PACKAGE INSERT

PARAGON RG-4™

Manufactured in
Paragon HDS® 100 (paflufocon D)

RIGID GAS PERMEABLE CONTACT LENSES FOR CORNEAL RESHAPING

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 practitioner. Contact lenses for corneal reshaping should be fitted only by a trained and certified contact lens fitter. Nonsterile. Clean and condition lenses prior to use.

WARNING: The 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 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.

PARAGON RG-4™ CONTACT LENSES FOR CORNEAL RESHAPING OVERNIGHT WEAR

DESCRIPTION

Paragon RG-4™ contact lenses are manufactured from Paragon HDS® 100. The reverse geometry design has a posterior surface consisting of four zones:

1. The central spherical or aspheric zone.
2. An annular "Reverse Zone(s)"surrounding the central zone with a curvature steeper (shorter radius) than the central zone.
3. An "Alignment Zone(s)" generally paralleling the underlying corneal surface.
4. Peripheral curve(s) with a radius selected to create "edge lift" to promote tear flow under the lens and avoid impingement of the peripheral curve on the cornea.

The lens design also includes a "rounded" edge terminus extending from the anterior to the posterior surfaces to promote comfort.

Paragon RG-4™ Contact Lenses for Corneal Reshaping are to be worn overnight with removal during all or part of each following day. The material is a thermoset fluorosilicone acrylate copolymer derived primarily from siloxane acrylate, trifluoroethyl methacrylate and methylmethacrylate with a water content of less than 1%. These contact lenses for corneal reshaping are available as lathe cut firm contact lenses with blue green, red and yellow tints containing D&C Green No. 6, D&C Red No. 17 and Perox Yellow No. 9 (4-[(2,4-dimethylphenyl)azo]-2,4-dihydro-5-methyl-2-phenyl-3H-pyrazol-3-one). These products may be plasma treated.

LENS PARAMETERS AVAILABLE (See Figure 1)

Chord Diameter (D)	7.0 to 12.0 mm
Optical Zone Diameter (OZ)	5.0 to 7.0 mm
Base Curve Radius (BCOR)	6.50 to 10.50 mm
Reverse Zone Width (R)	0.5 to 2 mm radius
Reverse Curve(s) Radius (RCR)	up to 2.0 mm steeper than Base Curve
Alignment Curve Width (A)	0.5 to 2.5 mm
Alignment Curve(s) Radius (ACR)	2.0 mm Flatter to 2.0 mm steeper than Base Curve
Peripheral Curve Width (P)	0.5 to 1.5 mm
Peripheral Curve(s) Radius (PCR)	2.0 mm to 10.0 mm flatter than Base Curve
Powers	-2.00 to +2.00 Diopters
Aspheric Lens Eccentricity	-1.5 to 1.5 (Oblate, Prolate or Tangent Conic)

ATTRIBUTES OF THE PARAGON RG-4™ LENS (paflufocon D)

Refractive Index	1.442 (Nd at 25°C)
Luminous Transmittance+ (Green)	95%
Luminous Transmittance+ (Yellow)	99%
Luminous Transmittance+ (Blue)	93%
Luminous Transmittance+ (Red)	89%
Wetting Angle (Receding)++	42°
Wetting Angle (Contact)+++	70°
Specific Gravity	1.10
Hardness (Shore D)	79
Water Content	<1%

+ Determination of the Spectral and Luminous Transmittance, ISO 8599:1994

++ Adapted from: A New Method for Wetting Angle Measurement; Madigan, et. al., International Eyecare, 01/1998, vol. 2, no. 1, p. 45

