductions to $\leq$ 20/40 and to slit lamp findings graded at level 3 (moderate). For subjects completing at least a day 1 visit there were 63 occurrences in 50 eyes of temporary loss of 2 or more lines of visual acuity. Of 186 subject eyes that continued to scheduled visits beyond day 1, and excluding observations at day 1 visits, there were 35 occurrences of temporary loss of 2 or more lines of visual acuity.

Of these occurrences 15 occurred on scheduled visits beyond the early fitting period*, and 7 were at Unscheduled or Discontinuation visits. The average duration for all occurrences until the investigator was able to bring the subject in and document recovery to better than 2 lines from baseline was 31.4 days. Although the range of durations until documented recovery** was 0 to 216 days (one subject could not be returned for documentation), the median duration was 18 days. Of the 15 occurrences beyond the early fitting period none were bilateral and the average logMAR acuity at the time of the first observation was 0.17 (better than 20/32 in that eye). Only two of these eyes demonstrated visual acuities worse than 20/40 when first observed and they were documented to have been resolved at their next follow-up visit in 7 and 21 days respectively.

*Period from dispense through successful 2-week visit

**Actual Recovery may have occurred earlier

Eight subjects presented with acuities of ≤ 20/40 during the course of the study. Two were observed only at the day 1 visit. One subject placed lens cleaner in his eye just after the 3-month visit but was not documented to have recovered until the 6-month visit, 89 days later. Excluding the subject who put cleaner in his eye, the range for time to documented recovery was 0.3 – 21 days with a median of 11days.

There were no slit lamp findings graded at level 4 (severe). All grade 2 or greater measures resolved without complication.

Three subjects (5 eyes) experienced grade 3 staining. No subjects with grade 3 staining required antibiotic treatment or lens wear discontinuation equal to two weeks. The table below summarizes the findings related to these events.

Eye	Date	Visit	Treatment for Grade 3 Staining
OD	06/10/04	Two Wk	Discontinued Lens Wear for 6 Days
OS	06/10/04	Two Wk	Discontinued Lens Wear for 6 Days
OD	05/27/04	Day One	Discontinued Lens Wear for 24 Hours
OD	07/15/04	Day One	Not Contact Lens Related - Discontinued Lens Wear for 1 Week
OS	07/15/04	Day One	Not Contact Lens Related - Discontinued Lens Wear for 1 Week

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

Summary of Key Safety Variables *

Criteria	1 Day		2 Weeks		1 Month		2 Months		3 Months		6 Months		Unscheduled**	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
n	196		168		158		164		160		144		210	
Adverse events													3	1.4
Loss of ≥ 2 lines BSCVA***	32††	16.3	9	5.4	4	2.5	2	1.2	4	2.5	5	3.5	7	3.3
BSCVA worse than 20/40 ***	4	2.0	3	1.8	1	0.6	0	0	1	0.6	1	0.7	2	1.0
Increase of > 1 D Refractive Cyl	2	1.0	4	2.4	2	1.3	1	0.6	0	0	0	0	6	2.9
Increase of > 2 D Refractive Cyl †	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Increase of > 1 D Corneal Cyl	16	8.2	8	4.8	5	3.2	7	4.3	12	7.5	10	6.9	12	5.7
Increase of > 2 D Corneal Cyl †	0	0	4	2.4	0	0	2	1.2	3	1.9	1	0.7	0	0

* Includes multiple interim observations of some events.

** Includes Discontinuation visits and regression study visits.

*** There were 35 incidents of loss ≥ 2 lines of vision (all documented to be temporary except one).

† All cylinder increases of ≥ 2 Diopters were temporary.

†† On the 32 day-one observations, 4 of these observations were still observed at the 2-week visit (in addition to the 9 new cases at 2 weeks noted in the table).

Patient Satisfaction

Fifty-nine of the 72 completed subjects (85.3%) rated their overall satisfaction with their unaided vision equivalent to very good or excellent at the 6 month visit compared to no subjects (0.0%) for the same equivalent rating pretreatment.

POSTMARKET SURVEILLANCE STUDY: INCIDENCE RATE OF MICROBIAL KERATITIS IN PEDIATRIC PATIENTS COMPARED TO ADULTS

The purpose of this postmarket surveillance study was to determine whether the incidence of microbial keratitis in pediatric patients, defined as persons under the age of 18, is higher than in adult patients wearing orthokeratology reshaping lenses overnight in patients fitted with either Paragon CRT®, Paragon CRT® 100, or Boston Orthokeratology (oprifocon A) Shaping Lenses. Bausch + Lomb and Paragon Vision Sciences collaboratively sponsored the study. The study question was whether the incidence of microbial keratitis is higher in pediatric patients than in adult patients.