+++ Sessile Drop Technique per ANSI Z80.20, 8.11

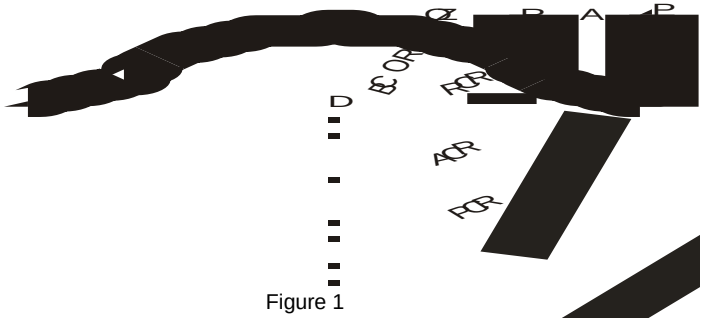


Figure 1

OXYGEN PERMEABILITY - PARAGON RG-4™ 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}
HDS 100	+1.25	100	0.20 - 0.22	0.157 - 0.199	64 - 50

* (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.

ACTIONS

Paragon RG-4™ Contact Lenses for Corneal Reshaping 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 RG-4™ Contact Lenses for Corneal Reshaping 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 RG-4™ contact lenses 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 RG-4™ (paflufocon D) rigid gas permeable contact lenses for corneal reshaping are indicated for use in the reduction of myopic refractive error in nondiseased eyes. The lenses are indicated for overnight wear in a corneal reshaping fitting program for the temporary reduction of up to 3.00 diopters of myopia in eyes with astigmatism up to 1.50 diopters. The lenses may be disinfected using only a chemical disinfection system.

> **Note:** To maintain the corneal reshaping 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 RG-4™ Contact Lenses for Corneal Reshaping 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 your contact lenses
- Any active corneal infection (bacterial, fungal or viral)
- If eyes become red or irritated

WARNINGS

Paragon RG-4™ Contact Lenses for Corneal Reshaping 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 RG-4™ Contact Lenses for Contact Lens Corneal Reshaping 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 Reshaping 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 YOUR 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 RG-4™ contact lenses manufactured from Paragon HDS® 100 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.

The safety and effectiveness of the Paragon RG-4™ design in the overnight wear modality was established partially on the basis of the experience with the Paragon CRT® 100 design in the same lens material. Therefore, some differences in efficacy may be observed.

Each Paragon RG-4™ lens is supplied nonsterile in an individual plastic case. The lens is shipped dry; or, wet shipped 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%). 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.

Patient

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 or 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: 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 nonmovement 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,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.

CLINICAL STUDY DATA

Corneal Refractive Therapy has been the subject of two controlled clinical studies sponsored by Paragon Vision Sciences. Both are reported here. One was a 3-month daily wear study in a reverse geometry lens design. The second was a 9-month overnight wear study in the CRT® lens design. Both studies support the safety and efficacy of corneal reshaping performed with those lens designs, and the Paragon RG-4™ lens design in accordance with their approved indications and labeling.

I. Paflufocon B in a Reverse Geometry Design* for Daily Wear for Myopia and Myopia with Astigmatism

A total of 184 (92 patients) eyes were enrolled in the clinical study with 114 eyes (57 patients) completing a minimum of 3 months of contact lens wear. Of the completed eyes a total of 113 eyes showed some reduction in myopic refractive error during the 3-month time period that the Paragon Quadra RG™ contact lenses for corneal refractive therapy were worn. The average reduction was 1.70 diopters with a range from 0.125 to 4.50 diopters.

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.

While all but one eye demonstrated a reduction in myopia, the amount of myopia reduced varied between patients and could not be predicted prior to treatment.

AVERAGE REDUCTION IN MYOPIA (Diopters)	
INITIAL- Myopia	REDUCTION - Myopia
-1.00 or less	0.79
-1.25 to -2.00	1.26
-2.25 to -3.00	1.93
-3.25 to -4.00	2.14
-4.25 to -5.00	2.04

*Although the trade name Quadra RG™ was used to designate the reverse geometry design used in the daily wear study; the Paragon RG-4™ is a lens of that design, and the references to Quadra RG™ in this clinical data should be considered applicable to the Paragon RG-4™.

Paragon Quadra RG™ contact lenses for corneal refractive therapy provided a temporary full reduction in some patients with up to -3.25 diopters of myopia. For patients with greater than -3.25 diopters of myopia only a partial reduction of myopia can be expected. The percentage of patients that can be expected to achieve full or partial temporary refractive reduction is shown in the following table.

PERCENT OF EYES THAT ACHIEVED FULL OR PARTIAL TEMPORARY REDUCTION OF MYOPIA				
INITIAL MYOPIA	FULL TEMPORARY REDUCTION	UP TO 0.50 D UNDER FULL REDUCTION	FINAL V.A.20/20 or better	FINAL V.A.20/40 or better
-1.00 D or less	58%	83%	58%	100%
-1.25 to - 2.00 D	35%	81%	66%	94%
-2.25 to - 3.00 D	12%	48%	41%	79%
-3.25 to - 4.00 D	8%	15%	15%	54%
-4.25 to - 5.00 D	0%	0%	0%	57%

For the patients (114 eyes) that completed this study, the initial visual acuity by best refraction was 20/20 or better for 84 (74%) eyes and 20/40 or better for all eyes. At the final visit, visual acuity with contact lenses was equal to or better than 20/20 for 104 (91%) eyes, 20/40 for 112 (98%) eyes with 2 eyes not reported. Two (2%) eyes had a one-line drop in visual acuity for contact lenses compared to best refraction, no eyes had a two-line drop or worse.

The percentage of eyes that achieved uncorrected visual acuity of 20/20 or better and 20/40 or better in relation to the initial myopia is given in the above table. A total of 46 (40%) eyes achieved a visual acuity of 20/20 or better and 87 (76 %) eyes achieved 20/40 or better.

EFFECTS ON ASTIGMATISM

Either increases or decreases in astigmatism may occur following corneal refractive therapy. Of the 114 eyes (57 patients) which completed the three month clinical study, 30% showed no change in refractive astigmatism, 38% showed a decrease of less than one diopter, 6% showed a decrease of one or more diopters, while 27% showed an increase one diopter or less and no one showed an increase greater than one diopter.

WEARING TIME

The average wearing time required for patients who wore Paragon Quadra RG™ contact lenses for corneal refractive therapy for various time periods was as follows:

Two weeks	9.6	hours/day
One month	9.0	hours/day
Two months	9.1	hours/day
Three months	9.4	hours/day

The study did not report how long the improved vision lasted once lenses were removed. There was considerable variability, however, as many patients required several hours more or less than the averages as shown for the three-month time period as follows:

Time Worn	Percent of patients
0 to 4 hours	5%
4.1 to 8 hours	34%
8.1 to 12 hours	35%
12.1 to 16 hours	26%

DAILY WEAR SAFETY SUMMARY, (Quadra RG™)

In this trial, 184 eyes of 92 patients were evaluated for safety of paflufocon B in three months daily wear corneal refractive therapy when treating myopia and myopia with astigmatism. This data is a reliable indicator of the safety of this material in a daily wear corneal refractive therapy modality. In this study analysis of safety outcomes was performed for BSCVA losses, slit lamp findings, symptoms and complaints, adverse events and complications.

Best Spectacle-Corrected Visual Acuity (BSCVA), (Quadra RG™)

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 upon removal of the lenses at the three-month visit. There were no losses worse than 1 line at the 3-month visit.

Slit Lamp Findings, (Quadra RG™)

There were 13 Grade 2 (mild) and 1 Grade 3 (moderate) observations at baseline. There were 978 observations for all scheduled and unscheduled follow-up visits. There were 20 Grade 2 observations (2%) during treatment and 1 Grade 3 observation (0.1%) reported. There was no Grade 4 (severe) observation reported that would constitute an adverse event.

The Grade 3 staining was related to a lens care solution and reported as a study related complication. There is a pattern of increased Grade 1 staining through the course of the study.

Symptoms and Complaints, (Quadra RG™)

Subjects were asked to report symptoms and complaints as part of the dispensing visit and each follow-up visit. These complaints were tabulated to provide a trend analysis during treatment. The symptoms of discomfort, itching and dryness are pervasive throughout the clinical trial. The reverse geometry lenses may demonstrate less comfort than conventional designs manufactured in the same material.