Study Design

The study identified patients fit by a randomly selected, stratified (low and high volume prescribers) sample of practitioners. The patient-sampling strategy was designed to identify enough patients that had been fit with corneal reshaping lenses with sufficient follow-up to provide 2000 patient-years of exposure. The primary endpoints for the study were defined as the incidence of microbial keratitis in pediatric and adult groups and the difference in rates between the two age groups.

Study Population

The retrospective study design did not use patient enrollment but rather the selection of practitioners. The random sampling strategy recruited equal numbers of low- and high-volume practitioners, but limited the number of patients contributed by any one practitioner to 50, in order to minimize the respondent burden and to avoid any single practice contributing a substantial proportion of the sample.

Patients were not prospectively enrolled according to strict inclusion and exclusion criteria, but instead were identified retrospectively through lens orders from 2005 and 2006.

Safety Evaluation

Participating practitioners reviewed their medical records for up to 50 patients, selected at random. Only data on lens wear from 2005 onwards and cases of possible microbial keratitis from 2005 onwards were analyzed in order to minimize bias. A total of 86 practitioners completed a standardized summary form to capture patient age, fitting date, and duration of lens wear. In addition, practitioners were asked to report any potential cases of microbial keratitis associated with the selected corneal reshaping lenses using the criterion of a painful red eye that required a visit to a doctor's office. The definition of microbial keratitis was one or more corneal stromal infiltrates greater than 1mm in size, pain more than mild, and one more of the following: anterior chamber reaction more than minimal, mucopurulent discharge, or positive corneal culture. Also considered was whether the practitioner prescribed treatment consistent with the standard of care for microbial keratitis in terms of choice of medication, frequency and duration of use.

An Outcomes Assessment Panel reviewed all potential cases of microbial keratitis masked to patient age. The Panel members were chosen based on their expertise in the assessment, evaluation, and management of contact lens-related complications. Individuals with associations with either sponsor were excluded.
The incidence rate and confidence intervals were estimated as the ratio of the number of cases in an age group divided by the years of lens wear. Confidence intervals for the difference in the incidence rates between pediatric and adult patients were also calculated.

Results

Of the 200 randomly selected practitioners, 9 could not be contacted. Of the 191 practitioners that could be contacted, 119 agreed to participate (62%) and of these, 86 returned completed forms, 11 withdrew, and 22 failed to submit data in spite of multiple reminders. Of the 72 non-participating practitioners (191 minus 119), approximately 10% declined to participate and the remainder would not return repeated phone calls from the Lead Investigator. The completed forms corresponded to 2202 lens order and represented unique 1494 patients. Limiting the sample to those beginning lens wear in 2005 or 2006 provided 2599 patient-years of lens wear (exceeding the goal of 2000) for 1317 patients (677 children and 640 adults). At the original fitting date the mean age of the pediatric group was 12.2 ± 2.5 years and the mean age of the adults were 38.0 ± 11.1 years. The mean follow-up for the pediatric group was 2.1 ± 0.8 years, with 620 (92%) having at least 12 months of follow-up. The mean follow-up for the adults was 1.8 ± 1.0 years, with 497 (78%) having at least 12 months of follow-up.

The Outcome Assessment Panel identified two cases of microbial keratitis with 2599 patient years of overnight corneal reshaping lens wear. Both cases of microbial keratitis occurred at least one year after fitting and neither resulted in any documented long-term loss of best corrected visual acuity. Table 1 summarizes the incidence data for microbial keratitis bases on the 2599 patient- year of lens wear. The overall estimated incidence of microbial keratitis is 7.7 per 10,000 patient-years including the estimated incidence of 13.9 per 10,000 patient-years for the pediatric group, and 0.0 per 10,000 patient-years for adults.

Table 1
Incidence of Microbial Keratitis
Patients with at least 3 Months of Lens Wear in 2005 and 2006

	Pediatric patient	Adults	Overall
N	677	640	1317
Cases	2	0	2
Years at Risk	1435	1164	2599
Incidence Rate per 10,000 patient-years	13.9	0.0	7.7

A conservative analysis of 685 patients who began wear of overnight corneal reshaping lenses after January 2005 and had at least one year of documented lens wear is presented in Table 2. These patients contribute a total of 1415 patient-years of lens wear (794 pediatric and 621 adult).

Table 2
Incidence of Microbial Keratitis
Patients with at least 1 Year of Lens Wear in 2005 and 2006

	Pediatric patient	Adults	Overall
N	378	307	685
Cases	2	0	2
Years at Risk	794	621	1415
Incidence Rate per 10,000 patient-years	25.2	0.0	14.1

Conclusion

The primary goal of the study was to compare the risk of microbial keratitis between children and adults with at least 3 months of lens wear.