The symptoms of discomfort, itching and dryness are pervasive throughout the clinical trial. The reverse geometry lenses may demonstrate less comfort than conventional designs manufactured in the same material.

Nine-four subjects were evaluated for treatment in the study. Two subjects withdrew prior to having lenses dispensed due to loss of interest. Of the remaining 92 subjects, 35 were discontinued. The reasons for discontinuation are reported in the following table.

Adverse Events and Complications, (Quadra RG™)
There were no severe adverse events reported in this study. 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. These reports were followed up, where necessary, with a phone call to the investigator. There were no losses or reductions of sight, or deaths attributable to treatment during the course of this trial.

Six study related complications were reported on adverse event case report forms. Five were rated as mild in severity and one was rated as moderate. Four were lens related, one was care product related and one was reported as not study related. All reported complications resolved with no sequelae.

Summary of Key Safety Variables, (Quadra RG™)
The reverse geometry lenses in paflufocon B have been profiled for safe and effective treatment of myopia and myopia with astigmatism.
A summary of the key safety and effectiveness variables is presented in the following table.

Reason for Discontinuation (N=35)

Reason for Discontinuation	Number of Patients
Clinical Reasons	
Unacceptable Vision	4
Lack of Comfort	6
Unacceptable Fit	2
Nonclinical Reasons	
Loss of Interest	4
Missed Visits	1
Moved	1
Voluntary Withdrawal *	17

* The majority of the lost to follow-up category were university students who returned home from the study location for summer break and were not able to continue in the follow-up visit sequence.

II. Paflufocon B and Paflufocon D in CRT® Lens Design for Overnight Wear for Myopia and Myopia with Astigmatism

Paragon CRT® and Paragon CRT® 100 Contact Lenses for Corneal Refractive Therapy 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 the contact lens fits your eye.

Summary of Key Safety Variables

Criteria	3 Months n	3 Months %
n	**114**	
Loss of ≥ 2 lines BSCVA	0	0
Serious Adverse Events	0	0
BSCVA worse than 20/40	0	0
BSCVA worse than 20/25***	0	0
Increase of > 1 D Refractive Cyl	0	0
Increase of > 2 D Refractive Cyl	0	0
Increase of > 1 D Corneal Cyl	7	6

* Excluding eyes intentionally undercorrected **
Includes eyes with a pretreatment BSCVA worse than 20/20
*** BSCVA 20/20 or better pretreatment

DEMOGRAPHIC INFORMATION

A total of 410 eyes (205 patients) were enrolled and treated. Data for 121 subjects (242 eyes) were analyzed following 9 months of treatment. The mean age of these subjects was 35 years (ranging from 12 to 56 years). There were 73 female and 48 male subjects comprised of 188 Caucasians, 1 African American, 13 Asian/Pacific Islanders, and 3 Hispanics.

The completed subjects included adolescents and adults. There were 24 adolescent subjects that completed 9 months of treatment.

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) N = 220

ATTEMPTED REDUCTION Myopia (D)	MEAN REDUCTION Myopia (D)*	MEAN RESIDUAL Myopia (D)*
-1.00 or less	-0.48	-0.33
-1.25 to -2.00	-1.32	-0.23
-2.25 to -3.00	-2.02	-0.49
-3.25 to -4.00	-3.13	-0.37
-4.25 to -5.00	-4.02	-0.39
-5.25 to -6.00	-4.97	-0.72
-6.25 or above	-4.44	-1.69

* Individual eyes of all efficacy qualified patients

Uncorrected Visual Acuity (UCVA)
Post treatment visual acuity was assessed on 159 eyes on whom full correction was attempted and who had been able to achieve 20/20 vision with the best spectacle correction. Fifty-nine percent of these eyes achieved 20/20 or better, 92% achieved 20/40 or better.

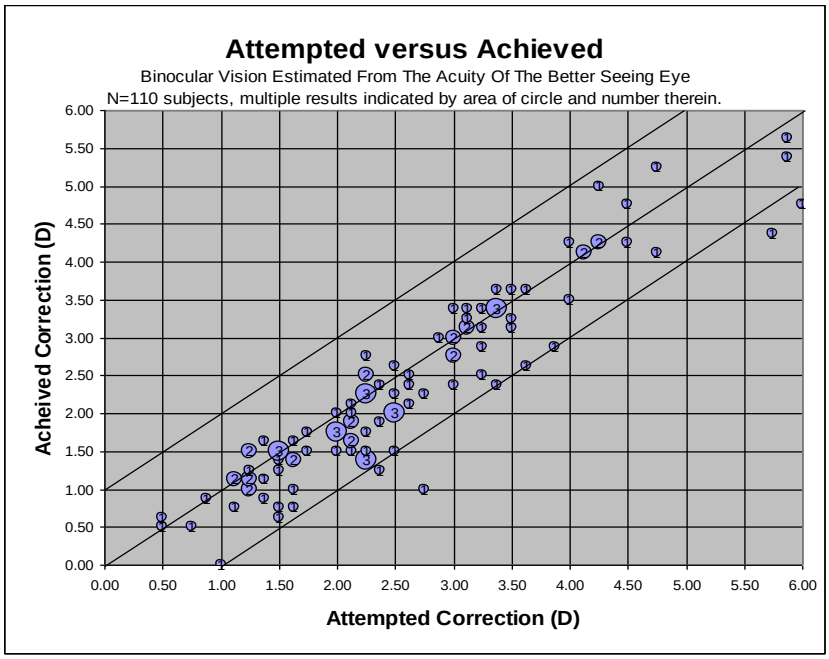
Paragon CRT® and Paragon CRT® 100 Contact Lenses for Corneal Refractive Therapy provided a temporary full reduction in some patients with up to -5.62 diopters of myopia. For patients with greater than -5.75 diopters of myopia only a partial reduction of myopia can be expected. The percentage of patients that can be expected to achieve full or partial temporary refractive reduction is shown in the following table.

PERCENT OF EYES THAT ACHIEVED FULL OR PARTIAL TEMPORARY REDUCTION OF MYOPIA				
INITIAL MYOPIA	FULL REDUCTION ± 0.50 D from Target*	UNDER FULL 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	75%	100%	71%	71%
-1.25 to - 2.00 D	81%	100%	73%	100%
-2.25 to - 3.00 D	63%	90%	53%	90%
-3.25 to - 4.00 D	64%	88%	64%	88%
-4.25 to - 5.00 D	73%	91%	23%	85%
-5.25 to - 6.00 D	62%	75%	33%	100%

* N=220 for reduction (all efficacy qualified eyes)
** N=159 for Final VA (only eyes with pretreatment of 20/20 and targeted for emmetropia)

Accuracy

Accuracy of outcome was evaluated by analysis of attempted versus achieved manifest refraction spherical equivalent. At the 9-month visit, 70% (153/220) of all 9-month efficacy qualified eyes were within 0.50 D attempted their spherical equivalent correction, and 92% (202/220) 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 myopic with treatment success.



There is reference in a published study[1] 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", 67% had 20/20 or better vision, and 94% 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 graphically depicts the accuracy of the treatment.

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 between 8 and 9 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 one-diopter regression point was chosen because it is the legal requirement in many states for driving.

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 table, 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 value found in the cell identified in this way represents the average number of hours that similar patients have experienced before their acuity has regressed to 20/40. This is only a guideline; every patient should test his/her vision as it relates to the requirements of their own daily schedules.

[1] 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

In the event that the projected value or the actual experience is not adequate for your patient's visual needs, four options are available.