In this retrospective study, the following rates of microbial keratitis were observed

- In Children: 2 cases of microbial keratitis were reported (13.9 per 10,000 patient-years). Both cases of microbial keratitis occurred at least one year after fitting and neither resulted in any documented long-term loss of best corrected visual acuity.
- In Adults: 0 cases of microbial keratitis were reported.

Results from this retrospective observational study are tentative and not conclusive. Results from a large well-controlled prospective clinical trial can provide more definitive results.

Data on rates of infectious corneal ulcers in children wearing other types of contact lenses is not available. For comparison, Poggio et al. (1989),* estimated the risk to be ~21 per 10,000 patient-years for extended-wear soft contact lenses (lenses worn overnight) and ~4 per 10,000 patient-years for daily wear soft contact lenses. Results from this retrospective observational study are tentative and not conclusive. Results from a large well-controlled prospective clinical trial can provide more definitive results.

Study Strength

Previous published studies have reported individual or small series of patients presenting with microbial keratitis, none have compared incidence among adult and pediatric populations.

This was a retrospective study which looked backward over a period of time to compare the frequency of microbial keratitis between the two groups. Retrospective studies are particularly useful in investigating diseases or adverse effects with low incidence of occurrence. This was a study (2599 patient-years) of randomly selected patients fitted by 86 randomly selected practitioners over two years. Cases were classified by independent group of experts using clear and established criteria and without knowledge of whether the patient was a child or adult.

STUDY LIMITATIONS

Retrospective studies are useful in providing estimates of relative risk; however, there can be limitations associated with retrospective design involving adverse events occurring in the past. Bias can be introduced with a retrospective design, for example, by practitioners or patients declining to participate. While study sites were selected at random, participation was voluntary and practitioners who had observed cases of microbial keratitis may have been less willing to participate. Although the retrospective analysis was of patients fitted over a two year period, the incidence rate calculations assume that the occurrence of microbial keratitis is constant over, i.e. there are assumptions associated with the use of constant-rate denominators. Such assumptions may not be valid as the risk may change over time. Patients were selected at random but lens were not documented beyond practitioner report. The practitioner's inability to confirm whether some patients wore the study lenses and whether they wore the lenses for the minimal time required may have inflated the total years at risk, thus artificially depressing the reported incidence of microbial keratitis and increasing the statistical power of the study. Nonetheless, 1158 of the 1317 patients had at least one year of wear documented by the practitioner and 81 patients were documented as discontinued by the practitioner. A total of 78 patients can be regarded as lost to follow-up. Only 86 out of the 200 (43%) targeted practitioners enrolled in the study by returning the completed form. The classification of microbial keratitis was determined by an Outcome Assessment Panel without direct contact with the patient or photographs. These factors should be considered when evaluating the significance of the results.

FITTING

NOTE: Contact lenses for Corneal Refractive Therapy should be fitted only by a contact lens fitter trained and certified in the fitting of conventional and sigmoid geometry contact lenses.

Conventional methods of fitting rigid contact lenses DO NOT APPLY to the Paragon Z CRT Contact Lenses for Contact Lens Corneal Refractive Therapy. For a description of fitting techniques, refer to the Professional Fitting And Information Guide – Paragon Z CRT . Copies are available from:

Paragon Vision Sciences, Inc. 1-800-528-8279
2120 W. Guadalupe Rd. 1-480-892-7602
Gilbert, Arizona 85233-2810 1-480-926-7369 FAX

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.

It is ideal for the patient to start with overnight wear the first night. A well fit lens provides for centration with the closed eye. The effects of lid interaction on blinking and gravity may result in lens decentration during open eye wear. Patients should be instructed to place the lens in the eye 15 to 20 minutes before going to sleep.

Patients must be cautioned; "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, the patient should be instructed to remove the lens, clean and rewet it and replace the lens. If the sensation continues, the lens should not be worn.

The patient should report for follow-up evaluation the morning after the first overnight wear. The visit is best scheduled within a few hours of awakening and the patient should report with the lens in place. This visit provides an excellent opportunity to evaluate lens centration and potential lens adherence.

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

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

Day 1	two periods of wear not to exceed 6 hours total
Day 2	6 hours
Day 3-5	8 hours
Day 6	overnight wear with follow-up visit within 24 hours

The cornea normally changes within five to eight hours of wear. The wearing schedule should be modulated to determine the MINIMUM wear required for myopic reduction. The average wearing time is between 8 and 10 hours. Determine the wearing time at which lens movement appears to stop. Attempt to maintain wearing time at this level.