1. If the patient's refraction on lens removal is more minus than +0.50 diopter, increase the treatment to come closer to this result.
2. Instruct the patient to wear their lenses longer in the morning before removal to extend the threshold for regression until later in the day.
3. Instruct the patient to carry their lenses with them and reinsert them anytime they feel their vision is inadequate for their visual requirements.
4. Issue the patient a pair of -1.00 diopter spectacles for use on those occasions when regression has reduced their acuity beyond the requirements of their activities.

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.

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 HOURS POST LENS REMOVAL UNTIL REGRESSION TO –1.0 DIOPTER (~20/40)				
		PRETREATMENT MANIFEST REFRACTIVE SPHERICAL EQUIVALENT				
REFRACTION AT LENS REMOVAL		**-1.25 to -2.00 (D)**	**-2.25 to -3.00 (D)**	**-3.25 to -4.00 (D)**	**-4.25 to -5.00 (D)**	**-5.25 to -6.00 (D)**
	+0.50	40 to 80+ Hrs	24 to 40 Hrs	18 to 24 Hrs	13 to 15 Hrs	11 to 13 Hrs
	+0.25	30 to 80+ Hrs	21 to 30 Hrs	16 to 21 Hrs	11 to 16 Hrs	10 to 11 Hrs
	Plano	22 to 44 Hrs	16 to 22 Hrs	13 to 18 Hrs	9 to 13 Hrs	7 to 8 Hrs
	-0.25	22 to 29 Hrs	16 to 20 Hrs	11 to 16 Hrs	7 to 11 Hrs	5 to 7 Hrs
	-0.50	18 to 24 Hrs	10 to 18 Hrs	7 to 10 Hrs	6 to 7 Hrs	3 to 5 Hrs
	-0.75	8 to 18 Hrs	5 to 8 Hrs	4 to 5 Hrs	3 to 4 Hrs	2 to 3 Hrs

OVERNIGHT WEAR SAFETY SUMMARY

In this trial, 408 eyes of 205 patients were evaluated for safety of paflufocon B and D in nine months overnight wear corneal refractive therapy when treating myopia and myopia with astigmatism. This data is a reliable indicator of the safety of these materials in an overnight corneal refractive therapy modality. 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)

There were no losses worse than 20/40 at the 9-month visit. At prior visits eyes measured worse than 20/40 BSCVA were re-tested when clinically appropriate with a contact lens in place. Three eyes found to have worse than 20/40 BSCVA did not have a contact lens applied because of the grade of staining. In the remaining cases the acuity improved to within one line of baseline BSCVA indicating that the loss was due to wavefront aberration in the anterior corneal plane.

There were no measures of permanent or persistent loss of 2 or more lines of vision. All eyes with BSCVA losses of 2 or more lines were re-examined at a subsequent visit and found to be within one line of the baseline measure.

Absence of Persistent Corneal Change

All eyes with treatment of 2 weeks or less were excluded from the analysis to prevent a bias toward short recovery time. At the same time, all eyes that discontinued prior to a scheduled visit biasing their recovery toward too short were excluded. Further, eyes of subjects who did not return every 4 weeks were excluded to avoid bias to a greater apparent time were excluded.

For eyes with 3 or more weeks of treatment, an average treatment of 3 months and scheduled post discontinuation follow-up, the mean recovery is less than 2 weeks. Of the eyes meeting the discontinuation follow up criteria, 68% (58/86 eyes) returned to their baseline measure in one week or less and 91% (78/86 eyes) recovered in five weeks or less. There is a trend of longer recovery time for higher pretreatment refractive error. The longest recovery period for a single eye was 14 weeks. The remainder of the eyes recovered in 9 weeks or less.

Slit Lamp Findings

There were no grade 2 or 3 observations at baseline. There were 2967 observations for all scheduled and unscheduled follow up visits. There were 120 grade 2 (mild) observations (4%) during treatment and 28 grade 3 (moderate) observations (< 1%) reported. There were no grade 4 (severe) observations reported that would constitute adverse events.

Of the 28 grade 3 reports, 18 were for edema, 9 for staining and 1 for injection. Seventeen of the 18 reports of edema were at one site. Given the disproportionate distribution one may suspect a number of factors. It is noteworthy that this site is more than 7000 feet above sea level. In only five of the 17 cases was lens wearing modulated. In the remaining 12, the edema resolved without intervention. Only 2 subjects were discontinued. All 18 cases resolved without further complication.

Of the 28 grade 3 reports, 9 were for staining and 1 was for injection. These occurred in 5 subjects. In each case lens wear was discontinued. Three subjects discontinued the study and 2 completed. All cases resolved without further complication.

Symptoms, Complaints and Discontinuations

Subjects were asked to report symptoms and complaints as part of the dispensing visit and each follow up visit. The symptom of discomfort was reported on average at 32%. Blur and variable vision are reported on average for 17% and 15% respectively. Dryness and scratchiness was reported on average for 11% of eyes. In general, symptoms were noted more often at dispensing and decreased during the study.
Of the 205 subjects, 83 were discontinued prior to the 9-month visit and 1 (2 eyes) was not due for the 9-month visit. This table reports the tabulation of subjects that were discontinued prior to the 9-month visit and the reason for discontinuation. The one subject that was reported to discontinue due to a protocol violation reported pregnancy and desire to discontinue at the 6-month follow-up visit.

Reason for Discontinuation (N=83 Subjects, 166 Eyes)		
Reason for Discontinuation	Number of Patients	% of All Patients
Clinical Reasons		
Unacceptable Vision	44	22
Lack of Comfort	8	4
Nonclinical Reasons		
Lack of Interest	12	6
Lost to follow-up	9	4
Other	6	3
Missed Visits	3	1
Protocol Violation	1	<1

The two clinical reasons for discontinuation are unacceptable vision and lack of comfort that account for 22 % (44/205) and 4 % (8/205) respectively. The total discontinuation rate for clinical reasons was 26 %.

Adverse Events and Complications

There were no severe adverse events reported in this study. 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. These reports were followed up, where necessary, with a phone call to the investigator. There were no persistent losses or reductions of sight, or deaths attributable to treatment during the course of this trial.

Four study related complications were reported on adverse event case report forms. Two were rated as mild in severity and two were rated as moderate. All reported complications resolved with no sequelae.

Summary of Key Safety and Effectiveness Variables

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

Patient Satisfaction

Based on their experience with their habitual correction (spectacles or contact lenses) pretreatment, 81% of subjects rated their overall satisfaction of their vision as very good or excellent (7-10 rating). At the 6-month and 9-month visits, 82% and 84% of the 110 efficacy qualified subjects rated their overall satisfaction of their unaided vision very good or excellent (7-10 rating).

Summary of Key Safety Variables		
Criteria	**9 Months Combined**	
	n	**%**
n	**240**	
Serious Adverse Events	0	0
Loss of ≥ 2 lines BSCVA	0	0
BSCVA worse than 20/40	0	0
Increase of > 1 D Refractive Cyl	2	1
Increase of > 2 D Refractive Cyl	0	0
Increase of > 1 D Corneal Cyl	9	4

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 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 (PARAGON RG-4™)

Note: Contact lenses for corneal reshaping should be fitted only by a trained and certified contact lens fitter.

Conventional methods of fitting rigid contact lenses DO NOT APPLY to the Paragon RG-4™ Contact Lenses for Corneal Reshaping. For a description of fitting techniques, refer to the Professional Fitting And Information Guide - PARAGON RG-4™. 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 (PARAGON RG-4™)

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.

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

The Retainer Lens schedule must be customized for each patient. The Retainer Lens wearing time begins with the same wearing time required for the last fitted Paragon RG-4™ Contact Lenses for Contact Lens Corneal Reshaping. 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 Reshaping 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 RG-4™ 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 RG-4™ Contact Lenses for Corneal Reshaping 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 the 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 RG-4™ lens is supplied nonsterile in an individual plastic case. The lens is shipped dry; or, wet shipped 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 base curve radius, dioptric power, diameter, center thickness, serial number, fill date and the color of the lens.

*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.

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