MYOPIC REDUCTION MAINTENANCE LENS (RETAINER LENS) WEARING SCHEDULE

With Paragon Z CRT contact lenses, the lens used to achieve refractive therapy is usually the lens used to maintain achieved correction. The Retainer Lens wearing time begins with the same wearing time required for the last fitted Paragon Z CRT Contact Lenses for Contact Lens Corneal Refractive Therapy. 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 patient may attempt to skip a night of wear to monitor the duration of visual improvement. This may continue for 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 Contact Lens Corneal Refractive Therapy 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.

LENS CARE DIRECTIONS

Your eye care practitioner will recommend his/her preferred, FDA approved lens care solutions for the cleaning, disinfection, storage and lubrication of your Paragon Z CRT rigid gas permeable contact lenses.

Follow the instructions provided with each lens care solution. Failure to adhere to these procedures may result in the development of serious ocular complications. A patient should not switch from one care system to another unless it has been determined by the eye care practitioner that this is necessary. Do not mix or alternate the disinfection and storage systems unless so indicated on the product label.

Inform the patient of the following lens care suggestions.

- Always wash and rinse your hands thoroughly before handling your contact lenses.
- Never use tweezers or other tools to remove your lens from the lens container. Pour the lens into your hand.
- Paragon Z CRT Contact Lenses for Corneal Refractive Therapy must be both cleaned and disinfected each time you remove them. One procedure does not replace the other. Cleaning is necessary to remove mucus and film from the lens surface. Disinfecting is necessary to destroy harmful germs. To minimize lens warpage during cleaning, the lenses should be cleaned in the palm of the hand rather than between the thumb and fingers.Patients should follow the complete recommended lens rubbing and rinsing times in the product labeling to adequately disinfect their lenses and reduce the risk of contact lens contamination. Reduced rubbing or rinsing times may not adequately clean their lenses.
- Clean one lens first. The recommended procedure is to always clean the same lens first to avoid mix-ups. Rinse the lens thoroughly as recommended by your lens care product manufacturer to remove the cleaning solution. Place the lens into the correct storage chamber and fill the chamber with the recommended disinfection system as recommended by your eye care practitioner. Clean and rinse the other lens in the same manner and place it in its chamber.
- Tightly close the top of each chamber of the lens storage case.
- To disinfect your lenses, leave them in the solution for at least the period indicated on the product label.
- Leave the lenses in the unopened storage case until you are ready to put them in your eye.

LENS CASE CLEANING AND MAINTENANCE

Contact lens cases can be a source of bacteria growth. Lens cases should be emptied, cleaned, rinsed with solutions recommended by the lens case manufacturer, and allowed to air dry. Lens cases should be replaced at regular intervals as recommended by the eye care practitioner.

ENZYME CLEANING

The eye care practitioner may recommend enzyme cleaning. Enzyme cleaning does not replace routine cleaning and disinfecting. The patient should carefully follow the instructions in the enzymatic cleaning labeling.

EMERGENCIES

If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, the patient should flush eyes immediately with tap water and then remove lenses promptly.

The patient should CONTACT THE EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

HOW SUPPLIED

CAUTION: Nonsterile lenses. Clean and condition lenses prior to use.

Each Paragon Z CRT lens is supplied nonsterile in an individual plastic case. The lens is shipped wet in Boston SIMPLUS® solution. This solution contains poloxamine, hydroxyalklphosphonate, boric acid, sodium borate, sodium chloride, hydroxypropylmethyl cellulose, Glucam and preserved with chlorhexidine gluconate (0.003%), polyaminopropyl biguanide (0.0005%).The case, packing slip or invoice is marked with the central base curve radius, dioptric power, overall diameter, Return Zone Depth, Landing Zone Angle, center thickness, serial number, ship date and the color of the lens. If the patient has experienced a prior history of allergy to any of these ingredients; remove the lens from the solution and soak the lens 24 hours in sterile unpreserved saline prior to cleaning, disinfecting and dispensing.
*Boston SIMPLUS® is a registered trademark of Bausch & Lomb

Never reuse the solution. You may store the lens in the unopened container until ready to dispense, up to a maximum of twenty-five (25) days from the Ship Date (see Packing Slip). When a lens has been stored for 25 days in its original packaging solution, it should be cleaned and disinfected with an FDA approved product and placed into inventory as you presently do with any other RGP lens held in your office. Follow the directions on the selected disinfecting solution regarding prolonged storage.

REPORTING OF ADVERSE REACTIONS

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

Paragon Vision Sciences, Inc. 1-800-528-8279
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